BIOSPECIFICS TECHNOLOGIES CORP
Form 10-Q
August 09, 2018

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, 2018
OR

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

For the transition period from _____to _____

001-34236
(Commission file number)

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

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

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

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

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

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

Large accelerated filer	Accelerated filer

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for comply with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

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 8, 2018
Common Stock ($.001 par value)	7,294,888

BIOSPECIFICS TECHNOLOGIES CORP.

TABLE OF CONTENTS

Table of Contents

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 continued commercialization of XIAFLEX to treat Dupuytren’s contracture and Peyronie’s disease; the continued marketing and commercialization of XIAFLEX to treat Dupuytren’s contracture and Peyronie’s disease in Europe, Eurasia, Japan, Canada, Australia and New Zealand; 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 XIAFLEX 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; the future receipt of payments from Endo, including milestone and royalty payments, in connection with the License Agreement; 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; whether and when we will hear from Endo the results of their ongoing commercial review regarding the XIAFLEX pipeline; the timing of Endo’s determination of clinical trial timelines for additional indications; the nature of our accounts receivable balance and the timing of the Company’s release of top-line data in connection with its Phase 1 clinical trial of XIAFLEX for the treatment of uterine fibroids. In some cases, these statements can be identified by forward-looking words such as “believe,” “expect,” “anticipate,” “estimate,” “likely,” “may,” “ “can,” and “could,” the negative or plural of these words, and other similar expressions. These forward-looking statements are predictions based on our current expectations and our projections about future events and various assumptions. There can be no assurance that we will realize our expectations or that our beliefs will prove correct. There are a number of important factors that could cause BioSpecifics’ actual results to differ materially from those indicated by such forward-looking statements, including the timing of regulatory filings and action; the ability of Endo and its partners, Asahi Kasei Pharma Corporation, Actelion 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 that will determine the amount of milestone, royalty, mark-up on cost of goods sold, license and sublicense income BioSpecifics may receive; the potential of XIAFLEX 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, 2017, its Quarterly Report on Form 10-Q for the quarter ended March 31, 2018 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.

Table of Contents

PART I – FINANCIAL INFORMATION

Item 1: Condensed Consolidated Financial Statements

BioSpecifics Technologies Corp.
Condensed Consolidated Balance Sheets

	June 30, 2018[(1)] (unaudited)	December 31, 2017 (audited)
Assets		
Current assets:		
Cash and cash equivalents	$12,960,475	$7,333,810
Short term investments	53,585,924	51,973,971
Accounts receivable	12,893,893	4,655,105
Deferred royalty buy-down	1,124,990	1,794,126
Prepaid expenses and other current assets	836,979	623,503
Total current assets	81,402,261	66,380,515
Long-term investments	7,163,483	5,745,974
Deferred royalty buy-down – long term, net	-	732,206
Deferred tax assets, net	321,603	1,739,706
Patent costs, net	442,968	397,993
Total assets	$89,330,315	$74,996,394
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$1,591,707	$933,998
Income tax payable	801,800	68,733
Deferred revenue	-	1,057,979
Accrued liabilities of discontinued operations	-	78,138
Total current liabilities	2,393,507	2,138,848
Long-term deferred revenue	-	5,340,708
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; 7,655,167 and 7,600,167 shares issued, 7,244,233 and 7,189,233 shares outstanding as of June 30, 2018 and December 31, 2017, respectively	7,655	7,600
Additional paid-in capital	34,424,632	33,468,323
Retained earnings	60,402,721	41,939,115
Treasury stock, 410,934 shares at cost as of June 30, 2018 and December 31, 2017	(7,898,200)	(7,898,200)
Total stockholders' equity	86,936,808	67,516,838
Total liabilities and stockholders' equity	$89,330,315	$74,996,394

See accompanying notes to condensed consolidated financial statements.

(1)As of January 1, 2018, the Company adopted the requirements of ASC 606 using the modified retrospective adoption method, and as a result, there is a lack of comparability of certain amounts to the prior periods presented. See Note 2 for additional discussion.

Table of Contents

BioSpecifics Technologies Corp.
Condensed Consolidated Income Statements
(unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2018[1]	2017	2018[1]	2017
Revenues:				
Royalties	$7,061,139	$6,531,107	$14,146,139	$14,217,317
Licensing revenues	35,270	4,409	39,679	8,818
Total Revenues	7,096,409	6,535,516	14,185,818	14,226,135
Costs and expenses:				
Research and development	211,796	337,731	407,023	592,512
General and administrative	1,985,212	2,315,283	4,054,845	4,741,000
Total Cost and Expenses	2,197,008	2,653,014	4,461,868	5,333,512
Operating income	4,899,401	3,882,502	9,723,950	8,892,623
Other income:				
Interest income	273,746	140,995	491,697	242,748
Other income	81,985	23,423	96,663	25,985
	355,731	164,418	588,360	268,733
Income before income tax expense	5,255,132	4,046,920	10,312,310	9,161,356
Provision for income tax expense	(954,465)	(1,422,829)	(2,033,039)	(3,192,512)
Net income	$4,300,667	$2,624,091	$8,279,271	$5,968,844
Basic net income per share	$0.60	$0.37	$1.15	$0.83
Diluted net income per share	$0.59	$0.36	$1.13	$0.81
Shares used in computation of basic net income per share	7,215,057	7,170,223	7,204,040	7,167,251
Shares used in computation of diluted net income per share	7,315,276	7,329,118	7,309,325	7,330,875

See accompanying notes to condensed consolidated financial statements.

[1] As of January 1, 2018, the Company adopted the requirements of ASC 606 using the modified retrospective adoption method, and as a result, there is a lack of comparability of certain amounts to the prior periods presented. See Note 2 for additional discussion.

Table of Contents

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

	Six Months Ended June 30,	
Cash flows from operating activities:	2018[1]	2017
Net income	$8,279,271	$5,968,844
Adjustments to reconcile net income to net cash provided by operating activities:		
Amortization	1,369,227	1,084,614
Stock-based compensation expense	96,314	66,952
Deferred tax expense	82,341	218,006
Extinguishment of accrued liabilities	(78,138)	-
Changes in operating assets and liabilities:		
Accounts receivable	(684,061)	(852,490)
Income tax receivable	(666,874)	204,506
Prepaid expenses and other current assets	(213,476)	(176,202)
Patent costs	(79,485)	-
Accounts payable and accrued expenses	118,696	423,848
Deferred revenue	(139,680)	(637,459)
Net cash provided by operating activities	8,084,135	6,300,619
Cash flows from investing activities:		
Maturity of marketable investments	37,279,000	32,855,741
Purchases of marketable investments	(40,596,520)	(37,669,248)
Net cash used in investing activities	(3,317,520)	(4,813,507)
Cash flows from financing activities:		
Proceeds from stock option exercises	860,050	258,250
Payments for repurchase of common stock	-	(478,762)
Net cash provided by (used in) financing activities	860,050	(220,512)
Increase in cash and cash equivalents	5,626,665	1,266,600
Cash and cash equivalents at beginning of year	7,333,810	4,763,364
Cash and cash equivalents at end of period	$12,960,475	$6,029,964
Supplemental disclosures of cash flow information:		
Cash paid during the period for:		
Interest	-	-
Taxes	$2,617,572	$2,770,000

[1]As of January 1, 2018, the Company adopted the requirements of ASC 606 using the modified retrospective adoption method, and as a result, there is a lack of comparability of certain amounts to the prior periods presented. See Note 2 for additional discussion.

See accompanying notes to condensed consolidated financial statements.

Table of Contents
BIOSPECIFICS TECHNOLOGIES CORP.
NOTES TO CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

June 30, 2018
(Unaudited)

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

We are a biopharmaceutical company involved in the development of an injectable collagenase clostridium histolyticum for multiple indications. We currently have a development and license agreement with Endo Global Ventures, a Bermuda unlimited liability company ("Endo Global Ventures"), an affiliate of Endo International plc ("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"). Injectable collagenase clostridium histolyticum is marketed as XIAFLEX® (or Xiapex® in Europe).

On February 1, 2016, we entered into with Endo the First Amendment (the "First Amendment") to the Second Amended and Restated Development and Licensing Agreement (the "Auxilium Agreement"), by and between us and Auxilium, now a wholly-owned subsidiary of Endo, to amend certain provisions of the Auxilium Agreement (as amended by the First Amendment, the "License Agreement"). The effective date of the First Amendment was 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.

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 of $0.75 million 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, plantar fibromatosis and human lipoma. Endo exercised, with our consent, an early opt-in for lateral hip fat and plantar fibromatosis in November 2015. Endo opted-in for human lipoma in July 2016. We manage the development of XIAFLEX for uterine fibroids and initiate the development of XIAFLEX in new potential indications, not licensed by Endo.

On November 8, 2016, following a change in Endo management, Endo announced that a commercial review is ongoing of the XIAFLEX exercised but non-marketed indications, including frozen shoulder, cellulite, lateral hip fat, plantar fibromatosis and human lipoma, so that Endo can best prioritize its R&D efforts and determine clinical trial timelines moving forward. On February 6, 2018, Endo initiated two identical Phase 3 RELEASE clinical trials of XIAFLEX for the treatment of cellulite. The multicenter, randomized, double-blind, placebo-controlled RELEASE studies will evaluate the safety and efficacy of XIAFLEX in reducing the appearance of cellulite.

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 and certain Eurasian countries 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 is

selling XIAFLEX for the treatment of Dupuytren's contracture in Japan. Endo is currently distributing XIAFLEX in Canada through Paladin Labs Inc., an operating company of Endo. In December 2016, Endo entered into a new out-licensing agreement with Actelion Pharmaceuticals Ltd. ("Actelion"), pursuant to which Actelion obtained marketing and commercial rights for XIAFLEX in Australia and New Zealand.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Except as detailed below, there have been no material changes to the Company's significant accounting policies during the six months ended June 30, 2018, as compared to the significant accounting policies disclosed in Note 2 of the Consolidated Financial Statements in the Company's Annual Report on Form 10-K for the year ended December 31, 2017.

Table of Contents

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 the risk factors discussed in Part I, Item 1A. Risk Factors in our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 14, 2018 and in Item 1A of Part 2 of our Quarterly Report on Form 10-Q for the quarter end March 31, 2018 filed with the SEC on May 10, 2018.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its subsidiary, Advance Biofactures Corp. 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 revenues, deferred tax assets, third party royalties and deferred royalty buy-down. We base our estimates on historical experience and on various other assumptions that we believe are reasonable, the results of which form the basis for making judgments about the carrying values of assets, liabilities and the amount of revenues and expenses. Actual results may differ from these estimates under different assumptions or conditions. For further details, see notes "Revenue Recognition", "Provision for Income Taxes" and "Third-Party Royalties and Royalty Buy-Down." Actual results may differ from those estimates.

Revenue Recognition

Beginning in 2014, Financial Accounting Standards Board ("FASB") issued several Accounting Standards Updates establishing ASC Topic 606, "Revenue from Contracts with Customers" ("ASC 606"). ASC 606 requires retrospective implementation, and replaces most industry-specific revenue recognition guidance in U.S. GAAP with a new principles-based, five-step revenue recognition model. The Company adopted ASC 606 effective January 1, 2018. Under ASC 606, we recognize revenues when our customer obtains control of promised goods or services, in an amount that reflects the consideration which we expect to receive in exchange for those goods or services. We recognize revenues following the five step model prescribed under ASC 606: (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation(s).

Revenues, and their respective treatment for financial reporting purposes under ASC 606 and our license agreement with Endo, are as follows:

Royalty / Mark-Up on Cost of Goods Sold

We receive royalty revenues on net sales and mark-up on cost of goods sold revenue in the U.S. under our License Agreement with Endo. These are presented in “Royalties” in our condensed consolidated statements of income. We do not have future performance obligations under this revenue stream. In accordance with ASC 606, we record these revenues based on estimates of the net sales that occurred during the relevant period. The relevant period estimates of these royalties are based on interim data provided by Endo (when available) and analysis of historical royalties and mark-up on cost of goods sold revenue that have been paid to us, adjusted for any changes in facts and circumstances, as appropriate. Differences between actual and estimated royalty revenues are adjusted for in the period in which they become known, typically the following quarter. The royalties payable by Endo to us are subject to set-off for certain patent costs.

Table of Contents

Licensing Revenue

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

The Company recognizes licensing revenues generated through development and/or commercialization agreements. The terms of these agreements typically include payment to the Company of one or more of the following: nonrefundable, upfront license fees; sublicensing; development and commercial milestone payments; development activities; and royalties on net sales of licensed products. Each of these types of payments results in licensing revenues except for revenues from royalties on net sales of licensed products and the mark-up of cost of goods sold revenues which are classified as royalty revenues. Revenue is recognized upon satisfaction of a performance obligation by transferring control of a good or service to the customer.

For each development and/or commercialization agreement that result in revenues, the Company identifies all performance obligations, aside from those that are immaterial which may include a license to intellectual property and know-how, development activities and/or transition activities. In order to determine the transaction price, in addition to any upfront payment, the Company estimates the amount of variable consideration at the outset of the contract either utilizing the expected value or most likely amount method, depending on the facts and circumstances relative to the contract. The Company constrains (reduces) the estimates of variable consideration such that it is probable that a significant reversal of previously recognized revenue will not occur throughout the life of the contract. When determining if variable consideration should be constrained, management considers whether there are factors outside the Company’s control that could result in a significant reversal of revenue. In making these assessments, the Company considers the likelihood and magnitude of a potential reversal of revenue. These estimates are re-assessed each reporting period as required.

If a license to the Company’s intellectual property is determined to be distinct from the other performance obligations identified in the arrangement, the Company recognizes revenues from nonrefundable, upfront license fees based on the relative standalone selling price prescribed to the license compared to the total value of the arrangement. The revenue is recognized when the license is transferred to the collaborator and the collaborator is able to use and benefit from the license. For licenses that are not distinct from other obligations identified in the arrangement, the Company utilizes judgment to assess the nature of the combined performance obligation to determine whether the combined performance obligation is satisfied over time or at a point in time. If the combined performance obligation is satisfied over time, the Company applies an appropriate method of measuring progress for purposes of recognizing revenue from nonrefundable, upfront license fees. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the measure of performance and related revenue recognition.

Development and Regulatory Milestone Payments

Depending on facts and circumstances, the Company may conclude that it is appropriate to include the milestone, representing variable consideration, in the estimated total transaction price, or that it is appropriate to fully constrain the milestone. The Company may include revenues from certain milestones in the total transaction price in a reporting period before the milestone is achieved if the Company concludes that achievement of the milestone is probable and that recognition of revenue related to the milestone will not result in a significant reversal in amounts recognized in future periods. The Company records a corresponding contract asset when this conclusion is reached. Milestone payments that have not been included in the transaction price to date are fully constrained. The Company re-evaluates the probability of achievement of such development milestones and any related constraint each reporting period. The Company adjusts its estimate of the total transaction price, including the amount of revenue that it has recorded, if necessary.

Table of Contents

RECENT ACCOUNTING PRONOUNCEMENTS

Accounting Pronouncements Adopted

Effective January 1, 2018, the Company adopted ASC 606, which provides principles for recognizing revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. The Company adopted ASC 606 on a modified retrospective basis through a cumulative adjustment to equity. See Note 2 – Significant Accounting Policies – Revenue Recognition.

The adoption of ASC 606 as of January 1, 2018, applying the modified-retrospective method, changed the timing of our recognition of royalty and mark-up cost of goods sold revenue. Beginning in 2018, we recorded these royalty revenues based on estimates of the net sales and mark-up cost of goods sold that occurred during the relevant period thereby eliminating the one quarter lag. Previously, these amounts were not recognized until they were fixed and determinable. In addition, deferred revenue associated with the prepayment of foreign mark-up on cost of goods sold revenue will no longer be recognized over time based on sales by non-affiliated sublicensees of Endo outside of the U.S. and, under ASC 606, would have been recognized when the transaction occurred in 2016.

The cumulative effect of applying the new guidance of ASC 606 to our License Agreement with Endo as of January 1, 2018 was recorded as an adjustment to retained earnings as of the adoption date. As a result of applying the modified retrospective method to adopt the new revenue guidance, the following adjustments were made to accounts on the Condensed Consolidated Balance Sheet as of January 1, 2018:

The Company recorded the following cumulative effect as of January 1, 2018, itemized here (in millions):

	As reported December 31, 2017	Adjustments		Adjusted January 1, 2018
Accounts receivable	$ 4.7	$ 7.6	(1)	$ 12.3
Deferred revenue	(6.4)	6.3	(2)	(0.1)
Deferred royalty buy-down	(2.5)	(0.4)	(3)	(2.9)
Accounts payable and accrued expenses -third party royalties	(0.4)	(0.5)	(3)	(0.9)
Deferred tax assets, net	1.7	(1.3)	(4)	0.4
Income tax payable	-	(1.4)	(5)	(1.4)
Retained earnings adjustment	$ (2.9)	$ 10.3		$ 7.4

(1) This adjustment represents the elimination of the one quarter lag by recognizing royalty revenues based on of XIALFLEX net sales and mark-up on cost of goods sold revenues reported to us by Endo for the fourth quarter of 2017.

(2) Represents the remaining deferred revenue balance of the prepaid mark-up on cost of goods sold based on sales by non-affiliated sublicensees of Endo outside of the U.S.

(3) Represents the amortization of the royalty buy-down and third party royalties expense associated royalty revenues based on XIALFLEX net sales reported to us by Endo for the fourth quarter of 2017.

(4) To reverse a deferred tax asset associated with the deferred revenue balance of the prepaid mark-up on cost of goods sold by non-affiliated sublicensees of Endo outside of the U.S.

(5) To create a tax liability associated the elimination of the one quarter lag by recognizing royalty revenues based on of XIALFLEX net sales and mark-up on cost of goods sold revenues reported to us by Endo for the fourth quarter of 2017.

At June 30, 2018, contract assets of $7.1 million for which there's an unconditional right to receive payment was included in accounts receivable on the condensed consolidated balance sheet.

In accordance with the new revenue standard requirements, the impact of adoption on our condensed consolidated balance sheet was as follows (in millions):

	June 30, 2018		
	As Reported	Balances Without Adoption of New Revenue Standard	Effect of Change Higher / (Lower)
Assets			
Accounts receivable	$12.9	$ 5.8	$ 7.1
Deferred royalty buy-down	1.1	1.3	(0.2)
Deferred tax assets	0.3	1.5	(1.2)
Liabilities			
Accounts payable and accrued expenses	1.6	1.1	0.5
Deferred revenue	-	0.9	(0.9)
Income tax payable	0.8	0.5	(1.3)
Deferred revenue, long term	-	4.9	(4.9)
Equity			
Retained earnings	60.4	50.7	9.7

Table of Contents

In accordance with the new revenue standard requirements, the impact of adoption on our condensed consolidated statement of operations for the three and six months ended June 30, 2018 was as follows (in millions):

	Three Months Ended June 30, 2018		
	As Reported	Balances Without Adoption of New Revenue Standard	Effect of Change Higher / (Lower)
Revenues			
Royalties	$ 7.1	$ 7.3	$ (0.2)
Costs and expenses			
General and administrative	$ 2.0	$ 2.0	$ -
Provision for income taxes	1.0	1.0	-
Net income	4.3	4.5	(0.2)

	Six Months Ended June 30, 2018		
	As Reported	Balances Without Adoption of New Revenue Standard	Effect of Change Higher / (Lower)
Revenues			
Royalties	$ 14.2	$ 15.0	$ (0.8)
Costs and expenses			
General and administrative	$ 4.1	$ 4.1	$ -
Provision for income taxes	2.0	2.2	(0.2)
Net income	8.3	8.9	(0.6)

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. The adoption of the new standard as of January 1, 2018 had no impact on our consolidated financial statements and related disclosure as we do not currently have any available-for-sale equity investments.

Table of Contents

Accounting Pronouncements Not Yet Adopted

In February 2016, FASB issued Accounting Standards Update (ASU) No. 2016-02, Leases (Topic 842) ("ASU 2016-02"). 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. We are currently evaluating the impact that the standard could have on our consolidated financial statements and related disclosures.

In June 2016, FASB issued ASU 2016-13, Financial Instruments - Credit Losses. The amendment revises the impairment model to utilize an expected loss methodology in place of the currently used incurred loss methodology, which will result in more timely recognition of losses on financial instruments, including, but not limited to, available for sale debt securities and accounts receivable. The Company is required to adopt this standard starting in the first quarter of fiscal year 2021. Early adoption is permitted. We are currently evaluating the impact of the adoption of this standard on our consolidated financial statements and related disclosures.

Cash, Cash Equivalents and Investments

Cash equivalents include only securities having a maturity of 90 days 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, municipal bonds and corporate bonds. All investments are classified as held to maturity. As of June 30, 2018 and December 31, 2017, the amortized cost of these investments was $60.7 million and $57.7 million, respectively. No unrealized gains or losses were recorded 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 June 30, 2018 and December 31, 2017, there were no recorded unrealized gains or losses on our investments as they are classified as held to maturity. As of June 30, 2018 and December 31, 2017, amortized cost basis of the investments approximated their fair value. At June 30, 2018 and December 31, 2017, the amortized premium included in interest income was $288,000 and $673,000, respectively.

The following table presents the Company's schedule of maturities at June 30, 2018 and December 31, 2017:

	Maturities as of June 30, 2018	Maturities as of December 31, 2017

	1 Year or Less	Greater than 1 Year	1 Year or Less	Greater than 1 Year
Municipal bonds	$4,870,100	$ -	$1,002,650	$100,000
Corporate bonds	45,120,776	5,417,988	48,143,495	3,155,573
Certificates of deposit	3,595,048	1,745,495	2,827,826	2,490,401
Total	$53,585,924	$ 7,163,483	$51,973,971	$5,745,974

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.

Table of Contents

As of June 30, 2018, 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 June 30, 2018 and December 31, 2017:

June 30, 2018	Type of Instrument	Fair Value	Level 1	Level 2	Level 3
Cash equivalents	Institutional Money Market	$ 4,928,319	$ 4,928,319	$ -	$ -
Cash equivalents	Municipal Bonds	2,520,000	2,520,000	-	-
Cash equivalents	Corporate Bonds	1,862,000	1,862,000	-	-
Investments	Municipal Bonds	4,870,100	-	4,870,100	-
Investments	Corporate Bonds	50,538,764	-	50,538,764	-
Investments	Certificates of Deposit	5,340,543	5,340,543	-	-

December 31, 2017	Type of Instrument	Fair Value	Level 1	Level 2	Level 3
Cash equivalents	Institutional Money Market	$3,108,549	$3,108,549	$-	$ -
Cash equivalents	Municipal Bonds	800,000	-	800,000	-
Investments	Municipal Bonds	1,102,650	-	1,102,650	-
Investments	Corporate Bonds	51,299,068	-	51,299,068	-
Investments	Certificates of Deposit	5,318,227	5,318,227	-	-

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 investments in FDIC insured certificates of deposits, municipal bonds and corporate bonds.

The Company is currently dependent on one customer, Endo, who generates almost all its revenues. For the three and six months ended June 30, 2018, licensing, sublicensing, milestones and royalty revenues under the License Agreement with Endo were approximately $7.1 million and $14.2 million, respectively, and for the three and six months ended June 30, 2017, the licensing, sublicensing, milestones and royalty revenues under the License Agreement with Endo were approximately $6.5 million and $14.2 million, respectively.

At June 30, 2018 and December 31, 2017, our accounts receivable balances from Endo were $12.9 million and $4.7 million, respectively.

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, 2018, there were no shares repurchased as compared to the repurchase of 9,283 shares at an average price of $51.57 in the corresponding 2017 period.

Table of Contents

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 June 30, 2018 and December 31, 2017 our accounts receivable balance was $12.9 million and $4.7 million, respectively, and was from one customer, Endo. With the adoption of ASC 606 as of January 1, 2018, using the modified-retrospective adoption method, we recorded an adjustment to our accounts receivable balance of $7.6 million related to royalties associated with the net sales of XIAFLEX that occurred during the fourth quarter of 2017 thereby eliminating the one quarter lag. (For more a more detailed discussion regarding ASC 606 see Note 2- SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - RECENT ACCOUNTING PRONOUNCEMENTS - Accounting Pronouncements Adopted.)

Deferred Revenue

With the adoption of ASC 606 using the modified retrospective adoption method as of January 1, 2018, the remaining deferred revenue balance associated with the mark-up on cost of goods sold for sales by non-affiliated sublicensees of Endo outside of the U.S. as of December 31, 2017 of $6.3 million was recorded as an adjustment to our retained earnings. Additionally, approximately $35,000 related to nonrefundable upfront product license fees for product candidates for which we have no remaining performance obligations was recognized during the second quarter of 2018. Finally, during the second quarter of 2018 we determined that the $100,000 related to a milestone payment withheld by Endo due to a foreign tax withholding was uncollectable and have reduced this amount to zero. As of June 30, 2018 and December 31, 2017, deferred revenue was zero and $6.4 million, respectively. (For more a more detailed discussion regarding ASC 606 see Note 2- SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - RECENT ACCOUNTING PRONOUNCEMENTS - Accounting Pronouncements Adopted.)

Reimbursable Third-Party Patent Costs

We accrue patent costs that are reimbursable to Endo by us under the License Agreement. We capitalize certain patent costs related to patent prosecution and maintenance and expense others. As of June 30, 2018 and December 31, 2017, our net reimbursable third party patent expense was $49,000 and zero, 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 under general and administrative in the quarter that the net sales have occurred. For the three and six month periods ended June 30, 2018, third-party royalty expenses were $0.5 million and $1.0 million, respectively. For the three and six month periods ended June 30, 2017, third-party royalty expenses were $0.4 million and $0.9 million, respectively. With the adoption of ASC 606 as of January 1, 2018 using the modified-retrospective adoption

method, we recorded an adjustment to our retained earnings for third party royalties expense of $0.5 million associated with the net sales of XIAFLEX that occurred during the fourth quarter of 2017 thereby eliminating the one quarter lag. 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 XIAFLEX and Xiapex are approved, marketed and sold. (For more a more detailed discussion regarding ASC 606 see Note 2- SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - RECENT ACCOUNTING PRONOUNCEMENTS - Accounting Pronouncements Adopted.)

Table of Contents

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, all of which have been paid as of June 30, 2018. Royalty obligations terminate five years after first commercial sale which occurred in January 2014. 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 and Xiapex for Peyronie's disease on an annual basis as measured by the proportion of the total estimated sales over the five year period. For the three and six months ended June 30, 2018 and 2017, we amortized approximately $0.5 million and $1.0 million related to this agreement, respectively and $0.4 million and $0.7 million for the three and six months ended June 30, 2017. With the adoption of ASC 606 as of January 1, 2018 using the modified-retrospective adoption method, we recorded an adjustment to our capitalized balance of $0.4 million related to royalties associated with the net sales of XIAFLEX that occurred during the fourth quarter of 2017 thereby eliminating the one quarter lag. As of June 30, 2018 and December 31, 2017, the remaining capitalized balances were approximately $1.1 million and $2.5 million, respectively. We perform an evaluation of the recoverability of the carrying value to determine if facts and circumstances indicate that the carrying value of the assets may be impaired and if any adjustment is warranted. As of June 30, 2018, there was no indicator that an impairment existed. (For more a more detailed discussion regarding ASC 606 see Note 2- SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES - RECENT ACCOUNTING PRONOUNCEMENTS - Accounting Pronouncements Adopted.)

Research and Development 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.

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 consultants. 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.

Table of Contents

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, the valuation assumptions that we use to value employee stock-based awards granted in future periods may change. For the six months ended June 30, 2018, we granted a total of 31,500 stock options with a weighted average grant date fair value of $18.00 per share.

The assumptions used in the valuation of stock options granted during the six months ended June 30, 2018 were as follows:

	Six Months Ended June 30, 2018	
Risk-free interest rate	2.62% to 2.81	%
Expected term of option	6.25 years	
Expected stock price volatility	39.6% to 39.7	%
Expected dividend yield	$ 0.0	

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 $63,000 and $96,000 for the three and six month periods ended June 30, 2018 and approximately $33,000 and $67,000 for the three and six months ended June 30, 2017, respectively.

Stock Option Activity

A summary of our stock option activity during the six months ended June 30, 2018 is presented below:

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at December 31, 2017	232,000	$ 21.56	2.52	$5,050,990
Grants	31,500	41.79	-	-
Exercised	(55,000)	15.64	-	1,454,650
Forfeitures or expirations	-	-	-	-
Outstanding at June 30, 2018	208,500	$ 26.18	3.37	$3,895,465
Exercisable at June 30, 2018	169,500	$ 22.77	2.04	$3,744,550

During the six months ended June 30, 2018 and 2017, the Company received approximately $860,000 and $258,000, 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 $44.86 on June 29, 2018, which would have been received by the option holders had all option holders exercised their options as of that date. We have approximately $611,000 in unrecognized compensation cost related to stock options outstanding as of June 30, 2018, which we expect to recognize over the next 3.31 years.

Table of Contents

Property and Equipment

Property and equipment are stated at cost, less accumulated depreciation. Machinery and equipment, furniture and fixtures, and autos are depreciated on a 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. At each of June 30, 2018 and December 31, 2017, property and equipment were fully depreciated.

Comprehensive Income

For each of the three and six month periods ended June 30, 2018 and 2017, 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 740-10-25-2. Under this method, deferred income taxes, when required, are provided on the basis of the difference between the financial reporting and income tax basis of assets and liabilities at the statutory rates enacted for future periods. In accordance with Accounting Standards Codification 740-10-45-25, Income Statement Classification of Interest and Penalties, we classify interest associated with income taxes under interest expense and tax penalties under other.

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 benefits recognized in the consolidated financial statements from such position are measured based on the largest benefit that has a greater than 50% likelihood of being realized upon the ultimate settlement. As of June 30, 2018 and December 31, 2017, the Company has not recorded any unrecognized tax benefits.

Commitments and Contingencies

On November 6, 2017, 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, 2018. Pursuant to the Extended Lease Agreement, the base rent is $11,165 per month and the Company may cancel the lease with three months’ prior written notice to the Landlord at any time during the term.

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 June 30,		Six Months Ended June 30,	
	2018	2017	2018	2017
Stock options	-	20,000	-	20,000

For the three and six months ended June 30, 2017, the Company had 20,000 options, which have an exercise price of $29.21, and would have vested upon the achievement of certain performance criteria, which were not met. These options would have expired on December 2, 2019. On October 25, 2017, these 20,000 options were cancelled due to a change in status of a certain consultant.

Table of Contents

4. ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following:

	June 30, 2018	December 31, 2017
Trade accounts payable	$34,553	$ 152,542
Accrued legal and other professional fees	219,223	150,691
Accrued payroll and related costs	182,746	215,322
Third party royalties	1,018,308	329,211
Other accruals	136,877	86,232
Total	$1,591,707	$ 933,998

5. PATENT COSTS

We amortize intangible assets with definite lives on a straight-line basis over their remaining estimated useful lives, ranging from two to ten 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. We analyze our intangible assets, specifically, capitalized patent costs, on an annual basis for any indicator that an impairment exists.

For the six months ended June 30, 2018, we increased our capitalized patent costs based on reports provided to us by Endo. Patent costs may be creditable against future royalty revenues. For each period presented below, net patent costs consisted of:

	June 30, 2018	December 31, 2017
Patents	1,004,502	$ 925,016
Accumulated amortization	(561,534)	(527,023)
	$442,968	$ 397,993

The amortization expense for patents for the three and six months ended June 30, 2018 was approximately $18,000 and $35,000, respectively and for the three and six months ended June 30, 2017 was approximately $10,000 and $20,000, respectively. The estimated aggregate amortization expense for the remaining six months of 2018 and each of the years below is approximately as follows:

July 1, 2018 - December 31, 2018	$36,000
2019	69,700
2020	53,700
2021	37,800
2022	37,800
Thereafter	208,000

6. 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 and other items. The provision for income taxes is based on an estimated effective tax rate derived from our consolidated earnings before taxes, adjusted for nondeductible expenses and other permanent differences for the fiscal year. For the three and six months ended June 30, 2018, the provision for income taxes was $1.0 million and $2.0 million, respectively. As of June 30, 2018 and December 31, 2017, our remaining deferred tax assets were approximately $0.3 million and $1.7 million, respectively.

For the three and six months ended June 30, 2017, the provision for income taxes was $1.4 million and $3.2 million, respectively.

Table of Contents

The estimated effective tax rate for the three and six months ended June 30, 2018 was 18.2% and 19.7%, respectively, of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in 2018. Our effective tax rate for the six months ended June 30, 2018 was impacted primarily by the Tax Cuts and Jobs Act of 2017, which was enacted on December 22, 2017 and lowered the U.S. corporate tax rate from 35% to 21%, beginning in 2018. Our effective tax rate was also impacted by the discrete impact of current period stock option exercises which impacts the effective rate in the period in which it occurs. The effective tax rate for the six months ended June 30, 2017 was 34.8% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2017 plus the effects of certain material discrete items that occurred in 2017.

As of June 30, 2018, the Company has no unrecognized tax benefits or related interest and penalties. Management does not believe that there is any tax position which it is reasonably possible that will result in unrecognized tax benefit within the next 12 months.

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 for multiple indications. We currently have a development and license agreement with Endo Global Ventures, a Bermuda unlimited liability company (“Endo Global Ventures”), an affiliate of Endo International plc (“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”). Injectable collagenase clostridium histolyticum is marketed as XIAFLEX® (or Xiapex® in Europe).

On February 1, 2016, we entered into with Endo the First Amendment (the “First Amendment”) to the Second Amended and Restated Development and Licensing Agreement (the “Auxilium Agreement”), by and between us and Auxilium, now a wholly-owned subsidiary of Endo, to amend certain provisions of the Auxilium Agreement (as amended by the First Amendment, the “License Agreement”). The effective date of the First Amendment was 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.

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 of $0.75 million 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, plantar fibromatosis and human lipoma. Endo exercised, with our consent, an early opt-in for lateral hip fat and plantar fibromatosis in November 2015. Endo opted-in for human lipoma in July 2016. We manage the development of XIAFLEX for uterine fibroids and initiate the development of XIAFLEX in new potential indications, not licensed by Endo.

On November 8, 2016, following a change in Endo management, Endo announced that a commercial review is ongoing of the XIAFLEX exercised but non-marketed indications, including frozen shoulder, cellulite, lateral hip fat, plantar fibromatosis and human lipoma, so that Endo can best prioritize its R&D efforts and determine clinical trial timelines moving forward. On February 6, 2018, Endo initiated two identical Phase 3 RELEASE clinical trials of XIAFLEX for the treatment of cellulite. The multicenter, randomized, double-blind, placebo-controlled RELEASE studies will evaluate the safety and efficacy of XIAFLEX in reducing the appearance of cellulite.

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 and certain Eurasian countries 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 is selling XIAFLEX for the treatment of Dupuytren's contracture in Japan. Endo is currently distributing XIAFLEX in Canada through Paladin Labs Inc., an operating company of Endo. In December 2016, Endo entered into a new out-licensing agreement with Actelion Pharmaceuticals Ltd. ("Actelion"), pursuant to which Actelion obtained marketing and commercial rights for XIAFLEX in Australia and New Zealand.

Table of Contents

Operational Highlights

Our Phase 1 clinical trial of Collagenase Clostridium Histolyticum (CCH) for the treatment of uterine fibroids is ongoing and we plan to announce the results in 2018. The study, being conducted at the Department of Gynecology & Obstetrics at Johns Hopkins University, is designed to enroll 15 female subjects treated prior to hysterectomy. The primary endpoint of the study will assess the safety and tolerability of a single injection of XIAFLEX directly into the uterine fibroids under transvaginal ultrasound guidance. The secondary endpoints will assess symptoms of pain and bleeding, quality of life throughout the study, shrinkage of XIAFLEX treated fibroids in size, increased rates of apoptosis in treated fibroids and a decrease in the collagen content of the treated fibroids. On March 12, 2018, we announced the presentation of interim data from our ongoing Phase 1 clinical trial of XIALEX for the treatment of uterine fibroids at the 65th Annual Scientific Meeting of the Society for Reproductive Investigation on Friday, March 9, 2018 in San Diego, CA. The data showed the safety and effectiveness of the XIALFEX injection method in five patients.

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, regulatory submissions 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 XIAFLEX for additional indications, obtain required regulatory approvals, manufacture XIAFLEX at an acceptable cost, in a timely manner and with appropriate quality, or successfully market products or maintain desired margins for products sold, and, as a result, we may not achieve sustained profitable operations.

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, 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 1 of our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 14, 2018 and under Item 1A of Part 2 of our Quarterly Report on Form 10Q for the quarter ended March 31, 2018 filed with the SEC on May 10, 2018.

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, 2018 and for the three and six months ended June 30, 2018 and 2017 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, 2017 balance sheet amounts and disclosures included herein have been derived from the Company's December 31, 2017 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, 2017 included in the Company's Annual Report on Form 10-K filed and with the unaudited condensed consolidated financial statements included in our Quarterly Report on Form 10-Q for the first quarter of 2018 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.

Table of Contents

Except as described in Note 2 to our accompanying Condensed Consolidated Financial Statements with respect to changes in our revenue recognition policy related to our adoption of the requirements of ASC 606, there have been no significant changes to our critical accounting policies and estimates during the three and six months ended June 30, 2018, compared to the critical accounting policies and estimates disclosed in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report on Form 10-K for the year ended December 31, 2017 and our Quarterly Report on Form 10-Q for the quarter ended March 31, 2018.

Reimbursable Third-Party Patent Costs

We accrue patent costs that are reimbursable to Endo by us under the License Agreement. We capitalize certain patent costs related to patent prosecution and maintenance and expense others. As of June 30, 2018 and December 31, 2017, our net reimbursable third party patent expense was $49,000 and zero, respectively.

Receivables

At June 30, 2018 and December 31, 2017 our accounts receivable balance which consists of royalties and a mark-up on costs of goods sold, was $12.9 million and $4.7 million, respectively, and was from one customer, Endo.

Deferred Revenue

We recognized the remaining $35,000 related to nonrefundable upfront product license fees for product candidates as there were no remaining performance obligations. In addition, we determined that the $100,000 related to a milestone payment withheld by Endo due to a foreign tax withholding was uncollectable and have reduced this amount to zero. As of June 30, 2018 and December 31, 2017, deferred revenue was zero and $6.4 million, 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 under general and administrative in the quarter that the net sales have occurred. For the three and six month periods ended June 30, 2018, third-party royalty expenses were $0.5 million and $1.0 million, respectively. For the three and six month periods ended June 30, 2017, third-party royalty expenses were $0.4 million and $0.9 million, respectively. 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 XIAFLEX and Xiapex are approved, marketed and sold.

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, all of which have been paid as of June 30, 2018. Royalty obligations terminate five years after first commercial sale which occurred in January 2014. 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 and Xiapex for Peyronie's disease on an annual basis as measured by the proportion of the total estimated sales over the five year period. For the three and six months ended June 30, 2018 and 2017, we

amortized approximately $0.5 million and $1.0 million related to this agreement, respectively and $0.4 million and $0.7 million for the three and six months ended June 30, 2017. As of June 30, 2018 and December 31, 2017, the remaining capitalized balances were approximately $1.1 million and $2.5 million, respectively. We perform an evaluation of the recoverability of the carrying value to determine if facts and circumstances indicate that the carrying value of the assets may be impaired and if any adjustment is warranted. As of June 30, 2018, there was no indicator that an impairment existed.

Table of Contents

Stock Based Compensation

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

Further, ASC 718 requires that employee stock-based compensation costs to be recognized over the requisite service period, or the vesting period, in a manner similar to all other forms of compensation paid to employees. The allocation of employee stock-based compensation costs to each operating expense line are estimated based on specific employee headcount information at each grant date and estimated stock option forfeiture rates and revised, if necessary, in future periods if actual employee headcount information or forfeitures differ materially from those estimates. As a result, the amount of employee stock-based compensation costs we recognize in each operating expense category in future periods may differ significantly from what we have recorded in the current period.

RESULTS OF OPERATIONS

THREE MONTHS ENDED JUNE 30, 2018 COMPARED TO THREE MONTHS ENDED JUNE 30, 2017

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 June 30, 2018 were $7.1 million as compared to $6.5 million in the corresponding 2017 period, an increase of $0.6 million or 9%. The increase in total revenues for the quarterly period was primarily due to royalties associated with higher net sales of XIAFLEX in Peyronies disease partially offset by lower mark-up on cost of goods sold revenue in prepaid foreign mark-up on cost of goods sold revenue recognized under new revenue standard ASC 606, as of January 1, 2018.

Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. For the three month periods ended June 30, 2018, we recognized the remaining $35,270 related to nonrefundable upfront product license fees for product candidates as there were no remaining performance obligations as compared to $4,409 in the 2017 period.

Milestone revenue recognized for the three months ended June 30, 2018 and 2017 was zero in each period.

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 month periods ended June 30, 2018 and 2017, R&D expenses were approximately $0.2 million and $0.3 million, respectively and in each case, are primarily related to the development work associated with our clinical,

preclinical and other R&D programs. The decrease in the 2018 period as compare to the 2017 period was mainly due to lower consulting fees associated with clinical, preclinical and other R&D programs.

We manage the development of XIAFLEX for uterine fibroids and initiate the development of XIAFLEX in new potential indications, not licensed by Endo. On April 18, 2017, we announced the initiation of an open-label, dose escalation Phase 1 clinical trial of XIAFLEX for the treatment of uterine fibroids. On March 12, 2018, we announced the presentation of data that shows the safety and effectiveness of the XIALFELX injection method in five patients.

Table of Contents

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

	Three Months Ended June 30, 2018	Three Months Ended June 30, 2017
Program		
Uterine Fibroids	$ 104,596	$ 107,746
Pre-clinical/other research projects	107,200	229,985

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 Xiapex, to continue to commercialize these drug candidates.

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

- the nature, timing and estimated costs of the efforts necessary to complete the development of our drug candidate projects;
- the anticipated completion dates for our drug candidate projects;
- the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future with respect to our drug candidate projects;
- the scope, rate of progress of our preclinical studies and other 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.

We believe that our current resources and liquidity are sufficient to advance our current clinical and R&D projects.

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 June 30, 2018 and 2017 were $2.0 million and $2.3 million, respectively. The decrease in general and administrative expenses was mainly due to the lower consulting and patent fees partially offset by higher amortization associated with deferred royalty buy-down and third party royalties associated with XIAFLEX.

Other Income

Other income for the three months ended June 30, 2018 was approximately $356,000 compared to $164,000 in the corresponding 2017 period. Other income consists of interest earned on our investments and product sales of collagenase for laboratory use.

Table of Contents

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. For the three month period ended June 30, 2018, our provision for income taxes was $1.0 million. Our deferred tax assets as of June 30, 2018 were $0.3 million. The estimated effective tax rate for the three months ended June 30, 2018 was 18.2% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in 2018. Our effective tax rate for the three months ended June 30, 2018 was impacted primarily by the Tax Cuts and Jobs Act of 2017, which was enacted on December 22, 2017 and lowered the U.S. corporate tax rate from 35% to 21%, beginning in 2018. Our effective tax rate was also impacted by the discrete impact of current period stock option exercises which impacts the effective rate in the period in which it occurs.

For the three month period ended June 30, 2017, the provision for income taxes was $1.4 million. The effective tax rate for the three months ended June 30, 2017 was 34.8% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2017 plus the effects of certain material discrete items that occurred in 2017.

Net Income

For the three months ended June 30, 2018, we recorded net income of $4.3 million, or $0.60 per basic common share and $0.59 per diluted common share, compared to a net income of $2.6 million, or $0.37 per basic common share and $0.36 per diluted common share, for the same period in 2017.

SIX MONTHS ENDED JUNE 30, 2018 COMPARED TO SIX MONTHS ENDED JUNE 30, 2017

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 six month period ended June 30, 2018 were $14.1 million as compared to $14.2 million in the corresponding 2017 period, a decrease of $0.1 million or 1%. The decrease in total revenues for the quarterly period was primarily due to lower mark-up on cost of goods sold revenue in the U.S and prepaid foreign mark-up on cost of goods sold revenue recognized under new revenue standard ASC 606, as of January 1, 2018, which was mostly offset by an increase in royalties associated with higher overall net sales of XIAFLEX in Peyronies 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 License Agreement in prior years and amortized them over the expected development period. For the six month periods ended June 30, 2018, we recognized the remaining $39,679 related to nonrefundable upfront product license fees for product candidates as there were no remaining performance obligations as compared to $8,818 in the 2017 period.

Milestone revenue recognized for the six months ended June 30, 2018 and 2017 was zero in each period.

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 month periods ended June 30, 2018 and 2017, R&D expenses were approximately $0.4 million and $0.6 million, respectively and in each case, are primarily related to the development work associated with our clinical, preclinical and other R&D programs. The decrease in the 2018 period as compare to the 2017 period was mainly due to lower consulting fees associated with clinical, preclinical and other R&D programs.

We manage the development of XIAFLEX for uterine fibroids and initiate the development of XIAFLEX in new potential indications, not licensed by Endo. On April 18, 2017, we announced the initiation of an open-label, dose escalation Phase 1 clinical trial of XIAFLEX for the treatment of uterine fibroids. On March 12, 2018, we announced the presentation of data that shows the safety and effectiveness of the XIALFELX injection method in five patients.

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

	Six Months Ended June 30, 2018	Six Months Ended June 30, 2017
Program		
Uterine Fibroids	$ 127,534	$ 228,132
Pre-clinical/other research projects	279,489	364,380

Table of Contents

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 Xiapex, to continue to commercialize these drug candidates.

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

- the nature, timing and estimated costs of the efforts necessary to complete the development of our drug candidate projects;
- the anticipated completion dates for our drug candidate projects;
- the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future with respect to our drug candidate projects;
- the scope, rate of progress of our preclinical studies and other 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.

We believe that our current resources and liquidity are sufficient to advance our current clinical and R&D projects.

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 six months ended June 30, 2018 and 2017 were $4.1 million and $4.7 million, respectively. The decrease in general and administrative expenses was mainly due to the lower consulting and patent fees partially offset by higher amortization associated with deferred royalty buy-down and third party royalties associated with XIAFLEX.

Other Income

Other income for the six months ended June 30, 2018 was approximately $0.6 million compared to $0.3 million in the corresponding 2017 period. Other income consists of interest earned on our investments and product sales of collagenase for laboratory use.

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. For the six month period ended June 30, 2018, our provision for income taxes was $2.0 million. Our deferred tax assets as of June 30, 2018 were $0.3 million. The estimated effective tax rate for the six months ended June 30, 2018 was 19.7% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2018 plus the effects of certain discrete items occurring in 2018. Our effective tax rate for the six months ended June 30, 2018 was impacted primarily by the Tax Cuts and Jobs Act of 2017, which was enacted on December 22, 2017 and lowered the U.S. corporate tax rate from 35% to 21%, beginning in 2018. Our effective tax rate was also impacted by the discrete impact of current period stock option exercises which impacts the effective rate in the period in which it occurs.

For the six month period ended June 30, 2017, the provision for income taxes was $3.2 million. The effective tax rate for the six months ended June 30, 2017 was 34.8% of pre-tax income reported in the period, calculated based on the estimated annual effective rate anticipated for the year ending December 31, 2017 plus the effects of certain material discrete items that occurred in 2017.

Table of Contents

Net Income

For the six months ended June 30, 2018, we recorded net income of $8.3 million, or $1.15 per basic common share and $1.13 per diluted common share, compared to a net income of $6.0 million, or $0.83 per basic common share and $0.81 per diluted common share, for the same period in 2017.

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 June 30, 2018 and December 31, 2017, we had cash and cash equivalents and investments in the aggregate of approximately $73.7 million and $65.1 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 from the date of this filing.

Net cash provided by operating activities for the six months ended June 30, 2018 was $8.1 million as compared to net cash provided by operating activities of $6.3 million in the 2017 period. Net cash provided by operating activities in the 2018 period was primarily attributable to our net income partially offset by an increase in accounts receivable of $0.7 million due to the timing of Endo's payment of our quarterly XIAFLEX royalties and accrued tax liability of $0.6 million. Non-cash items included amortization, stock-based compensation expense, and deferred taxes which was reduced by adjustments to reconcile net income to net cash provided by operating activities of $1.5 million. Net cash provided by operating activities in the 2017 period was primarily attributable to our net income of $6.0 million, an increase in operating assets and liabilities of $1.0 million of which $0.9 million was related to an increase in accounts receivable due to sales of XIAFLEX. Non-cash items included amortization, stock-based compensation expense, and deferred taxes which was reduced by adjustments to reconcile net income to net cash provided by operating activities of $1.4 million.

Net cash used in investing activities for the six months ended June 30, 2018 was $3.3 million as compared to $4.8 million for the corresponding 2017 period. The net cash used in investing activities in the 2018 period reflects the investment of $40.6 million and the maturing of $37.3 million in marketable securities. The net cash used in investing activities in the 2017 period reflects the investment of $37.7 million and the maturing of $32.9 million marketable securities.

Net cash provided by financing activities for the six months ended June 30, 2018 was approximately $0.9 million as compared to net cash used in financing activities of approximately $0.2 million in the corresponding 2017 period. In the 2018 period, net cash provided by financing activities was due to proceeds received from stock option exercises. In the 2017 period, net cash used in financing activities was mainly due to the repurchase of approximately $0.5 million of our common stock under our stock repurchase program partially offset by the proceeds received from stock option exercises of approximately $0.3 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 three months or less to be cash equivalents.

Our investment portfolio is subject to interest rate risk, although limited given the short term 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 June 30, 2018, amounting to approximately $73.7 million, were maintained in bank demand accounts, money market accounts, certificates of deposit, corporate bonds and 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.

Table of Contents

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 June 30, 2018.

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 it 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 control over financial reporting (as defined in Rules 13a–15(f) and 15d–15(f) under the Exchange Act) that occurred during the three months ended June 30, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II: OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

In addition to the other information contained elsewhere in this Report, you should carefully consider the risk factors discussed in "Part I, Item 1A. Risk Factors" our Annual Report on Form 10-K for the year ended December 31, 2017 filed with the SEC on March 14, 2018 and our Quarterly Report on Form 10-Q for the first quarter of 2018 filed with the SEC on May 10, 2018, which could materially affect our business, financial condition or future results.

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

During the six month period ended June 30, 2018, we did not issue any unregistered shares of securities.

Issuer Purchases of Equity Securities

During the six month period ended June 30, 2018, we did not repurchase any of our securities.

27

Table of Contents

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, 2018, (i) the Condensed Consolidated Statements of Operations, (ii) the Condensed Consolidated Statements of Cash Flows, and (iii) the Notes to the Condensed Consolidated Financial Statements.

* filed herewith
** furnished herewith

Table of Contents

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this Report to be signed on its behalf by the undersigned thereunto duly authorized.

BIOSPECIFICS TECHNOLOGIES CORP.
(Registrant)

Date: August 9, 2018 /s/ Thomas L. Wegman
Thomas L. Wegman
President, Principal Executive Officer and
Principal Financial Officer