FORM 10-K

BIOSPECIFICS TECHNOLOGIES CORP - BSTC

Filed: April 02, 2019 (period: December 31, 2018)

Annual report with a comprehensive overview of the company

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)
☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2018

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

Commission File Number: **001-34236**

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)

Registrant's telephone number, including area code: **516.593.7000**

Securities registered under Section 12(b) of the Exchange Act:

Title of each class	Name of each exchange on which registered
Common Stock	**The Nasdaq Global Market**

Securities registered under Section 12(g) of the Exchange Act: **NONE**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
☐Yes ☑No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act.
☐Yes ☑No

Indicate by check mark whether the registrant (1) 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 every Interactive Data File required to be submitted 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 such files). ☑Yes ☐No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐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", "smaller reporting company" and "emerging growth 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 complying 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

The aggregate market value of voting and non-voting common stock held by non-affiliates of the Registrant as of June 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $254 million.

The number of shares outstanding of the registrant's common stock as of April 1, 2019 is 7,286,902.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2019 Annual Meeting of Stockholders, which is expected to be filed with the Securities and Exchange Commission not later than 120 days after the end of the registrant's fiscal year ended December 31, 2018, are incorporated by reference into Part III of this annual report on Form 10-K. With the exception of the portions of the registrant's definitive proxy statement for its 2019 Annual Meeting of Stockholders that are expressly incorporated by reference into this Annual Report on Form 10-K, such proxy statement shall not be deemed filed as part of this Annual Report on Form 10-K.

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Introductory Comments

Throughout this annual report on Form 10-K (this "Report"), the terms "BioSpecifics," "Company," "we," "our," and "us" refer to BioSpecifics Technologies Corp. and its subsidiary, Advance Biofactures Corporation ("ABC-NY").

SPECIAL NOTE REGARDING 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 opportunity for minimally invasive non-surgical treatment XIAFLEX in several potential pipeline indications;
- whether and when the Company will hear from Endo International plc ("Endo") the results of their full commercial assessment and analysis regarding the XIAFLEX® research and development ("R&D") pipeline;
- the Company's ability to achieve its future growth initiatives with regard to Dupuytren's Contracture and Peyronie's disease;
- the expansion of the market for XIAFLEX® through future growth initiatives;
- whether treating uterine fibroids with XIAFLEX® will achieve the advantages over major surgery identified by the Company;
- Endo's interest in currently unlicensed indications, including capsular contracture of the breast, Dercum's disease, knee arthrofibrosis, urethral strictures, hypertrophic scars and keloids;
- whether XIAFLEX® will be the only U.S. Food and Drug Administration ("FDA") approved nonsurgical therapy for frozen shoulder (adhesive capsulitis);
- the projected receipt of payments from Endo and sublicense income payments based on Endo's partnerships;
- and the strength of the Company's IP portfolio.

In some cases, these statements can be identified by forward-looking words such as "expect," "plan," "anticipate," "potential," "estimate," "can," "will," "continue," 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, which will determine the amount of milestone, royalty, mark-up on cost of goods sold, license and sublicense income that 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 this Annual Report on Form 10-K for the year ended December 31, 2018, specifically in Part I, Item IA of this Report under the heading "Risk Factors" and under the section "Management's Discussion and Analysis." All forward-looking statements included in this Annual Report on Form 10-K for the year ended December 31, 2018 are made as of the date hereof, are expressly qualified in their entirety by the cautionary statements included in this Annual Report on Form 10-K for the year ended December 31, 2018 and, except as may be required by law, we assume no obligation to update these forward-looking statements.

PART I

Item 1. BUSINESS.

Overview

We are a biopharmaceutical company involved in the development of an injectable collagenase clostridium histolyticum (CCH) for multiple indications. Our subsidiary, ABC-NY, originally was formed in 1957 to develop collagenase for debridement of chronic wounds and severe burns; we divested this business in 2006. We maintain intellectual property with respect to injectable CCH that treats, among other indications, Dupuytren's contracture (DC), Peyronie's disease (PD), frozen shoulder syndrome, and removal of adipose tissue. Injectable CCH currently is approved and marketed in the U.S. under the trademark XIAFLEX® for the treatment of both DC and PD. XIAFLEX® is also commercialized in Japan, Europe (where it is marketed as Xiapex®), Canada, and Australia for DC, and for PD in Canada, Europe and Australia. We generate revenue primarily from our license agreement with Endo, under which 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®.

We have developed injectable CCH for 12 clinical indications to date, and currently are conducting exploratory clinical trials evaluating CCH as a treatment for a number of conditions, including uterine fibroids. Under our license agreement with Endo, Endo has the right to further develop CCH for Dupuytren's nodules, frozen shoulder, lateral hip fat, plantar fibromatosis, and human and canine lipomas on the medical therapeutic side, as well as other potential aesthetic indications, including frozen shoulder, cellulite, canine lipoma, lateral hip fat, plantar fibromatosis, and human lipoma. Additionally, we manage the development of XIAFLEX® for uterine fibroids and initiate the development of XIAFLEX® in new potential indications that are not licensed by Endo; Endo retains the right to opt-in to any indications other than other than dermal formulations labeled for topical administration.

Collagenase

Collagenase is the only protease that can hydrolyze the triple helical region of collagen under physiological conditions. The specific substrate collagen comprises approximately one-third of the total protein in mammalian organisms, and it is the main constituent of skin, tendon, and cartilage, as well as the organic component of teeth and bone. The body relies on endogenous collagenase production to remove dead tissue, and collagenase production is an essential biological mechanism, which regulates matrix remodeling and the normal turnover of tissue. The CCH used by us has a broad specificity towards all types of collagen and is acknowledged as much more efficient than mammalian collagenases. CCH cleaves the collagen molecule at multiple sites along the triple helix whereas the mammalian collagenase is only able to cleave the molecule at a single site along the triple helix.

Collagenase is widely used for cell dispersion for tissue disassociation and cell culture because it does not damage the cell membrane. Since the main component of scar tissue is collagen, collagenase has been used in a variety of clinical investigations to remove scar tissue without surgery.

License Agreement with Endo

On August 31, 2011, we entered into the Second Amended and Restated Development and License Agreement (as amended, the "License Agreement") with Auxilium Pharmaceuticals, Inc. ("Auxilium"), an entity that was acquired by Endo in 2015. The License Agreement originally was entered into in June 2004 to obtain exclusive worldwide rights to develop, market, and sell certain products containing our enzyme CCH, which Endo markets for approved indications under the trademark XIAFLEX®®. Endo's licensed rights concern the development and commercialization of products, other than dermal formulations labeled for topical administration. Currently, Endo's licensed rights cover the indications of DC, Dupuytren's nodules, PD, frozen shoulder, cellulite, canine and human lipomas, plantar fibromatosis, lateral hip fat, and other potential aesthetic indications. We and Endo may further expand the License Agreement to cover other indications as they are developed.

Under the License Agreement, Endo is responsible, at its own cost and expense, for developing the formulation and finished dosage form of products and arranging for the clinical supply of products. Endo has the option to license development and marketing rights to these indications based on a full analysis of the data from the clinical trials, which would transfer responsibility for the future development costs to Endo and trigger opt-in payments and potential future milestone and royalty payments to us.

The License Agreement extends, on a country-by-country and product-by-product basis, for the longer of the patent life, the expiration of any regulatory exclusivity period or twelve years from the effective date. Either party may terminate the License Agreement as a result of the other party's breach or bankruptcy.

Endo must pay us on a country-by-country and product-by-product basis a specified percentage, which typically is in the low double digits, of net sales for products covered by the License Agreement. This royalty applies to net sales by Endo or its sublicensees. Endo also is obligated to pay a percentage of any future regulatory or commercial milestone payments received from such sublicensees. In addition, Endo and its affiliates pay us an amount equal to a specified mark-up on certain cost of goods related to supply of XIAFLEX® (which mark-up is capped at a specified percentage of the cost of goods of XIAFLEX®) for products sold by Endo and its affiliates.

Pursuant to the License Agreement, Endo currently is selling XIAFLEX® in the U.S. for the treatment of DC and PD and is distributing XIAFLEX® in Canada through its operating company, Paladin Labs Inc. Additionally, Endo has entered into several non-affiliated sublicensee agreements (as permitted by the License Agreement), including the following:

- An agreement with Swedish Orphan Biovitrum AB ("Sobi"), pursuant to which Sobi has marketing rights for Xiapex® for the treatment of DC and PD in Europe and certain Eurasian countries;
- An agreement with Asahi Kasei Pharma Corporation ("Asahi"), pursuant to which Asahi has the right to commercialize XIAFLEX® for the treatment of DC and PD in Japan; and
- An agreement with Actelion Pharmaceuticals Ltd. ("Actelion"), pursuant to which Actelion obtained marketing and commercial rights for XIAFLEX® in Australia and New Zealand.

For additional information regarding the License Agreement, please see "Item 1. Business – Subsequent Events."

Operational Highlights

Endo-Marketed Indications

Dupuytren's Contracture.

CCH is currently approved and marketed in the U.S. under the trademark XIAFLEX®® for the treatment of DC. XIAFLEX®® is indicated for the treatment of adult patients with DC with an abnormal buildup of collagen in the hands, which limits or disables hand function. XIAFLEX® and Xiapex® are currently approved in the U.S., EU, Switzerland, Canada, Australia and Japan, among other jurisdictions, for the treatment of DC.

DC is a deforming condition of the hand in which one or more fingers contract toward the palm, often resulting in physical disability. The onset of DC is characterized by the formation of nodules in the palm that are composed primarily of collagen. As the disease progresses, the collagen nodules begin to form a cord causing the patient's finger(s) to contract, making it impossible to open the hand fully. Patients often complain about the inability to wash their hands, wear gloves, or grasp some objects. DC is a genetic condition that is more common in men than in women, and increases in incidence with age. Well-known individuals with DC include President Ronald Reagan, President George H. W. Bush, and Prime Minister Margaret Thatcher.

XIAFLEX® is the only drug approved by the FDA, the European Medicines Agency (the "EMA") and the Pharmaceuticals and Medical Devices Agency (the "PMDA") for the treatment of DC. Prior to FDA approval of XIAFLEX®, the only proven treatment for DC was surgery.

- Endo is currently distributing XIAFLEX® in Canada through Paladin Labs Inc.

- Sobi Partner Products, a business unit within Sobi, is primarily responsible for the applicable regulatory, clinical and commercialization activities for Xiapex® for DC in Europe, Russia and Turkey, and the Middle Eastern and North Africa. In November 2015, the EU Commission approved Sobi's label expansion for Xiapex®.

- In July 2014, Asahi successfully submitted an application to the PMDA for the potential approval of XIAFLEX® for the treatment of DC in Japan. In July 2015, Asahi received approval for its regulatory application to the PMDA for XIAFLEX® for the treatment of patients with DC in Japan. In August 2015, XIAFLEX® was listed on the Japanese National Health Insurance ("NHI") drug price standard for treatment of patients with DC. The first commercial sale of XIAFLEX® by Asahi for the treatment of DC in Japan occurred in September 2015.

Actelion has the marketing and commercial rights for XIAFLEX® in Australia and New Zealand.

Peyronie's Disease.

XIAFLEX® and Xiapex® are currently approved in the U.S., EU, Switzerland, Canada and Australia for the treatment of PD.

PD is characterized by the presence of a collagen plaque on the shaft of the penis, which can distort an erection and make intercourse difficult or impossible in advanced cases. In some mild cases, the plaque can resolve spontaneously without medical intervention. In severe cases, the penis can be bent at a 90-degree angle during erection. Significant psychological distress has been noted in patients with PD who are sexually active. Frequent patient complaints include increased pain, painful erections, palpable plaque, penile deformity, and erectile dysfunction. Patients with PD have been reported to have an increased likelihood of having DC, frozen shoulder, plantar fibromatosis, knuckle pads, hypertension and diabetes. PD is a disease with an initial inflammatory component. This inflammatory phase is poorly understood with a somewhat variable disease course and spontaneous resolution occurring in certain cases. After approximately 12 months of disease, the disease is reported to often develop into a more chronic, stable phase. PD is believed to be underdiagnosed and undertreated.

In December 2013, the FDA approved the supplemental biologics license application ("sBLA") submitted by Auxilium for XIAFLEX®. This is the first and only FDA-approved biologic therapy indicated for the treatment of PD in men with a palpable plaque and a curvature of 30 degrees or greater at the start of therapy. In June 2014, Sobi filed with the EMA to expand the label for Xiapex® to include the indication of PD. In February 2015, the EU Commission approved Sobi's expansion to market Xiapex® for the treatment of adult men with PD with a palpable plaque and curvature deformity of at least 30 degrees at the start of therapy. In October 2015, Xiapex® received approval from Swissmedic, the Swiss Agency for Therapeutic Products, for treatment of PD.

Indications that Endo has Under Development

In 2016, Endo announced that an ongoing commercial review of the non-marketed XIAFLEX® indications, including frozen shoulder, cellulite, canine lipoma, 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.

Cellulite (Edematous Fibrosclerotic Panniculopathy).

Edematous fibrosclerotic panniculopathy, commonly known as cellulite, describes a condition in which lobules of subcutaneous adipose tissue extend into the dermal layer. Cellulite can involve the loss of elasticity or shrinking of collagen cords, called septae, that attach the skin to lower layers of muscle. When fat in cellulite prone areas swells and expands, the septae tether the skin, which causes surface dimpling characteristic of cellulite. These changes can visibly affect the shape of the epidermis and resemble an orange peel-like dimpling of the skin.

Cellulite has been reported to occur in 85-98% of post-pubertal females and rarely in men, and it is believed to be prevalent in women of all races. Current treatments for cellulite include massage devices, creams, unapproved injectables, laser-based procedures or liposuction. There are no drugs currently approved by the FDA to treat cellulite, and devices cleared by the FDA to treat the condition have varying degrees of success in eliminating cellulite. Cellfina and Cellulaze, the devices of two competitors in the cellulite market, have already received medical device approval. Treatment with XIAFLEX® is intended to target and lyse, or break, those collagen tethers with the goal of releasing the skin dimpling and potentially resulting in smoothing of the skin.

Endo has global marketing rights for CCH for the treatment of cellulite. No FDA-approved pharmaceutical therapies are currently available for the treatment of cellulite.

In February 2018, Endo announced the initiation of two identical Phase 3 RELEASE clinical trials of XIAFLEX® for the treatment of cellulite. The multicenter, randomized, double-blind, placebo-controlled RELEASE studies evaluate the safety and efficacy of XIAFLEX® in reducing the appearance of cellulite. The Phase 3 RELEASE studies enrolled [840] women ([420] in each trial) age 18 years or older with moderate to severe cellulite in the U.S. Each subject received up to 3 treatment visits of XIAFLEX® (0.84 mg / treatment area, two treatment areas per visit) or placebo, with each treatment visit occurring approximately 21 days apart. Twelve injections were administered into cellulite dimples during each visit across each treatment area: the left and right buttock. At both the outset and conclusion of treatment, cellulite severity was assessed by each patient and clinician using two validated photonumeric cellulite severity scales developed by Endo and third-party psychometric experts. The primary endpoint is a composite responder analysis demonstrating at least a 2-level composite improvement, independently reported by both patient and clinician on the photonumeric scales of cellulite severity. Key secondary endpoints include the percentage of subjects that experience at least a 1-level or 2-level improvement in patient reported assessment, percentage of subjects with a 1-level composite improvement, percentage of satisfied subjects, change from baseline in a cellulite impact scale, i.e., patients' self-perception related to their cellulite, as well as the percentage of subjects with at least a 1-level or 2-level improvement in the GAIS.

In November 2018, Endo reported positive results from two Phase 3 clinical trials of CCH for the treatment of cellulite in the buttocks. Trial subjects receiving CCH showed highly statistically significant levels of improvement in the appearance of cellulite with treatment, as measured by the trials' primary endpoint. In addition, the RELEASE-1 trial passed 8 out of 8 key secondary endpoints and the RELEASE-2 trial passed 7 out of 8 key secondary endpoints. Finally, CCH was well-tolerated in the actively-treated subjects with most adverse events being mild to moderate in severity and primarily limited to the local injection area.

Frozen Shoulder (Adhesive Capsulitis).

Frozen shoulder syndrome is a clinical syndrome of pain and decreased motion in the shoulder joint which results from inflammation and thickening of the shoulder capsule due to collagen. It is estimated to affect 20 to 50 million people worldwide with a slightly higher incidence in women. It is estimated that 300,000 cases of frozen shoulder syndrome are diagnosed annually in the U.S. It typically occurs in adults between the ages of 40-70. It is estimated that 20% of diabetics have frozen shoulder syndrome. No FDA-approved pharmaceutical therapies are currently available for the treatment of frozen shoulder. The most common treatments for frozen shoulder syndrome are longer-term extensive physical therapy, manipulation under anesthesia, corticosteroids and/or arthroscopy, and some drugs are used to manage pain.

Phase 2 Study

In the first quarter of 2013, Auxilium reported the top-line results of its Phase 2a study. The Phase 2a study was an open-label, controlled dose-ranging study designed to assess the safety and efficacy of XIAFLEX® for the treatment of Stage 2 unilateral idiopathic frozen shoulder in comparison to an exercise-only control group. The study involved 50 adult men and women at 11 sites throughout the U.S. Four cohorts of 10 patients each received up to three ultrasound-guided extra articular injections of varying doses of XIAFLEX® (ranging from 0.29 mg to 0.58 mg in three different volumes; 0.5, 1.0, or 2.0 ml), separated by a minimum of 21 days. All patients were instructed to perform home shoulder exercises. The fifth cohort of 10 patients received no XIAFLEX® injections and only performed home shoulder exercises. The study's primary endpoint was the change (in degrees) from baseline to the day 92 follow-up in active forward flexion in the affected shoulder compared to the exercise-only cohort. Safety assessments were made during all study visits and immunogenicity testing was performed at screening and day 92.

Both the 0.58 mg (1 ml) and 0.58 mg (2 ml) dosing arms showed positive, statistically significant improvement from baseline in forward flexion vs. the exercise-only group. The 0.58 mg (1 ml) dosing arm also showed statistically significant improvement from baseline in shoulder abduction vs. the exercise-only group. Positive trends with improvement in degrees were also seen in other active range of motion, AROM, assessments vs. the exercise-only group. Twenty-nine study patients (72.5%) received three XIAFLEX® injections with 5 subjects receiving two injections and 6 subjects receiving one injection only.

Patients were also assessed using the American Shoulder and Elbow Surgeons, or ASES, Scale for function and pain. Both the 0.58 mg (1 ml) and 0.58 mg (2 ml) cohort demonstrated statistically significant improvement in pain and function over baseline scores vs. the exercise-only group ($p<0.05$).

Treatment-related adverse events with XIAFLEX® were mostly localized bruising, injection site pain and swelling, hematoma, and musculoskeletal pain. All such events resolved without intervention, and are consistent with XIAFLEX® use in other approved and potential indications. No subjects discontinued the study due to an adverse event. A shoulder MRI was performed on all patients at screening and day 92. Screening MRIs were performed to exclude the presence of other clinically significant conditions such as concomitant rotator cuff injury. Day 92 MRI evaluations indicated there were no rotator cuff injuries. There were no drug-related serious adverse events reported.

In the fourth quarter of 2013, Auxilium reported that it had initiated a Phase 2b double-blind, placebo-controlled study based on positive, statistically significant results in the Phase 2a study. The Phase 2b study evaluated the safety and efficacy of XIAFLEX® for the treatment of Stage 2 unilateral idiopathic frozen shoulder. Following the Acquisition, Endo assumed Auxilium's responsibilities with respect to the Phase 2b trial. Three hundred twenty-one adult men and women were enrolled at approximately 35 sites in the U.S. and Australia. Subjects were randomized 3:1 to receive XIAFLEX® or placebo and received up to three ultrasound-guided injections of study drug. Each injection was separated by a minimum of 21 days. All subjects also performed home shoulder exercises after the first injection.

The primary endpoint of the Phase 2b study was change in degrees from baseline to the day 95 follow-up visit in active forward flexion in the affected shoulder compared to placebo. Patients were assessed using the ASES Scale for function and pain as well as additional patient reported outcome measures. Safety assessments were made during all study visits and immunogenicity testing was performed at screening and at the end of the study.

On March 12, 2015, Endo provided an update on the results of the Phase 2b study without releasing all of the data. Endo noted strong drug effect and similar XIAFLEX® patient improvements in flexion, shoulder abduction and external and internal rotation seen across both Phase 2a and 2b trials and similar patient improvement in pain seen across both trials. Endo also noted an increased and unexpectedly robust placebo effect in those patients who did not receive XIAFLEX®.

We are awaiting the results of Endo's ongoing commercial review.

Dupuytren's Disease Nodules.

In December 2014, Auxilium completed a Phase 2a, double-blind, randomized, placebo-controlled, dose-ranging study to evaluate the safety and effectiveness of XIAFLEX® to treat Dupuytren's disease nodules. The study produced statistically significant results, which Endo announced in June 2015.

Human Lipoma.

Lipomas are benign fatty tumors that occur as bulges under the skin and affect humans and canines. It is estimated that lipomas are the primary diagnosis in approximately 600,000 human patients in the U.S. annually. The only proven therapy for lipoma treatment is surgery, which is often not practical for patients with multiple lipomas. Twenty percent of patients have multiple lipomas. Based on observations made during preclinical studies that a collagenase injection decreased the size of fat pads in animals, we initiated, monitored and supplied the requisite study drug for a Phase 1 open label clinical trial for the treatment of human lipomas with a single injection of collagenase. Favorable initial results (10 out of 12 patients had a 50-90% reduction in the size of the lipomas) from this trial for the treatment of human lipomas were presented at a meeting of the American Society of Plastic Surgeons.

In January 2014, we announced the top-line data from the Phase 2 dose escalation clinical trial of XIAFLEX® for the treatment of human lipoma. This Phase 2 open-label single-center dose escalation study assessed the safety and efficacy of XIAFLEX® in 14 patients with lipoma, divided into four dose cohorts. Each patient received a single injection of XIAFLEX® in 1 of 4 ascending doses based on the current commercial dose of XIAFLEX® in marketed indications, ranging from 0.058 mg (10% of commercial dose) to 0.44 mg (75% of commercial dose). The primary efficacy outcome was a statistically significant ($p<0.0001$) reduction in lipoma visible surface area as measured by caliper, combining all patients. Data showed patients in the highest dose group (75% of commercial dose) achieved the best efficacy results with an average of 67% reduction of lipoma visible surface area as measured by caliper at six months post-treatment. Additionally, data demonstrated that 75% of patients in the highest dose group achieved reduction of 50% or more in lipoma visible surface area. There were no drug-related serious adverse events reported during the trial. The most frequent treatment-related adverse events were localized to the injection site and included bruising, injection site swelling and injection site pain. These adverse events are consistent with those seen previously in clinical experience.

In August 2014, we initiated our randomized, double-blind, placebo-controlled Phase 2 clinical trial of XIAFLEX® for the treatment of lipoma. We completed patient enrollment during the fourth quarter of 2015. The study was conducted at two centers in the U.S. and enrolled 18 adult men and women presenting with at least 2 benign lipomas of similar size. Subjects were randomized to have two lipomas treated in immediate succession: 1 with XIAFLEX® and 1 with placebo. The primary endpoint of the Phase 2 clinical trial is the reduction in the measureable surface area of the target lipomas, as determined by caliper, at six months post injection. The secondary efficacy endpoints include responders at six months post injection who show a ≥50% decrease in lipoma surface area relative to baseline between XIAFLEX® and placebo, the change in the length of the target lipoma, the relative change in lipoma surface area as measured by caliper at 1 month and 3 months, and the relative change in lipoma volume as measured by MRI. The study also gathered qualitative lipoma characteristics and an assessment of patient satisfaction through a questionnaire administered to each subject prior to injection and at each follow-up visit.

In June 2016, we announced positive, statistically significant top-line results from our placebo-controlled, double-blind Phase 2 clinical trial. This trial, conducted in 19 patients with two or more benign lipomas, met its primary endpoint of reduction in the visible surface area of the target lipomas relative to placebo, as determined by caliper, at six months post injection (and also met all secondary efficacy endpoints). 81.3% reduction in the visible surface area for patients who received XIAFLEX® compared to a 2.1% increase for treatment with placebo in the target lipoma, as measured by caliper at six months post-treatment, resulting in an 83.4% difference in favor of XIAFLEX® ($p<0.0001$). 89.5% of XIAFLEX® patients (17 of 19 patients) were responders at six months post-injection (showed a ≥50% decrease in lipoma visible surface area relative to baseline) compared to 0% for placebo ($p<0.0001$). The mean decrease in the length of the target lipoma at 6 months was 64.8% from baseline for XIAFLEX® treated lipomas and 0.2% increase for placebo ($p<0.0001$). As measured by caliper, the mean decrease in lipoma visible surface area at 3 months was 62.5% for XIAFLEX® and 0.4% increase for placebo ($p<0.0001$). As measured by caliper, the mean decrease in lipoma visible surface area at 1 month was 26.8% for XIAFLEX® and 0.2% increase for placebo ($p=0.0042$). The mean decrease in lipoma volume as measured by MRI at 6 months was 47.2% for XIAFLEX® treated lipomas and 4.9% for placebo ($p=0.0013$). Patient satisfaction was assessed through a questionnaire administered to each subject prior to injection and at the 1-, 3- and 6-month follow-up visits. For the lipomas that received XIAFLEX® treatment, at 6 months, 57.9% of patients reported being very satisfied; 36.8 were somewhat satisfied and zero were not satisfied verses placebo where 21.1% were very satisfied; 15.8% were somewhat satisfied and 57.9% were not satisfied ($p=0.0010$ in favor of XIAFLEX®). There were no drug-related serious adverse events reported during the trial and XIAFLEX® was well-tolerated, with no trial dropouts. The most frequent treatment-related adverse events were localized to the injection site and included bruising, injection site swelling/pain and pruritus. These adverse events are consistent with those seen previously in clinical experience.

In June 2016, we announced positive, statistically significant top-line results from our placebo-controlled, double-blind Phase 2 clinical trial. This trial, conducted in 19 patients with two or more benign lipomas, met its primary endpoint of reduction in the visible surface area of the target lipomas relative to placebo, as determined by caliper, at six months post injection (and also met all secondary efficacy endpoints). There were no serious adverse events reported during the trial. Endo opted-in for human lipoma in July 2016.

In August 2016, we announced that Endo opted in to this indication. We are awaiting the results of Endo's ongoing commercial review.

Canine Lipoma.

Based on the encouraging results reported in the clinical investigations in human lipoma, we began clinical trials in canine lipoma. As many as 1.7 million canines per year are affected with lipomas in the U.S. Lipomas in older canines are very common, and lipomas that restrict motion in older canines are a serious problem. The only proven therapy for this condition is surgical excision of the lipoma, which necessarily involves the use of general anesthesia. There are approximately 1 million lipomas excised each year from dogs in the U.S.

In December 2013, we announced top-line data from Chien-804, the placebo-controlled, double-blind, randomized Phase 2 trial evaluating the efficacy of XIAFLEX® in canines with benign subcutaneous lipomas. The Chien-804 trial enrolled 37 dogs in a single injection study randomized 1:1 XIAFLEX® to placebo with lipoma volume being measured by CT scan and lipoma surface area being measured by caliper at baseline, 1 month and 90 days. The data at 90 days show a post-treatment difference in the mean percent change in lipoma volume by CT scan between the XIAFLEX® and placebo-treated groups of -11.58% (p=0.52), which was not statistically significant. The percent change at 90 days in mean visible surface area measured by caliper showed a difference of -44.12% versus 4.0% in the placebo group (p=0.006), which was statistically significant. Among those dogs whose lipomas decreased by 50% or more, the results achieved statistical significance and showed that the visible surface area as measured by caliper decreased by 50% or more in 45.0% of XIAFLEX®-treated dogs (9 out of 20) versus 0% of placebo-treated dogs (0 out of 17), with a p-value of 0.0015. A questionnaire administered to pet owners, while blinded to the study, showed 70.0% satisfaction with the results of XIAFLEX® treatment versus 23.6% satisfaction with the placebo results (p=0.0027). There were no drug-related serious adverse events reported during the trial. The most frequent treatment-related adverse events were local injection site reactions including bruising, injection site swelling, injection site pain and injection site edema. These adverse events are consistent with those seen previously in clinical experience in humans.

Endo is responsible for further development of this indication, but has not yet announced its plans for the indication.

Lateral Hip Fat.

Lateral hip fat accumulation is common among women particularly as they age and it is often very difficult to improve its appearance through exercise and diet alone. Patients frequently avoid exercise and are unable to restrict their caloric intake. The prevalence of lateral hip fat is similar to the prevalence of cellulite. In some cases, cyrolipolysis and liposuction are performed to remove the unsightly fat deposits in the lateral hip. There are no pharmaceutical products that are labeled for use on lateral hip fat in the U.S. In November 2015, with our consent, Endo exercised an early opt-in for XIAFLEX® for this potential indication. Endo is responsible for further development of this indication. We are awaiting the results of Endo's ongoing commercial review.

Plantar Fibromatosis.

Plantar fibromatosis, or Ledderhose disease, is a medical condition characterized by pain and disability caused by the thickening of the feet's deep connective tissue resulting in the formation of nodules or cords along the tendons of the foot. Patients with plantar fibromatosis often have DC and frozen shoulder. It is estimated that there are approximately 200,000 patients in the U.S. Treatment may include orthotics and anti-inflammatory drugs in the early stages of the disease, steroid injections and surgery in advanced cases. There are no pharmaceutical products that are FDA approved for use in this indication in the U.S. In November 2015, with our consent, Endo exercised an early opt-in for XIAFLEX® for this potential indication. Endo is responsible for further development of this indication. We are awaiting the results of Endo's ongoing commercial review.

BioSpecifics-Managed Indications

Uterine Fibroids.

Uterine fibroids are benign tumors that form on the wall of the uterus that contain large amounts of collagen and are associated with significant co-morbidities, which can include pain, decreased fertility, pregnancy complications, miscarriage, heavy menstrual bleeding and frequent urination. Uterine fibroids are the primary indication for hysterectomy in the U.S. Approximately 200,000 hysterectomies and 30,000 myomectomies are performed annually to treat fibroids. Uterine fibroids have been estimated to result in direct costs of $9.4 billion annually in the U.S., including costs for surgery, hospital admissions, outpatient visits and medications.

In October 2014, we published data showing that highly purified collagenase can reduce the rigidity of human uterine fibroid tissue and potentially shrink uterine fibroid tumors by interrupting the accumulation of poorly aligned and altered collagen. In May 2016, we announced that an article titled, "Loss of Stiffness in Collagen-Rich Uterine Fibroids after Digestion with Purified Collagenase Clostridium Histolyticum" was published in the May 2016 issue of American Journal of Obstetrics & Gynecology. The study, led by Dr. Phyllis Leppert, showed reduction in stiffness and demonstrated the benefits of XIAFLEX® as a potential non-surgical treatment for uterine fibroid patients.

On April 18, 2017, we announced that we had initiated an open-label, dose escalation Phase 1 clinical trial of XIAFLEX® for the treatment of uterine fibroids. The study, conducted at the Department of Gynecology & Obstetrics at Johns Hopkins University, consisted of 15 female subjects treated prior to hysterectomy. The primary endpoint of the study assessed the safety and tolerability of a single injection of XIAFLEX® directly into the uterine fibroids under transvaginal ultrasound guidance. The secondary endpoints assessed 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 October 31, 2018, we announced positive topline data from our Phase 1 trial of CCH for the treatment of uterine fibroids. The study met the primary endpoint of safety and tolerability of a single injection of XIAFLEX® directly into the uterine fibroids under transvaginal ultrasound guidance with no observed clinically significant adverse reactions. Pharmacodynamic changes were noted in all secondary endpoints, which included assessment of 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, with the exception of apoptosis.

Other Clinical Indications

Other clinical indications for which our collagenase injection has been tested include keloids, hypertrophic scars, scarred tendons, glaucoma, herniated intervertebral discs, and as an adjunct to vitrectomy. We are currently evaluating our options for development of additional indications using collagenase.

LICENSING AND MARKETING AGREEMENTS

The descriptions of the agreements set forth below do not purport to be complete and are qualified in their entirety by reference to the full text of the applicable agreement. The agreements described below are available as set forth below:

License Agreement	Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 1, 2011
First Amendment	Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 5, 2016
Second Amendment	Exhibit 10.1 to the Company's Current Report on Form 8-K Filed February 28, 2019
Dupuytren's License Agreement	Exhibit 10.1 to the Company's Current Report on Form 8-K filed November 28, 2006
Gelbard Amendment	Exhibit 10.1 to the Company's Amendment to Current Report on Form 8-K/A filed August 13, 2012
Frozen Shoulder License Agreement	Exhibit 10.2 to the Company's Current Report on Form 8-K filed November 28, 2006
Cellulite License Agreement	Exhibit 10.7 to the Company's Annual Report on Form 10-K filed March 15, 2013
Gerut License Agreement	Exhibit 10.8 to the Company's Annual Report on Form 10-K filed March 15, 2013

License Agreement with Endo

On August 31, 2011, we entered into License Agreement, as summarized above.

On February 1, 2016, we entered into the First Amendment (the "First Amendment") to the License Agreement. Pursuant to the First Amendment, the Company and Endo Global Ventures mutually agreed that in exchange for a $8.25 million lump sum payment, we will not receive future additional mark-up on cost of goods sold for sales by non-affiliated sublicensees of Endo outside of the U.S.; provided, however, that Endo will still be required to pay a mark-up on cost of goods sold for sales made in the "Endo Territory," which includes sales made in the U.S. and sales made in any other country where Endo sells the product directly or through affiliated sublicensees. We received this $8.25 million lump sum payment in February 2016 and began recognizing this income over time based on sales by non-affiliated sublicensees of Endo outside of the U.S. according to our revenue recognition policy in the second quarter of 2016.

Additionally, we agreed that Endo may opt-in early to indications, prior to our submission of a clinical trial report, with our consent, such consent not to be unreasonably withheld. For early opt-ins, Endo will be required to make an opt-in payment of $0.5 million on a per indication basis. For regular opt-ins, following our submission of a clinical trial report, Endo will be required to make an opt-in payment of $0.75 million on a per indication basis. Endo has opted-in to the following indications: frozen shoulder, cellulite, canine lipoma, lateral hip fat, plantar fibromatosis and human lipoma.

Pursuant to the License Agreement, we are entitled to receive certain up-front licensing and sublicensing fees, and milestone, mark-up on cost of goods sold and royalty payments. Through December 31, 2018, Endo has collectively paid us up-front licensing and sublicensing fees and milestone, mark-up on cost of goods sold and royalty payments under the License Agreement of $161.2 million, including fees relating to Endo's sublicensee agreements with Sobi, Asahi and Actelion. Additionally, Endo is obligated to make contingent milestone payments to us, with respect to each of frozen shoulder, cellulite and canine lipoma, lateral hip fat, plantar fibromatosis indications and human lipoma, upon the acceptance of the regulatory filing and upon receipt by Endo, its affiliate or sublicensee of regulatory approval. The remaining contingent milestone payments that may be received, in the aggregate, from Endo in respect of frozen shoulder, cellulite, canine lipoma, lateral hip fat, plantar fibromatosis and human lipoma are $6.0 million.

As discussed above, Endo has partnered with Sobi, Asahi and Actelion to commercialize XIAFLEX® and Xiapex® outside of the United States. Sobi has exclusive rights to commercialize Xiapex® for DC and PD, subject to applicable regulatory approvals, in 28 EU member countries, Switzerland, Norway, Iceland, 18 Central Eastern Europe/Commonwealth of Independent countries, including Russia and Turkey, and 22 Middle Eastern & North African countries. Sobi, via its Partner Products business unit, is primarily responsible for the applicable regulatory, and commercialization activities for Xiapex® in DC and PD in these countries.

Endo has granted to Asahi the exclusive right to develop and commercialize XIAFLEX® for the treatment of DC and PD in Japan. Actelion has marketing and commercial rights for XIAFLEX® in Australia and New Zealand.

Pursuant to the License Agreement, we will receive a certain percentage of milestone payments that each of Sobi, Asahi and Actelion pays to Endo. We will also receive royalties from net sales in Sobi and Asahi territories from Endo, which will be a specified percentage of what Endo receives. To the extent Endo enters into an agreement or agreements related to DC and PD in other territories, the percentage of sublicense income that Endo would pay us will depend on the territory, the stage of development and approval of XIAFLEX® for the particular indication at the time such other agreement or agreements are executed. Pursuant to the First Amendment, the Company no longer receives a mark-up on cost of goods sold for sales made by Endo outside of the U.S. to unaffiliated parties; provided, however, that if the sale is made outside of the U.S. by Endo directly, Endo is still required to pay us a mark-up on cost of goods sold.

Endo is required to pay on a country-by-country and product-by-product basis a low double digit royalty as a percentage of net sales for products covered by the License Agreement and sold in the United States, Europe, Canada, and certain Eurasian countries and Japan. In the case of products covered by the License Agreement and sold in other countries, or the Rest of the World (as defined in the License Agreement), Endo must pay us on a country-by-country and product-by-product basis a specified percentage of the royalties it is entitled to receive from a partner or partners with whom it has contracted for such countries. The royalty rate is independent of sales volume and clinical indication in the United States, Europe, Canada, Australia and certain Eurasian countries and Japan, but is subject to set-off in those other countries and the Rest of the World for certain expenses we owe to Endo relating to certain development and patent costs. In addition, the royalty percentage may be reduced if (i) market share of a competing product exceeds a specified threshold; or (ii) Endo is required to obtain a license from a third party in order to practice our patents without infringing such third party's patent rights. To date, neither Auxilium nor Endo has paid any royalties to third parties. In addition, if Endo out-licenses to a third party, then we will receive a specified percentage of certain payments made to Endo in consideration of such out-licenses.

These royalty obligations extend for the longer of the patent life (including pending patents), the expiration of any regulatory exclusivity period based on orphan drug designation or foreign equivalent thereof or June 3, 2016. Endo may terminate the License Agreement upon 90 days' prior written notice. If Endo terminates the License Agreement other than because of an uncured, material breach by us, all rights revert to us. Pursuant to our August 31, 2011 settlement agreement with Auxilium, we are now co-owners and two of our employees will be co-inventors of U.S. Patent No. 7,811,560 and any continuations and divisionals thereof. We expect that this patent will expire in July 2028.

On top of the payments set forth above, as a result of the First Amendment, Endo must pay to us an amount equal to a specified mark-up of the cost of goods sold for products sold in the Endo Territory (as defined in the License Agreement), which will always include sales made in the United States and sales made in any other country where Endo Global Ventures sells the product directly or through affiliated sublicensees. Pursuant to the First Amendment, in exchange for the $8.25 million lump sum payment, Endo is no longer required to pay for costs of goods sold for sales within the Partner II Territory or the Japan Territory (as defined in the License Agreement).

Endo is generally responsible, at its own cost and expense, for developing the formulation and finished dosage form of products and arranging for the clinical supply of products. Endo is generally responsible for all clinical development and regulatory costs for PD, DC, frozen shoulder, cellulite, canine lipoma, lateral hip fat, plantar fibromatosis, human lipoma and all additional indications for which it exercises its options.

For more information regarding the License Agreement, please refer to "Item 1. Business – Subsequent Events."

In-Licensing and Royalty Agreements

We have entered into several in-licensing and royalty agreements with various investigators, universities and other entities throughout the years. It is the policy of the Company not to announce publicly royalty rates for potential future indications under development before commercialization. It is important to emphasize that in-licensing royalty rates vary from indication to indication and it should not be assumed that the in-licensing royalty rates for potential future indications will be the same as those for currently marketed indications.

Dupuytren's Disease

On November 21, 2006, we entered into a license agreement (the "Dupuytren's License Agreement"), with the Research Foundation of the State University of New York at Stony Brook (the "Research Foundation"), pursuant to which the Research Foundation granted to us and our affiliates an exclusive worldwide license, with the right to sublicense to certain third parties, the know-how owned by the Research Foundation related to the development, manufacture, use or sale of (i) the collagenase enzyme obtained by a fermentation and purification process (the "Enzyme"), and (ii) all pharmaceutical products containing CCH or injectable collagenase, in each case to the extent it pertains to the treatment and prevention of Dupuytren's disease.

In consideration of the license granted under the Dupuytren's License Agreement, we agreed to pay to the Research Foundation certain royalties on net sales (if any) of pharmaceutical products containing CCH or injectable collagenase for the treatment and prevention of Dupuytren's disease (each a "Dupuytren's Licensed Product").

Our obligation to pay royalties to the Research Foundation with respect to sales by us, our affiliates or any sublicensee of any Dupuytren's Licensed Product in any country (including the U.S.) arises only upon the first commercial sale of such Dupuytren's Licensed Product on a country-by-country basis. The royalty rate is 0.5% of net sales. Our obligation to pay royalties to the Research Foundation will continue until the later of (i) the expiration of the last valid claim of a patent pertaining to the Dupuytren's Licensed Product; (ii) the expiration of the regulatory exclusivity period conveyed by the FDA's Office of Orphan Products Development ("OOPD"), with respect to the Dupuytren's Licensed Product; or (iii) June 3, 2016.

Unless terminated earlier in accordance with its termination provisions, the Dupuytren's License Agreement and the licenses granted under that agreement will continue in effect until the termination of our royalty obligations. After that, all licenses granted to us under the Dupuytren's License Agreement will become fully paid, irrevocable exclusive licenses.

Peyronie's Disease

On August 27, 2008, we entered into an agreement with Dr. Martin K. Gelbard (the "Gelbard Agreement") to improve the deal terms related to our future royalty obligations for PD by buying down our future royalty obligations with a one-time cash payment. On March 31, 2012, we entered into an amendment to the Gelbard Agreement, which enables us to buy down a portion of our future royalty obligations in exchange for an initial cash payment and five additional cash payments. We are currently making the payments to buy down the future royalty obligations, which royalty obligations terminate five years after the first commercial sale, which occurred in January 2014.

Frozen Shoulder

On November 21, 2006, we entered into a license agreement (the "Frozen Shoulder License Agreement") with the Research Foundation, pursuant to which the Research Foundation granted to us and our affiliates an exclusive worldwide license, with the right to sublicense to certain third parties, to know-how owned by the Research Foundation related to the development, manufacture, use or sale of (i) CCH and (ii) all pharmaceutical products containing CCH or injectable collagenase, in each case to the extent it pertains to the treatment and prevention of frozen shoulder.

Additionally, the Research Foundation granted to us an exclusive license to the patent applications in respect of frozen shoulder. The license granted to us under the Frozen Shoulder License Agreement is subject to the non-exclusive license (with right to sublicense) granted to the U.S. government by the Research Foundation in connection with the U.S. government's funding of the initial research.

In consideration of the license granted under the Frozen Shoulder License Agreement, we agreed to pay to the Research Foundation certain royalties on net sales (if any) of pharmaceutical products containing CCH or injectable collagenase for the treatment and prevention of frozen shoulder (each a "Frozen Shoulder Licensed Product"). In addition, the Company and the Research Foundation will share in any milestone payments and sublicense income received by us in respect of the rights licensed under the Frozen Shoulder License Agreement.

Our obligation to pay royalties to the Research Foundation with respect to sales by us, our affiliates or any sublicensee of any Frozen Shoulder Licensed Product in any country (including the U.S.) arises only upon the first commercial sale of a Frozen Shoulder Licensed Product. Our obligation to pay royalties to the Research Foundation will continue until, the later of (i) the expiration of the last valid claim of a university patent pertaining to a Frozen Shoulder Licensed Product or (ii) June 3, 2016.

Unless terminated earlier in accordance with its termination provisions, the Frozen Shoulder License Agreement and licenses granted under that agreement will continue in effect until the termination of our royalty obligations. After that, all licenses granted to us under the Frozen Shoulder License Agreement will become fully paid, irrevocable exclusive licenses.

Cellulite

We have two in-licensing and royalty agreements related to cellulite. On August 23, 2007, we entered into the license agreement ("Cellulite License Agreement"),with the Research Foundation, pursuant to which, the Research Foundation granted to the Company and its affiliates an exclusive worldwide license, with the right to sublicense to certain third parties, the know-how owned by the Research Foundation related to the manufacture, preparation, formulation, use or development of (i) CCH and (ii) all pharmaceutical products containing CCH, which are made, used and sold for the prevention or treatment of cellulite. Additionally, the Research Foundation granted to us an exclusive license to the patent applications in respect of cellulite. The license granted under the Cellulite License Agreement is subject to the non-exclusive license (with right to sublicense) granted to the U.S. government by the Research Foundation in connection with the U.S. government's funding of the initial research.

In consideration of the license granted under the Cellulite License Agreement, we agreed to pay to the Research Foundation certain royalties on net sales (if any) of pharmaceutical products containing CCH, which are made, used and sold for the prevention or treatment of cellulite (each a "Cellulite Licensed Product"). In addition, the Company and the Research Foundation will share in any milestone payments and sublicense income received by us in respect of the rights licensed under the Cellulite License Agreement. We paid a portion of the $0.5 million milestone payment we received from Auxilium in respect of its exercise of cellulite as an addition indication under the License Agreement, subject to certain credits for certain up-front payments we made to the Research Foundation.

Our obligation to pay royalties to the Research Foundation with respect to sales by us, our affiliates or any sublicensee of any Cellulite Licensed Product in any country (including the U.S.) arises only upon the first commercial sale of a Cellulite Licensed Product. Our obligation to pay royalties to the Research Foundation will continue until, the later of (i) the expiration of the last valid claim of a patent pertaining to a Cellulite Licensed Product or (ii) June 3, 2016. Valid claim is defined only to include an issued specified Research Foundation patent.

Unless terminated earlier in accordance with its termination provisions, the Cellulite License Agreement and licenses granted under that agreement will continue in effect until the termination of our royalty obligations. After that, all licenses granted to us under the Cellulite License Agreement will become fully paid, irrevocable exclusive licenses.

Removal or Treatment of Fat

On March 27, 2010, we entered into the in-licensing and royalty agreement with Dr. Zachary Gerut (the "Gerut License Agreement"), pursuant to which, Dr. Gerut granted to us and our affiliates an exclusive worldwide license, with the right to sublicense to certain third parties the know-how owned by Dr. Gerut related to the manufacture, preparation, formulation, use or development of (i) CCH and (ii) all pharmaceutical products containing CCH or injectable collagenase, in each case to the extent it pertains to the removal or treatment of fat. As the in-license granted under the Gerut License Agreement pertains to the treatment of fat, this in-license also relates to both human lipoma and canine lipoma.

In consideration of the license granted under the Gerut License Agreement, we agreed to pay to Dr. Gerut certain royalties on net sales (if any) of pharmaceutical products containing CCH that are made, used and sold for the removal or treatment of fat in humans or animals (each a "Gerut Licensed Product"). In addition, in the event the FDA approves a Gerut Licensed Product, we agreed to make a one-time stock option grant to Dr. Gerut with a strike price equal to the closing trading price on the day before the date of such grant.

Our obligation to pay royalties to Dr. Gerut with respect to sales by us, our affiliates or any sublicensee of any Gerut Licensed Product in any country (including the U.S.) arises only upon the first commercial sale of a Gerut Licensed Product. Our obligation to pay royalties to Dr. Gerut will continue until June 3, 2016 or such longer period as we continue to receive royalties for such Gerut Licensed Product.

Unless terminated earlier in accordance with its termination provisions, the Gerut License Agreement and licenses granted under that agreement will continue in effect until the termination of our royalty obligations. After that, all licenses granted to us under the Gerut License Agreement will become fully paid, irrevocable exclusive licenses.

Other Indications

We may enter into certain other license and royalty agreements with respect to other indications that we may elect to pursue.

COMPETITION

We and our licensees face worldwide competition from larger pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies that are developing and commercializing pharmaceutical products. Many of our competitors have substantially greater financial, technical and human resources than we have and may subsequently develop products that are more effective, safer or less costly than any products that we have developed, are developing, or will develop, or that are generic products. Our success will depend on our ability to acquire, develop and commercialize products and our ability to establish and maintain markets for our products that receive marketing approval. Our marketed indication for PD currently enjoys Orphan Drug Protection until December 6, 2020. Orphan drug status for DC expired on February 2, 2017. For more information on orphan drug designations, please see the discussion below. We may face greater competition, including from biosimilars, after the expiration of the orphan drug designations and the expiration of the 12-year marketing exclusivity under certain laws as further described below in "Public Health Service Act and Biologics Price Competition and Innovation Act".

GOVERNMENT REGULATION

Government authorities in the United States, at the federal, state, and local level, and in other countries, extensively regulate, among other things, the research, development, testing, approval, manufacture, packaging, storage, recordkeeping, labeling, advertising, promotion, distribution, reporting, marketing, import, and export of biopharmaceutical products such as those we and our partners are developing and have developed. In addition, manufacturers of biopharmaceutical products participating in Medicaid and Medicare are required to comply with mandatory price reporting, discount, and rebate requirements, among other requirements. Failure to comply with these requirements can result in exclusion from program coverage and debarment from government contracts. Federal law also limits the reimbursement rate Medicaid and Medicare pay providers. Many states have laws similar to federal laws that regulate marketing and sales within the state and some have imposed price reporting obligations and restrictions on price increases within the state. The processes for obtaining regulatory approvals in the United States and in foreign countries, along with subsequent compliance with applicable statutes and regulations, require the expenditure of substantial time and financial resources. In the United States, the FDA regulates our and our partners' products and product candidates as biologics, a drug subset, under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the Public Health Services Act ("PHSA"), and their implementing regulations.

Any product labeled for use in humans requires regulatory approval by government agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials to demonstrate their safety, purity, and potency, and must comply with additional regulatory requirements of the FDA and similar regulatory authorities in foreign countries, such as the EMA in Europe and the PMDA in Japan. Preclinical studies include laboratory evaluation of chemistry, pharmacology, toxicity, and product formulation, as well as animal studies to assess potential safety and efficacy. Clinical and preclinical trials must be conducted in accordance with the applicable regulatory standards, good clinical practices ("GCPs"), and good laboratory practices ("GLPs"), respectively. The process of obtaining marketing approvals and the compliance with federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources.

Clinical trials involve the administration of the investigational product candidate or approved products to human subjects under the supervision of qualified investigators. Each trial must be conducted under an FDA Investigational New Drug Application ("IND"). Prior to commencing the first clinical trial with a product candidate, an IND sponsor must submit the results of the preclinical tests and preclinical literature, together with manufacturing information, analytical data, any available clinical data or literature, and proposed clinical study protocols among other things, to the FDA as part of an IND. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, notifies the applicant of safety concerns or questions related to one or more proposed clinical trials and places the trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Clinical holds also may be imposed by the FDA at any time before or during trials due to safety concerns or non-compliance. As a result, submission of an IND may not result in FDA authorization to commence a clinical trial.

In addition to FDA review and supervision, each trial must also be reviewed, approved and conducted under the auspices of an independent institutional review board ("IRB"), and each trial must include the patient's informed consent. An IRB considers, among other things, whether the risks to individuals participating in the trials are minimized and are reasonable in relation to anticipated benefits, and whether the planned human subject protections are adequate. The IRB must continue to oversee the clinical trial while it is being conducted. Once an IND is in effect, each new clinical protocol and any amendments to the protocol must be submitted to the IND for FDA review, and to the IRB for approval. Investigators must also provide certain information to the clinical trial sponsors to allow the sponsors to make certain financial disclosures to the FDA. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study and the parameters to be used in assessing the safety and the effectiveness of the biologic, and a statistical analysis plan. A protocol for each clinical trial, and any subsequent protocol amendments, must be submitted to the FDA as part of the IND.

Typically, clinical evaluation involves a time-consuming and costly three-phase sequential process, but the phases may overlap.

- *Phase 1*—Studies are initially conducted in healthy human volunteers or subjects with the target disease or condition and test the product candidate for safety, dosage tolerance, structure-activity relationships, mechanism of action, absorption, metabolism, distribution, and excretion. If possible, Phase 1 trials may also be used to gain an initial indication of product effectiveness.

- *Phase 2*—Controlled studies are conducted in limited subject populations with a specified disease or condition to evaluate preliminary efficacy, identify optimal dosages, dosage tolerance and schedule, possible adverse effects and safety risks, and expanded evidence of safety.

- *Phase 3*—These adequate and well-controlled clinical trials are undertaken in expanded subject populations, generally at geographically dispersed clinical trial sites, to generate enough data to provide statistically significant evidence of clinical efficacy and safety of the product for approval, to establish the overall risk-benefit profile of the product, and to provide adequate information for the labeling of the product. Typically, two Phase 3 trials are required by the FDA for product approval.

There are typically multiple studies conducted within any given phase to collect the data necessary to support a marketing application. The 21st Century Cures Act, however, provides for FDA acceptance of new kinds of data such as patient experience data and, for appropriate indications sought through supplemental marketing applications, data summaries. Real world evidence may also be used to assist in clinical trial design. The FDA may also require, or companies may conduct, additional clinical trials for the same indication after a product is approved, referred to as Phase 4 studies. Moreover, FDA requires pediatric studies either before or after product approval, if the product candidate is not eligible for a waiver. Concurrent with clinical trials, companies usually complete additional animal studies, develop additional chemistry, manufacturing, and controls information, including stability, and finalize a process for manufacturing the product in commercial quantities in accordance with Current Good Manufacturing Practice ("cGMP") requirements.

Information about certain clinical trials, including a description of the study and study results, must be submitted within specific timeframes to the National Institutes of Health ("NIH"), for public dissemination on their clinicaltrials.gov website. Moreover, under the 21st Century Cures Act, manufacturers or distributors of investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions must have a publicly available policy concerning expanded access.

In addition to requirements concerning the conduct of clinical and preclinical trials, the manufacture of investigational biologics for the conduct of human clinical trials is subject to cGMP requirements. Sponsors of clinical trials must provide FDA annual updates on their development program and more frequent reports in the case of serious adverse events. Investigational biologics and active ingredients imported into the United States are also subject to regulation by the FDA relating to their labeling and distribution. Further, the export of investigational products outside of the United States is subject to regulatory requirements of the receiving country as well as U.S. export requirements.

Clinical testing may not be completed successfully within any specified time period, if at all. The FDA monitors the progress of all clinical trials that are conducted in the U.S. and may, at its discretion, reevaluate, alter, suspend or terminate the testing based upon the data accumulated to that point and the FDA's assessment of the risk/benefit ratio to the patient. The FDA can also provide specific guidance on the acceptability of protocol design for clinical trials. The FDA, an IRB, the Company or its partners may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk, the clinical trial is not being conducted in accordance with the FDA's or the IRB's requirements, the product has been associated with unexpected serious harm to the subjects, or based on evolving business objectives or competitive climate. The FDA can also request that additional clinical trials be conducted as a condition to product approval. During all clinical trials, physicians monitor the patients to determine effectiveness and/or to observe and report any reactions or other safety risks that may result from use of the product candidate.

Assuming successful completion of the required clinical trials, sponsors submit the results of preclinical studies and clinical trials, together with other detailed information including information on the chemistry, manufacture and control of the product, to the FDA, in the form of a Biologics License Application ("BLA"), requesting approval to market the product for one or more indications. In most cases, the BLA must be accompanied by a substantial user fee, which must be paid at the time of the first submission, if not waived. Orphan products, discussed further below, are not subject to application user fees unless the application includes an indication other than the orphan indication.

Within 60 days of receiving an application, the FDA determines if the application will be considered filed, meaning that it is substantially complete to permit a substantive review. If the FDA does not accept an application for filing, it must be resubmitted with the FDA requested information. Once the submission is accepted for filing, the FDA begins an in-depth substantive review to determine, among other things, whether a product is safe, pure, and potent, and whether the manufacturing methods and controls are adequate. The FDA also will inspect the product manufacturing facilities and selected clinical trial sites. The FDA will not approve the BLA unless cGMP and GCP compliance is satisfactory. The FDA may further refer a BLA to an advisory committee, which is a panel of experts, that recommend whether the application should be approved and under what conditions. The FDA aims to complete its review of standard BLAs within ten months from the 60-day filing date. This timeframe, however, may not be met or may be extended.

The FDA will issue an approval letter, authorizing commercial marketing, if it determines that the BLA, clinical and pre-clinical trial conduct, manufacturing process and manufacturing facilities are acceptable. If the FDA determines that the BLA, clinical or pre-clinical trial conduct, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in a complete response letter ("CRL"), indicating that the application is not ready for approval, and will often request additional testing, clinical trials, or information. If a CRL is issued, the applicant may either: (1) resubmit the BLA, addressing all of the deficiencies identified in the letter; (2) withdraw the application; or (3) request an opportunity for a hearing. The FDA has the goal of reviewing resubmissions in either two or six months of the resubmission date, depending on the kind of resubmission. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the BLA does not satisfy the regulatory criteria for approval and refuse to approve the BLA.

The testing and approval process requires substantial time, effort and financial resources, which may take several years to complete. The FDA may not grant approval on a timely basis, or at all. The Company or its partners may encounter difficulties or unanticipated costs in our or their efforts to secure necessary governmental approvals, which could delay or preclude us or them from marketing our products. Furthermore, the FDA may prevent a sponsor from marketing a product under a label for its desired indications or place other conditions, including restrictive labeling, on distribution as a condition of any approvals, which may impair commercialization of the product. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes and additional labeling claims, are subject to further FDA review and approval.

If the FDA approves the BLA, the product can be marketed to physicians to prescribe in the U.S. The FDA, however, may approve product candidates for fewer or more limited indications or uses than requested, may require significant safety warnings, including black box warnings, contraindications, and precautions, may grant approval contingent on the performance of costly post-marketing clinical trials, surveillance, or other requirements, including REMS, to monitor the safety or efficacy of the product, or may approve a product candidate with a label that does not include the labeling claims necessary or desirable for successful commercialization. The REMS plan could include medication guides, physician communication plans, and elements to assure safe use, such as restricted distribution methods, patient registries, or other risk minimization tools. An assessment of the REMS must also be conducted at set intervals. For example, the use of XIAFLEX® for the treatment of PD is subject to a REMS which requires health care provider training and certification, healthcare provider risk education, certification of dispensing pharmacies and health care settings, dispenser confirmation that the prescribing physician is certified under the REMS, Endo auditing of certified pharmacies and health settings, and patient risk education. Following product approval, a REMS may also be required by the FDA if new safety information is discovered and the FDA determines that a REMS is necessary to ensure that the benefits of the biologic outweigh the risks.

After approval, the sponsor must comply with a number of post-approval requirements, including delivering periodic reports to the FDA (i.e., annual reports), submitting descriptions of any adverse reactions reported, biological product deviation reporting, and complying with sampling and distribution requirements, including tracking and tracing requirements and suspect and illegitimate product investigation and notification requirements, ensuring products are properly imported and exported, as well as any other requirements set forth in the FDA's approval (such as REMS and Phase 4 studies). The holder of an approved BLA is further required to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling. The holder must also ensure compliance with other FDA requirements including requirements related to manufacturing, recordkeeping, advertising, marketing, promotion, and certain electronic records and signatures. For instance, the holder must ensure that approved products are not promoted for unapproved uses and are otherwise marketed in accordance with FDA's promotional requirements. Improper promotion can subject the holder to significant enforcement by FDA, other regulatory authorities, and private parties.

Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. Manufacturers and their subcontractors are required to register their facilities with the FDA and certain state agencies, list their products, and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMP which impose procedural and documentation requirements relating to manufacturing, quality assurance and quality control. In some case, after a BLA is approved, the product may also be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products before releasing the lots for distribution by the manufacturer. FDA regulations also require investigation and correction of any deviations from cGMP and specifications, and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other regulatory requirements. There also are continuing annual program user fee requirements for any approved products. Orphan products, however, may be exempt from program fees under certain circumstances.

In addition to studies requested by the FDA after approval, a sponsor may conduct other trials and studies to explore use of the approved product for treatment of new indications, which require submission of a supplemental or new BLA and FDA approval of the new labeling claims. The purpose of these trials and studies is to broaden the application and use of the product and its acceptance in the medical community.

We use, and will continue to use, third-party manufacturers to produce our products in clinical quantities. We additionally use third-party contract research organizations, clinical trial sites, and outside laboratories to conduct our clinical and preclinical studies. Future FDA inspections may identify compliance issues at our facilities, at the facilities of our contract manufacturers and other third parties or at those of our partners that may disrupt production or distribution, disrupt clinical or preclinical studies, or require substantial resources to correct. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in significant regulatory actions. Such actions may include restrictions on a product, studies, manufacturer or holder of an approved BLA, refusal to approve pending applications, license suspension or revocation, withdrawal of an approval, imposition of a clinical hold or termination of clinical trials, warning letters, untitled letters, cyber letters, modification of promotional materials or labeling, provision of corrective information, imposition of post-market requirements including the need for additional testing, imposition of distribution or other restrictions under a REMS, product recalls or withdrawals, product seizures or detentions, refusal to allow imports or exports, total or partial suspension of production or distribution, FDA debarment, injunctions, fines, consent decrees, corporate integrity agreements, debarment from receiving government contracts and new orders under existing contracts, exclusion from participation in federal and state healthcare programs, restitution, disgorgement, or civil or criminal penalties, including fines and imprisonment, and result in adverse publicity, among other adverse consequences. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

INTELLECTUAL PROPERTY AND RIGHTS

Our success will depend in part on our ability to protect our existing products and the products we acquire or in-license by obtaining and maintaining a strong proprietary position both in the U.S. and in other countries. To develop and maintain such a position, we intend to continue relying upon patent protection, trade secrets, know-how, continuing technological innovations and licensing opportunities. In addition, we intend to seek patent protection whenever available for any products or product candidates and related technology we develop or acquire in the future.

The following table sets forth information as of December 31, 2018 regarding our most significant patents:

Patent No.	Patent Expiration	Relevant Product/Technology	Ownership	Jurisdiction Where Granted
RE39,941	August 24, 2019	XIAFLEX®	Advance Biofactures Corporation	United States
6,022,539	June 3, 2019	XIAFLEX®	Advance Biofactures Corporation	United States
7,811,560	July 12, 2028	XIAFLEX®	AUXILIUM US HOLDINGS, LLC AUXILIUM INTERNATIONAL HOLDINGS, INC. ACTIENT HOLDINGS LLC ACTIENT PHARMACEUTICALS LLC SLATE PHARMACEUTICALS, INC. TIMM MEDICAL HOLDINGS, LLC ACTIENT THERAPEUTICS LLC 70 MAPLE AVENUE, LLC TIMM MEDICAL TECHNOLOGIES, INC. AUXILIUM PHARMACEUTICALS, INC.	United States
7,854,929	January 19, 2026	Method of treating lateral epicondylitis	Research Foundation for the State University of New York	United States
8,323,643	November 17, 2027	Method of treating adhesive capsulitis	Research Foundation for the State University of New York	United States
9,744,138	March 14, 2034	Method of treating uterine fibroids with collagenase and thermally responsive polymer	BSTC, Duke University, North Carolina Central University	United States
10,071,143	May 5, 2028	Method of treating carpal tunnel syndrome	Research Foundation for the State University of New York	United States
10,119,131	September 9, 2032	Method for fermenting clostripain-producing *Clostridium histolyticum* in peptone medium to produce collagenase	BSTC	United States
10,123,959	February 7, 2027	Method of treating cellulite	Research Foundation for the State University of New York	United States

Patents

We are the assignee or licensee of various U.S. patents, which have also been issued as patents in various foreign countries. Pursuant to our August 31, 2011 settlement agreement with Auxilium, we are now co-owners and papers will be filed to add two of our employees are co-inventors of U.S. Patent No. 7,811,560, entitled Compositions and Methods for Treating Collagen-Mediated Diseases, a patent relevant to XIAFLEX®, sold by Endo as a treatment for DC and PD. We expect this patent will expire in July 2028. In addition, we have licenses to other pending patent applications. Although we believe these patent applications, if they issue as patents, will provide a competitive advantage, the scope of the patent positions of pharmaceutical firms involves complex legal, scientific and factual questions and, as such, is generally uncertain. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of our current patent applications, or the products or product candidates we develop, acquire or license will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection, will be of any value to us or will be challenged, circumvented or invalidated by our competitors or otherwise.

While we attempt to ensure that our product candidates and the methods we employ to manufacture them do not infringe other parties' patents and proprietary rights, competitors or other parties may assert that we infringe their proprietary rights. Because patent applications in the U.S. and some other jurisdictions can proceed in secrecy until patents issue, third parties may obtain other patents without our knowledge prior to the issuance of patents relating to our product candidates, which they could attempt to assert against us. Also, since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications.

Although we believe that our product candidates, production methods and other activities do not currently infringe the intellectual property rights of third parties, we cannot be certain that a third party will not challenge our position in the future. If a third party alleges that we are infringing its intellectual property rights, we may need to obtain a license from that third party, but there can be no assurance that any such license will be available on commercially acceptable terms or at all. Any infringement claims that result in litigation could result in substantial cost to us and the diversion of management's attention from our core business. To enforce patents issued, assigned or licensed to us or to determine the scope and validity of other parties' proprietary rights, we may also become involved in litigation or in interference proceedings declared by the United States Patent and Trademark Office ("USPTO"), which could result in substantial costs to us or an adverse decision as to the priority of our inventions. We may be involved in interference and/or opposition proceedings in the future. We believe there will continue to be litigation in our industry regarding patent and other intellectual property rights.

As discussed above, we have licensed to Endo our injectable collagenase for the treatment of DC, PD, frozen shoulder, cellulite, canine lipoma, lateral hip fat, plantar fibromatosis and human lipoma. We have two use patents in the U.S. covering the enzyme underlying our injectable collagenase: one for the treatment of DC, which issued from a reissue proceeding in December 2007; and one for the treatment of PD. The Dupuytren's patent would have expired in 2014 were it not for an extension based on regulatory delay discussed below. Because of the extension, it has not expired yet. The Peyronie's patent expires in 2019. Both the Dupuytren's and Peyronie's patents are limited to the use of the enzyme for the treatment of DC and PD within certain dose ranges. An application to extend the term of the Dupuytren's patent to August 22, 2019 based upon regulatory delay in granting approval to sell XIAFLEX® was filed in the USPTO on April 1, 2010. On July 17, 2015, the USPTO granted the application extending the expiration date to August 24, 2019.

Orphan Drug Designations

Two indications, DC and PD, have received orphan drug designation from the OOPD. These indications did not receive the European equivalent of orphan drug designation.

The orphan drug provisions of the FDCA provide incentives to biologics sponsors to develop and supply products for the treatment of rare diseases, currently defined as diseases that affect fewer than 200,000 individuals in the U.S. or, for a disease that affects more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a product for such disease or condition will be recovered from its sales in the U.S. If there is a product already approved by the FDA that is intended for the same indication and that is considered by the FDA to be the same as the already approved product, sponsors must present a plausible hypothesis for clinical superiority to obtain orphan designation. This hypothesis must be demonstrated to obtain orphan exclusivity. Under the orphan regulations, the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for that product for the orphan indication which means the FDA may not approve any other application to market the same product for the same indication except in limited circumstances, such as a showing of clinical superiority over the product with orphan exclusivity. In the case of DC, orphan drug status expired on February 2, 2017; in the case of PD, orphan drug status expires on December 6, 2020. Orphan exclusivity would not prevent other products from being approved for the same indication or the same biologic from being approved for different indications. If granted, prior to product approval, orphan designation, companies developing orphan drugs may also be eligible for tax credits for expenses associated with clinical trials including a 20-year tax carry-forward, availability of FDA grants, and advice on design of the clinical development plan. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act.

Public Health Service Act and Biologics Price Competition and Innovation Act

XIAFLEX® is regulated and marketed as a biologic product pursuant to BLAs. The Company and its partners' other product candidates will also be regulated and marketed as biologic products pursuant to a BLA. XIAFLEX® was licensed based on a determination by the FDA of safety, purity, and potency as required under the PHSA. In 2010, Congress enacted the Biologics Price Competition and Innovation Act of 2009 ("BPCIA"), as part of the Patient Protection and Affordable Care Act, which amended the PHSA to create an abbreviated licensure pathway for products deemed to be biosimilar to or interchangeable with FDA-licensed reference biological products as well as protections for reference biologics.

Under the BPCIA, a reference biologic is granted 12 years of exclusivity from the time of first licensure. During this 12-year period, no application for a biosimilar product can be submitted for four years from the date of licensure of the reference product and FDA may not make a biosimilar product approval effective until the expiration of the 12 years. Not all reference product biologic applications and supplements, however, will qualify for 12 years of exclusivity. For instance, certain changes and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period. The BPCIA also includes provisions to protect reference products that have patent protection. The biosimilar product sponsor and reference product sponsor may exchange certain patent and product information for the purpose of determining whether there should be a legal patent challenge. Based on the outcome of negotiations surrounding the exchanged information, the reference product sponsor may bring a patent infringement suit and injunction proceedings against the biosimilar product sponsor. The biosimilar applicant may also be able to bring an action for declaratory judgment concerning the patent.

Under the BPCIA, following the expiration of a 12-year reference exclusivity period, the FDA may license under section 351(k) of the PHSA a biologic that it determines is biosimilar to or interchangeable with a reference product. Biosimilarity means that the section 351(k) product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the section 351(k) product and the reference product in terms of the safety, purity, and potency of the product. To be considered interchangeable, a product must be biosimilar to the reference product, be expected to produce the same clinical result as the reference product in any given patient, and, if administered more than once to an individual, the risks in terms of safety or diminished efficacy of alternating or switching between use of the product and its reference product is not greater than the risk of using the reference product without such alternation or switch. Interchangeable products may be substituted for the reference product without the intervention of the prescribing doctor. Licensure of a biosimilar or interchangeable product under section 351(k) generally requires less than the full complement of product-specific preclinical and clinical data required for innovator products licensed under section 351(a). The FDA has considerable discretion over the kind and amount of scientific evidence required to demonstrate biosimilarity and interchangeability. Depending on the product, additional periods of regulatory exclusivity may be available.

Trade Secrets

We also rely on trade secret protection for our confidential and proprietary information. No assurance can be given that others will not independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose such technology or that we can meaningfully protect our trade secrets.

It is our policy to require certain employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information developed or made known to the individual during the course of the individual's relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. In the case of employees, the agreements provide that all inventions conceived by the individual shall be our exclusive property. There can be no assurance, however, that these agreements will provide meaningful protection or adequate remedies for our trade secrets in the event of unauthorized use or disclosure of such information.

EMPLOYEES

The Company currently has five employees, all of whom are full-time, and three independent contractors.

CORPORATE INFORMATION

The Company was incorporated in Delaware in 1990; the Company's subsidiary, ABC-NY, was incorporated in New York in 1957. Our telephone number is 516-593-7000. Our corporate headquarters currently are located at 35 Wilbur St., Lynbrook, NY 11563, as further described in this Report under "Item 2 – Properties."

AVAILABLE INFORMATION

Our annual, quarterly and current reports, proxy statements and other information are filed or furnished with the SEC. These filings are available to the public over the Internet at the SEC's web site at http://www.sec.gov.

Our website address is www.biospecifics.com. We make available free of charge, through our website's "Investors" page, our annual, quarterly and current reports, and amendments to those reports, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Our Code of Ethics, which applies to all of our employees and non-employee directors, is available on the "Investors" page of our website at investors.biospecifics.com. You may request a copy of our SEC filings (excluding exhibits) and our Code of Ethics at no cost by writing or telephoning us at the above-referenced corporate address or telephone number.

The references to our web site and the SEC's web site are intended to be inactive textual references only and the contents of those websites are not incorporated by reference herein.

SUBSEQUENT EVENTS

On April 1, 2019, the Company appointed Dr. Ronald Law to the role of Principal Executive Officer of the Company and Mr. Pat Caldwell to the role of Principal Financial Officer, assuming both the principal financial officer and principal accounting officer functions on an interim basis pending an executive search being conducted by the Company.

On February 26, 2019, we and Endo entered into the Second Amendment to Second Amended and Restated Development and License Agreement (the "Second Amendment") to amend certain provisions of the License Agreement.

The Second Amendment has an effective date of January 1, 2019. Pursuant to the terms of the Second Amendment, we have consented to the assignment of the License Agreement by Endo Global Ventures to Endo Global Aesthetics Limited, an Irish private company and an affiliate of Endo Global Ventures that is indirectly wholly-owned by Endo. In addition, the Second Amendment amends certain provisions of the License Agreement to require Endo to provide timely estimates of royalties to assist us in complying with our financial reporting obligations.

Item 1A. RISK FACTORS

In addition to the other information included in this Report, the following factors should be considered in evaluating our business and future prospects. Any of the following risks, either alone or taken together, could materially and adversely affect our business, financial position or results of operations. If one or more of these or other risks or uncertainties materialize or if our underlying assumptions prove to be incorrect, our actual results may vary materially from what we projected. There may be additional risks that we do not presently know or that we currently believe are immaterial which could also impair our business or financial position.

Please also see the "Special Note Regarding Forward Looking Statements" on page 2 of this Annual Report on Form 10-K.

Risks Related to Our Limited Sources of Revenue

We are dependent on Endo for future opt-in, milestone, mark-up on cost of goods sold and royalty payments.

Our primary sources of revenues are from opt-in, milestone, mark-up on cost of goods sold and royalty payments from Endo under the License Agreement. As described in Item 1 above, under the License Agreement, in exchange for the right to receive royalties and other payments, we have granted to Endo the right to develop, manufacture, market and sell worldwide products (other than dermal formulations for topical administration) that contain collagenase for the treatment of DC, PD, frozen shoulder, cellulite, canine lipoma, plantar fibromatosis, lateral hip fat and human lipoma. However, we have no control over Endo's ability to successfully market, sell and manufacture products for the treatment of DC and PD, or, in the case of frozen shoulder, cellulite, canine lipoma, plantar fibromatosis, lateral hip fat and human lipoma, to pursue commercialization. Therefore, we may receive limited, if any, royalty payments from Endo.

Under the License Agreement, royalty payments are subject to set-off for certain expenses we owe Endo related to development and patent costs. While the deductions are increasing over time, we anticipate that the amount of royalties due to us will continue to exceed the amount of any set-offs.

In addition, we have granted to Endo an opt-in right to expand its license and development rights to one or more additional indications for injectable collagenase not currently licensed to Endo, including for the treatment of uterine fibroids. Endo may exercise its opt-in prior the Company's submission of a clinical trial report to Endo, with the Company's consent. Alternatively, Endo may opt-in following our submission of such a report. If Endo exercises its opt-in with respect to an additional indication, we are entitled to receive a one-time license fee for the rights to, as well as potential milestone, royalty and other payments with respect to, such new indication. If Endo does not exercise its opt-in for any additional indication, we may offer to any third party such development rights with regard to products in the Endo Territory (as defined in the License Agreement), provided that we first offer the same terms to Endo, or develop the product ourselves. Endo has no obligation to exercise its opt-in with respect to any such additional indication, and its decision to do so is in its complete discretion. Clinical trials can be expensive and the results are subject to different interpretations, and therefore, there is no assurance that after conducting Phase 2 clinical trials on any additional indication, and incurring the associated expenses, Endo will exercise its opt-in or we will receive any revenue from it. Under the License Agreement, we may only offer to a third party development rights with regard to products in the Endo Territory and not in Europe and certain Eurasian countries. Even if Endo exercises its opt-in as to any additional indication, its obligations to develop the product for such indication are limited to initiating Stage II Development (as defined in the License Agreement) for such additional indication within one year of exercising the opt-in as to such indication.

As there is uncertainty surrounding Endo's plans for licensed indications, decisions made by Endo may negatively impact our financial position.

We have no control over Endo's future plans for any licensed indications. We have received in the past, and are entitled to receive in the future, certain milestone payments from Endo in respect of its efforts to commercialize products, but we have no control over Endo's ability to achieve the milestones. As also described in Item 1 above, Endo has sublicensed to third parties some of the development and commercialization rights it licenses from us. Historically, we have received a percentage of the sublicense income that Endo receives from these third parties based on the achievement of certain regulatory and sales related milestones. There is, however, no guarantee that these third parties will continue to pursue development and commercialization of XIAFLEX® (or Xiapex® in Europe). If any third party stops pursuing such development and commercialization, sublicense income would no longer be payable to Endo or us.

Even if Endo or its sublicensees pursues development and commercialization, there is no guarantee that the FDA or equivalent foreign regulatory body will approve XIAFLEX® for a given indication or that commercialization will be successful. Moreover, Endo's review of pipeline indications has been ongoing since 2015; since that time, only the indication for cellulite has advanced in development.

The outcome and effects of Endo's ongoing commercial review of the XIAFLEX® exercised but non-marketed indications are uncertain.

Following the change in Endo management, Endo has announced a commercial review of the XIAFLEX® exercised but non-marketed indications, including frozen shoulder, canine lipoma, 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. At the present time, except for cellulite, which Endo is advancing in development, it is unclear how long this commercial review will take to complete and the effect that it will have on Endo's willingness to develop further such exercised but non-marketed indications. It is also unclear what effect, if any, the commercial review will have on the willingness of Endo to exercise its rights to opt in for any additional indications, including uterine fibroid.

Due to our dependence on Endo, Endo's failure to achieve projected revenues could have a material adverse effect on our business.

As discussed above, our performance is substantially dependent on Endo's performance, stability and success. Endo's operations are substantially dependent on the continued services and performance of its senior management and other key personnel as well as the stability and performance of its various business units. The on-going reshaping of Endo's business to delever, the restructuring of the generics business, and litigation and associated legal reserves could have the effect of distracting the attention of management and other resources away from the commercialization and further development of XIAFLEX®, thereby materially and adversely impacting our financial condition by slowing down the growth of, or reducing, XIAFLEX® sales and development and payments by Endo to us for royalties, cost of goods sold, milestones, and sublicense income.

Our dependence upon revenue from Endo makes us subject to the commercialization and other risk factors affecting Endo over which we have limited or no control, including those risk factors identified by Endo in its Form 10-K for the fiscal year ended December 31, 2018, filed on February 28, 2019.

Risks Related to Our Dependence on Endo

We are dependent upon revenue from Endo and Endo's operating success or failure has a significant impact on our potential royalty stream and other payment rights. The risk factors risks affecting Endo and, consequently, us, include the following. Moreover, to the extent that we are independently developing product candidates and indications, we will also be subject to the below risks:

Endo is subject to various regulations pertaining to the marketing of their products and services.

Endo is subject to various federal and state laws pertaining to healthcare fraud and abuse, including prohibitions on the offer of payment or acceptance of kickbacks or other remuneration for the purchase of Endo's products and services, including inducements to potential patients to request Endo's products and services and inducements to healthcare professionals to prescribe and use Endo's products. Additionally, product promotion, educational activities, support of continuing medical education programs, and other interactions with healthcare professionals and patients must be conducted in a manner consistent with the FDA regulations and the Anti-Kickback Statute. The Anti-Kickback Statute, with certain statutory exemptions and safe harbor regulations as interpreted through opinions published by the Office of the Inspector General of the Department of Health and Human Services ("HHS-OIG"), prohibits persons or entities from knowingly and willfully soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual, or the furnishing, recommending, or arranging for a good or service, for which payment may be made under federal healthcare programs, such as the Medicare and Medicaid programs. Violations of the Anti-Kickback Statute also carry potential federal False Claims Act liability. Additionally, many states have adopted laws similar to the Anti-Kickback Statute, without identical exceptions or exemptions. Some of these state prohibitions apply to referral of patients for healthcare items or services reimbursed by any third-party payer, not only the Medicare and Medicaid programs. Endo is also required to report pricing information and provide rebates to federal programs and discounts to federal purchasers as conditions of payment by Medicaid and Medicare. Noncompliance with these requirements subjects a company to potential False Claims Act liability and criminal, civil and administrative sanctions. Some states, such as California, also have their own price reporting obligations subject to state law. Any such new regulations or requirements may be difficult and expensive for Endo to comply with, may delay Endo's introduction of new products, may adversely affect Endo's total revenues and may have a material adverse effect on Endo's business, results of operations, financial condition and cash flows.

Sanctions for violating these laws include criminal penalties and civil sanctions and possible exclusion from federal funded healthcare programs such as Medicare and Medicaid as well as potential liability under the False Claims Act and applicable state false claims acts. There can be no assurance that Endo's practices will not be challenged under these laws in the future or that such a challenge would not have a material adverse effect on their business and Endo's business or results of operations.

In addition, Endo is subject to statutory and regulatory restrictions on the promotion of uses of prescription drugs that are not approved by the FDA. Although the FDA does not regulate a physician's choice of medications or treatments, the FDCA and FDA regulations and guidance significantly restrict the ability of pharmaceutical companies to communicate with patients, physicians, and other third-parties about unapproved product uses. FDA, Federal Trade Commission ("FTC"), the HHS-OIG, the Department of Justice ("DOJ") and various state Attorneys General actively enforce state and federal prohibitions on the promotion of unapproved uses, as well as prohibitions against promotional practices deemed false or misleading. A company that is found to have improperly promoted its products under these laws may be subject to significant liability, including significant administrative, civil, and criminal sanctions, including but not limited to, significant civil damages, criminal fines, and exclusion from participation in Medicare, Medicaid, and other federal healthcare programs. Applicable laws governing product promotion also provide for administrative, civil, and criminal liability for individuals, including, in some circumstances, potential strict vicarious liability. Conduct giving rise to such liability could also form the basis for private civil litigation by third-party payers or other persons allegedly harmed by such conduct, as well as qui tam actions under the federal False Claims Act in which the government could chose to intervene.

Endo has endeavored to establish and implement a corporate compliance program designed to prevent, detect, and correct violations of state and federal healthcare laws, including laws related to advertising and promotion of Endo's drugs. Nonetheless, the FDA, FTC, HHS-OIG, the DOJ and/or the state Attorneys General, and qui tam relators may take the position that Endo is not in compliance with such requirements, and, if such non-compliance is proven, Endo and, in some cases, individual employees, may be subject to significant liability, including the aforementioned administrative, civil, and criminal sanctions. This could have a material adverse effect on Endo's business and financial operations. For instance, while not related to XIAFLEX® or any of our product candidates, in 2014, Endo entered into a settlement and corporate integrity agreement to resolve criminal and civil liability arising from its marketing of an unrelated drug.

The pharmaceutical industry is heavily regulated, which creates uncertainty about Endo's ability to bring new products to market and imposes substantial compliance costs on their business.

Governmental authorities such as the FDA impose substantial requirements on the development, manufacture, holding, labeling, marketing, advertising, promotion, distribution and sale of therapeutic pharmaceutical products. Product candidates may not be marketed until completion of lengthy and detailed laboratory and clinical testing and other costly and time-consuming procedures, as well as the approval of marketing applications by regulatory authorities. A failure to obtain satisfactory results in required pre-marketing trials may prevent Endo from obtaining required regulatory approvals. The FDA may also require companies to conduct post-approval studies and post-approval surveillance regarding their drug products and does require companies to report adverse events and certain manufacturing issues.

Before obtaining regulatory approvals for the sale of any of Endo's new product candidates, Endo must demonstrate through preclinical studies and clinical trials that the product is safe, pure and potent for each intended use. Preclinical and clinical studies may fail to demonstrate the safety and effectiveness of a product. Likewise, Endo may not be able to demonstrate through clinical trials that a product candidate's therapeutic benefits outweigh its risks. Even promising results from preclinical and early clinical studies do not always accurately predict results in later, large scale trials. A failure to demonstrate safety and efficacy could or would result in Endo's failure to obtain regulatory approvals. Clinical trials can be delayed for reasons outside of Endo's control which can lead to increased development costs and delays in regulatory approval. For example, there is substantial competition to enroll patients in clinical trials and such competition has delayed clinical development of Endo's products in the past. For example, patients may not enroll in clinical trials at the rate expected or patients may drop out after enrolling in the trials or during the trials. In addition, Endo relies on collaboration partners that may control or make changes in trial protocol and design enhancements, or encounter clinical trial compliance-related issues, which may also delay clinical trials or require that clinical trials be suspended or terminated. Product supplies may be delayed or be insufficient to treat the patients participating in the clinical trials, or Endo, manufacturers, suppliers or other third parties may not meet the requirements of the FDA or foreign regulatory authorities, such as those relating to cGMP or GCPs. Such noncompliance may result in regulatory enforcement action and a regulatory authority's determination that a product candidate is not approvable. Endo also may experience delays in obtaining, or Endo may not obtain, required initial and continuing approval of Endo's clinical trials from institutional review boards and regulatory authorities. There may also be issues with study design and conduct that do not become apparent until a study is underway or completed. Endo cannot confirm that it will not experience delays or undesired results their clinical trials.

Endo cannot confirm that the FDA or foreign regulatory agencies will approve, clear for marketing or certify any products developed by Endo or that such approval will not subject the marketing of Endo's products to certain limits, such as limits on indicated use. The FDA or foreign regulatory authorities may not agree with Endo's study design, or assessment of the clinical data or they may interpret it differently. Such regulatory authorities may require additional or expanded clinical trials. Any limitation on use imposed by the FDA or delay in or failure to obtain FDA approvals or clearances of products developed by Endo would adversely affect the marketing of these products and Endo's ability to generate product revenue, which would adversely affect Endo's financial condition and results of operations.

In addition, with respect specifically to pharmaceutical products, the submission of a marketing application to the FDA with supporting clinical safety and efficacy data, for example, does not guarantee that the FDA will grant approval to market the product. Meeting the FDA's regulatory requirements to obtain approval to market a drug product, which varies substantially based on the type, complexity and novelty of the pharmaceutical product, typically takes years and is subject to uncertainty. The approval process for a new product varies in time. Approvals, if granted, may not include all uses (known as indications) for which a company may seek to market a product.

Further, once a product is approved for marketing, failure to comply with applicable regulatory requirements can result in regulatory enforcement actions, such as, but not limited to, warning, untitled, or cyber letters, suspensions or withdrawals of approvals or clearances, refusals to approve pending applications or supplements, seizures or recalls of products, injunctions against or other restrictions on the manufacture, holding, distribution, marketing and sale of a product, import or export refusals, product detention, promotional piece modifications and the issuance of corrective information, adverse publicity, regulatory authority issuance of public communications regarding products, holds or terminations on pre- or post-market studies, liability for harm cause to patients, reputational harm, civil and criminal sanctions, and FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements. Furthermore, changes in existing regulations or the adoption of new regulations could prevent Endo from obtaining, or affect the timing of, future regulatory approvals or clearances. Meeting regulatory requirements and evolving government standards may delay marketing of Endo's new products for a considerable period of time, impose costly procedures upon Endo's activities and result in a competitive advantage to larger companies that compete against Endo.

Based on scientific developments, post-market experience, or other legislative or regulatory changes, the current FDA standards of review for approving new pharmaceutical products, or new indications or uses for approved products, are sometimes more stringent than those that were applied in the past.

The FDA has the authority to require companies to undertake additional post-approval studies to assess known or signaled safety risks and to make any labeling changes to address those risks. The FDA also can require companies to formulate approved REMS to ensure a drug's benefits outweigh its risks either for approval or following approval. Moreover, following approval, discovery of new product issues could also result in the withdrawal of product approval, refusal to approve new product indications or similar products, holds or suspension of clinical studies, labeling restrictions, product recalls, changes in the way that the product is administered, produced or distributed, adverse publicity, public statements by regulators, post-approval study or REMS requirements liability for harm cause to patients, or the product becoming less competitive, among other consequences. The FDA's exercise of its authority under the FDCA could result in delays or increased costs during product development, clinical trials and regulatory review, increased costs to comply with additional post-approval regulatory requirements and potential restrictions on sales of approved products. Foreign regulatory agencies often have similar authority and may impose comparable requirements and costs. Post-marketing studies and other emerging data about marketed products, such as adverse event reports, may also adversely affect sales of Endo's products or prompt regulatory authorities to take regulatory actions with regard to the product. Furthermore, the discovery of significant safety or efficacy concerns or problems with a product in the same therapeutic class as one of Endo's products that implicate or appear to implicate the entire class of products could have an adverse effect on sales of Endo's product or, in some cases, result in product withdrawals or other regulatory action. Furthermore, new data and information, including information about product misuse or abuse at the user level, may lead government agencies, professional societies, practice management groups or patient or trade organizations to recommend or publish guidance or guidelines related to the use of Endo's products, which may lead to reduced sales of Endo's products.

The FDA regulates and monitors the quality of drug clinical trials to provide human subject protection and to support marketing applications. The FDA may place a hold on a clinical trial and may cause a suspension or withdrawal of product approvals if regulatory standards are not maintained. The FDA also regulates the facilities, processes, and procedures used to manufacture and market pharmaceutical products in the U.S. both for clinical supply and marketed products. Manufacturing facilities must be registered with the FDA and all commercially distributed products made in such facilities must be manufactured in accordance with the latest cGMP regulations, which are enforced by the FDA. Compliance with clinical trial requirements and cGMP regulations requires the dedication of substantial resources and requires significant expenditures. In the event an approved manufacturing facility for a particular drug is required by the FDA to curtail or cease operations, cannot produce products or product candidates in accordance with regulatory requirements, or otherwise becomes inoperable, or a third-party contract manufacturing facility faces manufacturing problems, the implementation of corrective actions, or obtaining the required FDA authorization to manufacture at the same or a different manufacturing site could be costly, and could result in production delays, which could adversely affect Endo's business, results of operations, financial condition and cash flow. Failure to abide by manufacturing requirements may also result in regulatory enforcement action, adverse publicity, and product recalls, among other consequences. Moreover, manufacturing challenges may also be faced as product development and approval progresses, such as challenges related to manufacturing scale up, qualification, and validation. In the event Endo or its manufacturers cannot successfully meet all manufacturing regulatory requirements, Endo's business may be adversely impacted.

The FDA is authorized to perform inspections of U.S. and foreign manufacturing facilities and clinical trial sites under the FDCA. Following such inspections, the FDA may issue a Form 483 Notice of Inspectional Observations. FDA may also issue an untitled letter that cites violations that do not meet the threshold of regulatory significance of a Warning Letter. FDA guidelines also provide for the issuance of Warning Letters for violations of "regulatory significance" for which the failure to adequately and promptly achieve correction may be expected to result in an enforcement action. FDA also may issue Warning Letters and untitled letters in connection with events or circumstances unrelated to an FDA inspection. Any of these may require Endo to modify certain activities identified by FDA.

Endo cannot determine what effect changes in regulations or legal interpretations or requirements by the FDA or the courts, when and if promulgated or issued, may have on Endo's business in the future. Changes could, among other things, require different labeling, monitoring of patients, interaction with physicians, education programs for patients or physicians, curtailment of necessary supplies, or limitations on product distribution. These changes, or others required by the FDA or Drug Enforcement Administration ("DEA") could have an adverse effect on the sales of these products. The evolving and complex nature of regulatory science and regulatory requirements, the broad authority and discretion of the FDA and the generally high level of regulatory oversight results in a continuing possibility that, from time to time, Endo will be adversely affected by regulatory actions despite Endo's ongoing efforts and commitment to achieve and maintain full compliance with all regulatory requirements.

Any issues that Endo or any other companies to which we grant licensing rights experience concerning regulatory and legal compliance generally, as well as the development, manufacturing, approval, sale, marketing, promotion, and distribution specifically of our products and/or product candidates may limit the opt-in, mark up on cost of goods sold, milestone and/or royalty payments that we are due under our agreements.

The availability of third-party reimbursement for Endo's products is uncertain, and thus Endo may find it difficult to maintain current price levels. Additionally, the market may not accept those products for which third-party reimbursement is not adequately provided.

Endo's ability to commercialize products depends, in part, on the extent to which reimbursement for the costs of these products is available from government healthcare programs, such as Medicaid and Medicare, private health insurers and others. Endo cannot be certain that, over time, third-party reimbursements for Endo's products will be adequate for Endo to maintain price levels sufficient for realization of an appropriate return on Endo's investment. Government payers, private insurers and other third-party payers are increasingly attempting to contain healthcare costs by (1) limiting both coverage and the level of reimbursement (including adjusting co-pays) for products approved for marketing by the FDA, (2) refusing, in some cases, to provide any coverage for uses of approved products for indications for which the FDA has not granted marketing approval and (3) requiring or encouraging, through more favorable reimbursement levels or otherwise, preferred therapeutically equivalent branded products and the substitution of generic alternatives to branded products.

Endo may experience pricing pressure on the price of Endo's products due to social or political pressure to lower the cost of drugs, which would reduce Endo's revenue and future profitability.

Federal and state health care programs are increasingly focused on the price of prescription drugs, including the expanded use of mandatory rebates and discounts and measures that penalize or prohibit price increases over inflation rates. Endo may experience downward pricing pressure on the price of Endo's products due to social or political pressure to lower the cost of drugs, which would reduce Endo's revenue and future profitability. Recent events have resulted in increased public and governmental scrutiny of the cost of drugs, especially in connection with price increases following companies' acquisitions of the rights to certain drug products. In particular, U.S. federal prosecutors recently issued subpoenas to a pharmaceutical company seeking information about its drug pricing practices, among other issues, and members of the U.S. Congress have sought information from certain pharmaceutical companies relating to post-acquisition drug-price increases. Endo's revenue and future profitability could be negatively affected if these inquiries were to result in legislative or regulatory proposals that limit Endo's ability to increase the prices of Endo's products.

Pressure from social activist groups and future government regulations may also put downward pressure on the price of drugs, which could result in downward pressure on the prices of Endo's products in the future.

If Endo's manufacturing facilities are unable to manufacture Endo's products or the manufacturing process is interrupted due to failure to comply with regulations or for other reasons, it could have a material adverse impact on Endo's business.

If any of Endo's manufacturing facilities or its third party manufacturing facilities fail to comply with regulatory requirements or encounter other manufacturing difficulties, it could adversely affect Endo's ability to supply products. All facilities and manufacturing processes used for the manufacture of pharmaceutical products are subject to inspection by regulatory agencies at any time and must be operated in conformity with cGMP and, in the case of controlled substances, DEA regulations. Compliance with the FDA's cGMP and DEA requirements applies to both drug products seeking regulatory approval and to approved drug products. In complying with cGMP requirements, pharmaceutical manufacturing facilities must continually expend significant time, money and effort in production, recordkeeping, quality assurance and quality control so that their products meet applicable specifications and other requirements for product safety, efficacy and quality. Failure to comply with applicable legal requirements subjects Endo and its third party manufacturing facilities to possible legal or regulatory action, including shutdown, which may adversely affect Endo's ability to supply the product. Additionally, Endo's or its third party manufacturing facilities may face other significant disruptions due to labor strikes, failure to reach acceptable agreement with labor unions, infringement of intellectual property rights, vandalism, natural disaster, storm or other environmental damage, civil or political unrest, export or import restrictions or other events. If Endo is unable to manufacture products at its or its third party manufacturing facilities because of regulatory, business or any other reasons, the manufacture and marketing of these products would be interrupted. This could have a material adverse impact on Endo's business, results of operation, financial condition, cash flows and competitive position, which could, in turn, materially impact our business.

For example, the manufacturing facilities that are qualified to manufacture CCH, which Endo sells under the trademark XIAFLEX® and may use from time to time in the research and development of CCH for other investigational indications, such as for cellulite, are subject to such regulatory requirements and oversight. If such facilities fail to comply with cGMP requirements, Endo may not be permitted to sell products or may be limited in the jurisdictions in which it is permitted to sell them. Further, if an inspection by regulatory authorities indicates that there are deficiencies, including non-compliance with regulatory requirements, Endo could be required to take remedial actions, stop production or close its facilities, which would disrupt the manufacturing processes, limit the supply of CCH and delay clinical trials and subsequent licensure and/or limit the sale of commercial supplies. In addition, future noncompliance with any applicable regulatory requirements may result in refusal by regulatory authorities to allow use of CCH in clinical trials, refusal of the government to allow distribution of CCH within the U.S. or other jurisdictions, criminal prosecution, fines, recall or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products, refusal to allow the entering into of federal and state supply contracts and follow-on civil litigation.

The regulatory approval process outside the U.S. varies depending on foreign regulatory requirements, and failure to obtain regulatory approval in foreign jurisdictions would prevent the marketing of Endo's products in those jurisdictions.

Endo has worldwide intellectual property rights to market many of Endo's products and product candidates and intends to seek approval to market certain of Endo's products outside of the U.S. Approval of a product by the regulatory authorities of foreign countries must be obtained prior to manufacturing or marketing that product in those countries. The approval procedure varies among countries and can involve additional testing and the time required to obtain such approval may differ from that required to obtain FDA approval. The non-U.S. regulatory approval process includes all of the risks associated with obtaining FDA approval set forth herein. Approval by the FDA does not secure approval by the regulatory authorities of any other country, nor does the approval by foreign regulatory authorities in one country secure approval by regulatory authorities in other foreign countries or the FDA. Moreover, the failure to obtain approval in one jurisdiction may compromise our or our partner's ability obtain approval elsewhere. If Endo fails to comply with these regulatory requirements or fails to obtain and maintain required approvals, Endo's target market will be reduced and Endo's ability to generate revenue from abroad will be adversely affected.

The expanding nature of Endo's business in global markets exposes Endo to risks associated with adapting to emerging markets and taking advantage of growth opportunities.

The globalization of Endo's business may expose Endo to increased risks associated with conducting business in emerging markets. Any difficulties in adapting to emerging markets could impair Endo's ability to take advantage of growth opportunities in these regions and a decline in the growth of emerging markets could negatively affect Endo's business, results of operations or financial condition.

The expansion of Endo's activities in emerging markets may further expose Endo to more volatile economic conditions and political instability. Endo also faces competition from companies that are already well established in these markets. Endo's inability to respond adequately to the unique characteristics of these markets, particularly with respect to their regulatory frameworks, the difficulties in recruiting qualified personnel, potential exchange controls, weaker intellectual property protection, higher crime levels and corruption and fraud, could have a material adverse effect on Endo's business.

Endo's policies and procedures, which are designed to help Endo, Endo's employees and agents comply with various laws and regulations regarding corrupt practices and anti-bribery, cannot guarantee protection against liability for actions taken by businesses in which Endo invests. Failure to comply with domestic or international laws could result in various adverse consequences, including possible delay in the approval or refusal to approve a product, recalls, seizures, withdrawal of an approved product from the market, or the imposition of criminal or civil sanctions, including substantial monetary penalties.

In addition, differences in banking systems and business cultures could have an adverse effect on the efficiency of internal controls over financial reporting matters. Given the significant learning curve to fully understand the emerging markets' business, operating environment and the quality of controls in place, Endo may not be able to adequately assess the efficiency of internal controls over financial reporting or the effects of the laws and requirements of the local business jurisdictions.

Many jurisdictions require specific permits or business licenses, particularly if the business is considered foreign. These requirements may affect Endo's ability to carry out Endo's business operations in emerging markets.

The risks of selling and shipping products and of purchasing components and products internationally may adversely impact Endo's revenues, results of operations and financial condition.

The sale and shipping of Endo's products and services across international borders is subject to extensive U.S. and foreign governmental trade regulations, such as various anti-bribery laws, including the U.S. Foreign Corrupt Practices Act, export control laws, customs and import laws, and anti-boycott laws. Endo's failure to comply with applicable laws and regulations could result in significant criminal, civil and administrative penalties, including, but not limited to, imprisonment of individuals, fines, denial of export privileges, seizure of shipments, restrictions on certain business activities, and exclusion or debarment from government contracting. Also, the failure to comply with applicable legal and regulatory obligations could result in the disruption of Endo's shipping and sales activities. Endo may not be able to import or export, or have products imported or exported, which would impact Endo's ability to successfully commercialize XIAFLEX, and pursue additional indications through its development programs. This may also impact our ability to pursue our product development efforts, as we are dependent on Endo for our supply of XIAFLEX.

In addition, some countries in which Endo's subsidiaries sell products are, to some degree, subject to political, economic and/or social instability. Endo's international sales operations expose Endo and Endo's representatives, agents and distributors to risks inherent in operating in foreign jurisdictions. These risks include:

- the imposition of additional U.S. and foreign governmental controls or regulations;
- the imposition of costly and lengthy new export or import licensing requirements;
- the imposition of U.S. and/or international sanctions against a country, company, person or entity with whom the company does business that would restrict or prohibit continued business with the sanctioned country, company, person or entity;
- economic and political instability or disruptions, including local and regional instability, or disruptions due to natural disasters, such as severe weather and geological events, disruptions due to civil unrest and hostilities, rioting, military activity, terror attacks or armed hostilities;
- changes in duties and tariffs, license obligations and other non-tariff barriers to trade;
- the imposition of new trade restrictions;
- imposition of restrictions on the activities of foreign agents, representatives and distributors;
- foreign tax authorities imposing significant fines, penalties and additional taxes;
- pricing pressure that Endo may experience internationally;
- laws and business practices favoring local companies;
- difficulties in enforcing or defending intellectual property rights; and
- exposure to different legal and political standards due to Endo's conducting business in several foreign countries.

Endo cannot provide assurance that one or more of these factors will not harm Endo's business. Additionally, Endo is experiencing fluidity in regulatory and pricing trends as a result of the Patient Protection and Affordable Care Act and the Health Care and Education Reconciliation Act of 2010. Any material decrease in Endo's international sales would adversely impact Endo's results of operations and financial condition.

If physicians do not prescribe XIAFLEX® or the medical profession or patients do not accept XIAFLEX®, our ability to grow or maintain revenues will be limited.

Our revenues are dependent on market acceptance of XIAFLEX®. Physician willingness to prescribe and patients' willingness to accept, as well as the ultimate profitability of XIAFLEX® depend on many factors, including:

- perceived safety and efficacy;
- convenience and ease of administration;
- incidence and severity of adverse side effects in both clinical trials and commercial use;
- the information in the approval product label, including the indications and any limitations and warnings;
- distribution and user restrictions;
- current standard of care;
- availability of alternative treatments or products, including biosimilars;
- cost effectiveness and pricing;
- the adequacy and effectiveness of Endo's sales force and that of any partner's sales force;
- Endo's ability to establish and maintain agreements with wholesalers, distributors, group purchasing organizations, pharmacy benefit managers, and similar organizations on commercially reasonable terms;
- the adequacy and effectiveness of Endo's production, distribution and marketing capabilities and those of Endo's international partners;

- publicity concerning Endo's products or competing products; and

- existence and level of third-party or government coverage or reimbursement for XIAFLEX® for the treatment of DC and PD and the price concessions required to obtain coverage.

Even though there is regulatory approval for XIAFLEX®, physicians may not prescribe, and patients may not accept, XIAFLEX® if Endo or its partners do not promote it effectively. If XIAFLEX® fails to achieve market acceptance, Endo may not be able to market and sell XIAFLEX® successfully, which would limit our ability to receive revenue and could harm our business.

We may not be able to obtain or maintain orphan drug exclusivity for XIAFLEX®, which could significantly harm our business.

Some jurisdictions, including Europe and the U.S., may designate drugs intended to treat relatively small patient populations as orphan drugs. Orphan drug exclusivity means that another application to market the same drug for the same indication may not be approved, except in limited circumstances, for a period of up to 10 years in Europe and for a period of seven years in the U.S. Orphan drug designation must be requested before submitting an application for marketing authorization. We or our partners may also seek orphan drug designation for other appropriate product candidates and indications. However, there is no guarantee that such a designation will be granted by the applicable regulatory authorities or that we will receive any periods of orphan drug exclusivity if our or our partners' product candidates or indications are approved.

Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process, but does make the product eligible for orphan drug exclusivity and, in the U.S., specific tax credits. The tax advantages, however, were limited in the 2017 Tax Cuts and Jobs Act. The FDA may also grant orphan drug designation to multiple sponsors for the same compound or active molecule and for the same indication. If another sponsor receives FDA approval for such product before we or our partners do, we or they would be prevented from launching the applicable product in the United States for the orphan indication for a period of at least seven years unless clinical superiority can be demonstrated.

Generally, if a product with an orphan drug designation subsequently receives the first marketing approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity.

The FDA granted orphan drug status to XIAFLEX® in the U.S. for the treatment of DC and PD; however, the orphan drug designation for DC expired on February 2, 2017. PD currently enjoys Orphan Drug Protection until December 6, 2020. Maintaining orphan drug designations and orphan drug exclusivity for XIAFLEX® for the treatment of PD may be critical to its success. Even with orphan drug exclusivity, we may not be able to maintain it. For example, if a competitive product is shown to be different or clinically superior, any orphan drug exclusivity we have obtained will not block the approval of such competitive product. Orphan drug exclusivity may also be lost under certain circumstances, such as if the FDA finds that the request for designation contained an untrue statement of material fact or omitted material information, if the FDA finds that the product candidate was not eligible for designation at the time of the submission of the request, or if a sufficient product supply cannot be assured to meet the needs of patients with the rare disease or condition. Moreover, orphan drug exclusivity may not effectively protect a product from competition as products that are different from our or our partners' products may be approved for the same condition or products that are the same can be approved for different conditions. Even with orphan drug exclusivity, physicians may prescribe and third-party payors may provide reimbursement for products off-label even if not indicated for the orphan condition.

Endo is dependent upon Endo's collaborative relationships with third parties to further develop and commercialize XIAFLEX® outside of the U.S. There may be circumstances that delay or prevent the ability of any of these third parties to develop and commercialize XIAFLEX®.

Sobi and Asahi have the right to develop and commercialize XIAFLEX®/Xiapex® in 71 Eurasian and African countries, in Japan, respectively. Actelion has marketing and commercial rights for XIAFLEX® in Australia and New Zealand. In addition, Endo may seek to enter into similar arrangements with other third parties with respect to the development and commercialization of XIAFLEX®/Xiapex® in the rest of the world. These collaborations are subject to the same risks of product development, compliance, and marketing as we and Endo are subject to. Should these collaborators fail to successfully develop, obtain any required marketing approvals for, abide by all regulatory requirements related to, and successfully commercialize XIAFLEX/Xiapex, our commercial prospects may be materially harmed. Endo is subject to a number of risks associated with Endo's dependence on Endo's collaborative relationship with these third parties, including:

- adverse decisions by a third party regarding the amount and timing of resource expenditures for the development and commercialization of XIAFLEX®/Xiapex®;
- possible disagreements as to the timing, nature and extent of Endo's development plans, including clinical trials or regulatory approval strategy;
- the right of a third party to terminate its collaboration agreement with Endo on limited notice upon the occurrence of certain defined events;
- loss of significant rights if Endo fails to meet Endo's obligations under the collaboration agreement;
- withdrawal of support by a third party following change of that third party's corporate strategy or due to competing priorities;
- changes in key management personnel at a third party that are members of the collaboration's various operating committees; and
- possible disagreements with a third party regarding the collaboration agreement or ownership of proprietary rights, including with respect to inventions discovered under the applicable collaborative agreement.

Due to these factors and other possible disagreements with a third party, including potential disputes over intellectual property ownership, Endo may be delayed or prevented from further developing, manufacturing or commercializing XIAFLEX® outside the U.S., or Endo may become involved in litigation or arbitration, which would be time consuming and expensive.

If a third party were to terminate its collaboration agreement with Endo, Endo would need to undertake development and marketing activities for XIAFLEX® in that third party's territory solely at Endo's own expense and/or seek another partner for some or all of these activities in that territory. If Endo pursued these activities in that territory on Endo's own, it would significantly increase Endo's capital and infrastructure requirements, and might limit the indications Endo is able to pursue and could prevent Endo from effectively developing and commercializing XIAFLEX®. If Endo sought to find another pharmaceutical company partner for some or all of these activities, Endo may not be successful in such efforts, or they may result in a collaboration that has Endo expending greater funds and efforts than the relationship with the terminating third party.

In general, Endo cannot control the amount and timing that Endo's third-party partners may devote to Endo's collaborations. Endo is relying on Endo's third-party partners to obtain regulatory approvals for and successfully commercialize XIAFLEX® in the relevant territories. If a third party fails to adequately market and promote XIAFLEX® in its territory, Endo may be unable to obtain any remedy against that third party and sales of XIAFLEX® may be harmed, which would negatively impact Endo's business, results of operations, cash flows and liquidity due to reduced milestone and royalty payments under the applicable third-party agreement and, subsequently, our business and results of operations. In addition, third-party partners may have difficulty obtaining reimbursement for their products and may withdraw from certain markets outside of the U.S.

As a condition for approval of XIAFLEX® for DC and for PD, Endo is required to comply with post-marketing requirements. Failure to comply with these requirements or any future post-marketing requirements, or the cost of compliance with such requirements, may harm our business.

The FDA or, for products outside the U.S. for which Endo holds the regulatory approvals, international regulatory agencies, can establish requirements for XIAFLEX® or Xiapex® with which Endo must comply. Data from preclinical testing and clinical trials are submitted to the FDA in a New Drug Applicable ("NDA") or BLA for marketing approval and to foreign government health authorities in a marketing authorization application, consistent with each health authority's specific regulatory requirements. The process of completing clinical trials for a new drug may take many years and require the expenditures of substantial resources. As a condition of approval, the FDA or foreign regulatory authorities may require further studies, including Phase 4 post-marketing studies and pediatric studies, to provide additional data. In September 2007, Congress passed legislation authorizing the FDA to require companies to undertake such studies to assess the risks of drugs known or signaling potential to have serious safety issues. For some drugs, the FDA may require a REMS, which could include medication guides, physician communication plans, or restrictions on distribution and use, such as limitations on who may prescribe the drug or where it may be dispensed or administered. Other post-marketing studies could be used to gain approval for the use of a product as a treatment for clinical indications other than those for which the product was initially tested. Also, the FDA or foreign government regulatory authorities require post-marketing reporting to monitor the adverse effects of drugs. Results of post-marketing programs may limit or expand the further marketing of the products. Failure to report or conduct the studies is considered a violation and can result in enforcement action. These studies or clinical trials could be time-consuming and costly and the results could have negative effects on Endo's ability to market the product.

Should FDA license a biosimilar product to XIAFLEX we and/or Endo may face increased competition sooner than otherwise anticipated.

XIAFLEX® is regulated and marketed as biologic products pursuant to BLAs. XIAFLEX® is licensed based on a determination by the FDA of safety, purity, and potency as required under the Public Health Service Act (PHSA). In 2010, Congress enacted the Biologics Price Competition and Innovation Act of 2009 (BPCIA), as part of the Patient Protection and Affordable Care Act, which amended the PHSA to create an abbreviated licensure pathway for products deemed to be biosimilar to or interchangeable with FDA-licensed reference biological products. Under the BPCIA, an approval for a biosimilar product cannot be made effective by the FDA until 12 years after the original branded product was approved under a BLA. Certain changes, however, and supplements to an approved BLA, and subsequent applications filed by the same sponsor, manufacturer, licensor, predecessor in interest, or other related entity do not qualify for the 12-year exclusivity period. Moreover, there have been efforts to decrease this period of exclusivity to a shorter timeframe. Future proposed budgets, international trade agreements and other arrangements or proposals may affect periods of exclusivity.

Under the BPCIA, following the expiration of a 12-year reference exclusivity period, FDA may license under section 351(k) of the PHSA that it determines is biosimilar to or interchangeable with a reference product licensed under section 351(a) of the PHSA. Biosimilarity is defined to mean that the section 351(k) product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and that there are no clinically meaningful differences between the section 351(k) product and the reference product in terms of the safety, purity, and potency of the product. To be considered interchangeable, a product must be biosimilar to the reference product, be expected to produce the same clinical result as the reference product in any given patient, and, if administered more than once to an individual, the risks in terms of safety or diminished efficacy of alternating or switching between use of the product and its reference product is not greater than the risk of using the reference product without such alternation or switch.

Once any reference exclusivity period for a BLA-licensed biologics expires, FDA may make an approval under section 351(k) effective for another company's BLA for a biosimilar or interchangeable version of our product. Although licensure of a biosimilar or interchangeable under section 351(k) is generally expected to require less than the full complement of product-specific preclinical and clinical data required for innovator products licensed under section 351(a), FDA has considerable discretion over the kind and amount of scientific evidence required to demonstrate biosimilarity and interchangeability.'

The FDA could determine that XIAFLEX® does not have exclusivity protection under the BPCIA.

We believe that XIAFLEX®, which was initially approved in 2010, would have exclusivity protection under the BPCIA through 2022. However, there is a risk that the FDA will not consider our product candidates to be reference products for competing products, potentially creating the opportunity for biosimilar competition sooner than anticipated. Additionally, this period of regulatory exclusivity does not apply to companies pursuing regulatory approval via their own traditional BLA, rather than via the abbreviated pathway. Moreover, the extent to which a biosimilar, once approved, will be substituted for any one of our reference products in a way that is similar to traditional generic substitution for non-biological products is not yet clear, and will depend on a number of marketplace and regulatory factors that are still developing. It is possible that payers will give reimbursement preference to biosimilars even over reference biologics absent a determination of interchangeability. Moreover, in an effort to increase competition and decrease drug prices, FDA is taking steps to facilitate biosimilar development and approval. Accordingly, we or our partners may face biosimilar competition sooner than expected.

For XIAFLEX® for PD, Endo is required to implement a REMS or other programs. Failure to comply, or the cost of compliance with such REMS or other programs, may harm our business.

The FDA is authorized to require Endo as the sponsor of an approved or unapproved marketing application to submit a proposed REMS if the FDA determines that a REMS is necessary to ensure that the benefits of a drug outweigh the risks of the drug. Failure to comply with the requirements of the approved REMS can render the drug misbranded. A violation of a REMS requirement is subject to civil penalties. Complying with the requirements of a REMS can be costly and time-consuming and adversely affect Endo's operations.

Because of the risks of corporal rupture (penile fracture) or other serious penile injury in the treatment of PD, XIAFLEX® is available only through the XIAFLEX® REMS Program. The required components of the XIAFLEX® REMS Program include healthcare provider training and certification, healthcare provider risk education, certification of dispensing pharmacies and healthcare settings, dispenser confirmation that the prescribing physician is certified under the REMS, Endo auditing of certified pharmacies and healthcare settings, and patient risk education. Because REMS can be burdensome and costly for sponsors to implement, and burdensome for healthcare providers, patients, and dispensers to follow, a REMS, such as the one for XIAFLEX, can materially limit a product's commercial prospects.

If we are unable to obtain opt-in, milestone, mark-up on cost of goods sold and royalty payments from Endo or meet our needs for additional funding from other sources, we may be required to limit, scale back or cease our operations.

Our business strategy contains elements that we will not be able to implement if we do not receive the anticipated opt-in, milestone, royalty or mark-up on cost of goods sold payments from Endo, or secure additional funding from other sources. While we anticipate being profitable on an ongoing, annual basis, our future funding requirements will depend on many factors, including:

- Endo's ability to manufacture and commercialize XIAFLEX® for which we would receive milestone, mark-up on cost of goods sold and royalty payments;
- The ability of Endo's sublicensees to commercialize XIAFLEX®/Xiapex® in their respective territories;
- the amount actually owed by us to Endo for certain patent costs;
- Endo's ability to successfully develop and receive regulatory approval for indications that it has exercised its opt-in rights for;
- the scope, rate of progress, cost and results of our clinical trials on additional indications, including uterine fibroids, for which Endo could exercise its opt-in to acquire its rights;
- Endo's ability to abide by and ensure third party compliance with the many regulatory requirements applicable to pharmaceutical products;
- the terms and timing of any future collaborative, licensing, co-promotion and other arrangements that we may establish;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights or defending against any other litigation; and
- the extent to which Endo may reallocate priority away from XIAFLEX®.

These factors could result in variations from our currently projected operating requirements. If our existing resources are insufficient to satisfy our operating requirements, we may need to limit, scale back or cease operations or, in the alternative, borrow money. Given our operations and history, we may not be able to borrow money on commercially reasonable terms, if at all. If we issue any equity or debt securities, the terms of such issuance may not be acceptable to us and would likely result in substantial dilution of our stockholders' investment. If we do not receive revenues from Endo, and are unable to secure additional financing, we may be required to cease operations.

We depend on Endo for the determination of royalty payments and cost of goods sold. While we have rights to audit Endo, the independent auditors may have difficulty determining the correct royalty and cost of goods sold calculations, we may not be able to detect errors and payment calculations may call for retroactive adjustments. We may have to exercise legal remedies to resolve any disputes resulting from the audit.

The royalty payments we receive are determined by Endo based on reported sales. Endo's calculation of the royalty payments is subject to and dependent upon the adequacy and accuracy of its sales and accounting functions. Endo's calculation of cost of goods sold are subject to and dependent upon the adequacy and accuracy of its internal accounting of costs. Errors may occur from time to time in these calculations. The License Agreement provides us the right to audit the calculations and sales data for the associated royalty payments. Although we may exercise our audit rights, such audits may occur many months following our recognition of the royalty revenue, may require us to adjust our royalty revenues in later periods and may require expense on the part of the Company. Further, Endo may be uncooperative or have insufficient records, which may complicate and delay the audit process. Although we may exercise our audit rights, we rely in the first instance on Endo to accurately report sales and calculate and pay applicable royalties. Such audits may occur many months following our recognition of the royalty revenue, may require us to adjust our royalty revenues in later periods and may require expense on the part of the Company. We also rely on Endo's cooperation and maintenance of sufficient records in performing such audits. If Endo is uncooperative or has insufficient records, it may complicate and delay the audit process. In the absence of such cooperation, we may be forced to exercise legal remedies to enforce our rights.

Our royalty revenue recognition is dependent upon the receipt of preliminary data from Endo.

We receive royalty revenues on net sales under our License Agreement with Endo. These are presented in "Royalties" in our consolidated statements of income. In accordance with Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers," 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 preliminary data provided by Endo and analysis of historical gross-to-net deductions, 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. While Endo is required (pursuant to the terms of the Second Amendment to the License Agreement) to provide us with timely estimates of royalties in order to assist us in complying with our financial reporting obligations, there is no guarantee that they will do so in a timely fashion, or at all.

In order to finance and to secure the rights to conduct clinical trials for products we have licensed to Endo, we have granted to third parties significant rights to share in royalty payments received by us and, in some case, milestone payments to be received by us.

To finance and secure the rights to conduct clinical trials for products we have licensed to Endo, we have granted to third parties certain rights to share in royalty payments and, in some cases milestone payments, received by us from Endo under the License Agreement. Consequently, we will be required to share a significant portion of the payments due to us from Endo under the Agreement.

If we breach our agreements with third parties or if there is a dispute concerning any of our agreements with third parties, our business could be materially harmed.

Our agreements with third parties impose on us various obligations, such as those related to intellectual property rights, non-competition, and development of products, as described throughout Item 1 of this Report. If we fail to comply with such obligations, or a counterparty to our agreements believes that we have failed to comply with such obligations, we may be sued and the costs of the resulting litigation could materially harm our business. Additionally, disputes may arise under these agreements, including with respect to the interpretation of such agreements and fee redeterminations or renegotiations thereof. These disputes may lead to litigation, termination of the agreement, or amendments that change our rights under the agreement, which could materially affect our financial position and materially harm our business. We agreed, for example, to resolve a dispute with Endo, to grant Endo an early opt-in to indications which may, if we consent, limit our ability to conduct clinical trials pursuant to the First Amendment which is described more fully in Item 1 above.

Our results of operations and financial position could be negatively impacted if our tax positions are challenged by tax authorities.

We are a U.S.-based company subject to taxes in certain U.S. jurisdictions. U.S. federal, state and local tax laws and regulations are extremely complex and subject to varying interpretations. Although we believe that our tax estimates and tax positions are reasonable, there can be no assurance that our tax positions will not be challenged by relevant tax authorities or that we would be successful in any such challenge. If we are unsuccessful in such a challenge, the relevant tax authorities may assess additional taxes, which could result in adjustments to, or impact the timing or amount of, taxable income, deductions or other tax allocations, which may adversely affect our results of operations and financial position.

Risks Related to Clinical Trials and Development of Drug Candidates

Our ability to conduct future clinical trials and develop products for injectable administration of collagenase may be limited by the License Agreement.

Under the License Agreement, we have the right to conduct trials, studies or development work for uterine fibroids, and, upon approval by the parties' joint development committee (the "JDC"), additional indications. Endo has pre-approved our protocol for uterine fibroids. However, certain material changes to the protocol must be approved by the JDC, and the JDC may decide not to approve such changes if the JDC has reasonable safety concerns. In addition, the JDC has the right to stop our study or trial in uterine fibroids if the rate of serious adverse events exceeds certain thresholds. If the JDC fails to approve changes to our protocol for uterine fibroids or if the JDC stops our studies or trials in uterine fibroids due to safety concerns, our ability to obtain milestones and royalty payments with respect to this indication would be limited. We may only conduct in vivo trials, studies or development work for additional indications beyond the pre-approved indications upon submission to and approval by the JDC of our development plan which includes in vivo studies of uterine fibroids.

In the case of indications in keloids, capsular contraction after breast augmentation, arthrofibrosis following total joint replacement in humans and equine suspensory ligament desmitis, the JDC may reject our submission only for reasonable safety concerns. The JDC may reject our submission for any other additional indications for safety or commercial concerns. If the JDC rejects our submissions in any additional indications, our ability to obtain opt-in, milestone and royalty payments with respect to those additional indications would be limited.

Additionally, under the License Agreement, we have licensed or granted options to certain of our rights to conduct clinical trials and develop products for injectable administration of collagenase. We agreed, for example, to certain non-competition provisions, which may limit our clinical development activities.

We are dependent on Endo for access to XIAFLEX®, which may limit our ability to conduct future clinical trials and to obtain the associated opt-in, milestone, mark-up on cost of goods sold payments and royalty payments under the License Agreement.

Under the License Agreement, we have agreed to buy at cost plus a mark-up XIAFLEX® from Endo for conducting our trials, studies and development work. If Endo does not supply XIAFLEX® to us, or supply XIAFLEX that meets regulatory qualify standards, our ability to conduct clinical trials using XIAFLEX® would be limited because we do not have the right to make XIAFLEX® or to purchase it from third parties. Similarly, any interruptions in Endo's manufacturing as a result of regulatory issues or noncompliance would limit our ability to conduct our trials. We may also be held responsible for any Endo departures from the applicable regulatory manufacturing requirements, to the extent it impacts our clinical supply. Moreover, our ability to use our own clinical material may be limited both by lack of availability and by certain potential regulatory restrictions.

If clinical trials for our potential new indications are delayed, we may not be able to obtain opt-in, milestone or royalty payments under the License Agreement for new indications. The regulatory approval of such new indications would also be delayed or may never be received.

Clinical trials that the Company, Endo, or our or their investigators may conduct may not begin on time or may need to be restructured or temporarily suspended after they have begun. Flaws in a clinical trial's design or conduct, may also not become apparent until the clinical trial is underway or complete, which may prevent regulatory approval, or require that clinical trials be modified or repeated. Clinical trials may be delayed, may never be completed or may need to be restructured for a variety of reasons, including delays, impediments or restructuring related to:

- changes to the regulatory approval process for product candidates;
- obtaining regulatory approval to commence or continue a clinical trial;
- timing of responses required from regulatory authorities;
- negotiating acceptable clinical trial agreement terms with prospective contract research organizations, investigators or trial sites;
- obtaining institutional review board, or equivalent, approval to conduct or continue a clinical trial at a prospective site;
- recruiting subjects to participate in a clinical trial and retaining subjects in the study;
- competition in recruiting clinical investigators;
- shortage or lack of availability of clinical trial supplies from external and internal sources;

- the need to repeat clinical trials as a result of inconclusive results or poorly executed testing, or to conduct additional clinical or preclinical trials or analyses;
- Clinical or pre-clinical trials, as well as commercial experience with similar products, may reveal undesirable side effects, which may require that clinical trials be halted or modified;
- failure to validate a patient-reported outcome questionnaire;
- the placement of a clinical hold on a study by regulatory authorities, the suspension of a study by an institutional review board, or a decision to suspend or terminate a study by us or our partners;
- the failure of third parties conducting and overseeing the operations of our clinical trials to perform their contractual or regulatory obligations in a timely fashion;
- exposure of clinical trial subjects to unexpected and unacceptable health risks or noncompliance with regulatory requirements, which may result in suspension of the trial; and
- manufacturing and/or distribution issues associated with clinical supplies.

Completion of clinical trials for each indication is required before commercialization. If Endo or the Company experience delays in, or termination of, clinical trials, or fails to enroll patients in clinical trials in a timely manner, or if the cost or timing of the regulatory approval process increases, our financial results and the commercial prospects for product candidates for new indications will be adversely impacted. Significant delays relating to development programs also could shorten any periods during which we or our partners may have the exclusive right to commercialize a product or allow competitors to bring products to market before we or our partners, potentially blocking our or our partner's ability to receive marketing approval. In addition, many of the factors that cause, or lead to, delays in clinical trials may ultimately lead to the denial of marketing approval.

The process of conducting clinical trials and developing product candidates involves a high degree of risk, may take several years, and may ultimately not be successful.

Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- clinical trials may show product candidates to be ineffective or not as effective as anticipated or to have harmful side effects or unforeseen results;
- experience with marketed versions of product candidates may reveal harmful side effects or other unforeseen results;
- regulatory authorities may disagree with study design, conduct, and/or data interpretation from preclinical and clinical trials, or may find that a product candidate's benefits do not outweigh its risks;
- regulatory authorities may take longer than anticipated to make a decision on the product candidates;
- regulatory authorities may require that we or our partners perform additional clinical or pre-clinical trials, or gather additional manufacturing information;
- our, our partners, or third party contractor failures to abide by the applicable regulatory requirements or study protocol;
- regulatory authorities may fail to approve or subsequently find fault with the product candidate manufacturing processes or the contract manufacturer's manufacturing facility for clinical and future commercial supplies;
- regulatory authorities may require that we or our partners undertake post-market testing, surveillance, or implement a REMS to maintain regulatory approval;
- product candidates may fail to receive regulatory approvals required to bring the products to market;
- manufacturing costs, the inability to scale up to produce supplies for clinical trials meeting the necessary quality standards, or other factors may make our product candidates uneconomical;
- changes in approval policies, data standards, statutes, and regulations; and

- the proprietary rights of others and their competing products and technologies may prevent product candidates from being effectively commercialized or from obtaining exclusivity.

Success in preclinical and early clinical trials does not ensure that large-scale clinical trials will be successful. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. The length of time necessary to complete clinical trials and to submit an application for marketing approval for a final decision by a regulatory authority varies significantly and may be difficult to predict. Any changes to the U.S. regulatory approval process could significantly increase the timing or cost of regulatory approval for product candidates making further development uneconomical or impossible. In addition, once Endo exercises its opt-in with respect to an additional indication, further clinical trials, development, manufacturing, marketing and selling of such product are out of our control. Our interest is limited to receiving opt-in, milestone, mark-up on cost of goods sold payments and royalty payments.

Successful development of drug candidates is inherently difficult and uncertain, and our long-term prospects depend upon our ability and the ability of our partners, particularly with respect to XIAFLEX®, to continue to successfully commercialize these drug candidates.

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

There is significant uncertainty regarding our and our partners' 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 and submit marketing applications;
- 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.

Even if we or our partners were to obtain approval, regulatory authorities may approve product candidates for fewer or more limited indications, populations, or uses, product candidates may contain significant safety warnings, including black box warnings, contraindications, and precautions, regulatory authorities may grant approval contingent on the performance of costly post-marketing clinical trials, surveillance, or other requirements, including REMS to monitor the safety or efficacy of the product, or regulatory authorities may approve a product candidate with a label that does not include the labeling claims necessary or desirable for the successful commercialization of that product candidate. Any of these scenarios could compromise the product candidate's commercial prospects.

Risks Related to Regulatory Requirements

We are subject to numerous complex regulatory requirements and failure to comply with these regulations, or the cost of compliance with these regulations, may harm our business.

Conducting clinical trials for human drugs and, in certain circumstances, veterinarian trials for animal drugs, and the testing, development and manufacturing and distribution of product candidates are subject to regulation by numerous governmental authorities in the U.S. and other jurisdictions, if we desire to export the resulting products to such other jurisdictions. These regulations govern or affect the testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, advertising and promotion of product candidates, as well as safe working conditions. Even after a product candidate has been approved, the FDA and comparable governmental authorities subject such product to continuing review and regulatory requirements including, for example, requiring the conducting and reporting of the results of certain clinical studies or trials and commitments to voluntarily conduct additional clinical trials. Noncompliance with any applicable regulatory requirements can result in warning, untitled, or cyber letters, suspensions or withdrawals of approvals or clearances, refusals to approve pending applications or supplements, seizures or recalls of products, injunctions against or other restrictions on the manufacture, holding, distribution, marketing and sale of a product, import or export refusals, product detention, promotional piece modifications and the issuance of corrective information, adverse publicity, regulatory authority issuance of public communications regarding products, holds or terminations on pre- or post-market studies, liability for harm cause to patients, reputational harm, civil and criminal sanctions, and FDA debarment, suspension and debarment from government contracts, and refusal of orders under existing government contracts, exclusion from federal healthcare programs, consent decrees, or corporate integrity agreements, among other consequences. In addition, regulatory approval could impose limitations on the indicated or intended uses for which product candidates may be marketed, and impose post-approval requirements. With respect to its approval of XIAFLEX® for the treatment of adult DC patients with a palpable cord; for example, the FDA and Auxilium agreed upon a REMS program consisting of a communication plan and a medication guide. The REMS program is no longer an FDA requirement for DC only. With respect to its approval of XIAFLEX® for PD, Auxilium, and now Endo, has further collaborated with the FDA for a REMS for XIAFLEX® for the treatment of PD in men with a palpable plaque and curvature deformity of 30 degrees or greater at the start of therapy. The required components of the XIAFLEX® REMS Program include healthcare provider training and certification, healthcare provider risk education, certification of dispensing pharmacies and healthcare settings, dispenser confirmation that the prescribing physician is certified under the REMS, Endo auditing of certified pharmacies and healthcare settings, and patient risk education.

Currently, there is a substantial amount of congressional and administrative review of the FDA and the regulatory approval process for drug candidates in the U.S. As a result, there may be significant changes made to the regulatory approval process in the U.S. In addition, the regulatory requirements relating to the development, manufacturing, testing, promotion, marketing and distribution of product candidates may change in the U.S. Such changes may increase our costs and adversely affect our operations.

Failure to comply with, or changes to applicable regulatory requirements may result in a variety of consequences, including the following:

- restrictions on our products or the manufacturing processes of such products;
- warning letters, untitled letters and cyber letters;
- withdrawal of a product from the market;
- voluntary or mandatory recall of a product;
- fines;
- suspension or withdrawal of regulatory approvals for a product;
- refusal to permit the import or export of our products;
- refusal to approve pending applications or supplements to approved applications that we submit;
- denial of permission to file an application or supplement in a jurisdiction;
- debarment, exclusion from participation in federal healthcare programs, exclusion or debarment from government contracting, consent decrees, or corporate integrity agreements;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties against us.

To the extent that the Company or its partners do not perform particular regulated functions ourselves but contract out to third parties, including contract manufacturers, contract research organizations, clinical trial sites, and laboratories, the Company or its partners may be held responsible for such third parties' failure to follow the applicable regulatory requirements.

Our corporate compliance program cannot guarantee that we are in compliance with all potentially applicable laws and regulations and we have incurred and will continue to incur costs relating to compliance with applicable laws and regulations.

As a biopharmaceutical company, we are subject to a large body of legal and regulatory requirements. In addition, as a publicly-traded company we are subject to significant regulations, including the Sarbanes-Oxley Act of 2002 ("SOX"), some of which have only recently been revised or adopted. We cannot assure you that we are or will be in compliance with all potentially applicable laws and regulations. Failure to comply with all potentially applicable laws and regulations could lead to the imposition of fines, cause the value of our common stock to decline, and impede our ability to raise capital or list our securities on certain securities exchanges. New rules could make it more difficult or costlier for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our committees and as executive officers. We cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs to comply with these rules and regulations.

We may fail to maintain effective internal controls over external financial reporting or such controls may fail or be circumvented.

SOX requires us to report annually on our internal controls over financial reporting, and our business and financial results could be adversely affected if we, or our independent registered public accounting firm, determine that these controls are not effective. In addition, any failure or circumvention of our internal controls and procedures or failure to comply with regulations concerning controls and procedures could have a material effect on our business, results of operation and financial condition. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our Board, our committees and as executive officers.

Risks Related to Our Industry and Growth

Adverse events or lack of efficacy in clinical trials may force us and/or our partners upon whom we are wholly dependent to stop development of our product candidates or prevent regulatory approval of our product candidates or significant safety issues could arise after regulatory approval of our products, any of which could materially harm our business.

The prescribing information for XIAFLEX for DC originally made available by Auxilium lists "tendon ruptures or other serious injury to the injected extremity" and one "anaphylactic reaction reported in a post-marketing clinical study in a patient who had previous exposure to XIAFLEX for the treatment of Dupuytren's contracture" as a reported serious adverse reaction to XIAFLEX and states that the most frequently reported adverse drug reactions in XIAFLEX clinical trials included swelling of the injected hand, contusion, injection site reaction, injection site hemorrhage, and pain in the treated extremity. The prescribing information notes that adverse reaction rates observed in clinical trials of a drug may not reflect those observed in practice because such trials "are conducted under widely varying conditions."

In the case of PD, the serious risks include penile fracture (corporal rupture) and other serious injuries to the penis such as hematoma. These serious risks are highlighted in the Boxed Warning within the Full Prescribing Information (the label).

Adverse events or lack of efficacy may force us to stop development of our product candidates or prevent or limit regulatory approval of our product candidates, which could materially harm our business. In addition, any adverse events or lack of efficacy may force Endo to stop development of the products we have licensed to it or prevent or limit regulatory approval of such products, which could materially impair all or a material part of the future revenue we hope to receive from Endo. Even if our product candidates receive regulatory approval, new safety issues may be reported and we or our partners may be required to amend the conditions of use for a product and may make it difficult to obtain product liability insurance for clinical trials. New safety issues following approval may also result in regulatory action, such as withdrawal of product approval, refusal to approve new product indications or similar products, holds or suspension of clinical studies, labeling restrictions, product recalls, changes in the way that the product is administered, produced or distributed, adverse publicity, public statements by regulators, post-approval study or REMS requirements, liability for harm cause to patients, or the product becoming less competitive, among other consequences.

We and our licensees face competition in our product development and marketing efforts from pharmaceutical and biotechnology companies, universities and other not-for-profit institutions.

The Company and its licensees face competition in our product development and marketing efforts from entities that have substantially greater research and product development capabilities and greater financial, scientific, marketing and human resources. These entities include pharmaceutical and biotechnology companies, as well as universities and not-for-profit institutions. The Company's and its licensees' competitors may succeed in developing products or intellectual property earlier than we or our licensees do, entering into successful collaborations before us or our licensees, obtaining approvals from the FDA or other regulatory agencies for such products before us or our licensees, or developing or marketing products that are more effective than those we or our licensees could develop or market. The success of any one competitor in these or other respects will have a material adverse effect on our business, our ability to receive opt-in payments from Endo or our ability to generate revenues from third-party arrangements with respect to additional indications for which Endo does not exercise its opt-in.

We may face financial pressures because of our lack of diversity in our research and product development.

All of our income is derived from products marketed by Endo and Endo has the right under the License Agreement to opt-in to all work we do in the Field (as defined in the License Agreement). Therefore, with respect to those products for which Endo opts-in, the Company's upside is limited by the License Agreement. For example, Endo may opt-in to an indication and then choose not to pursue vigorously the development of that indication which may result in the Company negotiating with Endo for repurchase rights to the indication. In order to eliminate this financial pressure and diversify our portfolio, we may choose to acquire or in-license non-collagenase opportunities.

Our strategy of generating growth through acquisitions and in-licensing deals may not be successful.

Because of limits in the License Agreement, our business strategy may include growing our business through acquisition and in-licensing transactions. We may not be successful in identifying, effectively evaluating, acquiring or in-licensing, and developing and commercializing additional products on favorable terms, or at all. Competition for attractive product opportunities is intense and may require us to devote substantial resources, both managerial and financial, to an acquisition or in-licensing opportunity.

Acquisition and in-licensing efforts can consume significant management attention and require substantial expenditures, which could detract from our other programs. In addition, we may devote significant resources to potential deals that are never completed. Even if we are successful in acquiring a product or company or obtaining licensing terms favorable to us, it may not result in a successfully developed or commercialized product or, even if an acquired product is commercialized, competing products or technologies could render a product noncompetitive, uneconomical or obsolete. Moreover, the cost of acquiring other companies or in-licensing products could be substantial. If we are unsuccessful in our efforts to acquire other companies or in-license and develop additional products, or if we acquire or in-license unproductive assets, it could have a material adverse effect on the growth of our business.

We may face pressure from activist stockholders to declare dividends which may negatively affect our business.

Campaigns by stockholders to effect changes at publicly-listed companies are sometimes led by investors seeking to increase short-term stockholder value by advocating corporate actions including special dividends. We have a substantial amount of cash reserves. Given our stockholder composition and other factors, it is possible such stockholder or future activist stockholders may attempt to effect a distribution of this cash. Responding to actions by such activist stockholders or others in the future would be costly and time-consuming, disrupt our operations and divert the attention of our Board and senior management from the pursuit of business strategies, including new collagenase or non-collagenase opportunities, acquisitions or in-licenses of other indications or technologies, which could adversely affect our results of operations and financial condition. Furthermore, if faced with actions by activist stockholders, we may not be able to respond effectively to such actions, which could be disruptive to our business.

If product liability lawsuits are brought against us or our partners, we may incur substantial liabilities.

Our business exposes us to potential liability risks that arise from the clinical testing and, if approved, the commercialization of our and our partners' products. We continue to have product liability exposure for topical products sold by us prior to the sale of our topical business. In addition to direct expenditures for damages, settlement and defense costs, there is a possibility of adverse publicity and loss of revenues as a result of product liability claims. Product liability claims can also result in regulatory consequences, such as the withdrawal of clinical trial participants, termination of clinical trials or programs, governmental authority investigations and enforcement actions, product recalls and withdrawals of approval, as well as labeling revisions. Product liability is a significant commercial risk for us. Plaintiffs have received substantial damage awards in some jurisdictions against pharmaceutical companies based upon claims for injuries allegedly caused by the use of their products. In addition, in the age of social media, plaintiffs' counsel now has a wide variety of tools to advertise their services and solicit new clients for litigation. Thus, any significant product liability litigation or mass tort in which we are a defendant may have a larger number of plaintiffs than such actions have seen historically because of the increasing use of widespread and media-varied advertising.

In addition, under the License Agreement, we are obligated to indemnify Endo and its affiliates for any harm or losses they suffer relating to any personal injury and other product liability resulting from our development, manufacture or commercialization of any injectable collagenase product. We have clinical trial and product liability insurance in the aggregate amount of $5.0 million dollars. We believe this is adequate in both scope and amount and has been placed with what we believe are reputable insurers. However, we may not be able to maintain our clinical trial and product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses. If losses from product liability claims exceed our insurance coverage, we may incur substantial liabilities that exceed our financial resources, and our business and results of operations may be harmed. Whether or not we are ultimately successful in product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which could impair our business

In addition, it may be necessary for us to recall or withdraw, either voluntarily or mandatorily, products that do not meet approved specifications or which subsequent data demonstrate may be unsafe or ineffective, which would also result in adverse publicity as well as in costs connected to the recall and loss of revenue.

Risks Related to Personnel

The loss of key personnel, including our principal executive officer and principal financial officer, could delay or prevent us from achieving our objectives.

Our business efforts could be affected adversely by the loss of one or more key members of our personnel, particularly Ronald Law, our principal executive officer, and Pat Caldwell, our principal financial/accounting officer. Mr. Law and Mr. Caldwell were only recently elevated to their respective positions following the death of our President, Mr. Wegman. We currently do not have key person insurance on any of our employees or key personnel.

Because we are a small biopharmaceutical-focused company with limited resources, we may be unable to attract and retain qualified personnel; the termination of relationships with key management, consulting and scientific personnel or the inability to recruit and retain additional personnel could prevent us from developing our technologies, conducting clinical trials and/or obtaining financing.

We are a small company and we rely heavily on third parties and outside consultants to conduct many important functions. As of December 31, 2018, we had six full-time employees and three independent consultants. We may require additional experienced executive, accounting, legal, administrative and other personnel from time to time in the future. Also, because of the specialized scientific nature of our business, our ability to develop products and to compete with our current and future competitors largely depends upon our ability to attract, retain and motivate highly-qualified managerial, consulting and scientific personnel. If we are unable to retain the services of one or more of the principal members of senior management, consultants or other key employees, our ability to implement our business strategy could be materially harmed. We face intense competition for qualified employees and consultants from biopharmaceutical companies, research organizations and academic institutions. Attracting, retaining or replacing these personnel on acceptable terms may be difficult and time-consuming given the high demand in our industry for similar personnel. There is intense competition for qualified personnel in the areas of our activities, and we cannot assure you that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business.

Risks Related to Intellectual Property Rights

If we are unable to obtain, maintain and enforce intellectual property protection covering our products, others may be able to make, use or sell products substantially similar to ours, which could adversely affect our ability to compete in the market.

Our commercial success depends, in part, on our ability to obtain, maintain and enforce patents, trade secrets, trademarks and other intellectual property rights and to operate without having third parties infringe, misappropriate or circumvent the rights that we own or license. If we are unable to obtain, maintain and enforce intellectual property protection covering our products, others may be able to make, use or sell products that are substantially similar to ours without incurring the sizeable development and licensing costs that we have incurred, which would adversely affect our ability to compete in the market. Our ability to stop third parties from making, using, selling, offering to sell or importing our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. However, the patent positions of biopharmaceutical companies, including ours, can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. Therefore, there is no assurance that our pending patent applications will result in the issuance of patents or that we will develop additional proprietary products which are patentable. Moreover, patents issued or to be issued to us may not provide us with any competitive advantage. Our patent position is subject to numerous additional risks, including the following:

- we may fail to seek patent protection for inventions that are important to our success;
- our pending patent applications may not result in issued patents;
- we cannot be certain that we were the first to invent the inventions covered by pending pre-America Invents Act patent applications or that we were the first to file such applications and, if we are not, we may be subject to priority disputes;
- we may be required to disclaim part or all of the term of certain patents or all of the term of certain patent applications;
- we may file patent applications but have claims restricted or we may not be able to supply sufficient data to support our claims and, as a result, may not obtain the original claims desired or we may receive restricted claims. Alternatively, it is possible that we may not receive any patent protection from an application;
- we could inadvertently abandon a patent or patent application, resulting in the loss of protection of certain intellectual property rights in a certain country. We, our collaborators or our patent counsel may take action resulting in a patent or patent application becoming abandoned which may not be able to be reinstated or if reinstated, may suffer patent term adjustments;
- the claims of our issued patents or patent applications when issued may not cover our products;
- no assurance can be given that our patents would be declared by a court to be valid or enforceable or that a competitor's technology or product would be found by a court to infringe our patents. Our patents or patent applications may be challenged by third parties in patent litigation or in proceedings before the USPTO or its foreign counterparts, and may ultimately be declared invalid or unenforceable, or narrowed in scope;
- there may be prior art of which we are not aware that may affect the validity or enforceability of a patent claim. There also may be prior art of which we are aware, but which we do not believe affects the validity or enforceability of a claim, which may, nonetheless, ultimately be found to affect the validity or enforceability of a claim;
- third parties may develop products which have the same or similar effect as our products without infringing our patents. Such third parties may also intentionally circumvent our patents by means of alternate designs or processes or file applications or be granted patents that would block or hurt our efforts;
- there may be dominating patents relevant to our product candidates of which we are not aware;
- our patent counsel, lawyers or advisors may have given us, or may in the future give us incorrect advice or counsel. Opinions from such patent counsel or lawyers may not be correct or may be based on incomplete facts;
- obtaining regulatory approval for biopharmaceutical products is a lengthy and complex process, and as a result, any patents covering our product candidates may expire before, or shortly after such product candidates are approved and commercialized;

- the patent and patent enforcement laws of some foreign jurisdictions do not protect intellectual property rights to the same extent as laws in the U.S., and many companies have encountered significant difficulties in protecting and defending such rights in foreign jurisdictions. If we encounter such difficulties or we are otherwise precluded from effectively protecting our intellectual property rights in foreign jurisdictions, our business prospects could be substantially harmed; and

- we may not develop additional proprietary technologies that are patentable.

Any of these factors could hurt our ability to gain full patent protection for our products. Registered trademarks and trademark applications in the U.S. and other countries are subject to similar risks as described above for patents and patent applications.

Moreover, we may be subject to a third-party pre-issuance submission of prior art to the USPTO, or become involved in opposition, nullity, derivation, reexamination, inter partes review, post-grant review or interference proceedings challenging our patent rights or the patent rights of others. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or drugs and compete directly with us, without payment to us or result in our inability to manufacture or commercialize drugs without infringing third-party patent rights. In addition, if the breadth or strength of protection provided by our patents and patent applications is threatened, it could dissuade companies from collaborating with us to seek patent protection or to license, develop or commercialize current or future product candidates.

Developments in patent law could have a negative impact on our business.

From time to time, the United States Supreme Court (the "Supreme Court"), other federal courts, the United States Congress, or the USPTO, may change the standards of patentability and any such changes could have a negative impact on our business.

Two cases involving diagnostic method claims and "gene patents" have recently been decided by the Supreme Court. On March 20, 2012, the Supreme Court issued a decision in *Mayo Collaborative v. Prometheus Laboratories* ("Prometheus"), a case involving patent claims directed to optimizing the amount of drug administered to a specific patient. According to that decision, Prometheus' claims failed to incorporate sufficient inventive content above and beyond mere underlying natural correlations to allow the claimed processes to qualify as patent-eligible processes that apply natural laws. On June 13, 2013, the Supreme Court subsequently decided *Association for Molecular Pathology v. Myriad Genetics* ("Myriad'), a case brought by multiple plaintiffs challenging the validity of patent claims held by Myriad Genetics, Inc. relating to the breast cancer susceptibility genes BRCA1 and BRCA2, holding that genomic DNA that exists in nature, even if isolated, such as the DNA constituting the BRCA1 and BRCA2 genes, is not patentable subject matter under 35 U.S.C. §101.

On March 4, 2014, the USPTO issued a memorandum to patent examiners providing guidance for examining claims reciting laws of nature/natural principles, natural phenomena, and/or natural products for patent eligibility in view of the Supreme Court decisions in Prometheus and Myriad. The guidance indicates that claims reciting such natural products, even in combination, that do not significantly differ from such natural products could be rejected as directed to non-statutory subject matter. That guidance was replaced by a memorandum issued December 15, 2014, that modified some of the earlier guidance, but a number of the aspects have not substantially changed, and it is too soon to determine how the revised guidance will be applied. These guidelines, and the Myriad discussion that isolation of natural products may not confer eligibility under 35 U.S.C. §101, are relevant to our patent portfolio and thus enforcement of these patents.

A further case relevant to these issues was decided by the Supreme Court on June 19, 2014, in *Alice Corp. v. CLS Bank International*, 573 U.S. 208, 134 S. Ct. 2347 (2014) ("Alice"). While the Alice case related to computer-implemented inventions, the holding in that case, which also related to natural laws or "abstract ideas" has been used to reject claims in applications directed to other technologies. As a result of the Alice case, the March guidance issued by the USPTO was replaced by the memorandum issued December 15, 2014, that modified some of the earlier guidance. In June of 2015, an additional case was decided by the Federal Circuit, namely, *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) ("Sequenom"). The Federal Circuit affirmed the district court, finding that methods of detecting paternally inherited nucleic acids were not patent eligible. Sequenom's petition for rehearing *en banc* and its petition for *certiorari* to the Supreme Court were both denied.

On July 30, 2015, the USPTO issued a "July 2015 Update on Subject Matter Eligibility," which provided further guidance, as well as examples of patent-eligible and patent-ineligible subject matter, which was largely directed to computer-implemented inventions. However, in May of 2016, the USPTO issued an additional "Subject Matter Eligibility Update," as well as "Subject Matter Eligibility Examples: Life Sciences," which included examples of eligible and non-eligible claims relating to vaccines, diagnosis and treatment of disease, dietary sweeteners, screening for gene alterations, a paper-making machine, and a process for hydrolysis of fat. Additional business method examples were issued in December of 2016. These examples are useful guidance for drafting eligible claims in the chemical and biological arts. In addition, the USPTO provided an additional memorandum in November of 2016, summarizing more recent decisions by the Federal Circuit in the area of software claim eligibility.

In 2018, the USPTO provided additional guidance by issuing charts and Quick Reference Sheets (March 14, 2018 and May 3, 2018) that list various subject matter eligibility decisions, including those identifying abstract ideas; memoranda on various subject matter eligibility decisions (April 2, 2018 [*Finjan Inc. v. Blue Coat Systems, Inc*., 879 F.3d 1299 (Fed. Cir. 2018) and *Core Wireless Licensing S.A.R.L., v. LG Electronics, Inc.,* 880 F.3d 1356 (Fed. Cir. 2018)], April 19, 2018 [*Berkheimer v. HP Inc.,* 881F.3d 1360 (Fed. Cir. 2018) and *Aatrix Software, Inc. v. Green Shades Software, Inc*., 882 F.3d 1121 (Fed. Cir. 2018)], June 7, 2018 [*Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals* , 887 F.3d 1117 (Fed. Cir. 2018)]; and training materials on what constitutes a "well-understood, routine, conventional activity" (May 7, 2018). In addition, the Manual of Patent Examining Procedure was amended in 2018 (Chapter 2106) to incorporate this information.

On January 7, 2019, along with providing additional Examples 37-42, the USPTO issued its "2019 Revised Patent Subject Matter Eligibility Guidance" ("Guidance") in an effort to provide more consistency and predictability in the analysis of whether subject matter is patent eligible under 35 U.S.C. § 101. 84 Fed. Reg. 50. This Guidance made changes to what is recognized as Step 2A of the eligibility test, to include a "Prong One" that provides grouping of abstract idea exceptions, and a "Prong Two," that requires an examiner to "evaluate whether the claim as a whole integrates the recited judicial exception into a practical application of the exception."

In light of the developing case law and guidance from the USPTO on subject matter eligibility, we cannot assure you that our efforts to seek patent protection for our technology and products will not be negatively impacted by the guidance issued by the USPTO, the decisions described above, rulings in other cases, or changes in guidance or procedures issued by the USPTO, or changes in statutes implemented by Congress.

Furthermore, we cannot fully predict what impact the Supreme Court's decisions in *Prometheus, Myriad* and *Alice* may have on the ability of biopharmaceutical companies or other entities to obtain or enforce patents relating to purified natural products in the future. The *Prometheus, Myriad* and *Alice* decisions are relatively recent, and the contours of when claims to laws of nature, natural phenomena or natural products meet the patent eligibility requirements are not clear and may take many years to develop via interpretation in the courts. Thus, we may not be able to defend successfully the validity of our patents if challenged.

In addition, the Leahy-Smith America Invents Act (the "America Invents Act"), which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process. These changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed new and untested regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act. Substantive changes to patent law associated with the America Invents Act may affect our ability to obtain patents, and, if obtained, to enforce or defend them. Accordingly, it is not clear what, if any, impact the America Invents Act will ultimately have on the cost of prosecuting our patent applications, our ability to obtain patents based on our discoveries and our ability to enforce or defend any patents that may issue from our patent applications, all of which could have a material adverse effect on our business.

The laws of foreign countries may not protect our rights to the same extent as the laws of the U.S. or vice-versa. For example, European patent law restricts the patentability of methods of treatment of the human body more than U.S. law. Publications of discoveries in the scientific literature often lag behind the actual discoveries, and utility, or equivalent, patent applications in the U.S. and other jurisdictions are typically not published until 18 months after the filing date of such patent applications, or in some cases, not at all. Therefore, we cannot know with certainty whether we were the first to make the inventions claimed in our owned or licensed patents or pending patent applications, or that we were the first to file for patent protection of such inventions. As a result, the issuance, scope, validity, enforceability and commercial value of our patent rights are highly uncertain. Our pending and future patent applications may not result in patents being issued that protect our product candidates, in whole or in part, or which effectively prevent others from commercializing competitive technologies and drugs. Changes in either the patent laws or interpretation of the patent laws in the U.S. and other countries may diminish the value of our patents or narrow the scope of our patent protection.

If we breach any of the agreements under which we license rights to products or technology from others, we could lose license rights that are critical to our business and our business could be harmed.

We are a party to a number of license agreements by which we have acquired rights to use the intellectual property of third parties that are necessary for us to operate our business. If a third party terminates its agreement, whether by its terms or due to our breach, our right to use such third party's intellectual property may negatively affect our licenses to Endo, and, in turn, their obligation to make opt-in, milestone, mark-up on cost of goods sold, royalty or other payments to us.

Our ability and the ability of our licensees and collaborators to develop and license products based on our patents may be impaired by the intellectual property of third parties.

Endo's and the Company's commercial success in developing and manufacturing collagenase products based on our patents is dependent on the products not infringing the patents or proprietary rights of third parties. While we currently believe that the Company's and its licensees and collaborators have freedom to operate in the collagenase market, others may challenge that position in the future. There has been, and we believe that there will continue to be, significant litigation in the pharmaceutical industry regarding patent and other intellectual property rights.

Third parties could bring legal actions against us, our licensees, licensors or collaborators claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or products. A third party might request a court to rule that the patents we in-licensed or licensed to others, or those we may in-license in the future, are invalid or unenforceable. In such a case, even if the validity or enforceability of those patents were upheld, a court might hold that the third party's actions do not infringe the patent we license to others, which could, in effect, limit the scope of our patent rights and those of our licensees or collaborators.

Our agreement with Endo requires us to indemnify them against any claims for infringement based on the use of our technology. If we become involved in any litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. If Endo becomes involved in such litigation, it could also consume a substantial portion of their resources, regardless of the outcome of the litigation, thereby jeopardizing their ability to commercialize candidate products and/or their ability to make opt-in, milestone, mark-up on cost of goods sold or royalty payments to us. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to permit ourselves and our licensees, licensors or collaborators to conduct clinical trials, manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. However, there can be no assurance that any such license will be available on commercially acceptable terms or at all. Ultimately, the Company and its licensees or collaborators could be prevented from commercializing a product, or forced to cease some aspect of their or our business, as a result of patent infringement claims, which could harm our business or right to receive opt-in, milestone, mark-up on cost of goods sold and royalty payments.

Our intellectual property may be infringed by a third party.

Third parties may infringe one or more of our issued patents or trademarks. We cannot predict if, when or where a third party may infringe one or more of our issued patents or trademarks. To counter infringement, we may be required to file infringement claims, which can be expensive and time-consuming. Moreover, there is no assurance that we would be successful in a court of law in proving that a third party is infringing one or more of our issued patents or trademarks. Any claims we assert against perceived infringers could also provoke these parties to assert counterclaims against us, alleging that we infringe their intellectual property. In addition, in a patent infringement proceeding, a court may decide that a patent of ours is invalid or unenforceable, in whole or in part, construe the patent's claims narrowly and/or refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question, any of which may adversely affect our business. Even if we are successful in proving in a court of law that a third party is infringing one or more of our issued patents or trademarks there can be no assurance that we would be successful in halting their infringing activities, for example, through a permanent injunction, or that we would be fully or even partially financially compensated for any harm to our business. We may be forced to enter into a license or other agreement with the infringing third party at terms less profitable or otherwise commercially acceptable to us than if the license or agreement were negotiated under conditions between those of a willing licensee and a willing licensor.

Additionally, we may not become aware of a third-party infringer within legal timeframes for compensation or at all, thereby possibly losing the ability to be compensated for any harm to our business. Such a third party may be operating in a foreign country where the infringer is difficult to locate and/or the intellectual property laws may be more difficult to enforce. Some third-party infringers may be able to sustain the costs of complex infringement litigation more effectively than we can because they have substantially greater resources. Any inability to stop third-party infringement could result in loss in market share of some of our products or even lead to a delay, reduction and/or inhibition of the development, manufacture or sale of certain products by us. There is no assurance that a product produced and sold by a third-party infringer would meet our or other regulatory standards or would be safe for use. Such third-party infringer products could irreparably harm the reputation of our products thereby resulting in substantial loss in market share and profits.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that the Company or its employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of our employees' former employers or other third parties. We may also be subject to claims that former employers or other third parties have an ownership interest in our patents. Litigation may be necessary to defend against these claims. There is no guarantee of success in defending these claims, and if we do not prevail, we could be required to pay substantial damages and could lose rights to important intellectual property. Even if we are successful, litigation could result in substantial cost and be a distraction to our management and other employees.

Risks Related to our Common Stock

We have no current plan to pay dividends on our common stock and investors must rely on an increase in stock price for any return on their investment.

We retain the earnings that we generate. Currently, we do not have any plans to pay dividends on our common stock. Because we historically have not declared dividends, stockholders must rely on an increase in the stock price for any return on their investment in us. Investors will not receive any funds absent a sale of their shares. We cannot assure investors of a positive return on their investment when they sell their shares.

Our stock price has, in the past, been volatile, and the market price of our common stock may drop below the current price.

Our stock price has, at times, been volatile. Currently, our common stock is traded on The Nasdaq Global Market ("Nasdaq"), and is thinly traded.

Market prices for securities of pharmaceutical, biotechnology and specialty pharmaceutical companies have been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- results of our clinical trials;
- failure of any product candidates we have licensed to Endo to achieve commercial success;
- failure of Endo to exercise any opt in rights to new indications;
- regulatory developments in the U.S. and foreign countries;
- developments or disputes concerning patents or other proprietary rights;
- litigation involving us or our general industry, or both;
- future sales of our common stock by the estate of our former Chairman and Chief Executive Officer, directors, officers, or others;
- changes in the structure of healthcare payment systems, including developments in price control legislation;
- departure of key personnel;
- termination of agreements with our licensees or their sublicensees;

- announcements of material events by those companies that are our competitors or perceived to be similar to us;
- changes in estimates of our financial results;
- investors' general perception of us;
- general economic, industry and market conditions; and
- the reallocation by Endo of its priorities away from XIAFLEX®.

If any of these risks occurs, or continues to occur, it could cause our stock price to fall and may expose us to class action lawsuits that, even if unsuccessful, could be costly to defend and a distraction to management.

We cannot guarantee that we will repurchase our common stock pursuant to our stock repurchase program or that our stock repurchase program will enhance long-term stockholder value. Stock repurchases could also increase the volatility of the price of our common stock and could diminish our cash reserves.

In August 2018, our Board authorized an increase in the repurchase amount of our stock repurchase program under which we are authorized to repurchase shares of our common stock for an aggregate purchase price not to exceed $3.0 million in open market transactions in compliance with SEC Rule 10b-18. Although our Board has authorized the stock repurchase program, the stock repurchase program does not obligate us to repurchase any specific dollar amount or to acquire any specific number of shares. Stock will be purchased from time to time, in the open market in compliance with SEC Rule 10b-18, subject to market conditions and applicable state and federal securities laws. The timing and amount of repurchases, if any, will depend upon several factors, including market and business conditions, the trading price of our common stock and the nature of other investment opportunities. In addition, repurchases of our common stock pursuant to our stock repurchase program could affect the market price of our common stock or increase its volatility. For example, the existence of a stock repurchase program could cause our stock price to be higher than it would be in the absence of such a program and could potentially reduce the market liquidity for our stock. Additionally, our stock repurchase program could diminish our cash reserves, which may impact our ability to finance future growth and to pursue possible future strategic opportunities and acquisitions. There can be no assurance that any stock repurchases will enhance stockholder value because the market price of our common stock may decline below the levels at which we determine to repurchase our stock. Although our stock repurchase program is intended to enhance long-term stockholder value, there is no assurance that it will do so and short-term stock price fluctuations could reduce the program's effectiveness.

Actual or potential sales of our common stock by our directors, employees and consultants, during open trading windows and pursuant to pre-arranged stock trading plans, could cause our stock price to fall or prevent it from increasing for numerous reasons, and actual or potential sales by such persons could be viewed negatively by other investors.

We have a number of insiders that own significant blocks of our common stock. If one or more of these stockholders sell large portions of their holdings in a relatively short time, for liquidity, tax, or other reasons, the prevailing market price of our common stock could be negatively affected. In addition, it is possible that our executive officers, consultants, or non-employee members of our Board could sell shares of our common stock during an open trading window under our Insider Trading Policy. These transactions and the perceived reasons for these transactions could be viewed negatively by other investors and could have a negative effect on the prevailing market price of our common stock.

In accordance with the guidelines specified under Rule 10b5-1 of the Exchange Act, and our policies regarding stock transactions, certain of our directors and consultants have adopted and may continue to adopt stock trading plans pursuant to which they have arranged to sell shares of our common stock from time to time in the future. Generally, sales under such plans by our directors require public filings. Actual or potential sales of our common stock by such persons could cause the price of our common stock to fall or prevent it from increasing for numerous reasons. For example, a substantial number of shares of our common stock becoming available (or being perceived to become available) for sale in the public market could cause the market price of our common stock to fall or prevent it from increasing.

Our outstanding options to purchase shares of common stock could have a possible dilutive effect.

As of December 31, 2018, options to purchase 175,500 shares of common stock were outstanding. In addition, as of December 31, 2018, a total of 147,598 options were available for grant under our stock option plans. The issuance of common stock upon the exercise of these options could adversely affect the market price of the common stock or result in substantial dilution to our existing stockholders.

If securities analysts do not publish research reports about the Company's or Endo's business or if they downgrade the Company, Endo or our sector, the price of our common stock could decline.

The trading market for our common stock will depend in part on research reports that industry or financial analysts publish about the Company and its business and about Endo. If analysts downgrade us or any of our licensees, including Endo, or other research analysts downgrade the industry in which we operate or the stock of any of our competitors or licensees, the price of our common stock may decline. Additionally, we currently only have one analyst covering our stock. We lack the potential benefit that coverage by other analysts may provide.

Provisions in our certificate of incorporation and bylaws may prevent or frustrate a change in control.

Provisions of our certificate of incorporation and bylaws may discourage, delay or prevent a merger, acquisition or other change in control that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions:

- provide for a classified Board;
- give our Board the ability to designate the terms of and issue new series of preferred stock without stockholder approval, commonly referred to as "blank check" preferred stock, with rights senior to those of our common stock;
- limit the ability of the stockholders to call special meetings; and
- impose advance notice requirements on stockholders concerning the election of directors and other proposals to be presented at stockholder meetings.

In addition, in May 2002, the Board implemented a rights agreement, commonly known as a Poison Pill, which effectively discourages or prevents acquisitions of more than 15% of our common stock in transactions (mergers, consolidations, tender offer, etc.) that have not been approved by our Board. The rights agreement has since been amended as follows:

- In February 2011 to increase the threshold from 15% to 18% and extend the expiration date for an additional two years, to May 31, 2014.
- In February 2014, to extend the term for an additional two years, to May 31, 2016.
- In May 2016, to extend the term for an additional two years, to May 31, 2018.
- In May 2018, to extend the term for an additional two years, to May 31, 2020.

These provisions could make it more difficult for common stockholders to replace members of the Board. Because our Board is responsible for appointing the members of our management team, these provisions could in turn affect any attempt to replace the current management team.

If our principal stockholders, executive officers and directors choose to act together, they may be able to control our operations, acting in their own best interests and not necessarily in the interest of other stockholders.

As of March **[__]**, 2019 our executive officers and directors, and their affiliates, in the aggregate, beneficially owned shares representing approximately 20.5% of our common stock. Beneficial ownership includes shares over which an individual or entity has investment or voting power and includes shares that could be issued upon the exercise of options within 60 days. As a result, if these stockholders were to choose to act together, they may be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, they could control the election of directors and approval of any merger, consolidation or sale of all or substantially all of our assets. This concentration of ownership could have the effect of delaying, deferring or preventing a change in control or impeding a merger or consolidation, takeover or other business combination that could be favorable to other stockholders.

This significant concentration of share ownership may adversely affect the trading price for our common stock because investors often perceive disadvantages in owning stock in companies with controlling stockholders.

Item 1B. UNRESOLVED STAFF COMMENTS

None.

Item 2. PROPERTIES

Our corporate headquarters are currently located at 35 Wilbur St., Lynbrook, NY 11563 (the "Headquarters") and consists of approximately 10,000 square feet of leased office and lab space.

On August 14, 2018, the Company entered into an agreement with 35 Wilbur Street Associates, LLC (the "Landlord") to extend the term of the lease to the Headquarters for an additional one-year period (the "2018 Extended Lease Agreement"). The one-year extension will end on November 30, 2019. Pursuant to the 2018 Extended Lease Agreement, the base rent is $11,500 per month and the Company may cancel the lease with three months' prior written notice to the Landlord at any time during the term.

Item 3. LEGAL PROCEEDINGS

None.

Item 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

Item 5. MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS, AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock currently trades under the symbol BSTC on Nasdaq. On April 1, 2019, the last reported sale price of our common stock was $60.46 per share.

The table below sets forth the high and low closing sale prices for our common stock as reported by and as quoted by NASDAQ for each of the quarterly periods in 2018 and 2017:

2018	HIGH	LOW
Fourth Quarter	$ 66.30	$ 52.08
Third Quarter	$ 62.50	$ 43.06
Second Quarter	$ 45.12	$ 40.54
First Quarter	$ 44.98	$ 38.05

2017	HIGH	LOW
Fourth Quarter	$ 48.93	$ 42.81
Third Quarter	$ 52.05	$ 45.00
Second Quarter	$ 58.00	$ 48.15
First Quarter	$ 57.19	$ 49.35

These quotations reflect inter-dealer prices, without retail mark-up, mark-down or commission and may not represent actual transactions.

Holders of Record

As of April 1, 2019, there were approximately 55 holders of record of our common stock. Because many of such shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these nominees and we believe that the total number of beneficial owners is considerably higher.

Dividends

It has been our policy to retain potential earnings to finance the growth and development of our business and not pay dividends, and we have no current plans to pay dividends. Any payment of cash dividends in the future will depend upon our financial condition, capital requirements and earnings as well as such other factors as our Board of Directors (the "Board") may deem relevant.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2018 with respect to the shares of our common stock that may be issued under our existing equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))

	(a)	(b)	(c)
Equity compensation plans approved by security holders(1)	175,500	$37.73	147,598
Equity compensation plans not approved by security holders	-	-	-
Total	175,500	$37.73	147,598

(1) Please see Note 9, “Stockholders’ Equity,” of the notes to the consolidated financial statements for a description of the material features of each of our plans.

[Note: We deleted the “Securities Authorized for Issuance under Equity Compensation Plans” table, as this will need to go in the 2019 Proxy (due to a new equity plan being put up for SH approval.]

Recent Sales of Unregistered Securities

For the year ended December 31, 2018, we did not issue any unregistered shares of securities.

Issuer Purchases of Equity Securities (1)

For the fourth quarter ended December 31, 2018, we repurchased 7,626 shares.

The following table presents a summary of share repurchases made by us during the year ended December 31, 2018:

Month	Total Number of Shares Purchased (2)	Average Price Paid Per Share(3)	Total Number of Shares Purchased as Part of Publicly Announced Plan	Maximum Dollar Value of Shares that may yet be Purchased under the Plan
				$ 3,000,000(1)
September 1, 2018 – September 30, 2018	43,705	$ 58.55	318,719	440,950
October 1, 2018 – October 31, 2018	5,069	57.97	323,788	147,117
November 1, 2018 – November 30, 2018	1,350	58.52	325,138	68,121
December 1, 2018 – December 31, 2018	1,207	56.59	326,345	-

(1) On August 9, 2018, we announced that our Board of Directors had authorized the repurchase of up to $3.0 million of our common stock under the stock repurchase program.

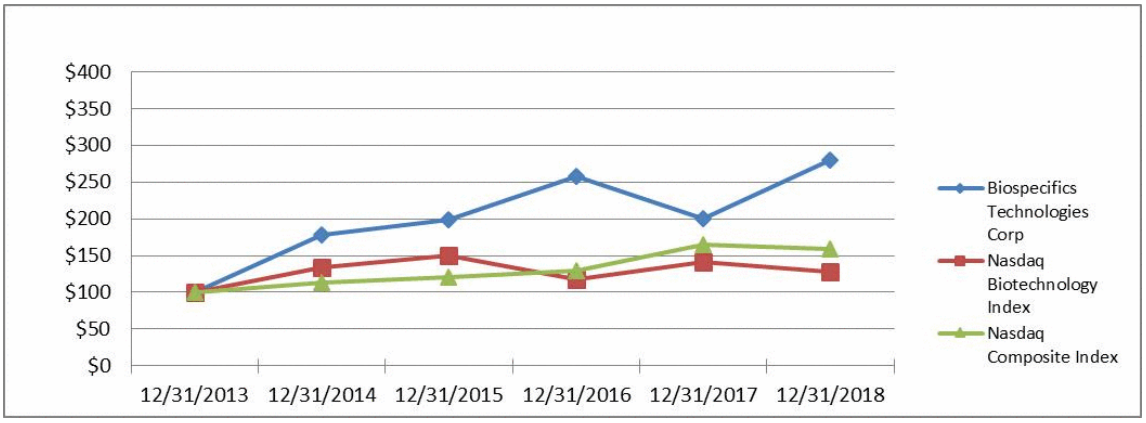
(2) The purchases were made in open-market transactions in compliance with Rule 10b-18 or under the Company's 10b-18 plan.

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

Performance Graph

The graph below compares the cumulative total stockholder return on our common stock with the cumulative total stockholder return of (i) the Nasdaq Biotechnology Index, and (ii) the Nasdaq Composite Index, assuming an investment of $100 on December 31, 2013, in our common stock; the stocks comprising the Nasdaq Composite Index; and the stocks comprising the Nasdaq Biotechnology Index.

Comparison of Cumulative Total Return* Among BioSpecifics Technologies Corp, the Nasdaq Biotechnology Index and the Nasdaq Composite Index



	12/31/2013	12/31/2014	12/31/2015	12/31/2016	12/31/2017	12/31/2018
Biospecifics Technologies Corp	$ 100.00	$ 178.22	$ 198.29	$ 257.04	$ 199.95	$ 279.65
Nasdaq Biotechnology Index	$ 100.00	$ 134.10	$ 149.42	$ 117.02	$ 141.66	$ 128.45
Nasdaq Composite Index	$ 100.00	$ 113.40	$ 119.89	$ 128.89	$ 165.29	$ 158.87

* Total return assumes $100 invested on December 31, 2013 in our common stock, the Nasdaq Composite Index, and the Nasdaq Biotechnology Index and reinvestment of dividends through fiscal year ended December 31, 2018.

Item 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes appearing elsewhere in this Report. The consolidated statements of income data for the years ended December 31, 2018, 2017 and 2016 and the consolidated balance sheet data as of December 31, 2018 and 2017 have been derived from our audited consolidated financial statements and related notes, which are included elsewhere in this Report. The consolidated statement of income data for the years ended December 31, 2015 and 2014 and the consolidated balance sheet data as of December 31, 2016, 2015 and 2014 have been derived from audited financial statements which do not appear in this Report. The historical results presented are not necessarily indicative of results to be expected in any future period.

Consolidated Statement of Income Data	**Years Ended December 31,**				
	2018	**2017**	**2016**	**2015**	**2014**
Total revenues	$ 32,961,443	$ 27,443,752	$ 26,250,955	$ 22,750,135	$ 14,044,624
Operating expenses:					
Research and development	756,776	1,223,277	1,327,923	1,034,288	1,263,512
General and administrative	8,805,989	8,542,324	7,896,616	7,272,532	5,814,185
Total costs and expenses	9,562,765	9,765,601	9,224,539	8,306,820	7,077,697
Operating income	**23,398,678**	**17,678,151**	**17,026,416**	**14,443,315**	**6,966,927**
Other income:					
Interest income	1,294,651	636,568	295,783	92,926	32,158
Other	103,948	51,074	52,805	14,719	33,582
	1,398,599	687,642	348,588	107,645	65,740
Income before income tax	24,797,277	18,365,793	17,375,004	14,550,960	7,032,667
Provision for income tax expense	(4,744,008)	(7,037,527)	(6,002,765)	(4,933,328)	(2,386,707)
Net income	**$ 20,053,269**	**$ 11,328,266**	**$ 11,372,239**	**$ 9,617,632**	**$ 4,645,960**
Earnings per common share:					
Basic	**$ 2.77**	**$ 1.58**	**$ 1.61**	**$ 1.41**	**$ 0.72**
Diluted	**$ 2.73**	**$ 1.55**	**$ 1.56**	**$ 1.32**	**$ 0.66**
Shares used in calculation of net income per common share:					
Basic	**7,242,212**	**7,170,701**	**7,061,404**	**6,827,355**	**6,477,457**
Diluted	**7,333,368**	**7,321,805**	**7,283,262**	**7,272,989**	**7,079,570**

	Years Ended December 31,				
Consolidated Balance Sheet Data:	**2018**	**2017**	**2016**	**2015**	**2014**
Cash and cash equivalents	$ 13,176,452	$ 7,333,810	$ 4,763,364	$ 5,137,875	$ 9,810,816
Investments	68,806,977	57,719,945	48,026,242	31,944,083	12,150,436
Total assets	100,092,042	74,996,394	64,696,280	45,698,113	31,026,824
Total stockholders' equity	97,588,519	67,516,838	56,281,943	44,810,209	30,256,855

Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our consolidated financial statements and the related notes appearing at the end of this Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Report, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. You should review the "Risk Factors" section of this Report for a discussion of important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis.

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 (DC) and Peyronie's disease (PD), 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, and invests in 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 within this Annual Report on Form 10-K for the year ended December 31, 2018.

Critical Accounting Policies, Estimates and Assumptions

The preparation of consolidated financial statements in conformity with U.S. GAAP requires the use of management's estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. 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 other relevant data including interim data provided by Endo 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 Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers" ("ASC 606"). ASC 606 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 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 preliminary gross sales data provided by Endo and analysis of historical gross-to-net adjustments. Differences between actual and estimated royalty revenues are adjusted for in the period in which they become known. The royalties payable by Endo to us are subject to set-off for certain patent costs.

Licensing Revenue

We include revenue recognized from upfront licensing, sublicensing and milestone payments in "License Revenues" in our 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.

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 PD. 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 January 1, 2018. Royalty obligations terminate five years after the 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 on an annual basis as measured by the proportion of sales of XIAFLEX® and Xiapex for PD to the total estimated sales over the five-year period. We perform an evaluation of the recoverability of the carrying value to determine if facts and circumstances indicate that the carrying value of the assets may be impaired and if any adjustment is warranted. Based on our evaluation as of December 31, 2018, no impairment existed and no adjustment was warranted. **(**For more a more detailed discussion regarding ASC 606, see Note 2**-** *Summary of Significant Accounting Policies – Recent Accounting Pronouncements - Accounting Pronouncements Adopted.*)

Income Taxes. Our 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 ASC 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 ASC 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.

Results of Operations for Years Ended December 31, 2018, 2017 and 2016

Revenues

The following table summarizes our primary sources of revenue during the periods presented:

	Year Ended December 31		
	2018	**2017**	**2016**
Royalties	$ 32,921,764	$ 27,426,117	$ 25,431,012
Licensing revenue	39,679	17,635	819,943
Total revenues	**$ 32,961,443**	**$ 27,443,752**	**$ 26,250,955**

Royalties

Royalties consist of royalties and the mark-up on cost of goods sold under the License Agreement.

Royalty and the mark-up on cost of goods sold revenues recognized under the License Agreement for years ended December 31, 2018 and 2017 were $33.0 million and $27.4 million, respectively. The increase in 2018 as compared to the same period in 2017 of $5.6 million, or 20%, was primarily due to the increased sales of XIAFLEX® for the treatment of PD and DC reported to us by Endo.

Royalty and the mark-up on cost of goods sold revenues recognized under the License Agreement for years ended December 31, 2017 and 2016 were $27.4 million and $25.4 million, respectively. The increase in 2017 as compared to the same period in 2016 of $2.0 million, or 8%, was primarily due to the increased sales and a slight price increase of XIAFLEX® for the treatment of PD and DC reported to us by Endo.

Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones.

The following table summarizes our licensing revenues under our agreement with Endo during the periods presented:

	Year Ended December 31		
	2018	**2017**	**2016**
Licensing fees	$ -	$ -	$ 750,000
Development licensing fees	39,679	17,635	41,443
Milestones	-	-	28,500
Total Licensing revenues	**$ 39,679**	**$ 17,635**	**$ 819,943**

Licensing fees recognized for the years ended December 31, 2018 were $39,679, $17,635 in 2017 and $0.8 million in the 2016 period. In the 2016 period, licensing fees recognized of $0.8 million were related to the exercise of an opt-in right by Endo for the human lipoma indication.

Development licensing fees recognized for XIAFLEX® are related to the cash payments received under the License Agreement in prior years and amortized over the expected development period. For the year ended December 31, 2018, we recognized the remaining nonrefundable upfront product license, in accordance with ASC 606, of $39,679 as compared to $17,635 in the 2017 period. For the year ended December 31, 2017, we recognized development licensing fees of $17,635 as compared to $41,433 in the 2016 period. This decrease was directly related to the stage of development for certain indications.

Milestone revenue recognized for the years ended December 31, 2018 and 2017 were zero in each annual period.

Milestone revenue recognized for the year ended December 31, 2016 was $28,500. The $28,500 milestone revenue recognized in the 2016 period related to the approval of XIAFLEX® in Australia for the treatment of PD by Actelion.

Research and Development Activities

R&D expenses include, but are not limited to, internal costs, such as salaries and benefits, costs of materials, lab expense, facility costs and overhead. R&D expenses also consist of third party costs, such as medical professional fees, product costs used in clinical trials, consulting fees and costs associated with clinical study arrangements.

R&D expenses were $0.8 million and $1.2 million, respectively, for the years ended December 31, 2018 and 2017, representing a decrease in 2017 of $0.4 million, or 33%. The decrease in the 2018 period as compared to the 2017 period was mainly due to lower consulting fees associated with clinical costs and other R&D programs.

R&D expenses were $1.2 million and $1.3 million, respectively, for the years ended December 31, 2017 and 2016, representing a decrease in 2017 of $0.1 million, or 8%. This decrease in R&D expenses are primarily related to the timing of our uterine fibroid clinical program in 2017 and the completion of the phase 2 clinical trial of CCH for the treatment of human lipoma in 2016.

We manage the development of CCH for uterine fibroids and initiate the development of CCH in new potential indications, not licensed by Endo. In April 2017, we initiated of an open-label, dose escalation Phase 1 clinical trial of CCH for the treatment of uterine fibroids. On October 31, 2018, we announced positive topline data from this trial.

We have finished the development work on human lipomas. On July 29, 2016, Endo exercised its opt-in right under the license agreement with respect to the human lipoma indication.

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

Program	Year Ended December 31, 2018	Year Ended December 31, 2017	Year Ended December 31, 2016
Human Lipoma	$ -	$ -	$ 412,933
Uterine Fibroids	311,863	500,719	214,221
Pre-clinical/other research projects	444,913	722,558	700,769

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 successfully commercialize these drug candidates.

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

- the nature, timing and estimated costs of the efforts necessary to complete the development of our drug candidate projects;
- the anticipated completion dates for our drug candidate projects;
- the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future with respect to our drug candidate projects;
- the scope, rate of progress of our preclinical studies and other 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 were $8.8 million and $8.5 million for the years ended December 31, 2018 and 2017, respectively. The increase in general and administrative expenses of $0.3 million, or 4%, in the 2018 period as compared to 2017 was mainly due to the increased amortization of the deferred royalty buy-down, third party royalties, and legal fees partially offset by lower patent, investor relations and consulting fees.

General and administrative expenses were $8.5 million and $7.9 million for the years ended December 31, 2017 and 2016, respectively. The increase in general and administrative expenses of $0.6 million, or 8%, in the 2017 period as compared to 2016 was mainly due to the increased amortization of the deferred royalty buy-down, third party royalties, and legal fees partially offset by lower consulting and patent fees.

Other Income

Other income consists primarily of interest earned on our investments and a limited amount related to product sales of collagenase for laboratory use. Other income for the years ended December 31, 2018, 2107 and 2016 was $1.4 million, $0.7 million and $0.3 million, respectively.

Provision for Income Taxes

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

The provision for income taxes in 2018 was $4.7 million as compared to $7.0 million in 2017.

Our effective tax rate for 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 of 19.13% 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 provision for income taxes in 2017 was $7.0 million as compared to $6.0 million in 2016. Our effective tax rate of 38.32% 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. And by the Tax Cuts and Jobs Act of 2017, which was enacted on December 22, 2017.

In 2016, our deferred tax assets increased by $2.7 million due to the deferred revenue associated with the receipt of $8.25 million under the First Amendment with Endo on sales by non-affiliated sublicensees of Endo outside of the U.S. During 2016, the Company has recorded $0.3 million of excess tax benefits resulting from the exercise of stock options which was recorded in additional paid in capital.

Financial Condition, 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 December 31, 2018, 2017 and 2016, we had cash and cash equivalents and investments in the aggregate of approximately $82.0 million, $65.1 million, and $52.8 million, respectively.

Sources and Uses of Cash

Operating Activities

Net cash provided by operating activities was $17.7 million, $13.2 million and $16.4 million for the 2018, 2017 and 2016 periods.

Net cash provided by operating activities for 2018 was primarily attributable to our net income of $20.1 million, adjustments to reconcile net income to net cash provided by operating activities related to amortization, stock-based compensation expense and deferred tax expense of $2.7 million partially offset by an increase in accounts receivable of $4.3 million due to an increase in XIAFLEX® net sales and the implementation of ASC 606, accrued tax liability of $0.8 million and accounts payable and other accrue expenses of $0.3 million.

Net cash provided by operating activities for 2017 was primarily attributable to our net income of $11.3 million, adjustments to reconcile net income to net cash provided by operating activities related to amortization, stock-based compensation expense and deferred tax expense of $3.9 million and a decrease in operating assets and liabilities of $2.1 million of which $1.2 million was related to the recognition of revenue from the First Amendment with Endo for mark-up on cost of goods sold for sales by non-affiliated sublicensees, a reduction in our income tax receivable, and an increase in accounts receivable of $0.8 million related to royalties due from Endo.

Net cash provided by operating activities for 2016 was primarily attributable to our net income of $11.4 million, an increase in operating assets and liabilities of $5.8 million of which $7.4 million was related to the First Amendment with Endo for mark-up on cost of goods sold for sales by non-affiliated sublicensees of Endo outside of the U.S. partially offset by an increase in accounts receivable of $1.3 million related to royalties due from Endo. 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 $0.8 million.

The majority of our cash expenditures in 2018, 2017, and 2016 were to fund R&D, our general and administrative business activities and our stock repurchase program.

Investing Activities

Net cash used in investing activities was $11.5 million, $10.4 million and $16.7 million in 2018, 2017 and 2016, respectively.

The net cash used in investing activities in the 2018 period reflects the investment of $86.6 million in marketable securities offset by the maturing of investments of $75.2 million.

The net cash used in investing activities in the 2017 period reflects the investment of $64.7 million in marketable securities offset by the maturing of investments of $54.3 million.

The net cash used in investing activities in the 2016 period reflects the investment of $59.9 million in marketable securities and the maturing of investments of $43.2 million.

Financing Activities

Net cash used in financing activities was approximately $0.4 million, $0.2 million and $34,000 in 2018, 2017 and 2016, respectively.

In 2018, net cash used in financing activities was mainly related to the repurchase of our common stock under our stock repurchase program of $3.0 million offset stock option exercise proceeds of $2.6 million.

In 2017, net cash used in financing activities was mainly related to the repurchase of our common stock under our stock repurchase program of $0.6 million offset stock option exercise proceeds of $0.4 million.

In 2016, net cash used in financing activities was mainly related to the repurchase of our common stock under our stock repurchase program of $1.0 million offset by excess tax benefits related to share-based payments and stock option exercise proceeds of $1.0 million.

Contractual Commitments

We are involved with licensing of products which are generally associated with payments to third parties from whom we have licensed the product. Such payments may take the form of an up-front payment; milestone payments which are paid when certain parts of the overall development program are accomplished; payments upon certain regulatory events, such as the filing of an IND, an NDA or BLA or approval of an NDA or BLA, or the equivalents in other countries; and payments based on a percentage of sales.

We may also out-license products, for which we hold the rights, to other companies for commercialization in other territories, or at times, for other uses. When this happens, the payments to us would also take the same form as described above.

Operating Leases

Our operating leases are principally for facilities and equipment. We currently lease approximately 10,000 square feet of space at our headquarters in Lynbrook, New York which expires in November 2019. Additionally, we lease certain vehicle and certain office equipment which generally expire in 2022 and 2020, respectively.

Operating lease expenses amounted to approximately $136,000, $132,000 and $127,000 for the years ended December 31, 2018, 2017 and 2016, respectively.

Future minimum annual payments required under non-cancelable operating leases are approximated as follows:

Year ending December 31,		
2019	$	133,000
2020		3,400
2021		2,300
2022		600

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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to market risk related to changes in interest rates. As of December 31, 2018, we invested our cash in a variety of financial instruments, principally money market funds, certificates of deposit, municipal bonds, and corporate bonds. Most of our interest-bearing securities are subject to interest rate risk and could decline in value if interest rates fluctuate. Our investment portfolio is comprised of marketable securities of highly rated financial institutions and investment-grade debt instruments, and we have guidelines to limit the term-to-maturity of our investments. Based on the type of securities we hold, we do not believe that a change in interest rates would have a material impact on our financial statements. If interest rates were to increase or decrease by 100 basis points the fair value of our investment portfolio would (decrease) increase by approximately ($62,000) and $507,000, respectively. All investments are classified as held to maturity.

Item 8. FINANCIAL STATEMENTS

For the discussion of Item 8, “Financial Statements” please see the Consolidated Financial Statements, beginning on page F-1 of this Report.

Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None

Item 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to provide reasonable assurance that information required to be disclosed in our reports 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 SEC’s rules and forms, and that such information is accumulated and communicated to the management of the Company (the “Management”), including our principal executive officer and our principal financial officer, as appropriate, to allow timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, Management recognized that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives.

The Company, under the supervision and with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of its disclosure controls and procedures (as defined in Rules 13a-15(e) or 15d-15(e) under the Exchange Act) as of the end of the period covered by this Annual Report. Based on that evaluation, our principal executive officer and principal financial officer concluded, as of the end of the period covered by this Annual Report, that the Company's disclosure controls and procedures were effective in the timely and accurate recording, processing, summarizing and reporting of material financial and non-financial information within the time periods specified within the SEC's rules and forms. Our principal executive officer and principal financial officer also concluded that our disclosure controls and procedures were effective to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is accumulated and communicated to our Management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure. **[Note to Pat: We revised to track the SOX language a bit more precisely.]**

Management's Annual Report on Internal Control Over Financial Reporting

Our Management is responsible for establishing and maintaining adequate internal control over financial reporting for the Company as defined in Rule 13a-15(f) under the Exchange Act. The Company's internal control over financial reporting is designed to provide reasonable assurance to the Company's management and Board regarding the preparation and fair presentation of published financial statements and the reliability of financial reporting.
Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2018. In making this assessment, management used the 2013 criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in *Internal Control – Integrated Framework*. We believe that, as of December 31, 2018, the Company's internal control over financial reporting was effective based on such criteria.

EisnerAmper LLP, the independent registered public accounting firm that audited our Consolidated Financial Statements included in this Report, audited the effectiveness of our internal control over financial reporting as of December 31, 2018, as stated in their report which is included in Part IV, Item 15 of this Report.

Changes in Internal Control Over Financial Reporting

Except as noted below, 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 our most recent fiscal quarter that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting. We corrected our material weakness in internal controls identified by us concerning our royalty revenue recognition process, which occurred for the period ended June 30, 2018, by obtaining timely interim data for two consecutive quarterly periods ended September 30, 2018 and December 31, 2018 on royalties so that our estimates are not based solely on our analysis of historical data. In addition, on February 26, 2019, we entered into an amendment to certain provisions of the License Agreement which requires Endo to provide timely estimates of royalties to assist the Company in complying with its financial reporting obligations.

Item 9B. OTHER INFORMATION

Not applicable.

PART III

Item 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by Items 401, 405, 407(c)(3), 407(d)(4), and 407(d)(5) of Regulation S-K is included in our Proxy Statement for the 2019 Annual Meeting of Stockholders (the "Proxy Statement") to be filed with the SEC pursuant to Regulation 14A within 120 days of December 31, 2018, and is incorporated herein by reference.

The information required by Item 406 of Regulation S-K is set forth in Part I, Item 1 of this Annual Report on Form 10-K under the caption "Available Information."

Item 11. EXECUTIVE COMPENSATION

The information required by Items 402, 407(e)(4), and 407(e)(5) of Regulation S-K is included in the Proxy Statement, and is incorporated herein by reference.

Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The information required by Item 201(d) of Regulation S-K is set forth in Part II, Item 5 of this Annual Report on Form 10-K under the caption "Securities Authorized for Issuance under Equity Compensation Plans."

The information required by Item 403 of Regulation S-K is included in the Proxy Statement, and is incorporated herein by reference.

Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

The information required by Items 404 and 407(a) of Regulation S-K is included in the Proxy Statement, and is incorporated herein by reference.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information required by Item 9(e) of Schedule 14A is included in the Proxy Statement, and is incorporated herein by reference.

PART IV

Item 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

a) The following documents are filed as part of this Annual Report:

(1) Consolidated Financial Statements (See Index to Consolidated Financial Statements on page F-1)

(2) Financial Statement Schedules

All schedules to the consolidated financial statements are omitted as the required information is either inapplicable or presented in the consolidated financial statements.

(3) Exhibits

The information required by this Item is set forth in the Exhibit Index hereto which is incorporated herein by reference.

b) Exhibits

The information required by this Item is set forth in the Exhibit Index hereto which is incorporated herein by reference.

BIOSPECIFICS TECHNOLOGIES CORP.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2018, 2017 and 2016

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of BioSpecifics Technologies Corp.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of BioSpecifics Technologies Corp. and subsidiary (the "Company") as of December 31, 2018 and 2017, and the related consolidated statements of income, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2018 and 2017, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the Company's internal control over financial reporting as of December 31, 2018, based on criteria established in *Internal Control - Integrated Framework* (*2013*) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"), and our report dated April 2, 2019 expressed an unqualified opinion.

Change in Accounting Principle

As discussed in Note 2 to the financial statements, the Company has changed its method of accounting for revenue in the year ended December 31, 2018 due to the adoption of Accounting Standards Codification Topic 606, "Revenue from Contracts with Customers".

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2014

EISNERAMPER LLP
New York, New York
April 2, 2019

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of BioSpecifics Technologies Corp.

Opinion on Internal Control over Financial Reporting

We have audited BioSpecifics Technologies Corp. and subsidiary's (the "Company") internal control over financial reporting as of December 31, 2018, based on criteria established in the *Internal Control - Integrated Framework* (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission ("COSO"). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2018, based on criteria established in the *Internal Control - Integrated Framework* (*2013*) issued by COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) ("PCAOB"), the consolidated balance sheets of BioSpecifics Technologies Corp. and subsidiary as of December 31, 2018 and 2017, and the related consolidated statements of income, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2018, and the related notes and our report dated April 2, 2019 expressed an unqualified opinion.

Basis for Opinion

The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

Definition and Limitations of Internal Control over Financial Reporting

An entity's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. An entity's internal control over financial reporting includes those policies and procedures that (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the entity; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the entity are being made only in accordance with authorizations of management and directors of the entity; and (iii) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the entity's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

/s/ EisnerAmper LLP

EISNERAMPER LLP
New York, New York
April 2, 2019

BioSpecifics Technologies Corp.
Consolidated Balance Sheets

	December 31, 2018	December 31, 2017
Assets		
Current assets:		
Cash and cash equivalents	$ 13,176,452	$ 7,333,810
Short term investments	67,707,143	51,973,971
Accounts receivable	16,518,687	4,655,105
Deferred royalty buy-down	184,931	1,794,126
Prepaid expenses and other current assets	646,749	623,503
Total current assets	**98,233,962**	**66,380,515**
Long-term investments	1,099,834	5,745,974
Deferred royalty buy-down – long term, net	-	732,206
Deferred tax assets, net	313,768	1,739,706
Patent costs, net	444,478	397,993
Total assets	**$ 100,092,042**	**$ 74,996,394**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	1,798,588	$ 933,998
Income tax payable	704,934	68,733
Deferred revenue	-	1,057,979
Accrued liabilities of discontinued operations	-	78,138
Total current liabilities	**2,503,522**	**2,138,848**
Long-term deferred revenue	-	5,340,708
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Series A Preferred stock, $.50 par value, 700,000 shares authorized; none outstanding	-	-
Common stock, $.001 par value; 10,000,000 shares authorized; 7,738,167 and 7,600,167 shares issued, 7,275,902 and 7,189,233 outstanding at December 31, 2018 and 2017, respectively	7,738	7,600
Additional paid-in capital	36,302,446	33,468,323
Retained earnings	72,176,719	41,939,115
Treasury stock, 462,265 and 410,934 shares at cost as of December 31, 2018 and 2017	(10,898,383)	(7,898,200)
Total stockholders' equity	**97,588,520**	**67,516,838**
Total liabilities and stockholders' equity	**$ 100,092,042**	**$ 74,996,394**

See accompanying notes to consolidated financial statements

BioSpecifics Technologies Corp.
Consolidated Statements of Income

	Years Ended December 31,		
	2018	**2017**	**2016**
Revenues:			
Royalties	$ 32,921,764	$ 27,426,117	$ 25,431,012
Licensing revenue	39,679	17,635	819,943
Total revenues	**32,961,443**	**27,443,752**	**26,250,955**
Costs and expenses:			
Research and development	756,776	1,223,277	1,327,923
General and administrative	8,805,989	8,542,324	7,896,616
Total costs and expenses	**9,562,765**	**9,765,601**	**9,224,539**
Operating income	**23,398,678**	**17,678,151**	**17,026,416**
Other income:			
Interest income	1,294,651	636,568	295,783
Other	103,948	51,074	52,805
	1,398,599	687,642	348,588
Income before income tax	24,797,277	18,365,793	17,375,004
Income tax provision	(4,744,008)	(7,037,527)	(6,002,765)
Net income	**$ 20,053,269**	**$ 11,328,266**	**$ 11,372,239**
Earnings per common share:			
Basic	**$ 2.77**	**$ 1.58**	**$ 1.61**
Diluted	**$ 2.73**	**$ 1.55**	**$ 1.56**
Shares used in calculation of net income per common share:			
Basic	**7,242,212**	**7,170,701**	**7,061,404**
Diluted	**7,333,368**	**7,321,805**	**7,283,262**

See accompanying notes to consolidated financial statements

BioSpecifics Technologies Corp.
Consolidated Statements of Stockholders' Equity

	Common Stock Shares	Common Stock Amount	Additional Paid in Capital	Retained Earnings	Treasury Stock	Stockholder Equity Total
Balances - December 31, 2015	**7,290,167**	**7,290**	**31,797,418**	**19,238,610**	**(6,233,109)**	**44,810,209**
Issuance of common stock upon stock option exercise	265,000	265	711,135	-	-	711,400
Stock compensation expense	-	-	133,904	-	-	133,904
Repurchases of common stock	-	-	-	-	(1,048,592)	(1,048,592)
Excess tax benefits from share-based payment arrangements	-	-	302,783	-	-	302,783
Net income	-	-	-	11,372,239	-	11,372,239
Balances - December 31, 2016	**7,555,167**	**$ 7,555**	**$ 32,945,240**	**$ 30,610,849**	**$ (7,281,701)**	**$ 56,281,943**
Issuance of common stock upon stock option exercise	45,000	45	395,705	-	-	395,750
Stock compensation expense	-	-	127,378	-	-	127,378
Repurchases of common stock	-	-	-	-	(616,499)	(616,499)
Net income	-	-	-	11,328,266	-	11,328,266
Balances - December 31, 2017	**7,600,167**	**$ 7,600**	**$ 33,468,323**	**$ 41,939,115**	**$ (7,898,200)**	**$ 67,516,838**
Adjustments to prior periods from adopting ASC606	-	-	-	10,184,335	-	10,184,335
Issuance of common stock upon stock option exercise	138,000	138	2,570,692	-	-	2,570,830
Stock compensation expense	-	-	263,431	-	-	263,431
Repurchases of common stock	-	-	-	-	(3,000,183)	(3,000,183)
Net income	-	-	-	20,053,269	-	20,053,269
Balances - December 31, 2018	7,738,167	$ 7,738	$ 36,302,446	$ 72,176,719	$ (10,898,383)	$ 97,588,520

See accompanying notes to consolidated financial statements

BioSpecifics Technologies Corp.
Consolidated Statements of Cash Flows

	Years Ended December 31,		
Cash flows from operating activities:	**2018**	**2017**	**2016**
Net income	**$ 20,053,269**	**$ 11,328,266**	**$ 11,372,239**
Adjustments to reconcile net income to net cash provided in operating activities:			
Amortization	2,432,941	2,239,551	1,691,539
Stock-based compensation expense	263,431	127,378	133,904
Deferred tax expense	90,176	1,550,416	(2,667,150)
Extinguishment of accrued liabilities	(78,138)	-	-
Changes in operating assets and liabilities:			
Accounts receivable	(4,308,855)	(844,313)	(1,262,872)
Income tax receivable / payable	(763,740)	563,444	422,132
Prepaid expenses and other current assets	(23,246)	842	(240,535)
Patent costs	(121,199)	(204,416)	(23,341)
Accounts payable and accrued expenses	325,577	195,349	127,640
Deferred royalty buy-down	-	(600,000)	(600,000)
Deferred revenue	(139,680)	(1,198,863)	7,398,793
Net cash provided by operating activities from operations	**17,730,536**	**13,157,654**	**16,352,349**
Cash flows from investing activities:			
Maturities of marketable securities	75,170,817	54,320,741	43,242,679
Purchases of marketable securities	(86,629,358)	(64,687,200)	(59,935,130)
Net cash used in investing activities from operations	**(11,458,541)**	**(10,366,459)**	**(16,692,451)**
Cash flows from financing activities:			
Proceeds from stock option exercises	2,570,830	395,750	711,400
Repurchases of common stock	(3,000,183)	(616,499)	(1,048,592)
Excess tax benefits from share-based payment arrangements	-	-	302,783
Net cash used in financing activities	**(429,353)**	**(220,749)**	**(34,409)**
Increase (decrease) in cash and cash equivalents	5,842,642	2,570,446	(374,511)
Cash and cash equivalents at beginning of year	7,333,810	4,763,364	5,137,875
Cash and cash equivalents at end of year	**$ 13,176,452**	**$ 7,333,810**	**$ 4,763,364**
Supplemental disclosures of cash flow information:			
Cash paid during the year for:			
Interest	$ -	$ -	$ -
Taxes	$ 5,417,572	$ 5,400,000	$ 7,945,000

See accompanying notes to consolidated financial statements

BIOSPECIFICS TECHNOLOGIES CORP.

Notes to Consolidated Financial Statements
December 31, 2018, 2017 and 2016

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 October 31, 2018, we announced positive topline data from our Phase 1 trial of Collagenase Clostridium Histolyticum (CCH) for the treatment of uterine fibroids. The study met the primary endpoint of safety and tolerability with no observed clinically significant adverse reactions. We have submitted the full data to be presented at an upcoming medical meeting.

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.

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

Principles of Consolidation

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

Critical Accounting Policies, Estimates and Assumptions

The preparation of consolidated financial statements in conformity with U.S. Generally Accepted Accounting Principles ("GAAP") requires the use of management's estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. The Company makes certain assumptions and estimates for its deferred tax assets and deferred royalty buy-down. Actual results could differ from those estimates.

Cash, Cash Equivalents and Investments

Cash equivalents include only securities having a maturity of three months or less at the time of purchase. Investments are stated on an amortized cost basis. The Company limits its credit risk associated with cash, cash equivalents and investments by placing its investments with banks it believes are highly creditworthy and with highly rated money market funds, certificates of deposit, municipal bonds and corporate bonds. All investments are classified as held to maturity. As of December 31, 2018 and 2017, the amortized cost of these investments was $68.8 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 December 31, 2018 and 2017, there were no recorded unrealized gains or losses on our investments as they are held to maturity. As of December 31, 2018 and 2017, amortized cost basis of the investments approximate their fair value. In 2018 and 2017, the amortized premium included in interest income was $372,000 and $673,000, respectively.

The schedule of maturities at December 31, 2018 and 2017 are as follows:

	Maturities as of December 31, 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	$ 1,295,350	$ -	$ 1,002,650	$ 100,000
Corporate Bonds	61,321,162	1,099,834	48,143,495	3,155,575
Certificates of deposit	5,090,631	-	2,827,826	249,019
Total	**$ 67,707,143**	**$ 1,099,834**	**$ 51,973,971**	**$ 5,745,974**

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.

At December 31, 2018 our accounts receivable balance was $16.5 million 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.

At December 31, 2017 our accounts receivable balance was $4.7 million and was from one customer, Endo.

The Company is currently dependent on one customer, Endo, who generates almost all its revenues. For the years ended December 31, 2018, 2017 and 2016, the licensing, sublicensing, milestones and royalty revenues under the License Agreement with Endo were approximately $33.0 million, $27.4 million and $26.3 million, respectively.

Revenue Recognition

Beginning in 2014, Financial Accounting Standards Board ("FASB") issued several Accounting Standards Updates establishing Accounting Standards Codification ("ASC") Topic 606, "Revenue from Contracts with Customers" ("ASC 606"). ASC 606 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 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 preliminary gross sales data provided by Endo and analysis of historical gross-to-net adjustments. Differences between actual and estimated royalty revenues are adjusted for in the period in which they become known. The royalties payable by Endo to us are subject to set-off for certain patent costs.

Licensing Revenue

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

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.

Since the license provided to Endo allows them to use the underlying intellectual property as it was at the point it was transferred, the license grants to Endo a right to use the intellectual property. Revenue is recognized upon the satisfaction of a performance obligation, which occurs when the license is transferred to the customer.

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.

Treasury Stock

The Company accounts for treasury stock under the cost method and includes treasury stock as a component of stockholders' equity. For the year ended December 31, 2018, we repurchased 51,331 shares at an average price of $58.45 as compared 12,048 shares at an average price of $51.17 in the 2017 period. In the 2016 period, we purchased 27,298 shares at an average price of $38.41.

Receivables

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 December 31, 2018 and 2017, our accounts receivable balance was $16.5 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.

Deferred Revenue

As of December 31, 2018 and 2017, deferred revenue was zero and $6.4 million, respectively. 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 2018. Finally, during 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.

Reimbursable Third Party Development Costs

We accrued patent expenses that are reimbursable by us under the License Agreement. We capitalize certain patent costs related to estimated third-party development costs that are reimbursable under the License Agreement. As of December 31, 2018 and 2017, our net reimbursable third party patent expense accrual was approximately $40,000 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 sales data 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 years ended December 31, 2018, 2017 and 2016, third party royalty expenses were $2.4 million, $1.8 million and $1.6 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 are approved.

Royalty Buy-Down

On March 31, 2012, we entered into an amendment to our existing agreement with Dr. Martin K. Gelbard, dated August 27, 2008, related to our future royalty obligations in connection with Peyronie's disease. The amendment enabled 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 December 31, 2018. Royalty obligations terminate five years after the 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 on an annual basis as measured by the proportion of sales of XIAFLEX for Peyronie's disease to the total estimated sales over the five-year period. 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. For the years ended December 31, 2018, 2017, and 2016, we amortized approximately $2.0 million, $1.5 million and $1.0 million related to this agreement, respectively. As of December 31, 2018 and 2017, the remaining capitalized balances were approximately $185,000 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 December 31, 2018, there was no indicator that an impairment existed.

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 organizations. In the normal course of business, we contract with third parties to perform various clinical trial activities in the ongoing development of potential drugs. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, the completion of portions of the clinical trial, or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual cost of services received and efforts expended. As such, expenses related to each patient enrolled in a clinical trial are recognized 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.

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 ASC 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 ASC 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 December 31, 2018 and December 31, 2017, the Company has not recorded any unrecognized tax benefits.

Stock-Based Compensation

The Company has one stock-based compensation plan in effect. ASC 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 consolidated statements of operations.

Under ASC 718, we estimate the fair value of our employee stock option awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of an award. When establishing an estimate of the expected term of an option award, we use the simplified method. 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.

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.

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 an annual basis and when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable. As of December 31, 2018, there was no indicator that an impairment existed.

For the year ended December 31, 2018 and 2017, we capitalized patent costs related to patent prosecution and maintenance of approximately $121,000 and $204,000 based on the most current information reported to us by Endo. As of December 31, 2018 and 2017, the Company's estimated patent costs which are reimbursable to Endo under the License Agreement are $40,000 and zero, respectively. These patent costs are creditable against future royalty revenues. For each period presented below net patent costs consisted of:

	December 31,	
	2018	2017
Patents	$ 1,046,216	$ 925,016
Accumulated Amortization	(601,738)	(527,023)
Net Patent Costs	$ 444,478	$ 397,993

The amortization expense for patents for the years ended December 31, 2018, 2017 and 2016 were approximately $75,000, $65,000 and $40,000, respectively. The estimated aggregate amortization expense for each of the next five years is approximately as follows:

2019	$ 75,200
2020	58,300
2021	41,500
2022	41,500
2023	41,500

Adopted Accounting Standard

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 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)	(0.6)(3)	(1.0)
Deferred tax assets, net	1.7	(1.3)(4)	0.4
Income tax payable	-	(1.4)(5)	(1.4)
Retained earnings adjustment	$ (2.9)	$ 10.2	$ 7.3

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

At December 31, 2018, contract assets of $10.0 million for which there's an unconditional right to receive payment were included in accounts receivable on the consolidated balance sheet.

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

	December 31, 2018		
	As Reported	Balances Without Adoption of New Revenue Standard	Effect of Change Higher / (Lower)
Assets			
Accounts receivable	$ 16.5	$ 6.8	$ 9.7
Deferred royalty buy-down	0.2	0.2	-
Deferred tax assets	0.3	1.4	(1.1)
Liabilities			
Accounts payable and accrued expenses	1.8	1.0	0.8
Deferred revenue	-	1.0	(1.0)
Income tax payable	0.7	(1.2)	1.9
Deferred revenue, long term	-	4.3	(4.3)
Equity			
Retained earnings	72.2	61.0	11.2

In accordance with the new revenue standard requirements, the impact of adoption on our consolidated statement of operations for the three and twelve months ended December 31, 2018 was as follows (in millions):

	Three Months Ended December 31, 2018		
	As Reported	Balances Without Adoption of New Revenue Standard	Effect of Change Higher / (Lower)
Revenues			
Royalties	$ 9.9	$ 8.5	$ 1.4
Costs and expenses			
General and administrative	$ 2.5	$ 2.4	$ 0.1
Provision for income taxes	1.5	1.0	0.5
Net income	6.2	5.2	1.0

	Twelve Months Ended December 31, 2018		
	As Reported	Balances Without Adoption of New Revenue Standard	Effect of Change Higher / (Lower)
Revenues			
Royalties	$ 33.0	$ 31.7	$ 1.3
Costs and expenses			
General and administrative	$ 8.8	$ 8.7	$ 0.1
Provision for income taxes	4.7	4.5	0.2
Net income	20.1	19.1	1.0

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.

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 ASC 606. 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 do not expect the standard will have a material impact on our consolidated financial statements due to the short term nature of our lease for our headquarters.

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.

3. FAIR VALUE MEASUREMENTS

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.

As of December 31, 2018, the Company held certificates of deposit and money market accounts 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 December 31, 2018 and 2017:

December 31, 2018	Type of Instrument	Fair Value	Level 1	Level 2	Level 3
Cash equivalents	Institutional Money Market	$ 6,078,025	$ 6,078,025	$ -	$ -
Investments	Municipal Bonds	1,295,350	-	1,295,350	-
Investments	Corporate Bonds	62,420,996	-	62,420,996	-
Investments	Certificates of Deposit	5,090,631	5,090,631	-	-

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	-	-

4. EARNINGS PER SHARE

Basic earnings per share is computed by dividing net income by the weighted-average number of common shares outstanding during the period. Diluted earnings per share is computed by dividing net income by the weighted-average number of common shares outstanding during the period increased to include all additional common shares that would have been outstanding assuming potentially dilutive common shares, resulting from option exercises, had been issued and any proceeds thereof used to repurchase common stock at the average market price during the period.

	2018	2017	2016
Net income	$ 20,053,269	$ 11,328,266	$ 11,372,239
Weighted average shares:			
Basic	7,242,212	7,170,701	7,061,404
Effect of dilutive securities:			
Stock options	91,156	151,104	221,858
Diluted	**7,333,368**	**7,321,805**	**7,283,262**
Net income per share:			
Basic	**$ 2.77**	**$ 1.58**	**$ 1.61**
Diluted	**$ 2.73**	**$ 1.55**	**$ 1.56**

We exclude from earnings per share the weighted-average number of securities whose effect is anti-dilutive. There were 50,000 and 20,000 options to purchase shares excluded from the calculation of earnings per share for the periods ended December 31, 2018 and December 31, 2016, respectively, because their effect is anti-dilutive.

5. PROPERTY, PLANT AND EQUIPMENT

Property and equipment are stated at cost, less accumulated depreciation. Machinery and equipment, furniture and fixtures, and autos are depreciated on the straight-line basis over their estimated useful lives of 5 to 10 years. Leasehold improvements are amortized over the lesser of their estimated useful lives or the remaining life of the lease. As of December 31, 2018, 2017 and 2016, property, plant and equipment were fully depreciated.

6. COMPREHENSIVE INCOME

For the years ended 2018, 2017, 2016, we had no components of other comprehensive income other than net income itself.

7. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued expenses consist of the following:

	December 31,	
	2018	2017
Trade accounts payable and accrued expenses	$ 122,199	$ 481,753
Accrued legal and other professional fees	308,725	150,691
Accrued payroll and related costs	173,123	215,322
Third party royalties	1,168,837	-
Other accruals	25,704	86,232
	$ 1,798,588	$ 933,998

8. INCOME TAXES

The provision for income taxes consists of the following:

	Year ended December 31,		
	2018	2017	2016
Current taxes:			
Federal	$ 4,612,874	$ 5,513,691	$ 8,571,034
State	40,958	(26,580)	98,881
Total current taxes	4,653,832	5,487,111	8,669,915
Deferred taxes:			
Federal	86,634	1,548,247	(2,647,363)
State	3,542	2,169	(19,787)
Total deferred taxes	90,176	1,550,416	(2,667,150)
Total provision for income taxes	$ 4,744,008	$ 7,037,527	$ 6,002,765

On December 22, 2017, President Trump signed comprehensive tax legislation commonly referred to as the Tax Cuts and Job Act ("Tax Act"). The Tax Act makes complex changes to the tax law which will impact the 2017 year, including but not limited to a re-measurement of deferred tax assets and liabilities as a result of the corporate tax rate change from 35% to 21%. Based on the initial analysis of the Tax Act, the Company has made reasonable estimates of its 2017 impact and due to the federal corporate rate reduction, a re-measurement of deferred tax assets and liabilities resulted in the recording of a charge of approximately $1.1 million. Upon the completion of the 2017 U.S. federal corporate income tax return during the fourth quarter of 2018, we finalized our analysis of the Act and determined no additional adjustments were required.

The effective income tax rate of the Company differs from the federal statutory tax rate due to the following items:

	Year ended December 31,		
	2018	**2017**	**2016**
Statutory rate	21.00%	35.00%	35.00%
State income taxes, net of federal income tax benefit	0.13%	(0.08)%	0.26%
Stock-based compensation	(1.64)%	(3.33)%	(0.50)%
Deferred rate change	0.01%	6.21%	-
Miscellaneous other, net	(0.37)%	0.52%	(0.21)%
Effective tax rate	19.13%	38.32%	34.55%

The decrease in the effective tax rate in 2018 compared to 2017 was primarily due to lowered federal income tax rates as a result of U.S. Tax Reform.

The increase in the effective tax rate in 2017 compared to 2016 was primarily due to the deferred rate change which resulted from lowered federal income tax rates as a result of U.S. Tax Reform and the adoption of ASU No. 2016-09.

Deferred income taxes reflect the tax effects of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the carrying amounts for income tax purposes. The components of deferred income tax assets and liabilities are as follows:

	December 31,	
	2018	**2017**
Deferred revenue	$ -	$ 1,344,232
Stock option based compensation	239,492	322,524
Other	74,276	72,950
Net deferred tax asset	**$ 313,768**	**$ 1,739,706**

Qualified stock option compensation, recorded in the Company's consolidated financial statements, is not deductible for tax purposes which increases the Company's effective tax rate. Deferred tax assets, including those associated with non-qualified stock option compensation, are reviewed and adjusted for apportionment and tax law changes in various jurisdictions.

As of December 31, 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.

Deductibility of Executive Compensation

Section 162(m) of the Internal Revenue Code denies a federal income tax deduction for certain compensation in excess of $1.0 million per year paid to certain employees of publicly traded companies. Beginning January 1, 2018, on account of the passage and signing of the Tax Reform Act, this limitation will apply to the chief executive officer, chief financial officer, any other named executive officers and anyone who is such a covered person after December 31, 2016. Prior to January 1, 2018, this limitation only applied to the chief executive officer and the three most highly-paid executive officers of the Company (other than the chief executive officer and chief financial officer). In addition, prior to January 1, 2018, compensation that met the requirements of performance-based compensation under Section 162(m) of the Internal Revenue Code was excluded from the deduction limit. Beginning January 1, 2018 (with the exception of certain grandfathered arrangements), a deduction will be denied for any compensation payable to covered employees that exceeds $1.0 million, regardless of whether such compensation is performance-based compensation. To retain highly skilled executives and remain competitive with other employers, the compensation committee may authorize compensation that will not be deductible under Section 162(m) or otherwise.

9. STOCKHOLDERS' EQUITY

Stock Option Plan

At December 31, 2018, we have one stock option plan, the Amended and Restated 2001 Stock Option Plan ("2001 Plan"). Under the 2001 Plan, qualified incentive stock options and non-qualified stock options may be granted to purchase up to an aggregate of 2,050,000 shares of the Company's common stock, subject to certain anti-dilution provisions. The exercise price per share of common stock may not be less than 100% (110% for qualified incentive stock options granted to stockholders owning at least 10% of common shares) of the fair market value of the Company's common stock on the date of grant. In general, the options vest and become exercisable in four equal annual installments following the date of grant, although the Company's Board, at its discretion, may provide for different vesting schedules. The options expire 10 years (five years for qualified incentive stock options granted to stockholders owning at least 10% of common shares) after such date. As of December 31, 2018, options to purchase 175,500 shares of common stock were outstanding under the 2001 Plan, and a total of 147,598 shares remain available for grant under the 2001 Plan.

Stock-Based Compensation

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.

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

	December 31,		
	2018	**2017**	**2016**
General and administrative	$ 263,431	$ 127,378	$ 133,904
Total stock-based compensation expense	**$ 263,431**	**$ 127,378**	**$ 133,904**

Stock Options

During the year ended December 31, 2018, we granted 81,500 stock options with a weighted average grant date fair value of $22.31. No stock options were granted during the years ended December 31, 2017 and 2016. The following table presents assumptions used to estimate the fair values of the stock options granted in the periods presented:

	2018	2017	2016
Risk-free interest rate	2.62% - 2.94%	-	-
Expected volatility	39.4% - 39.9%	-	-
Expected life (in years)	6.25	-	-
Dividend yield	-	-	-

The summary of the stock options activity is as follows for year ended:

	Shares	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2016	297,000	20.14	3.10	10,561,380
Grants	-	-	-	-
Exercised	(45,000)	8.79	-	1,554,100
Forfeitures or expirations	(20,000)	29.21	-	-
Outstanding at December 31, 2017	232,000	21.56	2.52	5,050,990
Grants	81,500	51.42	-	-
Exercised	(138,000)	18.63	-	3,720,149
Outstanding at December 31, 2018	175,500	37.73	6.33	4,014,235
Vested and expected to vest at December 31, 2018	175,500	$ 37.73	6.33	4,014,235
Exercisable at December 31, 2018	86,500	$ 24.84	3.22	$ 3,093,460

The following table summarizes information relating to stock options by exercise price at December 31, 2018:

	Outstanding Shares			Exercisable Shares		
Option Exercise Price	Number of Shares	Weighted Average Life (years)	Weighted Average Exercise Price	Number of Shares	Weighted Average Option Price	Weighted Average Life (years)
$ 13.24 - 15.85	30,000	3.85	$ 15.80	30,000	$ 15.80	3.85
$ 17.00 - 29.21	34,000	0.62	24.34	34,000	24.34	0.62
$ 37.64 - 57.38	111,500	8.73	47.71	22,500	37.64	6.31
	175,500	6.33	$ 37.73	86,500	$ 24.84	3.22

During the years 2018, 2017 and 2016, $2.6 million, $0.4 million and $0.7 million proceeds were received from stock options exercised, respectively. Aggregate intrinsic value represents the total pre-tax intrinsic value, based on the closing price of our common stock of $60.60 on December 31, 2018, which would have been received by the option holders had all option holders exercised their options as of that date. Total unrecognized compensation cost related to non-vested stock options outstanding as of December 31, 2018 was approximately $1,696,000 which we expect to recognize over a weighted-average period of 3.64 years.

10.COMMITMENTS AND CONTINGENCIES

Lease Agreements

The Company's corporate headquarters are currently located at 35 Wilbur St., Lynbrook, NY 11563 (the "Headquarters"). On November 1, 2016, the Company entered into an agreement with 35 Wilbur Street Associates, LLC (the "Landlord") to extend the term of the lease to the Headquarters for an additional one year period (the "2016 Extended Lease Agreement"). The one-year extension ended on November 30, 2017. Pursuant to the 2016 Extended Lease Agreement, the base rent was $10,757 per month and the Company was able to cancel the lease with three months' prior written notice to the Landlord at any time during the term. The 2016 Extended Lease Agreement was filed with the SEC as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q on November 9, 2016.

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 "2017 Extended Lease Agreement"). The one-year extension will end on November 30, 2018. Pursuant to the 2017 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. The 2017 Extended Lease Agreement was filed with the SEC as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q on November 9, 2017. Additionally, we lease certain vehicle and certain office equipment which generally expire in 2022 and 2020, respectively.

On August 14, 2018, 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 "2018 Extended Lease Agreement"). The one-year extension will end on November 30, 2019. Pursuant to the 2018 Extended Lease Agreement, the base rent is $11,500 per month and the Company may cancel the lease with three months' prior written notice to the Landlord at any time during the term. The 2018 Extended Lease Agreement was filed with the SEC as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q on November 9, 2018.

Future minimum annual rental payments required under non-cancelable operating leases are $126,500 at year end December 31, 2018.

Expense under all operating leases amounted to approximately $136,000, $132,000 and $127,000 for 2018, 2017 and 2016, respectively.

Future minimum annual payments required under non-cancelable operating leases are approximated as follows:

Year ending December 31,		
2019	$	133,000
2020		3,400
2021		2,300
2022		600

11.RELATED PARTY TRANSACTIONS

During the fiscal years ended December 31, 2018, 2017 and 2016 there were no related party transactions.

12.EMPLOYEE BENEFIT PLANS

ABC-NY has a 401(k) Profit Sharing Plan for employees who meet minimum age and service requirements. Contributions to the plan by ABC-NY are discretionary and subject to certain vesting provisions. The Company made no contributions to this plan for fiscal years 2018, 2017 or 2016.

14.SELECTED QUARTERLY DATA (Unaudited)

The following table sets forth certain unaudited quarterly data for each of the four quarters in the years ended December 31, 2018 and 2017. The data has been derived from the Company's unaudited consolidated financial statements that, in management's opinion, include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of such information when read in conjunction with the Consolidated Financial Statements and Notes thereto. The results of operations for any quarter are not necessarily indicative of the results of operations for any future period.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year ended December 31, 2018				
Net revenues	$ 7,089,409	$ 7,850,774	$ 8,168,081	$ 9,853,179
Operating profit	4,824,549	5,595,026	5,773,379	7,205,724
Net income	3,978,604	4,847,931	5,043,050	6,183,684
Basic earnings per share	$ 0.55	$ 0.67	$ 0.69	$ 0.85
Diluted earnings per share	$ 0.54	$ 0.66	$ 0.69	$ 0.84

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year ended December 31, 2017				
Net revenues	$ 7,690,619	$ 6,535,516	$ 6,516,108	$ 6,701,509
Operating profit	5,010,121	3,882,502	3,983,760	4,801,768
Net income	3,344,753	2,624,091	2,714,832	2,644,590
Basic earnings per share	$ 0.47	$ 0.37	$ 0.38	$ 0.37
Diluted earnings per share	$ 0.46	$ 0.36	$ 0.37	$ 0.36

EXHIBIT INDEX

Exhibit Number	*Description of Exhibit*
3.1	Company's Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 of the Company's Annual Report on Form 10-KSB filed March 2, 2007 (File No. 000-19879))
3.2	Company's Amended and Restated By-laws, as amended February 25, 2014 (incorporated by reference to Exhibit 3.2 of the Company's Annual Report on Form 10-K filed March 7, 2014 (File No. 001-34236))
3.3	Amendment to Amended and Restated By-laws (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed February 26, 2014 (File No. 001-34236))
4.1	Rights Agreement, dated May 14, 2002, by and between the Company and OTC Corporate Transfer Service Company (incorporated by reference to Exhibit 1 to the Company's Form 8-A filed May 30, 2002 (File No. 000-19879))
4.2	Amendment No. 1 to Rights Agreement, dated June 19, 2003, by and between the Company and OTC Corporate Transfer Service Company (incorporated by reference to Exhibit 10.19 of the Company's Annual Report on Form 10-KSB filed March 2, 2007 (File No. 000-19879))
4.3	Amendment No. 2 to Rights Agreement, dated February 3, 2011, by and between the Company and OTC Corporate Transfer Service Company (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed February 4, 2011 (File No. 001-34236))
4.4	Amendment No. 3 to Rights Agreement, dated March 5, 2014, by and between the Company and Worldwide Stock Transfer, LLC (as successor in interest to OTC Corporate Transfer Service Company) (incorporated by reference to Exhibit 4.4 of the Company's Annual Report on Form 10-K filed March 7, 2014 (File No. 001-34236))
4.5*	Amendment No. 4 to Rights Agreement, dated May 27, 2016, by and between the Company and Worldwide Stock Transfer, LLC (as successor in interest to OTC Corporate Transfer Service Company)
4.6*	Amendment No. 5 to Rights Agreement, dated May 11, 2018, by and between the Company and Worldwide Stock Transfer, LLC (as successor in interest to OTC Corporate Transfer Service Company)
10.1	BioSpecifics Technologies Corp. 1997 Stock Option Plan (incorporated by reference to Exhibit 4.1 of the Company's Form S-8 filed September 26, 1997 (File No. 333-160583))
10.2	BioSpecifics Technologies Corp. Amended and Restated 2001 Stock Option Plan (incorporated by reference to Appendix D of the Company's Definitive Proxy Statement on Schedule 14A filed April 30, 2009 (File No. 001-34236))
10.3	Agreement of Lease, dated November 21, 2013, by and among the Company, ABC-NY and 35 Wilbur Street Associates, LLC (incorporated by reference to Exhibit 10.1 of the Company's Annual Report on Form 10-K filed March 7, 2014 (File No. 001-34236))
10.4	Lease Renewal Letter Agreement, dated August 14, 2015, by and among the Company, ABC NY and 35 Wilbur Street Associates, LLC (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed November 9, 2015 (File No. 001-34236))
10.5	Lease Renewal Letter Agreement, dated November 1, 2016, by and among the Company, ABC NY and 35 Wilbur Street Associates, LLC (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed November 9, 2016 (File No. 001-34236))
10.6	Lease Renewal Letter Agreement, dated November 6, 2017, by and among the Company, ABC NY and 35 Wilbur Street Associates, LLC (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed November 9, 2017 (File No. 001-34236))
10.7	Lease Renewal Letter Agreement, dated August 14, 2018, by and among the Company, ABC NY and 35 Wilbur Street Associates, LLC (incorporated by reference to Exhibit 10.1 of the Company's Quarterly Report on Form 10-Q filed November 9, 2017 (File No. 001-34236))

10.8	Asset Purchase Agreement, dated March 3, 2006, by and among the Company, ABC-NY and DFB Biotech, Inc. (incorporated by reference to Exhibit 2.1 of the Company's Current Report on Form 8-K filed March 9, 2006 (File No. 000-19879))
10.9	Amendment to Asset Purchase Agreement, dated January 8, 2007, by and among the Company, ABC-NY and DFB Biotech, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed January 12, 2007 (File No. 000-19879))
10.10	Dupuytren's License Agreement, dated November 21, 2006, by and between the Company and the Research Foundation of the State University of New York for and on behalf of Stony Brook University (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed November 28, 2006 (File No. 000-19879))
10.11	Frozen Shoulder License Agreement, dated November 21, 2006, by and between the Company and the Research Foundation of the State University of New York for and on behalf of Stony Brook University (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed November 28, 2006 (File No. 000-19879))
10.12	Cellulite License Agreement, dated August 23, 2007, by and between the Company and the Research Foundation of the State University of New York for and on behalf of Stony Brook University (incorporated by reference to Exhibit 10.7 of the Company's Annual Report on Form 10-K filed March 15, 2013 (File No. 001-34236))
10.13	License Agreement, dated March 27, 2010, by and between the Company and Zachary Gerut, M.D. (incorporated by reference as Exhibit 10.8 of the Company's Annual Report on Form 10-K filed March 15, 2013 (File No. 001-34236))
10.14	Second Amended and Restated Development and License Agreement, dated August 31, 2011, by and between the Company and Auxilium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed September 1, 2011 (File No. 001-34236))
10.15	First Amendment to Second Amended and Restated Development and License Agreement, dated February 1, 2016, by and between the Company and Endo Global Ventures (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed February 5, 2016 (File No. 001-34236))
10.16	Second Amendment to Second Amended and Restated Development and License Agreement, dated February 26, 2019, by and between the Company and Endo Global Ventures (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed February 28, 2019 (File No. 001-34236))
10.17	Settlement Agreement, dated August 31, 2011, by and between the Company and Auxilium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed September 1, 2011 (File No. 001-34236))
10.18	Amended and Restated Agreement, dated August 27, 2008, by and between ABC-NY and Dr. Marty Gelbard (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed September 5, 2008 (File No. 001-19879))
10.19	Amendment to Amended and Restated Agreement, dated March 31, 2012, by and between ABC-NY and Dr. Marty Gelbard (incorporated by reference to Exhibit 10.1 of the Company's Amendment to Current Report on Form 8-K/A filed August 13, 2012 (File No. 001-34236))
10.20†	Non-Employee Director Change of Control Agreement, dated June 18, 2007, by and between the Company and Michael Schamroth (incorporated by reference to Exhibit 10.22 of the Company's Annual Report on Form 10-KSB filed September 26, 2007 (File No. 000-19879))
10.21†	Non-Employee Director Change of Control Agreement, dated June 18, 2007, by and between the Company and Dr. Paul Gitman (incorporated by reference to Exhibit 10.23 of the Company's Annual Report on Form 10-KSB filed September 26, 2007 (File No. 000-19879))

10.22†	Non-EmployAs required under theee Director Change of Control Agreement, dated April 22, 2015, by and between the Company and Jyrki Mattila (incorporated by reference to Exhibit 10.19 of the Company's Annual Report on Form 10-K filed March 14, 2016 (File No. 001-34236))
10.23†	Executive Employment Agreement, dated August 5, 2008, by and between the Company and Thomas L. Wegman (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed August 8, 2008 (File No. 000-19879))
10.24†*	Offer Letter, dated November 15, 2018, by and between and Dr. Ronald E. Law
10.25†*	Amendment to Offer Letter, dated March 4, 2019, by and between and Dr. Ronald E. Law
10.26†*	Second Amendment to Offer Letter, dated April 1, 2019, by and between and Dr. Ronald E. Law
10.27†*	Confidentiality and Inventions Assignment Agreement, dated November 16, 2018, by and between and Dr. Ronald E. Law
10.28†*	Consulting Agreement, dated April 1, 2019, by and between the Company and Patrick M. Caldwell
10.29†*	Amended and Restated Indemnification Agreement, dated September 12, 2012, by and between the Company and Patrick M. Caldwell
14.1	Company's Amended and Restated Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14.1 of the Company's Annual Report on Form 10-K filed March 14, 2018 (File No. 001-34236))
21.1*	Subsidiaries of the Company
23.1*	Consent of EisnerAmper LLP, Independent Registered Accounting Firm
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101*	The following materials from the Company's Annual Report on Form 10-K for the year ended December 31, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the Consolidated Balance Sheets, (ii) the Consolidated Statements of Income, (iii) Consolidated Statements of Stockholders' Equity, (iv) the Consolidated Statements of Cash Flows, and (v) Notes to Consolidated Financial Statements

* Filed herewith
** Furnished herewith
† Identifies exhibits that consist of a management contract or compensatory arrangement

SIGNATURES

In accordance with section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant caused this Report on Form 10-K to be signed on its behalf by the undersigned, thereto duly authorized individual.

Date: April 2, 2019

BIOSPECIFICS TECHNOLOGIES CORP.

By: /s/ Ronald Law
Name: Ronald Law
Title: Principal Executive Officer

In accordance with the Securities Exchange Act of 1934, this Report has been signed below by the following persons on behalf of the Registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE
/s/ Ronald Law Name: Ronald Law Date: April 2, 2019	Principal Executive Officer (Principal Executive Officer)
/s/ Pat Caldwell Name: Pat Caldwell Date: April 2, 2019	Principal Financial Officer (Principal Financial Officer and Principal Accounting Officer)
Name: Dr. Paul Gitman Date: April 2, 2019	Director
/s/ Michael Schamroth Name: Michael Schamroth Date: April 2, 2019	Director
/s/ Dr. Mark Wegman Name: Dr. Mark Wegman Date: April 2, 2019	Director
/s/ Toby Wegman Name: Toby Wegman Date: April 2, 2019	Director
Name: Dr. Jyrki Mattila Date: April 2, 2019	Director
/s/ Jennifer Chao Name: Jennifer Chao Date: April 2, 2019	Director

Exhibit 4.5

FOURTH AMENDMENT TO RIGHTS AGREEMENT

This FOURTH AMENDMENT (this "Amendment"), dated as of May 27, 2016, to the RIGHTS AGREEMENT, dated as of May 14, 2002, as amended on June 19, 2003, and as further amended on of February 3, 2011 and March 5, 2014 (the "Rights Agreement"), between BioSpecifics Technologies Corp., a Delaware corporation (the "Company"), and Worldwide Stock Transfer, LLC (as successor in interest to OTC Corporate Transfer Service Company) as Rights Agent (the "Rights Agent").

WHEREAS the Company may from time to time supplement or amend the Rights Agreement in accordance with the provisions of Section 27 thereof; and

WHEREAS the Company desires to amend certain provisions of the Rights Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth in the Rights Agreement and this Amendment, the parties hereto hereby agree as follows:

1. Section 7. Section 7(a) of the Rights Agreement is hereby amended by deleting the reference to "May 31, 2016" in clause (i) thereof and inserting "May 31, 2018" in place thereof.

2. Exhibit B. Exhibit B to the Rights Agreement is hereby amended by deleting all references therein to "May 31, 2016" and inserting "May 31, 2018" in place thereof.

3. Exhibit C. Exhibit C to the Rights Agreement is hereby amended by deleting all references therein to "May 31, 2016" and inserting "May 31, 2018" in place thereof.

4. Full Force and Effect. Except as expressly amended hereby, the Rights Agreement shall continue in full force and effect in accordance with the provisions thereof.

5. Governing Law. This Amendment shall be deemed to be a contract made under the laws of the State of Delaware and for all purposes shall be governed by and construed in accordance with the laws of such State applicable to contracts to be made and performed entirely within such State; provided, however, that all provisions regarding the rights, duties and obligations of the Rights Agent shall be governed by and construed in accordance with the laws of the State of New York applicable to contracts made to be performed entirely within such State.

6. Counterparts; Effectiveness. This Amendment may be executed in any number of counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument. This Amendment shall be effective as of the date hereof.

7. Descriptive Headings. Descriptive headings of the several Sections of this Amendment are inserted for convenience only and shall not control or affect the meaning or construction of any of the provisions hereof.

8. Rights Agreement as Amended. From and after the date hereof, any reference to the Rights Agreement shall mean the Rights Agreement as amended hereby.

9. Severability. If any term, provision, covenant or restriction of this Amendment is held by a court of competent jurisdiction or other authority to be invalid, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions of this Amendment shall remain in full force and effect and shall in no way be affected, impaired or invalidated.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed as of the day and year first above written.

BIOSPECIFICS TECHNOLOGIES CORP.

By: Thomas L. Wegman

Name: Thomas L. Wegman

Title: President

WORLDWIDE STOCK TRANSFER, LLC

By: Yonah J. Kopstick

Name: Yonah J. Kopstick

Title: Senior Vice President

Exhibit 4.6

FIFTH AMENDMENT TO RIGHTS AGREEMENT

This FIFTH AMENDMENT (this "Amendment"), dated as of May 11, 2018, to the RIGHTS AGREEMENT, dated as of May 14, 2002, as amended on June 19, 2003, and as further amended on of February 3, 2011, March 5, 2014 and May 27, 2016 (the "Rights Agreement"), between BioSpecifics Technologies Corp., a Delaware corporation (the "Company"), and Worldwide Stock Transfer, LLC (as successor in interest to OTC Corporate Transfer Service Company) as Rights Agent (the "Rights Agent").

WHEREAS the Company may from time to time supplement or amend the Rights Agreement in accordance with the provisions of Section 27 thereof; and

WHEREAS the Company desires to amend certain provisions of the Rights Agreement as set forth herein.

NOW, THEREFORE, in consideration of the foregoing and the mutual agreements set forth in the Rights Agreement and this Amendment, the parties hereto hereby agree as follows:

1. Section 7. Section 7(a) of the Rights Agreement is hereby amended by deleting the reference to "May 31, 2018" in clause (i) thereof and inserting "May 31, 2020" in place thereof.

2. Exhibit B. Exhibit B to the Rights Agreement is hereby amended by deleting all references therein to "May 31, 2018" and inserting "May 31, 2020" in place thereof.

3. Exhibit C. Exhibit C to the Rights Agreement is hereby amended by deleting all references therein to "May 31, 2018" and inserting "May 31, 2020" in place thereof.

4. Full Force and Effect. Except as expressly amended hereby, the Rights Agreement shall continue in full force and effect in accordance with the provisions thereof.

5. Governing Law. This Amendment shall be deemed to be a contract made under the laws of the State of Delaware and for all purposes shall be governed by and construed in accordance with the laws of such State applicable to contracts to be made and performed entirely within such State; provided, however, that all provisions regarding the rights, duties and obligations of the Rights Agent shall be governed by and construed in accordance with the laws of the State of New York applicable to contracts made to be performed entirely within such State.

6. Counterparts; Effectiveness. This Amendment may be executed in any number of counterparts and each of such counterparts shall for all purposes be deemed to be an original, and all such counterparts shall together constitute but one and the same instrument. This Amendment shall be effective as of the date hereof.

7. Descriptive Headings. Descriptive headings of the several Sections of this Amendment are inserted for convenience only and shall not control or affect the meaning or construction of any of the provisions hereof.

8. Rights Agreement as Amended. From and after the date hereof, any reference to the Rights Agreement shall mean the Rights Agreement as amended hereby.

9. Severability. If any term, provision, covenant or restriction of this Amendment is held by a court of competent jurisdiction or other authority to be invalid, void or unenforceable, the remainder of the terms, provisions, covenants and restrictions of this Amendment shall remain in full force and effect and shall in no way be affected, impaired or invalidated.

[Remainder of page intentionally left blank]

IN WITNESS WHEREOF, the parties hereto have caused this Amendment to be duly executed as of the day and year first above written.

BIOSPECIFICS TECHNOLOGIES CORP.

By: /s/ Thomas L. Wegman

Name: Thomas L. Wegman

Title: President

WORLDWIDE STOCK TRANSFER LLC

By: /s/ Yonah J. Kopstick

Name: Yonah J. Kopstock

Title: Senior Vice President

Exhibit 10.24

[Advance Biofactures Corporation Letterhead]

November 15, 2018

Dr. Ronald E. Law

Re: Offer of employment

Dear Dr. Law:

I am pleased to offer you a position with Advance Biofactures Corporation ("Advance Biofactures") as Senior Vice President of Business Development and Licensing. If you accept this offer, you will begin employment with us on November 15, 2018. As Senior Vice President of Business Development and Licensing, you will report directly to me, in my capacity as President of Advance Biofactures. Your primary workplace shall be your home office in Lake Barrington, Illinois, and you will travel to Advance Biofactures's headquarters in Lynbrook, New York as needed.

If you decide to join us, your twice monthly compensation will be $11,250.00, which equates to an annual salary of $270,000.00, and which will be paid, less applicable withholdings and deductions, in accordance with Advance Biofactures's normal payroll procedures on the middle of the month and end of the month. The first payday is November 30, 2018. Your position will be at 75% of full time and will be exempt from eligibility for overtime pay.

You will also receive a signing bonus in the amount of $75,000.00, less applicable withholdings and deductions, to be paid within four (4) weeks after you commence employment, provided you remain employed as of the payment date.

Subject to Board approval and the terms of the Amended and Restated 2001 Stock Option Plan, you will be awarded options to purchase 50,000 shares in BioSpecifics Technologies Corp., our parent company, that will vest over four years commencing on the first anniversary of your start date. All of our employees, including myself, are technically employed by Advance Biofactures.

You will also receive a bonus in the form of a cash payment of $25,000.00, and options to purchase 25,000 shares in BioSpecifics Technologies Corp., after the execution of a non-collagenase in-licensing agreement (including Genascence) which has first been duly approved by the Board of Directors of BioSpecifics Technologies Corp. The cash payment of $25,000.00 shall be payable to you within fifteen (15) business days after the execution of said Board-approved non-collagenase in-licensing agreement. The options to purchase said 25,000 shares will vest over four years commencing on the first anniversary of signing said Board-approved non-collagenase in-licensing agreement.

You may be eligible to participate in those employee benefit plans that Advance Biofactures maintains, in accordance with the terms and eligibility requirements of those plans. Currently Advance Biofactures maintains a medical insurance plan. In addition, you will be eligible for ten (10) days of vacation each year, to be taken in accordance with Advance Biofactures's vacation policy. Advance Biofactures may modify salary and benefits, as well as its employment policies, from time to time as it deems necessary.

Upon your presentation of reasonably acceptable documentation of expenses, Advance Biofactures will reimburse you for internet, phone, and computer services related to business communications. Advance Biofactures will also reimburse you for business travel. For travel under four hours, Advance Biofactures will reimburse you for economy-level seating. For travel over four hours, Advance Biofactures will reimburse you for business- or first-class seating.

You agree that you will resign as Oramed Pharmaceuticals Inc.'s and any and all of its parents', subsidiaries', and affiliates' (collectively, "Oramed") Chief Strategy Officer before you commence employment with Advance Biofactures. Advance Biofactures will permit you to continue to serve as an advisor to Oramed, subject to the following conditions: (1) any work you do for Oramed will not interfere with, or limit, the time you spend on your duties for Advance Biofactures; (2) any activity you engage in on behalf of entities other than Advance Biofactures will be on the "sell" side of the industry, and you will take all appropriate steps to ensure conflicts of interest do not arise, except that, subject to clause (3) below in this paragraph, you may continue to do work for Oramed solely in the area of oral peptides on either the "buy" side or the "sell" side of the industry; and (3) any relationship between you and Oramed will terminate on or before one year after the date you sign this agreement.

Advance Biofactures is excited about the prospect of you joining the company and looks forward to a beneficial and fruitful relationship. Nevertheless, you should be aware that your employment with Advance Biofactures is for no specified period and constitutes at-will employment. As a result, you are free to resign at any time, for any reason or no reason at all. Similarly, Advance Biofactures is free to terminate its employment relationship with you at any time, for any legal reason, with or without cause and with or without notice. We request that, in the event of your resignation, you give Advance Biofactures at least thirty days' notice. By accepting this offer of employment, you agree that your employment is at-will, and acknowledge that no one, other than the President of Advance Biofactures, has the authority to promise you, either orally or in writing, anything to the contrary. Any such agreement must be in writing and signed by both you and the President of Advance Biofactures to be effective.

Our offer to you is contingent upon: (1) satisfactory verification of your references; (2) satisfactory completion of your background check (a consent form for which will be provided under separate cover); (3) your providing adequate documentation that you are authorized to work in the United States; and (4) your execution of the Confidentiality and Inventions Assignment Agreements which will be provided to you by Advance Biofactures.

You represent and agree that: (i) you are not a party to or subject to any restrictive covenants, legal restrictions or other agreements in favor of any entity or person, including, but not limited to, Oramed, that would in any way preclude or limit your ability to work for Advance Biofactures, including, but not limited to, employment agreements, non-competition agreements, non-solicitation agreements or confidentiality agreements, except that, pursuant to a limited non-compete agreement between you and Oramed, you are prohibited from competing with Oramed in the area of oral peptides, and you represent and agree that you will not do any work for Advance Biofactures in the area of oral peptides during any period during which such restriction applies pursuant to said agreement between you and Oramed; (ii) as of the date hereof, you are not in breach of any obligation owed to any former or current employer including, but not limited to, Oramed (including, but not limited to, any obligation to not use or disclose confidential information of a former or current employer); (iii) you will not breach any such obligation or agreement covered in (i) and (ii) by accepting employment with Advance Biofactures; and (iv) you have returned to all prior employers including, without limitation, Oramed or (if permitted) destroyed any confidential or proprietary information belonging to such employers. You agree not to bring any third party confidential information to Advance Biofactures, including that of any former employer including, without limitation, Oramed, and you agree that in performing your duties for Advance Biofactures you will not in any way utilize any such information.

Any controversy arising out of or relating to your employment with Advance Biofactures, this letter agreement or the breach of this letter agreement shall be settled by binding arbitration in New York, New York in accordance with the Employment Dispute Resolution Rules of the American Arbitration Association ("AAA") (before a single arbitrator) and judgment upon the award rendered may be entered in any court having jurisdiction thereof. The AAA rules may be accessed at https://www.adr.org/sites/default/files/EmploymentRules_Web.pdf. Any award made by such arbitrator shall be final, binding and conclusive on the parties for all purposes. This arbitration clause shall not apply to workers' compensation claims, unemployment insurance claims or any claim which is not subject to mandatory arbitration by law. THE PARTIES HEREBY WAIVE THEIR RIGHTS TO HAVE ALL SUCH CLAIMS FILED IN COURT INCLUDING THE RIGHT TO A JURY TRIAL.

This letter shall be governed by the law of the State of New York without regard to its provisions regarding conflict or choice of law. The terms described in this letter replace all prior agreements, understandings, and promises between you and Advance Biofactures concerning the terms and conditions of your employment. This letter, including, but not limited to, its at-will employment provision, may not be modified or amended except by a written agreement signed by Advance Biofactures's President and by you.

To indicate your acceptance of this offer, please sign and date this letter in the space provided below and return it to me. A duplicate original is enclosed for your records.

We look forward to your favorable reply and to working with you at Advance Biofactures.

Sincerely,

/s/ Thomas Wegman
Thomas Wegman, President

I understand and agree to the foregoing terms and conditions of employment with Advance Biofactures. I further understand that I am employed at will and that I or Advance Biofactures may terminate my employment at any time and for any lawful reason with or without notice.

/s/ Ronald E. Law
Dr. Ronald E. Law

Date: November 15, 2018

Exhibit 10.25

[Advance Biofactures Corporation Letterhead]

March 4, 2019

Dr. Ronald E. Law

Re: Amendment to Offer Letter

Dear Ron:

This letter amends your employment offer letter from Advance Biofactures Corporation ("Advance Biofactures") dated November 15, 2018 (the "Offer Letter") in only two respects: the portion of your full working time that you are spending working for Advance Biofactures and your compensation. This letter confirms that commencing January 24, 2019, you are spending 100% of your full working time working for Advance Biofactures, and your twice monthly compensation has increased proportionately, effective January 24, 2019, to $15,000.00, which equates to an annual salary of $360,000.00. In all other respects the offer letter remains unchanged.

To indicate your agreement to this amendment to the Offer Letter please sign and date this letter in the space provide below and return it to me. A duplicate original is enclosed for your convenience.

Sincerely,

/s/ Thomas Wegman

I understand and agree to the foregoing amendment.

/s/ Ronald E. Law
Dr. Ronald E. Law

March 6, 2019
Date

Exhibit 10.26

[Advance Biofactures Corporation Letterhead]

April 1, 2019

Dr. Ronald E. Law

Re: Second Amendment to Offer Letter

Dear Ron:

This letter further amends your employment offer letter from Advance Biofactures Corporation ("ABC") dated November 15, 2018 (the "Offer Letter"), as amended by the letter dated March 4, 2019 in only the following four respects:

1. Effective April 1, 2019, your title shall be Principal Executive Officer on an interim basis.

2. Commencing April 1, 2019, your twice monthly compensation has increased, to $15,625.00, which equates to an annual salary of $375,000.00.

3. If ABC terminates your employment without Cause (other than due to your death or inability to perform the essential functions of your job with any accommodation required by law), you shall be entitled to receive as severance (subject to Section 4(b) below), a lump sum payment in the amount of Ninety-Three Thousand Seven Hundred Fifty and 00/100 Dollars ($93,750.00). Payment of such amount shall be made within thirty (30) days after the separation agreement referred to in Section 4(b) below becomes irrevocable.

(a) Definitions. For purposes of this Agreement:

(i) "Cause" means a finding by ABC that you (i) have materially failed to perform your duties as Principal Executive Officer, which failure has not been remedied by you within thirty (30) days after written notice has been provided to your of such material failure, (ii) have engaged in disloyalty to ABC, including, without limitation, fraud, embezzlement, theft, commission of a felony or proven dishonesty, (iii) have disclosed trade secrets or confidential information of ABC to persons not entitled to receive such information, (iv) have breached any written non-competition or non-solicitation agreement between you and ABC, or (v) have engaged in such other behavior detrimental to the interests of ABC as ABC determines.

(b) Release of Claims. As a condition of receiving any severance for which you otherwise qualify under this Section 4, you agree to execute, deliver and not revoke, within 60 days following the date of termination of your employment, a separation agreement containing a general release of ABC, its affiliates, and their respective employees, officers, directors, owners and members from any and all claims, obligations and liabilities of any kind whatsoever, including, without limitation, those arising from or in connection with your employment by ABC (including, without limitation, civil rights claims), in such form as is requested by the Company, such separation agreement to be delivered, and to have become fully irrevocable, on or before the end of such 60-day period. If such a separation agreement described in the immediately preceding sentence has not been executed and delivered and become irrevocable on or before the end of such 60-day period, no amounts or benefits under this Section 4 shall be or become payable.

In all other respects, the offer letter remains unchanged.

To indicate your agreement to this Second Amendment to the Offer Letter please sign and date this letter in the space provide below and return it to me. A duplicate original is enclosed for your convenience.

Sincerely,

/s/ Jenn Chao
Jenn Chao
Chair of the Compensation Committee

I understand and agree to the foregoing amendment.

/s/ Ronald E. Law
Dr. Ronald E. Law

April 1, 2019
Date

Exhibit 10.27

ADVANCE BIOFACTURES CORP.

CONFIDENTIALITY AND INVENTIONS ASSIGNMENT AGREEMENT
November 16, 2018

In consideration and as a condition of my employment, or continued employment, by Advance Biofactures Corp., a New York corporation (the "Company"), and the compensation now and hereafter paid to me, I hereby agree as follows:

1. Employment with Company.

1.1 Employment commenced on November 15, 2018. It is understood and agreed that this is an employment at will and either party may terminate this Agreement without cause on notice. Any notice of termination shall be in writing, given personally or by Certified Mail, Return Receipt Requested.

1.2 During the term of my employment with the Company, I agree to devote my entire time and attention and to give my best and undivided efforts and service to the business and the interests of the Company (and its subsidiaries and affiliates) in such capacities and in performance of such duties as the Company may from time to time direct, which may include but not be limited to improving, developing and/or inventing processes, products, assays and analytic methods. I agree that this provision is subject to the terms in my offer letter regarding my relationship with Oramed Pharmaceuticals Inc.

2. Nondisclosure

2.1 Recognition of Company's Rights; Nondisclosure. At all times during my employment by the Company and thereafter, I will hold in strictest confidence and will not disclose, use, lecture upon, or publish any of the Company's Proprietary Information (defined below), except as such disclosure, use, lecture, or publication may be required in connection with my work for the Company, or unless an officer or other authorized representative of the Company (other than me) expressly authorizes such in writing. I will obtain the Company's prior written approval before publishing or submitting for publication any material (written, oral, or otherwise) that relates to my work at the Company or incorporates any Proprietary Information. Notwithstanding the foregoing, disclosure of any Proprietary Information shall not be prohibited if such disclosure is directly related to a valid and existing order of a court or other governmental body or agency within the United States; *provided*, *however*, that I shall have first given prompt notice to the Company of any possible or prospective order and the Company shall have been afforded a reasonable opportunity to prevent or limit any such disclosure. I hereby assign to the Company any rights I may have or acquire in any Proprietary Information and recognize that all Proprietary Information shall be the sole property of the Company and its assigns.

2.2 Proprietary Information. The term "Proprietary Information" means any and all confidential or proprietary knowledge, data or information of the Company or any of its subsidiaries or controlled affiliates. By way of illustration but not limitation, "Proprietary Information" includes: (a) developments, inventions, ideas, data, programs, other works of authorship, designs and techniques, trade secrets, mask works, processes, formulas, source and object codes, algorithms, compositions of matter, methods (including, without limitation, methods of use or delivery), know-how, technology, improvements and discoveries (hereinafter collectively referred to as "Inventions"); (b) information regarding plans for research, development, new services or products, marketing and selling, business plans, budgets and unpublished financial statements, licenses, prices and costs, clients, customers, and suppliers; and (c) information regarding the skills and compensation of the employees and/or consultants of the Company or any of its subsidiaries or controlled affiliates. For purposes of this Employee Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement (this "Agreement"), the term "Proprietary Information" shall not include information which is or becomes publicly available without breach of: (i) this Agreement; (ii) any other agreement or instrument to which the Company or any of its subsidiaries or controlled affiliates is a party or a beneficiary; or (iii) any duty owed to the Company or any of its subsidiaries or controlled affiliates by me or by any third party; *provided*, *however*, that if I shall seek to disclose, use, lecture upon, or publish any Proprietary Information, I shall bear the burden of proving that any such information shall have become publicly available without any such breach.

2.3 Third Party Information. I understand that the Company or any of its subsidiaries or controlled affiliates has received and in the future will receive from third parties confidential or proprietary information ("Third Party Information") subject to a duty to maintain the confidentiality of such information and to use it only for certain limited purposes. During the term of my employment by the Company and thereafter, I will hold Third Party Information in the strictest confidence and will not disclose to anyone (other than personnel of the Company or any of its subsidiaries or controlled affiliates who need to know such information in connection with their work for the Company or any of its subsidiaries or controlled affiliates) or use, except in connection with my work for the Company or any of its subsidiaries or controlled affiliates, Third Party Information unless expressly authorized by an officer or other authorized representative of the Company (other than me) in writing. I hereby assign to the Company any rights I may have or acquire in any Third Party Proprietary Information during my employment with the Company.

2.4 No Improper Use of Information of Prior Employers and Others. During my employment by the Company, I will not improperly use or disclose any confidential information or trade secrets, if any, of any former employer or any other person to whom I have an obligation of confidentiality, and I will not bring onto the premises of the Company or any of its subsidiaries or controlled affiliates any unpublished documents or any property belonging to any former employer or any other person to whom I have an obligation of confidentiality unless consented to in writing by that former employer or person. I will use in the performance of my duties to the Company or any of its subsidiaries or controlled affiliates only information which is generally known and used by persons with training and experience comparable to my own, which is common knowledge in the industry or otherwise legally in the public domain, or which is otherwise provided or developed by, or on behalf of, the Company or any of its subsidiaries or controlled affiliates.

2.5 Reports to Government Entities. Nothing in this Agreement restricts or prohibits me from initiating communications directly with, responding to inquiries from, providing testimony before, providing confidential information to, reporting possible violations of law or regulation to, or from filing a claim or assisting with an investigation directly with a self-regulatory authority or a government agency or entity, including without limitation, the U.S. Equal Employment Opportunity Commission, the Department of Labor, the National Labor Relations Board, the U.S. Department of Justice, the U.S. Securities and Exchange Commission, the U.S. Commodities Futures Trading Commission, the Financial Industry Regulatory Authority, the Occupational Safety and Health Administration, the U.S. Congress, any other federal, state, or local government agency or commission, and any agency Inspector General (collectively, the "Regulators"), or from making other disclosures that are protected under the whistleblower provisions of federal, state, or local law or regulation. I do not need the prior authorization of the Company to engage in conduct protected by this paragraph, and I do not need to notify the Company that I have engaged in such conduct. This agreement does not limit my right to receive an award from any Regulator that provides awards for providing information relating to a potential violation of the law. However, to the maximum extent permitted by law, I am waiving my right to receive any individual monetary relief from the Company resulting from such claims or conduct, regardless of whether I or another party filed the claim or reported the conduct. I recognize and agree that, in connection with any such activity outlined above, I must inform the Regulators, my attorney, a court or a government official that the information I am providing is confidential. Despite the foregoing, I am not permitted to reveal to any third-party, including any governmental, law enforcement, or regulatory authority, information I came to learn during the course of my employment with the Company that is protected from disclosure by any applicable privilege, including but not limited to the attorney-client privilege and/or attorney work product doctrine. The Company does not waive any applicable privileges or the right to continue to protect its privileged attorney-client information, attorney work product, and other privileged information.

2.6 Defend Trade Secrets Act. Pursuant to 18 U.S.C. § 1833(b), I will not be held criminally or civilly liable under any Federal or State trade secret law for the disclosure of a trade secret of the Company or any of its subsidiaries or controlled affiliates that (a) I make (i) in confidence to a Federal, State, or local government official, either directly or indirectly, or to my attorney and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) I make in a complaint or other document that is filed under seal in a lawsuit or other proceeding. If I file a lawsuit for retaliation by the Company for reporting a suspected violation of law, I may disclose any such trade secret to my attorney and use any such trade secret information in the court proceeding, if I (x) file any document containing any such trade secret under seal, and (y) do not disclose any such trade secret, except pursuant to court order. Nothing in this Agreement is intended to conflict with 18 U.S.C. § 1833(b) or create liability for disclosures of trade secrets that are expressly allowed by 18 U.S.C. § 1833(b).

3. Assignment of Inventions

3.1 Proprietary Rights. The term "Proprietary Rights" means all trade secret, patent, copyright, mask work and other intellectual property rights throughout the world.

3.2 Prior Inventions. Any and all Inventions (whether patented or unpatented) that I have, alone or jointly with others, conceived, developed or reduced to practice, or caused to be conceived, developed or reduced to practice, prior to the commencement of my employment with the Company (collectively referred to as "Prior Inventions") are either my property or the property of third parties and are excluded from the scope of this Agreement, except if and to the extent the provisions set forth below in this Section 2.2 are made expressly applicable to Prior Inventions. To preclude any possible uncertainty, I have set forth on *Exhibit A* (Prior Inventions) attached hereto a list of Prior Inventions. If disclosure of any Prior Invention would cause me to violate any prior confidentiality agreement, I understand that I am not to disclose such Prior Invention or to list such Prior Inventions in *Exhibit A* but am only to disclose a cursory name for each such invention, a listing of the party or parties to whom it belongs, and the fact that full disclosure as to such inventions has not been made for that reason. A space is provided on *Exhibit A* for such purpose. If I do not attach such disclosure, I am representing thereby that there are no Prior Inventions. Notwithstanding the foregoing provisions of this Section 2.2 that provide that Prior Inventions are excluded from the scope of this Agreement, I agree that I will not incorporate, or permit to be incorporated, Prior Inventions in any Company Inventions (as defined in Section 2.3 below), or any product, process or machine of the Company or any of its subsidiaries or controlled affiliates, without the Company's prior written consent. If, in the course of my employment with the Company, I incorporate a Prior Invention into any Company Inventions or into a product, process or machine of the Company or any of its subsidiaries or controlled affiliates, then, notwithstanding the foregoing provisions of this Section 2.2 that provide that Prior Inventions are excluded from the scope of this Agreement, the Company is hereby granted and shall have a nonexclusive, royalty free, irrevocable, perpetual, worldwide license (with rights to sublicense through multiple tiers of sublicensees) to make, cause to be made, modify, cause to be modified, use, cause to be used and sell or cause to be sold such Prior Invention. In addition, and notwithstanding anything express or implied in the foregoing provisions of this Section 2.2 to the contrary, any Invention that would otherwise be a Prior Invention for purposes of this Section 2.2 shall not be deemed or treated as a Prior Invention for purposes of this Section 2.2 if the Company or any of its subsidiaries or controlled affiliates acquires ownership of such Invention, or if the Company or any of its subsidiaries or controlled affiliates licenses such Invention, pursuant to the provisions of a separate agreement entered into by the Company or any of its subsidiaries or controlled affiliates with me or any other person.

3.3 Assignment of Inventions. Subject to this Section 2.3 and to Sections 2.5 and 2.6, I hereby assign to the Company all my right, title and interest in and to any and all Inventions (and all Proprietary Rights with respect thereto), whether or not patentable or registrable under copyright or similar statutes that are made, conceived, reduced to practice or learned by me, either alone or jointly with others, whether or not during regular business hours, if: (i) such Invention is made, conceived, reduced to practice, or learned by me during the term of my employment with the Company or within 1 year after my resignation or termination from the Company; or (ii) such Inventions arise out of, are based upon, or result from the use of, any Proprietary Information or Third Party Information made available to me or to which I had access as an employee of the Company. Inventions assigned pursuant to this Section 2 to the Company, or to a third party as directed by the Company pursuant to Section 2.5 below, are hereinafter referred to as "Company Inventions." At the request of the Company at any time and from time to time, I will execute and deliver any and all instruments, documents and agreements reasonably requested by the Company for purposes of confirming my assignment to the Company of all of my right, title and interest in and to any and all Company Inventions (and all Proprietary Rights with respect thereto), including, without limitation, at any time when any such Company Inventions (or any Proprietary Rights with respect thereto) are first reduced to practice or first fixed in a tangible medium, as applicable.

For the avoidance of doubt, notwithstanding any contrary provision contained herein, nothing contained in this Agreement shall require the assignment of any Invention (or Proprietary Right with respect thereto) made or conceived by me during the period of my employment with the Company to the extent such assignment is prohibited by any applicable state or federal law.

3.4 Letters Patent. I agree to accept as full consideration the sum of one hundred dollars ($100.00) for the assignment to the Company of all my rights, title and interest in and to each such invention, discovery and improvement described in Section 3.3, including all patent applications filed thereon and patents issued on such applications and will give to the Company the right to have United States Letters Patent issued thereon in its name and the right to apply for and obtain patents on any such inventions in any and all countries foreign to the United States as the Company may select, and to claim the right of priority under any applicable International Convention or treaty.

3.5 Obligation to Keep Company Informed. During the period of my employment with the Company and thereafter, I will promptly disclose to the Company fully and in writing all Company Inventions authored, conceived or reduced to practice by me, either alone or jointly with others. In addition, during the period of my employment with the Company, I will promptly disclose to the Company all patent applications filed by me or on my behalf that claim any Company Invention.

3.6 Government or Third Party. I also agree to assign all my right, title and interest in and to any particular Company Invention to a third party, including without limitation the United States, as directed by the Company.

3.7 Works for Hire. I acknowledge that all original works of authorship which are made by me (solely or jointly with others) within the scope of my employment with the Company and which are protectable by copyright are "works made for hire," pursuant to the United States Copyright Act (17 U.S.C., Section 101).

3.8 Enforcement of Proprietary Rights. I will assist the Company in every proper way in obtaining, and from time to time enforcing, United States and foreign Proprietary Rights relating to Company Inventions in any and all countries. To that end I will promptly execute, verify and deliver such documents and perform such other acts (including appearances as a witness) as the Company may reasonably request for use in applying for, obtaining, perfecting, evidencing, sustaining and enforcing such Proprietary Rights and the assignment thereof. In addition, I will promptly execute, verify and deliver assignments of such Proprietary Rights to the Company or its designee. My obligation to assist the Company with respect to Proprietary Rights relating to such Company Inventions in any and all countries shall continue beyond the termination of my employment with the Company, but the Company shall compensate me at a reasonable rate after my termination for the time actually spent by me at the Company's request on such assistance.

In the event the Company is unable for any reason, after reasonable effort, to secure my signature on any document needed in connection with the actions specified in the preceding paragraph, I hereby irrevocably designate and appoint the Company and its duly authorized officers and agents as my agents and attorneys-in-fact, subject to full power of substitution and resubstitution, which appointment is coupled with an interest, to act for and in my behalf to execute, verify and file any such documents and to do all other lawfully permitted acts to further the purposes of the preceding paragraph with the same legal force and effect as if executed by me. I hereby waive and quitclaim to the Company any and all claims, of any nature whatsoever, which I now or may hereafter have for infringement of any Proprietary Rights assigned hereunder to the Company.

4. Records. I agree to keep and maintain adequate and current records (in the form of notes, memoranda, sketches, drawings and in any other form that may be required by the Company) of all Proprietary Information and all Company Inventions made, conceived, developed or reduced to practice by me, which records shall be available to and remain the sole property of the Company at all times.

5. No Conflicting Obligation. I represent that my performance of all the terms of this Agreement and as an employee of the Company has not breached, and does not and will not breach, any agreement to keep in confidence information acquired by me in confidence or in trust prior to, or outside the scope of, my employment by the Company and any agreement not to compete with the business of any third party, including, but not limited to, Oramed. I have not entered into, and I agree I will not enter into, any agreement, either written or oral, in conflict herewith.

6. Return of Company Documents. When I leave the employ of the Company, I will deliver to the Company any and all notes, memoranda, specifications, drawings, devices, formulas, and documents, together with all copies thereof, and any other material containing or disclosing any Company Inventions, Third Party Information or Proprietary Information of the Company. I further agree that, during the term of my employment with the Company or at any time thereafter, any property situated on the premises of the Company or any of its subsidiaries or controlled affiliates, including disks and other storage media, filing cabinets or other work areas, is subject to inspection by Company personnel at any time with or without notice.

7. Legal and Equitable Remedies. Because my services are personal and unique and because I may have access to and become acquainted with the Proprietary Information of the Company, the Company shall have the right to enforce this Agreement and any of its provisions by injunction, specific performance, or other equitable relief, without bond and without prejudice to any other rights and remedies that the Company may have for a breach of this Agreement. In the event that the Company enforces the provisions of Section 4 or Section 5 hereof through a court order, I agree that the restrictions contained in Section 4 or Section 5, as the case may be, shall remain in effect for a period of one year from the effective date of such court order.

8. Notices. Any notices required or permitted hereunder shall be given to the appropriate party at the address specified below or at such other address as the party shall specify in writing. Such notice shall be deemed given upon personal delivery to the appropriate address, one (1) business day after dispatch if sent by nationally recognized courier or overnight delivery service, on the date of dispatch if sent by facsimile or electronic mail for which confirmation of transmission is provided or, if sent by certified or registered mail, three (3) business days after the date of mailing.

9. General Provisions

9.1 Governing Law; Consent to Personal Jurisdiction. This Agreement will be governed by and construed according to the laws of New York, as such laws are applied to agreements entered into and to be performed entirely within New York between New York residents. I hereby expressly consent to the personal jurisdiction of the state and federal courts located in New York for any lawsuit filed there against me by the Company arising from or related to this Agreement.

9.2 Severability. In the event any provision or portion of this Agreement may be held to be invalid, prohibited or unenforceable for any reason, unless such provision is narrowed by judicial construction, this Agreement shall be construed as if such provision has been more narrowly drawn so as not to be invalid, prohibited or unenforceable. If, notwithstanding the foregoing, any provision may nevertheless be held to be invalid, prohibited or unenforceable for any reason then, and to that extent only, such provision shall be ineffective without affecting or invalidating the remaining portion of such provision or the other provisions of this Agreement.

9.3 Successors and Assigns. This Agreement will be binding upon my heirs, executors, administrators and other legal representatives and will be for the benefit of the Company, its successors, and its assigns. Without limiting the generality of the foregoing, if I become an employee of any subsidiary or controlled affiliate of the Company, then (i) such subsidiary or controlled affiliate shall be deemed and treated as an intended third party beneficiary of this Agreement to the same extent as if such subsidiary or controlled affiliate were a party to this Agreement and (ii) each reference in this Agreement to the term "Company" shall be deemed to be a reference to whichever of Kytopen Corp. and/or such subsidiary or controlled affiliate is my employer.

9.4 Survival. The provisions of this Agreement shall survive the termination of my employment with the Company and the assignment of this Agreement by the Company to any successor in interest or other assignee.

9.5 Employment. I agree and understand that nothing in this Agreement shall confer any right on me or the Company with respect to continuation of my employment with the Company, nor shall it interfere in any way with my right or the Company's right to terminate my employment at any time, with or without cause.

9.6 Waiver. No waiver by the Company of any breach of this Agreement shall be valid unless in writing and signed by the party giving such waiver and no such waiver shall be a waiver of any preceding or succeeding breach. No waiver by the Company of any right under this Agreement shall be construed as a waiver of any other right. The Company shall not be required to give notice to enforce strict adherence to all terms of this Agreement.

9.7 Entire Agreement. This Agreement is the final, complete and exclusive agreement of the parties with respect to the subject matter hereof and supersedes all prior agreements relating to the subject matter hereof and merges all prior discussions between us. No modification of or amendment to this Agreement, nor any waiver of any rights under this Agreement, will be effective unless in writing and signed by the party to be charged.

9.8 Counterparts. This Agreement may be signed in counterparts, each shall be deemed an original and shall together constitute one agreement.

9.9 Acknowledgement. I acknowledge that this Agreement is a condition to my employment with the Company and that I have had a full and adequate opportunity to read, understand and discuss with my advisors, including legal counsel, the terms and conditions contained in this Agreement prior to signing hereunder.

[Remainder of page intentionally left blank]

I have read this Agreement carefully and understand its terms. I have completely filled out *EXHIBIT A* to this Agreement.

/s/ Ronald Law
Dr. Ronald E. Law

Address:
Date: November 15, 2018

Accepted and Agreed:
Advance Biofactures CORP.

By:/s/ Thomas Wegman
Name: Thomas Wegman
Title: President

Address:
Date: November 15, 2018

Exhibit A

TO: **Advance Biofactures Corp.**

FROM: **Ronald Law**

DATE: **[_____], 20[__]**

SUBJECT: Prior Inventions

1. The following is a list of Prior Inventions (as defined in the Employee Proprietary Information, Inventions, Non-Competition and Non-Solicitation Agreement between me and Kytopen Corp. (the "Company")):

☐ Additional sheets attached.

2. I acknowledge that this *Exhibit A*, if completed, forms a part of the Employee Proprietary Information and Inventions Agreement to which the Company and I are parties.

Exhibit 10.28

CONSULTING AGREEMENT
Effective Date: April 1, 2019

THIS CONSULTING AGREEMENT (this "Agreement"), is entered into by and between BioSpecifics Technologies Corporation, a Delaware corporation ("BSTC" or the "Company"), and Pat Caldwell, an individual, with a primary address at 13485 Harding Avenue, San Martin, California 95046 ("Consultant"), as of the date set forth above (the "Effective Date"). BSTC and Consultant may each be referred to as a "Party" or together, the "Parties".

WHEREAS, BSTC wishes to obtain the services of Consultant for certain purposes, and Consultant wishes to provide such services, all subject to the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the mutual covenants contained herein, the receipt and sufficiency of which are hereby acknowledged, BSTC and Consultant hereby agree to be legally bound as follows:

1. **Services.**

During the Term, Consultant shall perform for BSTC the consulting services described in Schedule 1 (the "Services").

2. **Compensation.**

2.1 Fees for Services. In connection with the Services, BSTC shall pay Consultant a monthly stipend of Thirty Thousand Dollars ($30,000) for each completed one (1) month period, which shall be payable in accordance with Section 2.5.

2.2 Restricted Stock Units. Provided this Agreement has not earlier been terminated for Cause (as defined below), after the new equity incentive plan of BSTC is adopted and made effective (which is expected to follow BSTC's annual meeting in June 2019), pursuant to award agreements which shall govern such awards, BSTC shall issue to Consultant, on a quarterly basis after the end of each quarter commencing on the Effective Date (i.e. July 1, 2019), five hundred (500) restricted stock units ("RSUs") up to a maximum of two thousand (2,000) RSUs. Twenty-five per cent (25%) of each RSU award will vest each year, on the first through fourth anniversaries of the date of issuance to Consultant, provided that Consultant continues to provide Services to BSTC through the applicable vesting date, and all outstanding RSUs will vest immediately if BSTC terminates Consultant's Services without Cause.

2.3 Benefits. Consultant is not an employee of BSTC and will not be entitled to participate in or receive any benefit or right as a Company employee under any Company employee benefit and welfare plan, including employee insurance, pension, savings and security plans as a result of Consultant entering into this Agreement.

2.4 Expenses. BSTC shall reimburse Consultant for all reasonable expenses incurred by Consultant in connection with the performance of the Services, including travel expenses. Consultant shall invoice BSTC for such expenses, which invoice shall include reasonable supporting documentation (such as copies of receipts) verifying such expenses, in accordance with Section 2.5.

2.5 Invoicing and Payment. Consultant shall use his reasonable efforts to consolidate invoices deliverable pursuant to this Section 2 into no more than one (1) invoice per month. BSTC shall pay all invoices within ten (10) business days of receipt of invoice.

2.6 Taxes and Withholdings. All taxes relating to Consultant's performance under this Agreement shall be the responsibility of Consultant. In particular, Consultant shall be solely responsible for the payment of all federal, state and local taxes or contributions imposed or required under unemployment insurance, social security and income tax laws that pertain to the compensation paid or reimbursements provided to Consultant.

3. **Duties of Consultant**.

3.1 Availability; Communication, Reports and Performance. Consultant shall be available to BSTC at its offices or such other places as the Parties may agree, at such times as the Parties may agree, and shall be available for telephone consultations as requested by BSTC. Consultant shall perform all Services in a prompt and professional manner. Consultant shall not be entitled to subcontract any of his obligations hereunder.

3.2 Efforts of Consultant. Consultant shall perform all Services conscientiously and in a professional and timely manner, and devote his best efforts and abilities thereto. Consultant shall observe all policies and procedures of BSTC, and such other directives as may be promulgated from time to time by BSTC's officers or board of directors. In addition, Consultant shall follow generally accepted professional standards of care and all applicable federal, national, state, and local laws, rules and regulations of each country where Services shall be conducted.

3.3 No Conflicting Agreements. Consultant represents and warrants that Consultant is not a party to any existing agreement that would prevent Consultant from entering into and performing Consultant's obligations under this Agreement in accordance with its terms. Consultant shall not enter into any agreement that is in conflict with, or that would prohibit or impair the performance of, Consultant's obligations under this Agreement in accordance with its terms.

3.4 Independent Contractor. Consultant understands and agrees that he is acting solely as an independent contractor of BSTC in performing any of the Services and as such agrees that, at all times, Consultant is not an employee of BSTC. Consultant is free to perform services for any other person provided that Consultant does not breach any obligations owed to the Company

4. **Confidentiality.**

4.1 Company Confidential Information. Consultant shall hold in strict confidence, and not use, except for the benefit of BSTC, and not disclose to any person or entity without written authorization of BSTC, any Confidential Information (as defined below). "Confidential Information" means any proprietary or confidential information of BSTC, including technical data, trade secrets or know-how, including research, product plans, products, services, customer lists and customers, markets, software, developments, inventions, processes, formulas, technology, designs, drawings, engineering, marketing, distribution and sales methods and systems, sales and profit figures, finances and other business information disclosed to Consultant by or on behalf of BSTC, either directly or indirectly, whether in writing, orally or by drawings or inspection of documents or other tangible property; provided, that Confidential Information shall not include any of the foregoing items to the extent they have become publicly known and made generally available through no wrongful act of Consultant.

4.2 Third Party Information Held by Consultant. Consultant represents and warrants that Consultant shall not improperly use or disclose to BSTC or any of its directors, officers, employees or agents, any Confidential Information of any current or former client or other person or entity with whom Consultant has an agreement or duty to keep such information confidential, and that Consultant shall not bring onto the premises of BSTC any such information in any medium unless consented to in writing by such client, person or entity. In the event of Consultant's breach of this Section 4.2, Consultant shall ensure that BSTC may freely and fully utilize the information so disclosed for any and all purposes.

4.3 Third Party Information Held by BSTC. Consultant recognizes that BSTC has received, and in the future may receive, from third parties Confidential Information subject to a duty on BSTC's part to maintain the confidentiality of such information and to use it only for certain limited purposes. Consultant shall hold all such information in strict confidence and not disclose it to any person or entity or use it except as necessary in carrying out Services, consistent with BSTC's agreement with such third party. For purposes of this Agreement, such third party information shall be deemed part of the Confidential Information of BSTC.

4.4 Required Disclosure of Confidential Information. If Consultant is required by law or court or governmental order to disclose Confidential Information, Consultant shall give BSTC prompt written notice of such requirement such that BSTC shall have the opportunity to apply for a protective order, injunction or for confidential treatment of such Confidential Information. Notwithstanding the forgoing, any information disclosed by Consultant pursuant to a court or governmental order shall remain Confidential Information, and may not be disclosed under any other circumstances unless and until the Confidential Information so disclosed becomes publicly known and generally available through no wrongful act of Consultant.

4.5 Reports to Government Entities. Nothing in this Agreement shall prohibit or restrict Consultant from lawfully (A) initiating communications directly with, cooperating with, providing information to, causing information to be provided to, or otherwise assisting in an investigation by the Securities and Exchange Commission ("SEC"), the Department of Justice, the Congress, or any other governmental or regulatory agency, entity, or official(s) or self-regulatory organization (collectively, "Governmental Authorities") regarding a possible violation of any law, rule, or regulation; (B) responding to any inquiry or legal process directed to Consultant individually (and not directed to BSTC) from any such Governmental Authorities, including an inquiry about the existence of this Agreement or its underlying facts or circumstances; (C) testifying, participating or otherwise assisting in an action or proceeding by any such Governmental Authorities relating to a possible violation of law; or (D) making any other disclosures that are protected under the whistleblower provisions of any applicable law, rule, or regulation. Nor does this Agreement require Consultant to obtain prior authorization from BSTC before engaging in any conduct described in this paragraph, or to notify BSTC that Consultant has engaged in any such conduct.

4.6 U.S. Defend Trade Secrets Act. The U.S. Defend Trade Secrets Act of 2016 ("DTSA") provides that an individual shall not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that is made (a) (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney, and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (b) in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. In addition, DTSA provides that an individual who files a lawsuit for retaliation by an employer for reporting a suspected violation of law may disclose the trade secret to the attorney of the individual and use the trade secret information in the court proceeding, if the individual (x) files any document containing the trade secret under seal; and (y) does not disclose the trade secret, except pursuant to court order. Nothing in this Agreement is intended to limit any rights under such federal law.

5. **Term and Termination.**

5.1 Termination by BSTC. BSTC shall have the right to terminate this Agreement, without notice or penalty, upon the occurrence of any of the following events: (a) the Consultant fails to perform Services as contemplated in this Agreement, (b) Consultant breaches its obligations under this Agreement or (c) the death or disability of Consultant. In addition, BSTC shall have the right, without penalty, to terminate this Agreement upon providing thirty (30) days prior written notice to Consultant.

5.2 Obligations. Upon termination, except as set forth in Section 5.3 below, BSTC shall have no obligation to pay Consultant any fees or expenses that accrued subsequent to (a) a notice of breach of Consultant's obligations hereunder, (b) the failure of Consultant to perform the Services as contemplated by this Agreement or (c) the commission of fraud upon BSTC by Consultant.

5.3 Severance. If BSTC terminates this Agreement without Cause (other than due to Consultant's death or inability to provide the Services), Consultant shall be entitled to receive as severance (subject to Section 5.3(b)) (i) a lump sum payment in the amount of Three Hundred Sixty Thousand and 00/100 Dollars ($360,000.00); and (ii) if the Consultant has not been issued a total of two thousand (2,000) RSUs at such time, then the Company shall issue to the Consultant the difference between two thousand (2,000) RSUs and the number of RSUs actually issued to the Consultant, which RSUs will be fully vested at the time of issuance Payment of such amount and issuance of the RSUs, if any, shall be made within thirty (30) days after the separation agreement referred to in Section 5.3(b) below becomes irrevocable.

(a) Definitions. For purposes of this Agreement:

(i) "Cause" means a finding by a majority of the Board of Directors of BSTC that Consultant (i) has materially breached this Agreement, which breach has not been remedied by Consultant within thirty (30) days after written notice has been provided to Consultant of such breach, (ii) has engaged in disloyalty to BSTC that involves personal profit in connection with BSTC or any other entity having a business relationship with BSTC, including, without limitation, fraud, embezzlement or, theft from BSTC (iii) has committed a felony involving moral turpitude or any type of fraud, (iii) has disclosed trade secrets or confidential information of BSTC to persons not entitled to receive such information, or (iv) has engaged in such other misconduct, including the blatant disregard of the policies of BSTC, which is materially injurious to the financial condition or business reputation of, or otherwise materially injurious to, BSTC.

(b) Release of Claims. As a condition of receiving any severance for which Consultant otherwise qualifies under Section 5.3, Consultant agrees to execute, deliver and not revoke, within 60 days following the date of termination of this Agreement, a separation agreement containing a general release of BSTC, its affiliates, and their respective employees, officers, directors, owners and members from any and all claims, obligations and liabilities of any kind whatsoever, including, without limitation, those arising from or in connection with Consultant's provision of services to BSTC or this Agreement (including, without limitation, civil rights claims), in such form as is requested by the Company, such separation agreement to be delivered, and to have become fully irrevocable, on or before the end of such 60-day period. If such a separation agreement described in the immediately preceding sentence has not been executed and delivered and become irrevocable on or before the end of such 60-day period, no amounts or benefits under Section 5.3 shall be or become payable.

5.4 Survival. The provisions of Sections 4, 5, and 6 shall survive the expiration or termination of this Agreement. The expiration or termination of this Agreement shall not impair any right or obligation of any Party accruing prior to the effective date of such expiration or termination.

6. **Miscellaneous.**

6.1 Notices. All notices and other communications required or permitted hereunder shall be in writing and deemed to have been given when hand delivered, or mailed by registered or certified mail or overnight courier with tracking capabilities, as follows or as a Party may otherwise notify to the other in accordance with this Section 7 (provided that such notice of change of address or recipient shall be deemed given only when received):

If to BSTC, to:
BioSpecifics Technologies Corp
35 Wilbur St.
Lynbrook, NY 11563

Attention: Principal Executive Officer

If to Consultant, to:
Pat Caldwell

Attention: Mr. Caldwell

6.2 Property; Return or Destruction. Consultant shall not remove any property from BSTC's premises without prior written authorization from BSTC; provided, however, the Consultant will be entitled to use BSTC property at his home subject to suitable protection for confidentiality. Promptly upon the expiration or termination of this Agreement, and earlier if requested by BSTC at any time, Consultant shall deliver to BSTC (and shall not keep in Consultant's possession or deliver to anyone else) or, at BSTC's option, destroy all Confidential Information of BSTC (and all embodiments thereof) and all software, documentation, devices, records, data, notes, reports, proposals, lists, correspondence, specifications, drawings, blueprints, sketches, materials, equipment, other documents or property, or reproductions of any aforementioned items, or any other work product whatsoever, developed by Consultant as part of or in connection with the Services or otherwise belonging to BSTC. Consultant shall certify in writing as to such complete return or destruction.

6.3 Indemnification. Consultant shall indemnify BSTC for all costs, fees (including reasonable attorneys' fees), expenses, losses and other damages arising from (a) any injury to person or damage to property caused by Consultant, (b) any breach of this Agreement by Consultant or (c) Consultant's negligence or willful misconduct except in each case to the extent that BSTC has an indemnification obligation to Consultant pursuant to that Indemnification Agreement (the "Consultant Indemnification Agreement") between BioSpecifics Technologies Corp. and Consultant with an effective date of September 18, 2012, which remains in full force and effect, and is unaffected by this Agreement.

6.4 Advice of Counsel. Each Party acknowledges that, in executing this Agreement, such Party has had the opportunity to seek the advice of independent legal counsel, and has read and understood all of the terms and provisions of this Agreement. Furthermore, this Agreement shall not be construed against any Party by reason of the drafting or preparation hereof.

6.5 Assignment; No Third Party Beneficiaries. BSTC may assign this Agreement without the prior written consent of Consultant. Consultant hereby acknowledges and agrees that the duties and responsibilities of Consultant hereunder are of a personal nature and shall not be assignable or delegable in whole or in part by Consultant. All of the terms and provisions of this Agreement shall be binding upon and inure to the benefit of and be enforceable by the respective heirs, executors, administrators, legal representatives, successors and permitted assigns of the Parties. Nothing in this Agreement, express or implied, is intended to confer on any person or entity other than the Parties hereto or their respective successors and permitted assigns, any benefits, rights or remedies.

6.6 Governing Law, Arbitration and Attorney Fees. This Agreement shall be governed by and interpreted in accordance with the laws of the State of New York, United States of America, without giving effect to any conflict of laws provisions. Any controversy arising out of or relating to this Agreement, the breach of this Agreement, or any dispute between Consultant and BSTC shall be settled by binding arbitration in New York, New York in accordance with the Commercial Arbitration Rules of the American Arbitration Association ("AAA") before a single arbitrator and judgment upon the award rendered may be entered in any court having jurisdiction thereof. The AAA rules may be accessed at https://www.adr.org/sites/default/files/CommercialRules_Web.pdf. Any award made by such arbitrator shall be final, binding and conclusive on the parties for all purposes. This arbitration clause shall not apply to any claim which by law is not subject to mandatory arbitration. THE PARTIES HEREBY WAIVE THEIR RIGHTS TO HAVE ALL SUCH CLAIMS FILED IN COURT INCLUDING THE RIGHT TO A JURY TRIAL. The prevailing Party in any dispute or legal action regarding the subject matter of this Agreement shall be entitled to recover its attorney's fees and costs.

6.7 Equitable Relief. Consultant agrees that the limitations on its ability to compete with BSTC and to solicit BSTC's employees and customers as set forth in Sections 3.5 and 3.6, as well as the confidentiality, assignment, licensing and related obligations in Sections 4 and 5 are reasonably necessary to protect BSTC's legitimate business interests. Consultant acknowledges that such limitations will not constitute or cause it any undue hardship. Consultant further agrees that it would be impossible or inadequate to measure and calculate BSTC's damages from any breach of the covenants set forth in Sections 3, 4 and 5 of this Agreement, and that a breach of such covenants could cause serious and irreparable injury to BSTC. Accordingly, BSTC shall be entitled, in addition to any other right or remedy available to it, to an injunction from a court or an arbitrator of competent jurisdiction restraining such a breach (or threatened breach) and to specific performance of any such Section. Consultant further agrees that no bond or other security shall be required in obtaining such equitable relief and Consultant hereby consents to the issuance of such injunction and to the ordering of specific performance.

6.8 Entire Agreement, Amendment and Waiver. This Agreement (including the schedule(s) hereto) contains the entire understandings of the Parties and, together with the Consultant Indemnification Agreement, supersedes all previous agreements (oral and written), negotiations and discussions with respect to the Services. The Parties may modify any of the provisions hereof only by an instrument in writing duly executed by the Parties. No waiver of any rights under this Agreement shall be effective unless in writing signed by the Party to be charged.

6.9 Severability. In the event of the invalidity of any provisions of this Agreement containing any gaps, the Parties agree that such invalidity or gap shall not affect the validity of the remaining provisions of this Agreement. The Parties will replace an invalid provision or fill any gaps with valid provisions, which most closely approximate the purpose and economic effect of the invalid provision or, in the case of a gap, the Parties' presumable intentions.

6.10 Interpretation. The headings in this Agreement are intended solely for convenience or reference and shall be given no effect in the construction or interpretation of this Agreement. The words "include", "includes" and "including" (and words of similar meaning) shall be deemed to be followed by the phrase "without limitation".

6.11 Survival. The rights and obligations of the Parties, which by intent or meaning have validity beyond such termination (including rights with respect to confidentiality and inventions) shall survive the termination or expiration of this Agreement.

6.12 Counterparts. This Agreement may be executed in two (2) or more counterparts, including by "PDF" exchange, each of which shall be deemed to be an original as against any Party whose signature appears thereon, but all of which together shall constitute but one and the same instrument.

[Signature Page Follows]

IN WITNESS WHEREOF, the undersigned, intending to be legally bound, have duly executed this Agreement as of the Effective Date.

BIOSPECIFICS TECHNOLOGIES CORP.

/s/ Jenn Chao
Authorized Signature

Name: Jenn Chao
Title: Chair of the Compensation Committee

PAT CALDWELL

/s/ Pat Caldwell
Pat Caldwell

Signature Page to Consulting Agreement

SCHEDULE 1
Services

Consultant shall perform on an interim, part-time basis all of the services typically performed by an Principal Financing/Accounting Officer of a Nasdaq publicly-traded company such as BioSpecifics Technologies Corp.

Schedule 1 to Consulting Agreement

Exhibit 10.29

Patrick M. Caldwell Amended and Restated Indemnification Agreement

Effective as of September 18, 2012

Patrick M. Caldwell

Dear Patrick,

In connection with the engagement of Patrick M. Caldwell ("PMC") to advise and assist the undersigned (together with its affiliates and subsidiaries, referred to as the "Company") with the matters set forth in the oral agreement between the Company and PMC (the "Agreement"), in the event that PMC becomes involved in any capacity in any claim, suit, action, proceeding, investigation or inquiry (including, without limitation, any stockholder or derivative action or arbitration proceeding) (collectively, a "Proceeding") in connection with any matter in any way relating to or referred to in the Agreement or arising out of the matters contemplated by the Agreement, including, without limitation, related services and activities prior to the date of the Agreement, the Company agrees to indemnify, defend and hold PMC harmless to the fullest extent permitted by law, from and against any losses, claims, damages, liabilities and expenses in connection with any matter in any way relating to or referred to in the Agreement or arising out of the matters contemplated by the Agreement, including, without limitation, related services and activities prior to the date of the Agreement, except to the extent that it shall he determined by a court of competent jurisdiction in a judgment that has become final in that it is no longer subject to appeal or other review that such losses, claims, damages, liabilities and expenses resulted primarily from the gross negligence or willful misconduct of PMC. In addition, in the event that PMC becomes involved in any capacity in any Proceeding in connection with any matter in any way relating to or referred to in the Agreement or arising out of the matters contemplated by the Agreement, the Company will reimburse PMC for its legal and other expenses (including the cost of any investigation and preparation) as such expenses are incurred by PMC in connection therewith within twenty (20) days of a written request from PMC therefor. If such indemnification were not to be available for any reason, the Company agrees to contribute to the losses, claims, damages, liabilities and expenses involved (i) in the proportion appropriate to reflect the relative benefits received or sought to be received by the Company and its stockholders and affiliates and other constituencies, on the one hand, and PMC, on the other hand, in connection with the matters contemplated by the Agreement or (ii) if (but only if and to the extent) the allocation provided for in clause (i) is for any reason held unenforceable; in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) but also the relative fault of the Company and its stockholders and affiliates and other constituencies, on the one hand, and the party entitled to contribution, on the other hand, as well as any other relevant equitable considerations. The Company agrees that for the purposes of this paragraph the relative benefits received, or sought to be received, by the Company and its stockholders and affiliates and other constituencies, on the one hand, and the party entitled to contribution, on the other hand, in connection with the matters contemplated by the Agreement shall be deemed to be in the same proportion that the total value received or paid or contemplated to be received or paid by the Company or its stockholders or affiliates and other constituencies, as the case may be, as a result of or in connection with the matters (whether or not consummated) for which PMC has been retained to perform financial services bears to the fees paid to PMC under the Agreement; provided, that in no event shall the Company contribute less than the amount necessary to assure that PMC is not liable for losses, claims, damages, liabilities and expenses in excess of the amount of fees actually received by PMC within the past twelve (12) months pursuant to the Agreement. Relative fault shall be determined by reference to, among other things, whether any alleged untrue statement or omission or any other alleged conduct relates to information provided by the Company or other conduct by the Company (or its employees or other agents), on the one hand, or by PMC, on the other hand. The Company will not settle any Proceeding in respect of which indemnity may be sought hereunder, whether or not PMC is an actual or potential party to such Proceeding, without PMC prior written consent, which consent shall not be unreasonably withheld if, in connection with such settlement, PMC is fully released fi-om all liabilities. The foregoing indemnity and contribution agreement shall be in addition to any rights that any indemnified party may have at common law or otherwise.

The Company agrees that PMC shall not have any liability to the Company or any person asserting claims on behalf of or in right of the Company in connection with or as a result of either engagement under the Agreement or any matter referred to in the Agreement, including, without limitation, related services and activities prior to the date of the Agreement, except to the extent that it shall be determined by a court of competent jurisdiction in a judgment that has become final in that it is no longer subject to appeal or other review that any losses, claims, damages, liabilities or expenses incurred by the Company resulted primarily from the gross negligence or willful misconduct of PMC in performing the services that are the subject of the Agreement.

THIS INDEMNIFICATION AGREEMENT AND ANY CLAIM, COUNTERCLAIM OR DISPUTE OF ANY KIND OR NATURE WHATSOEVER ARISING OUT OF OR IN ANY WAY RELATING TO THIS INDEMNIFICATION AGREEMENT ("CLAIM). DIRECTLY OR INDIRECTLY, SHALL BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH THE LAWS OF THE STATE OF NEW YORK. EXCEPT AS SET FORTH BELOW, NO CLAIM MAY BE COMMENCED, PROSECUTED OR CONTINUED IN ANY COURT OTHER THAN THE COURTS OF THE STATE OF NEW YORK LOCATED IN THE CITY AND COUNTY OF NEW YORK OR IN THE UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK, WHICH COURTS SHALL HAVE EXCLUSIVE JURISDICTION OVER THE ADJUDICATION OF SUCH MATTERS, AND THE COMPANY AND PMC CONSENT TO THE JURISDICTION OF SUCH COURTS AND PERSONAL SERVICE WITH RESPECT THERETO. THE COMPANY HEREBY CONSENTS TO PERSONAL JURISDICTION, SERVICE AND VENUE IN ANY COURT IN WHICH ANY CLAIM ARISING OUT OF OR IN ANY WAY RELATING TO THIS INDEMNIFICATION AGREEMENT IS BROUGHT BY ANY THIRD PARTY AGAINST PMC OR ANY INDEMNIFIED PARTY. EACH OF PMC AND THE COMPANY WAIVES ALL RIGHT TO TRIAL BY JURY IN ANY PROCEEDING OR CLAIM (WHETHER BASED UPON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR IN ANY WAY RELATING TO THIS INDEMNIFICATION AGREEMENT. THE COMPANY AGREES THAT A FINAL JUDGMENT IN ANY PROCEEDING OR CLAIM ARISING OUT OF OR IN ANY WAY RELATING TO THIS INDEMNIFICATION AGREEMENT BROUGHT IN ANY SUCH COURT SHALL BE CONCLUSIVE AND BINDING UPON THE COMPANY AND MAY BE ENFORCED IN ANY OTHER COURTS THE JURISDICTION OF WHICH THE COMPANY IS OR MAY BE SUBJECT, BY SUIT UPON SUCH JUDGMENT.

This Indemnification Agreement shall bind and inure to the benefit of PMC's heirs and representatives and any successor in interest of the Company in connection with the transfer or sale of all or substantially all of the assets of the Company or in the event of its merger or consolidation with another company. Any other purported assignment of this Indemnification Agreement shall be null and void.

Notwithstanding any other provisions in this Indemnification Agreement to the contrary, the Company shall indemnify PMC against all expenses incurred by PMC in any Proceeding between the Company and PMC involving the interpretation or enforcement of the rights of PMC under this Indemnification Agreement, other than with respect to claims and/or defenses asserted by a PMC in any such Proceeding that a court of competent jurisdiction determines were frivolous or made in bad faith.

The Company will pay PMC within 20 days of invoice at his normal consulting rate (currently $200/hour and $2,000/day) for any time he spends in connection with any Proceeding, including but not limited to document production, preparing for and/or participating in depositions, meeting with Company representatives and travel time. The Company will also within 20 days of invoice reimburse all reasonable out of pocket costs or expenses, including reasonable attorneys' fees and costs. For the sake of clarity, PMC may retain legal counsel to represent his interest in connection with any Proceeding, unless the use of counsel chosen by PMC to represent him would present such counsel with a conflict of interest.

The above applies whether the Proceeding, claim, litigation or other legal proceeding is initiated by the Company or a third party and whether PMC is individually named or not.

The Company shall promptly add PMC to its Directors and Officers Liability Insurance Policy as a named insured as a consultant, with coverage terms no less than for the Company's officers and directors. The Company shall provide evidence of such insurance to PMC. In the event that such insurance is cancelled or otherwise lapses for any reason, the Company shall provide PMC with prompt written notice within 14 days of such event.

For the avoidance of doubt, that certain indemnification agreement by and between PMC and the Company dated October 30, 2006 is hereby amended and restated in its entirety by the foregoing.

[signature page follows]

The foregoing Indemnification Agreement shall remain in full force and effect notwithstanding any termination of PMC's engagement. This Indemnification Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which shall constitute one and the same agreement.

Very truly yours,

BIOSPECIFICS TECHNOLOGIES CORP,

By: /s/ Thomas Wegman
Thomas Wegman
President

Accepted and agreed to as of
the date first above written:

By: /s/ Patrick M. Caldwell
Patrick M. Caldwell

Exhibit 21.1

List of Subsidiaries

Advance Biofactures Corp., a New York corporation

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statement of BioSpecifics Technologies Corp. on Form S-8 (No. 333-160583) of our reports dated April 2, 2019, on our audits of the consolidated financial statements as of December 31, 2018 and 2017 and for each of the years in the three-year period ended December 31, 2018 and the effectiveness of BioSpecifics Technologies Corp.'s internal control over financial reporting as of December 31, 2018, which reports are included in this Annual Report on Form 10-K to be filed on or about April 2, 2019.

/s/ EisnerAmper LLP

EISNERAMPER LLP
New York, New York
April 2, 2019

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO RULES 13a-14(a) AND 15d-14(a) OF
THE SECURITIES EXCHANGE ACT OF 1934

I, Ron Law, Principal Executive Officer, certify that:

1. I have reviewed this annual report on Form 10-K of BioSpecifics Technologies Corp.for the fiscal year ended December 31, 2018;

2. Based on my knowledge, the report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and to the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: April 2, 2019

/s/ Ronald Law
Ronald Law
Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO RULES 13a-14(a) AND 15d-14(a) OF
THE SECURITIES EXCHANGE ACT OF 1934

I, Pat Caldwell, Principal Financial Officer, certify that:

1. I have reviewed this annual report on Form 10-K of BioSpecifics Technologies Corp. for the fiscal year ended December 31, 2018;

2. Based on my knowledge, the report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and to the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal controls over financial reporting.

Date: April 2, 2019

/s/ Pat Caldwell
Pat Caldwell
Principal Financial Officer

Exhibit 32.1

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO SECTION 906 OF
THE SARBANES-OXLEY ACT OF 2002**

In connection with the Annual Report of BioSpecifics Technology Corp. (the "Company") on Form 10-K for the fiscal year ended December 31, 2018, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), we, Ronald Law, Principal Executive Officer of the Company, and Pat Caldwell, Principal Financial Officer of the Company, each certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, based on each of our knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: April 2, 2019

/s/ Ronald Law

Ronald Law
Principal Executive Officer

/s/ Pat Caldwell

Pat Caldwell
Principal Financial Officer