BIOSPECIFICS TECHNOLOGIES CORP
Form 10-K
March 31, 2009

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)
Q ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2008**

£ 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: **0-19879**

BIOSPECIFICS TECHNOLOGIES CORP.

(Exact name of registrant as specified in its charter)

Delaware	**11-3054851**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
35 Wilbur Street, Lynbrook, NY	**11563**
(Address of principal executive offices)	(Zip Code)

516.593.7000
Registrant s telephone number, including area code:

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 Stock Market LLC**

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 Q 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 Q No

Note Checking the box above will not relieve any registrant required to file reports pursuant to Section 13 or 15(d) of the Exchange Act from their obligations under those Sections.

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. Q 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. £

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

Large accelerated filer £ Accelerated filer £
Non-accelerated filer £ (Do not check if a smaller reporting company) Smaller reporting company Q
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
£ Yes Q No

The aggregate market value of voting and non-voting common stock held by non-affiliates of the Registrant as of June 30, 2008, the last business day of the registrant s most recently completed second fiscal quarter, was approximately $70,828,160.

Note If a determination as to whether a particular person or entity is an affiliate cannot be made without involving unreasonable effort and expense, the aggregate market value of the common stock held by non-affiliates may be calculated on the basis of assumptions reasonable under the circumstances, provided that the assumptions are set forth in this Form.

The number of shares outstanding of the registrant s common stock as of March 2, 2009 is 6,008,801.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s definitive proxy statement for its 2009 Annual Meeting of Stockholders scheduled to be held on June 17, 2009, 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, 2008, 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 2009 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 Terminology

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

Introductory Comments Forward-Looking Statements

This Report includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, estimates, potential, or continue or the negative thereof or oth terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this report are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth below, and for the reasons described elsewhere in this report. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

PART I

Item 1. DESCRIPTION OF BUSINESS.

Overview

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. (Auxilium) for injectable collagenase (which Auxilium has named XIAFLEX™ (formerly known as AA4500)) for clinical indications in Dupuytren s disease, Peyronie s disease and frozen shoulder (*adhesive capsulitis*), and Auxilium has an option to acquire additional indications that we may pursue, including cellulite and lipomas.

Development of Injectable Collagenase for Multiple Indications

We are developing an injectable collagenase for multiple indications. The most advanced indications are for the treatment of Dupuytren s disease, Peyronie s disease and frozen shoulder. On June 3, 2004, we entered into a development and license agreement with Auxilium, as amended on May 10, 2005 and December 15, 2005, respectively (the Prior Auxilium Agreement), pursuant to which we granted to Auxilium an exclusive worldwide license to develop products containing our injectable collagenase for the treatment of Dupuytren s disease, Peyronie's disease and frozen shoulder, as well as an exclusive option to develop and license the technology for use in additional indications other than dermal formulations labeled for topical administration.

On December 11, 2008, the parties amended and restated the development and license agreement (the Auxilium Agreement), which became effective on December 17, 2008 upon the execution and effectiveness of the Development, Commercialization and Supply Agreement, dated December 17, 2008 (the Pfizer Agreement) between Auxilium International Holdings, Inc., a wholly owned subsidiary of Auxilium, and Pfizer, Inc. (Pfizer), pursuant to which Pfizer will market XIAFLEX for the treatment of Dupuytren s disease and Peyronie s disease in Europe and various other territories. The Auxilium Agreement amends and restates in its entirety the Prior Auxilium Agreement.

The Auxilium Agreement and other licensing agreements are discussed more fully in this Item 1, under the section titled Licensing and Marketing Agreements.

In its Form 10-K filed with the Securities and Exchange Commission (the SEC or the Commission) on February 26, 2009, Auxilium noted the following key points in regards to XIAFLEX:

> We believe that XIAFLEX has the potential to become a blockbuster. For Dupuytren s and Peyronie s, we believe there is a large unmet medical need for a non-surgical solution to these debilitating diseases and that the data from our well-controlled phase II studies in Peyronie s and phase III studies in Dupuytren s are encouraging. The product has received orphan drug designation in the U.S. for both indications, and our preliminary market research leads us to believe that urologists and orthopedic surgeons would be very likely to use the product to delay or avoid surgery. Based on market research that we conducted several years ago, physicians indicate that there are potentially 450,000 patients on an annual basis in the U.S. and Europe who could be candidates for XIAFLEX with approximately 240,000 for the treatment of Dupuytren s and approximately 210,000 for the treatment of Peyronie s. These patients represent an annual market potential in excess of $1 billion, assuming that we are able to price treatments using XIAFLEX on a basis comparable to the cost of surgery for these indications.

In its Form 10-K filed with the SEC on February 26, 2009, Auxilium stated that it is currently evaluating the options that we have for commercializing XIAFLEX in other indications and territories of the world. In the event that Auxilium does license XIAFLEX in other indications, we will be entitled to receive a certain percentage of sublicense income and milestone payments for such indications pursuant to the terms of the Auxilium Agreement.

Background on 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 *Clostridial* collagenase produced by us has a broad specificity towards all types of collagen and is acknowledged as much more efficient than mammalian collagenases. *Clostridial* collagenase 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. Because collagenase does not damage the cell membrane, it is widely used for cell dispersion for tissue disassociation and cell culture. 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. Histological and biochemical studies have shown that the tissue responsible for the deformities associated with Dupuytren s disease and Peyronie s disease is primarily composed of collagen. The contracture associated with Dupuytren s disease is an example of a disease that results from excessive collagen formation. Surgical removal of scar tissue has the potential to result in complications including increased scar formation. Due to the highly specific nature of the enzyme, we consider its use to be more desirable than the application of general proteolytic enzymes for the removal of unwanted tissue. Treatment with injectable collagenase for removal of excessive scar tissue represents a first in class non-invasive approach to this unmet medical need. New uses involving the therapeutic application of exogenous collagenase to supplement the body s own natural enzymes are periodically being proposed.

Collagenase for Treatment of Dupuytren s Disease

Dupuytren s disease 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 Dupuytren s disease 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. Dupuytren s disease has a genetic basis and it is most prevalent in individuals of northern European ancestry. Well-known individuals with Dupuytren s disease include President Ronald Reagan and Prime Minister Margaret Thatcher.

The only proven treatment for Dupuytren s disease is surgery. Recurrence rates can range from 26-80%. The post surgical recovery is often associated with significant pain, delayed return to work, and extended periods of postoperative physical therapy. Because many of the individuals with Dupuytren s disease are older than 60 years of age, there is considerable resistance from the patients to undergo the surgical procedure, which also involves the risk of general anesthesia. We anticipate that many of the patients who are now willing to live with the disease, given the current treatment options, would be receptive to an alternative treatment involving an injection into the hand that could be performed in an office setting.

Hand surgeons note that the Dupuytren s disease surgery is tedious, lengthy and poorly reimbursed in the U.S. In a conference on February 8, 2007, Auxilium stated that the average cost of Dupuytren s disease surgery is $5,000 in the U.S. and $3,500 in Europe. Auxilium has reported that U.S. based hand surgeons would recommend the use of collagenase injection on 76% of the patients who are candidates for surgery. This figure is consistent with an earlier survey that we conducted, which found that U.S. hand surgeons would recommend the use of collagenase injection on 80% of patients considered eligible for Dupuytren s disease surgery. Both of these surveys were conducted prior to the results of the Auxilium Phase III trials being available.

Phase III Clinical Trials

Phase III clinical results with injectable collagenase manufactured by us were published in the July-August 2007 issue of the *Journal of Hand Surgery*. The study was designed and monitored by us in collaboration with Marie Badalamente, Ph.D. and Lawrence Hurst, M.D., who are clinical investigators from the Department of Orthopaedics, at the State University of New York, Health Science Center at Stony Brook, New York. Auxilium issued a press release on July 24, 2007 based on their statistical analysis of the results. Please see Development Status under this Item 1 for information regarding the results of this trial.

33 of 35 patients who entered the double-blind phase of the trial completed the study and 19 of them entered the open label extension. In the double-blind phase of the study, 23 patients received injectable collagenase and 12 received placebo. The results show that 21 of 23 patients (91%) treated with up to 3 injections of injectable collagenase achieved clinical success (reduction in joint contracture to within 0° to 5° of normal) in the double-blind phase. 12 of 14 (86%) of metacarpophalangeal (MP) joints and 9 of 9 (100%) proximal intraphalangeal (PIP) joints were successfully treated. No patient treated with placebo achieved clinical success.

Of the 19 patients who entered the open label phase, 15 had previously received placebo, and 4 had received the active drug but required further treatment due to incomplete success or treatment failure or needed treatment for other contractures. 17 of 19 patients (89%) who received up to 3 injections of injectable collagenase achieved clinical success in at least 1 treated joint in the open label phase. 14 of 16 (88%) of MP joints and 13 of 19 (68%) PIP joints were successfully treated.

Clinical success was achieved in a median of 8 days during the double-blind phase. The time for achievement of clinical success ranged between 1 and 29 days in the open label extension phase of the study.

An evaluation of the long-term durability of treatment was conducted for patients treated in this Phase III trial and its open label extension. At the 24-month follow up, recurrence of contracture of at least 20° was favorable compared to the long-term results observed post surgery according to the investigators. Of the 54 successfully treated joints, all were followed up for 24 months. At one year, 5 of 54 joints had a recurrence (6%) and at two years, 5 of 27 joints had a recurrence (18%). Dr. Badalamente stated that reported recurrence rates post surgery vary widely, from 26% to 80%.

The most common adverse events were pain and swelling of the hand at the injection site and post-injection temporary swelling of a modest nature in the lymph node area of the armpit. There were no nerve or arterial injuries. Adverse events were generally mild to moderate in nature and resolved without treatment within 30 days.

Auxilium conducted Phase III trials with injectable collagenase that was manufactured under their control. The Phase III trials were designed as randomized double blind placebo controlled clinical investigations and the blinded efficacy clinical investigations were designated as CORD 1 and CORD II. In its Form 10-K filed with the SEC on February 26, 2009, Auxilium stated:

> In December 2007, patient enrollment was completed in Auxilium s second U.S. phase III pivotal trial (CORD I) and its Australian phase III study (CORD II) of XIAFLEX for the treatment of Dupuytren s. CORD I data were released in June 2008. A modified intent to treat analysis yielded 306 patients. CORD I successfully met the primary endpoint with a p value of <0.001: 64 % of XIAFLEX patients vs. 6.8% of placebo patients achieved a reduction in contracture to ≤5 degrees of normal 30 days after the last injection. On average, Dupuytren s patients who achieved the primary endpoint received 1.5 XIAFLEX injections. In addition to the primary endpoint, there were 26 secondary endpoints that were measured, each of which was met with statistical significance. The average percent improvement in contracture from baseline was 79.3% (50.2° average contracture at baseline down to 12.1° average contracture after treatment) for primary joints treated with XIAFLEX, compared to placebo patients, where the average contracture for joints was 49.1° at baseline and improved to an average of 45.7° after placebo treatment (8.6% reduction) (p<0.001). 84.7% of patients (172 of 203) treated with XIAFLEX achieved greater than 50% reduction in their contracture compared with baseline, compared with 11.7% of patients (12 of 103) treated with placebo (p<0.001). In CORD II, 44.4% of XIAFLEX patients vs. 4.8% of placebo patients achieved the primary endpoint, a reduction in the angle of a patient s joint contracture to ≤5 degrees of normal, as measured by digital goniometer, 30 days after the last injection. These double blind studies along with the open label Joint I and II studies will provide most of the patient safety database for the BLA submission. The safety of XIAFLEX was assessed in 1,082 subjects who received at least one injection of XIAFLEX in over 2,600 joints. The most common adverse events were related to the injection or the subsequent procedure to disrupt the cord. These reactions were mild to moderate in intensity, and occurred within approximately four weeks of injection. The reactions generally resolved without intervention within approximately four weeks. The most frequently reported adverse events included peripheral edema, contusion, injection site reaction, injection site hemorrhage, and pain in extremity. In the clinical studies there were four serious adverse events related to effect of XIAFLEX on collagen. There were three cases of tendon rupture and one case of pulley injury reported in patients who received XIAFLEX during the clinical development program. There were no reports of injury to nerves or blood vessels of the treated finger following treatment with XIAFLEX.

Phase II Trials

A Phase II clinical study was designed to evaluate the relative safety and efficacy of collagenase compared to placebo injection in improving the degree of flexion deformity, and range of finger motion in patients with Dupuytren s disease. The investigation was carried out as a randomized, double-blind, placebo-controlled clinical trial using collagenase or placebo. 36 MP patients and 13 PIP patients were enrolled in the study. The success rate was determined one month after the first injection of collagenase or placebo. The overall success rate, defined by the primary endpoint of reduction in contracture to within 0º 5º of normal, was 14 out of 18 patients (78%) for MP joints (p=0.001) and approximately 70% for PIP joints. Adverse events reported during this protocol included pain and swelling of the hand, bruising, and post-injection self-limiting swelling of the lymph nodes. Some patients experienced transient increases in blood pressure on the day of injection, which were attributed to anxiety in anticipation of the treatment. Only one serious adverse event was reported and it was not attributed to the study drug by the clinical investigator.

This study demonstrated a statistically significant reduction in contracture to within 0º-5° of normal at day 30 and improved range of motion at 7 and 14 days and at day 30 after a single injection of collagenase into the cord affecting the MP joint.

A second Phase II study designed as a double-blind, randomized, parallel group, placebo-controlled, dose response clinical trial was conducted. 55 MP patients and 25 PIP patients with a mean baseline fixed flexion deformity of 49 degrees were enrolled in the study at two centers. Patients were treated with low (2,500), mid (5,000) or high (10,000) number of units of collagenase or placebo. The overall success rate and primary endpoint were defined as reduction in contracture to within 0º 5º of normal 30 days after the first injection.

18 out of the 23 patients (78%) who received the high number of units returned to normal extension (0º-5º) at 30 days post-treatment as compared to 10 out of 22 (45%) in the mid number of units group, and nine out of 18 (50%) in the low number of units group. There was no response to placebo in any patient. For PIP joints, 5 out of 7 (71%) patients who received the high number of units of collagenase returned to normal extension at the one month post-treatment as compared to 4 out of 7 (57%) patients in the mid number of units group, 2 out of 4 (50%) in the low number of units group and 0 out of 7 (0%) in the placebo group. For MP joints, 13 out of 16 (81%) patients who received the high number of units group of collagenase returned to normal extension at the one month post-treatment as compared to 6 out of 15 (43%) patients in the mid number of units group, 7 out of 14 (50%) in the low number of units group and 0 out of 10 (0%) in the placebo group.

The investigators did not attribute any of the serious adverse events that occurred to the study drug.

Development Status

In a press release dated March 2, 2009, Auxilium announced that it filed a Biologics License Application (BLA) for the treatment of Dupuytren s disease on February 27, 2009. Auxilium also announced that it has requested a Priority Review designation for the BLA submission from the U.S. Food and Drug Administration (FDA) and that it expects to hear from the FDA on Priority Review designation within approximately 60 days of the filing date. If granted, the FDA has a goal to take action on the BLA within six months from the date of submission. In its Current Report on Form 8-K filed on December 3, 2008, Auxilium announced that Pfizer expects to file XIAFLEX for approval for the treatment of Dupuytren s disease in Europe in 2010.

Collagenase for Treatment of Peyronie s Disease

Peyronie s disease affects the penis and it 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. The plaque is not elastic and it does not stretch during erection. In some mild cases, the plaque can resolve spontaneously without

medical intervention. The most common plaque forms on the top of the penis causing the penis to arc upward. In severe cases, the penis can be bent at a 90-degree angle during erection. Significant psychological distress has been noted in patients with Peyronie s disease who are sexually active. Frequent patient complaints include increased pain, painful erections, palpable plaque, penile deformity, and erectile dysfunction. Patients with Peyronie s disease have been reported to have an increased likelihood of having Dupuytren s disease, frozen shoulder, plantar fibromatosis, knuckle pads, hypertension and diabetes. Peyronie s disease typically affects males in the range of 40-70 years. The cause of Peyronie s disease is unknown, although some investigators have proposed that it may be due to trauma or an autoimmune component. A number of researchers have suggested that the incidence of Peyronie s disease has increased due to the use of erectile dysfunction drugs.

Surgery is the only proven treatment for Peyronie s disease and the results are variable. Surgery often results in shortening of the penis. Auxilium has reported that 33% of Peyronie s disease patients who undergo surgery are subsequently dissatisfied with the results and they frequently require a penile implant. Patients with Peyronie s disease strongly desire therapeutic alternatives to surgery. Auxilium has reported that 90% of urologists would use collagenase injection to delay or avoid surgery and this finding is consistent with a survey of urologists conducted for us.

Histological and biochemical studies indicate that the scarring on the penis due to Peyronie s disease is composed primarily of collagen.

An investigator carried out a positive Phase I clinical trial in which he treated approximately 180 patients in an open label trial. In addition, two positive open label clinical trials have been conducted by an independent investigator at Tidewater Urology in Norfolk, Virginia, which is the largest center for treatment of Peyronie s disease in the world.

Auxilium announced on October 25, 2006 the results of two Phase II trials. Auxilium stated:

> Both studies were open label and up to 12 months in duration. They were conducted to evaluate the efficacy and tolerability of AA4500 in the treatment of Peyronie s disease. Clinical success was defined as change from baseline in deviation angle of at least 25 percent.
>
> In Study A (n=25) [25 patients], 3 injections of AA4500, each administered on a separate day, were given over 7-10 days. Patients received a second series of 3 injections 12 weeks later. Patients were evaluated at three, six, and nine months post-last injection. The mean baseline deviation angle was 52.8 degrees. At months three and six, 58 percent and 53 percent of patients (respectively) achieved clinical success with respect to deviation angle.
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> The best results were achieved with a three-treatment series of three injections each in Study B (n=10) [10 patients]. In Study B, patients received three injections of AA4500 administered one per day, separated by at least one day each, over a one week timeframe. Patients received two additional series of 3 injections, each spaced 6 weeks apart. The mean baseline deviation angle was 50.2 degrees. At 9 month follow up (post-first injections), 25 percent or greater reduction in deviation angle was achieved in 8/9 patients who completed the study (89 percent, 1 patient had 24 percent reduction in deviation angle). Based on the investigator s global assessment, 67 percent of subjects were very much improved or much improved after treatment with AA4500.
>
> The most common adverse events reported in both studies were local administration site reactions that were mid or moderate in severity, non-serious, and resolved in time without medical attention.

An article was published by Gerald H. Jordan, M.D. in the *Journal of Sexual Medicine* in January 2008, titled The Use of Intralesional Clostridial Collagenase Injection Therapy for Peyronie s Disease: A Prospective, Single-Center, Non-Placebo Controlled-Study. The details from the article s abstract are as follows:

> Methods. Twenty-five patients aged 21-75 years who were referred to a single institution with a well-defined Peyronie s disease plaque were treated with three intralesional injections of clostridial collagenase 10,000 units in a small volume (0.25 cm^3 per injection) administered over 7-10 days, with a repeat treatment (i.e., three injections of collagenase 10,000 units/0.25 cm^3 injection over 7-10 days) at 3 months. Primary efficacy measures were changes from baseline in the deviation angle and plaque size. Secondary efficacy end points were patient responses to a Peronie s disease questionnaire and improvement according to the investigator s global evaluation of change.

Main Outcome Measure. The primary efficacy measures were change in deviation angle and change in plaque size. Secondary and points were patient questionnaire responses and improvement according to the investigators global evaluation of change.

Results. Significant decreases from baseline were achieved in the mean deviation angle at months 3 ($P = 0.0001$) and 6 ($P = 0.0012$), plaque width at months 3 ($P = 0.0018$) and 6 ($P = 0.0483$). More than 50% of patients in this series considered themselves very much improved or much improved at all time points in the study, and the drug was generally well tolerated.

Conclusion. The benefits of intralesional clostridial collagenase injections in this trial lend support to prior studies supporting its use in the management of Peyronie s disease. A double-blind, placebo-controlled study is currently under development.

Development Status

In a press release dated February 2, 2009, Auxilium announced that it has completed patient enrollment in its Phase IIb trial of XIAFLEX for the treatment of Peyronie s disease and that all patients have received their first injection of either XIAFLEX or placebo in accordance with the study design. Auxilium stated that due to the high level of interest from patients and physicians, [Auxilium] exceeded its enrollment target of 120 patients. As stated in the press release, the Phase IIb study is a randomized, double-blind, placebo-controlled study that is designed to assess the safety and efficacy of XIAFLEX, when administered two times a week every six weeks for up to three treatment cycles (2 x 3), in subjects with Peyronie s disease. The study is being conducted at 12 sites throughout the U.S., and patients will be monitored for 36 weeks following the first injection. In its presentation materials filed with its Form 8-K on March 19, 2009, Auxilium stated that top line results of the IIb trial are expected to be released in the fourth quarter of 2009.

Collagenase For Treatment of Frozen Shoulder (*Adhesive Capsulitis*)

Frozen shoulder is a clinical syndrome of pain and decreased motion in the shoulder joint. It is estimated to affect 2-5% of the general population with a slightly higher incidence in women. It is estimated that 700,000 patients visit doctors annually in the U.S. in connection with frozen shoulder. It typically occurs between the ages of 40-70. Individuals with insulin dependent diabetes have been reported to have a 36% higher incidence rate and are more likely to have bilateral symptoms.

Results of a Phase II randomized double-blind, placebo controlled, dose response study were presented at the annual meeting of the American Academy of Orthopaedic Surgeons (AAOS) in March 2006. Based on Auxilium s prior review of the data contained in the oral presentation, they elected to exercise their option to develop and commercialize this additional indication for collagenase injection in December 2005. In its Form 10-K filed on February 26, 2009, Auxilium reported that it has started certain non-clinical activities that it believes are necessary for advancing the program to the next stage of clinical trials.

Other Clinical Indications For Collagenase

Lipomas

Lipomas are benign fatty tumors that occur as bulges under the skin. An open label clinical trial has been completed for treatment of lipomas utilizing a single injection of collagenase. Based on observations made during preclinical studies that a collagenase injection decreased the size of fat pads in animals, a Phase I open label clinical trial was conducted. Favorable initial results (10 out of 12 patients had a 50-90% reduction in the size of the lipomas) from this study for treatment of lipomas were presented at a meeting of the American Society of Plastic Surgeons. BioSpecifics has not announced plans for any new studies in lipomas.

Cellulite

Cellulite is a condition characterized by dimpling of the skin and a mattress phenomenon typically affecting the thighs and buttocks. It is due to irregular and discontinuous subcutaneous connective tissue. An open label study has been completed to assess whether injectable collagenase can restore the cellulite-affected areas to a more cosmetically acceptable appearance. An abstract of an article titled Collagenase Injection in the Treatment of Cellulite by A. Dagum and M.Badalamente, describing the promising results of this study was published in *Plastic and Reconstructive Surgery* on September 15, 2006. BioSpecifics has not announced plans for any new studies in cellulite.

Total Patient Exposure

Clinical investigations with our collagenase injection have been conducted in the treatment of herniated disc disease, keloids and hypertrophic scars, as an adjunct to vitrectomy, Peyronie s disease, Dupuytren s disease, glaucoma, frozen shoulder, lipoma, flexor tendon adhesions and cellulite. In a press release dated March 2, 2009, Auxilium announced that the BLA submission for the treatment of Dupuytren s disease was based on data from a total of 1,082 patients who received in excess of 2,600 injections for treatment of Dupuytren s disease in trials sponsored by Auxilium. In addition, BioSpecifics has treated over 1,200 patients in its own clinical studies.

LICENSING AND MARKETING AGREEMENTS

Topical Collagenase Agreement

In connection with the sale of our topical collagenase business to DFB Biotech, Inc. and its affiliates (DFB) in March 2006, we continue to receive payments for certain technical assistance and certain transition services that we provide to DFB as well as earn out payments based on the sales of certain products. In 2008, we received $200,000 of technical assistance related payments and as of December 31, 2008, we have received a total of $1.0 million in consulting fees. Our consulting obligations generally expire during March 2011. In addition, we recognized $0.5 million in earn out payments from DFB in connection with the net sales of topical collagenase in 2008.

Auxilium Agreement

On June 3, 2004, we entered into the Prior Auxilium Agreement, which was amended on May 10, 2005 and December 15, 2005, respectively. On December 11, 2008, the parties entered into the Auxilium Agreement, which amended and restated in its entirety the Prior Auxilium Agreement and became effective on December 17, 2008 upon the effectiveness of the Pfizer Agreement between Auxilium and Pfizer, pursuant to which Pfizer will market XIAFLEX for the treatment of Dupuytren s disease and Peyronie s disease in Europe and various other territories set forth in the Pfizer Agreement (the Pfizer Territory). Under the Auxilium Agreement, in 2009 we received $6.375 million of the $75 million upfront payment paid to Auxilium by Pfizer and will receive 8.5% of the $410 million in potential additional milestone payments that may be made by Pfizer to Auxilium under the Pfizer Agreement. Of these additional milestones, $150 million are tied to regulatory milestones and $260 million are based on sales milestones.

Under the Auxilium Agreement, we granted to Auxilium exclusive worldwide rights to develop, market and sell certain products containing our injectable collagenase. Auxilium s licensed rights concern the development of products, other than dermal formulations labeled for topical administration, and currently its licensed rights cover the indications of Dupuytren s disease, Peyronie s disease and frozen shoulder. Auxilium may further expand the Auxilium Agreement, at its option, to cover other indications that we may develop. Pfizer is responsible for marketing XIAFLEX for both Dupuytren's disease and Peyronie's disease in the Pfizer Territory. In addition, Pfizer will be primarily responsible for regulatory activities for XIAFLEX in the Pfizer Territory.

The royalty obligations under the Auxilium Agreement extend, on a country-by-country and product-by-product basis, for the longer of the patent life (including Auxilium patents and patent applications), the expiration of any regulatory

exclusivity period or June 3, 2016. Auxilium may terminate the Auxilium Agreement upon 90 days prior written notice. In January 2006, Auxilium filed a patent application with regard to the composition and manufacturing process for XIAFLEX which, if granted, would expire in January 2027.

Auxilium is generally responsible, at its own cost and expense (excluding the third party costs for the development of the lyophilization of the injection formulation, which are shared equally by the parties), for developing the formulation and finished dosage form of products and arranging for the clinical supply of products. Auxilium is responsible for all clinical development and regulatory costs for Peyronie s disease, Dupuytren s disease, frozen shoulder and all additional indications for which they exercise their options.

We have the option, exercisable no later than six months after FDA approval of the first New Drug Application (NDA) or BLA with respect to a product, to assume the right and obligation to supply, or arrange for the supply from a third party other than a back-up supplier qualified by Auxilium, of a specified portion of Auxilium s commercial product requirements in all countries and territories of the world excluding the Pfizer Territory (the Auxilium Territory). The Auxilium Agreement provides that Auxilium may withhold a specified amount of a milestone payment until (i) we execute an agreement, containing certain milestones, with a third party for the commercial manufacture of the product, (ii) we commence construction of a facility, compliant with Current Good Manufacturing Practices (cGMP), for the commercial supply of the product or (iii) 30 days after we notify Auxilium in writing that we will not exercise the supply option. If we exercise the supply option, commencing on a specified date from the date of regulatory approval, we will be responsible for supplying either ourselves or through a third party other than a back-up supplier qualified by Auxilium, a specified portion of the commercial supply of the product for the Auxilium Territory. If we do not exercise the supply option, then Auxilium will be responsible for arranging for the entire commercial product supply. In the event that we do exercise the supply option, then we and Auxilium are required to use commercially reasonable efforts to enter into a commercial supply agreement on customary and reasonable terms and conditions which are not worse than those with back-up suppliers qualified by Auxilium.

Auxilium must pay us on a country-by-country and product-by-product basis a specified percentage of worldwide net sales for products covered by the Auxilium Agreement. Such percentage may vary depending on whether we exercise the supply option. In addition, the percentage may be reduced if (i) we fail to supply commercial product supply in accordance with the terms of the Auxilium Agreement; (ii) market share of a competing product exceeds a specified threshold; or (iii) Auxilium is required to obtain a license from a third party in order to practice our patents without infringing such third party s patent rights. In addition, if Auxilium out-licenses to a third party, then we will receive a specified percentage of certain payments made to Auxilium in consideration of such out-licenses.

In addition to the payments set forth above, Auxilium must pay to us an amount equal to a specified mark-up of the cost of goods sold for products sold by Auxilium or Pfizer that are not manufactured by or on behalf of us, provided that, in the event that we exercise the supply option, no payment will be due for so long as we fail to supply the commercial supply of the product in accordance with the terms of the Auxilium Agreement.

Auxilium will be obligated to make contingent milestone payments upon the acceptance of the regulatory filing and receipt by Auxilium, its affiliate or sublicensee of regulatory approval. Through December 31, 2008, Auxilium paid us up-front licensing and sublicensing fees and milestone payments under the Auxilium Agreement of $14.4 million. Auxilium could make in excess of $5 million of additional contingent milestone payments for exercised indications under the Auxilium Agreement if all existing conditions are met. Additional milestone obligations will be due if Auxilium exercises an option to develop and license XIAFLEX for additional medical indications.

In addition to the milestone payments from Auxilium, the Company is entitled, specifically in the case of the Auxilium Agreement, to 8.5% of all sublicense income that Auxilium receives from Pfizer under the Pfizer Agreement, which includes $410 million in potential milestone payments that may be made by Pfizer to Auxilium, of which $150 million are tied to regulatory milestones and $260 million are based on sales milestones.

In its Form 10-K filed with the SEC on February 26, 2009, Auxilium stated that it is currently evaluating the options that we have for commercializing XIAFLEX in other indications and territories of the world. In the event that Auxilium does license XIAFLEX in other indications, we will be entitled to receive a certain percentage of sublicense income and milestone payments for such indications pursuant to the terms of the Auxilium Agreement.

A copy of the Auxilium Agreement was filed on Form 8-K with the SEC on December 19, 2008. The foregoing descriptions of the Auxilium Agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the agreement.

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.

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, to 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 the Enzyme 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 the Enzyme 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 the Company, its 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 Orphan Product Division with respect to the Licensed Product or (iii) June 3, 2016.

Unless terminated earlier in accordance with its termination provisions, the Dupuytren s License Agreement and licenses granted thereunder will continue in effect until the termination of our royalty obligations. Thereafter, 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 to improve the deal terms related to our future royalty obligations for Peyronie s disease by buying down our future royalty obligations with a one-time cash payment. A copy of the agreement was filed on Form 8-K with the SEC on September 5, 2008.

Frozen Shoulder

On November 21, 2006, we also 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) the Enzyme and (ii) all pharmaceutical products containing the Enzyme 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 the Enzyme or injectable collagenase for the treatment and prevention of frozen shoulder (each a Frozen Shoulder Licensed Product). In addition, we 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 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 thereunder will continue in effect until the termination of our royalty obligations. Thereafter, all licenses granted to us under the Frozen Shoulder License Agreement will become fully paid, irrevocable exclusive licenses.

In connection with the execution of the Dupuytren s License Agreement and the Frozen Shoulder License Agreement, certain up-front payments were made by us to the Research Foundation and the clinical investigators working on the Dupuytren s disease and frozen shoulder indications for the Enzyme.

Other Indications

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

COMPETITION

We 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.

RESEARCH AND DEVELOPMENT

Cost of Research and Development Activities

During fiscal years 2008 and 2007, the Company invested $439,919 and $2,489,122, respectively, in research and development activities.

Dupuytren s Disease

Following an end-of-Phase II meeting with the FDA, we supplied requisite study drug, initiated and monitored a pivotal clinical trial for the treatment of Dupuytren s disease. The results of the Phase III clinical trial with injectable collagenase manufactured by us were published in the July-August 2007 issue of the *Journal of Hand Surgery*, as discussed in this Item 1, under the section titled Collagenase for Treatment of Dupuytren s Disease.

Peyronie s Disease

Based on clinical trial protocols submitted to the FDA, we supplied requisite study drug, initiated and monitored clinical investigations for the treatment of Peyronie s disease, which were described by Auxilium in their press release dated October 25, 2006. An excerpt of this press release appears in this Item 1, under the section titled Collagenase for Treatment of Peyronie s Disease.

Frozen Shoulder

We have supplied requisite study drug, initiated and monitored a Phase II clinical trial using the injectable enzyme in the treatment of frozen shoulder. Three different doses of the enzyme were compared to placebo in this double-blind, randomized trial in 60 patients. The results from this trial suggest that local injection of the enzyme are encouraging and may be effective in patients suffering from frozen shoulder. Additional studies are needed to assess the optimal

dose and dosing regimen of injectable collagenase in this indication. In its press release dated December 20, 2005, concurrent with its exercise of its option with respect to frozen shoulder, Auxilium reported: AA4500 is a very important product candidate for Auxilium, and we believe the addition of a third indication for this development program enhances the commercial potential of AA4500. In its Form 10-K filed on February 26, 2009, Auxilium stated that an estimated 3% of people develop frozen shoulder over their lifetime and that women tend to be affected more frequently than men.

Additional Clinical Indications

Lipomas

As described in this Item 1, under the section titled Other Clinical Indications for Collagenase, we have supplied requisite study drug, initiated and monitored a positive open label clinical study for the treatment of lipomas with injectable collagenase. These results suggest the possibility of chemical liposuction BioSpecifics has not announced plans for new studies in lipomas.

Cellulite

As described in this Item 1, under the section titled Other Clinical Indications for Collagenase, we have referenced the promising open label clinical trial results for the treatment of cellulite with injectable collagenase. These results suggest the possibility of chemical liposuction. BioSpecifics has not announced plans for new studies in cellulite.

New Products

We continue to review selectively new technologies and products in the areas of wound healing, tissue remodeling and anti fibrotic therapy for possible acquisition or in-licensing.

GOVERNMENT REGULATION

All of our products labeled for use in humans require regulatory approval by government agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials to demonstrate safety and efficacy and other approval procedures of the FDA and similar regulatory authorities in foreign countries. Various federal, state, local, and foreign statutes and regulations also govern testing, manufacturing, labeling, distribution, storage and record-keeping related to such products and their promotion and marketing. The process of obtaining these approvals and the compliance with federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. In addition, the current political environment and the current regulatory environment at the FDA could lead to increased testing and data requirements which could impact regulatory timelines and costs.

Clinical trials involve the administration of the investigational product candidate or approved products to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study, the parameters to be used in assessing the safety and the effectiveness of the drug. Typically, clinical evaluation involves a time-consuming and costly three-phase sequential process, but the phases may overlap. Each trial must be reviewed, approved and conducted under the auspices of an independent institutional review board, and each trial must include the patient s informed consent.

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 or we 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 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 drug candidate.

Assuming successful completion of the required clinical trials, drug developers 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 NDA or BLA, requesting approval to market the product for one or more indications. In most cases, the NDA/BLA must be accompanied by a substantial user fee. The FDA reviews an NDA/BLA to determine, among other things, whether a product is safe and effective for its intended use.

Before approving an application, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve the application unless cGMP compliance is satisfactory. The FDA will issue an approval letter if it determines that the application, manufacturing process and manufacturing facilities are acceptable. If the FDA determines that the application, manufacturing process or manufacturing facilities are not acceptable, it will outline the deficiencies in the submission and will often request additional testing or information. Notwithstanding the submission of any requested additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval and refuse to approve the application by issuing a not approvable letter.

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. We may encounter difficulties or unanticipated costs in our efforts to secure necessary governmental approvals, which could delay or preclude us from marketing our products. Furthermore, the FDA may prevent a drug developer 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 NDA or BLA, the drug can be marketed to physicians to prescribe in the U.S. After approval, the drug developer 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 drug sampling and distribution requirements. The holder of an approved NDA/BLA is required to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. Drug manufacturers and their subcontractors are required to register their facilities and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMP which imposes procedural and documentation requirements relating to manufacturing, quality assurance and quality control. 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 aspects of regulatory compliance. The FDA may require post-market testing and surveillance to monitor the product s safety or efficacy, including additional studies to evaluate long-term effects.

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

We use, and will continue to use, third party manufacturers to produce our products in clinical quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer or holder of an approved NDA/BLA, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. 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

PATENT PROTECTION

Patents

We are the assignee or licensee of five U.S. patents, which have received patent protection in various foreign countries. In addition, we have licenses to other pending patent applications. There can be no assurances when, if ever, such patents will be issued, or that such patents if issued, will be of any value to us.

The scope of the intellectual property rights held by pharmaceutical firms involves complex legal, scientific and factual questions and consequently 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 or will be challenged, circumvented or invalidated. Because patent applications in the U.S. and some other jurisdictions are sometimes maintained in secrecy until patents issue, and 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. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office (the USPTO), or a foreign patent office to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued and challenged, in a court of competent jurisdiction would be found valid or enforceable. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

Although we believe these patent applications, if they issue as patents, will provide a competitive advantage, the patent positions of pharmaceutical and biotechnology companies are highly uncertain and involve complex legal and factual questions. We may not be able to develop patentable products or processes and may not be able to obtain patents from pending applications. Even if patent claims are allowed, the claims may not issue, or in the event of issuance, may not be sufficient to protect our technology. In addition, any patents or patent rights we obtain may be circumvented, challenged or invalidated by our competitors.

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 on their proprietary rights. Additionally, because patent prosecution can proceed in secret prior to issuance of a patent, 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.

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 acceptable terms or at all. Any infringement claim that results in litigation could result in substantial cost to us and the diversion of management s attention from our core business. To enforce patents issued 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 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.

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.

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.

We licensed to Auxilium our injectable collagenase for the treatment of Dupuytren s and Peyronie s diseases as well as frozen shoulder. In addition to the marketing exclusivity which comes with its orphan drug status as a treatment for Dupuytren s and Peyronie s diseases, the enzyme underlying this product candidate is covered by two use patents in the U.S., one for the treatment of Dupuytren s disease, which issued from a reissue proceeding in December 2007, and one for the treatment of Peyronie s disease. The Dupuytren s patent expires in 2014, and 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 Dupuytren s and Peyronie s diseases within certain dose ranges. In its Form 10-K filed with the SEC on February 26, 2009, Auxilium stated that while XIAFLEX does not have orphan drug status for any indication in Europe, foreign patents cover these products in certain countries, and on approval of XIAFLEX for a first indication in Europe, we expect the product will benefit from 10 years of market exclusivity and 8 years of data exclusivity. We may obtain an additional year of market exclusivity if the regulatory authorities approve an additional indication that they determine to represent a significant clinical benefit.

Orphan Drug Designations

The FDA s Office of Orphan Products Development (OOPD) administers the major provisions of the Orphan Drug Act (the Act), an innovative program that provides incentives for sponsors to develop products for rare diseases. The incentives for products that qualify under the Act include seven-year exclusive marketing rights post FDA approval, 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 orphan drug provisions of the Federal Food, Drug, and Cosmetic Act also provide incentives to drug and biologics suppliers to develop and supply drugs 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 drug for such disease or condition will be recovered from its sales in the U.S. Under these provisions, a supplier of a designated orphan product can seek tax benefits, and 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. It would not prevent other drugs from being approved for the same indication.

Two indications, Dupuytren s disease and Peyronie s disease, have received orphan drug status from the OOPD.

EMPLOYEES

The Company currently has five employees, who are all full-time employees.

CORPORATE INFORMATION

BioSpecifics Technologies Corp. was incorporated in Delaware in 1990. ABC-NY was incorporated in New York in 1957. Our corporate headquarters are located at 35 Wilbur St., Lynbrook, NY 11563. Our telephone number is 516-593-7000.

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.

Risks Related to Our Limited Sources of Revenue

Our future revenue is primarily dependent upon option, milestone and contingent royalty payments from Auxilium and technical assistance payments and contingent earn out payments from DFB.

Our primary sources of revenues are from (i) option, milestone and contingent royalty payments from Auxilium under the Auxilium Agreement, (ii) payments from DFB for technical assistance we provide and contingent earn out payments from DFB and (iii) the sale of small amounts of collagenase for laboratory research.

Under the Auxilium Agreement, in exchange for the right to receive royalties and other rights, we granted to Auxilium the right to develop, manufacture, market and sell worldwide products (other than dermal formulations for topical administration) that contain collagenase for the treatment of Dupuytren s and Peyronie s diseases and frozen shoulder, subject to certain reversionary rights. However, we may not receive any royalty payments from Auxilium because we have no control over Auxilium s decision to pursue commercialization, or its ability to successfully manufacture, market and sell candidate products for the treatment of Dupuytren s and Peyronie s diseases, and frozen shoulder. Subject to certain conditions, we have retained an option to manufacture a portion of the developed product for the Auxilium Territory licensed to Auxilium after it has been marketed for several years. We have received in the past, and are entitled to receive in the future, certain milestone payments from Auxilium in respect of its efforts to commercialize such candidate products. However, we have no control over Auxilium s ability to achieve the milestones. Additionally, under the Auxilium Agreement, we are entitled to receive 8.5% of all sublicense income that Auxilium receives from Pfizer under the Pfizer Agreement, which payments are dependent on the achievement by Pfizer of certain regulatory and sales related milestones, of which we have no control.

We have also retained the right to pursue other clinical indications for injectable collagenase, and have granted to Auxilium an option to expand its license and development rights to one or more additional indications (Additional Indications) for injectable collagenase not currently licensed to Auxilium, including lipomas and cellulite. The option is exercisable as to any such Additional Indications for which we have submitted a Phase II clinical trial report to Auxilium and which meet other criteria provided in the Auxilium Agreement. Upon Auxilium s exercise of the option with respect to any Additional Indication, it must pay to us a one-time license fee for the rights to such new indication. In addition, we are also entitled to receive milestone payments and, subject to commercialization of any Additional Indications, royalty payments with respect to any such Additional Indications. If Auxilium does not exercise its option as to any Additional Indication, we may offer to any third party such development rights with regard to products in the Auxilium Territory, provided that we first offer the same terms to Auxilium, or to develop the product ourselves. Auxilium has no obligation to exercise its option 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, therefore, there is no assurance that after conducting Phase II clinical trials on any Additional Indication, and incurring the associated expenses, Auxilium will exercise its option or we will receive any revenue from it. Under the Auxilium Agreement, we may only offer to a third party development rights with regard to products in the Auxilium Territory and not in the Pfizer Territory. Auxilium s ability to develop or commercialize Additional Indications in the Pfizer Territory are subject to negotiation with Pfizer under the terms of the Pfizer Agreement.

As part of the sale of our topical collagenase business to DFB, we are entitled to receive earn out payments in respect of sales of certain products developed and manufactured by DFB that contain collagenase for topical administration. However, our right to receive earn out payments from DFB is dependent upon DFB s decision to pursue, and its ability to succeed in, the manufacture and commercialization of such products, and achieve certain sales thresholds at which its obligations to pay earn out payments to us would commence. We are aware that DFB has certain competitive products that may adversely affect the volume of sales of those topical collagenase products for which we are entitled to earn out payments.

We also agreed to provide technical assistance to DFB s affiliate, DPT Lakewood, for a fixed period of time in consideration for certain payments and we are required to maintain certain scientific resources and records in order to

provide such assistance and be entitled to receive such payments.

Our dependence upon revenue from Auxilium and DFB make us subject to the commercialization and other risk factors affecting those two companies over which we have limited or no control.

Auxilium has disclosed in its securities filings a number of risk factors to consider when evaluating its business and future prospects. Given our dependence upon revenue from Auxilium, Auxilium s operating success or failure has a significant impact on our potential royalty stream and other payment rights. As such, we refer you to the full text of Auxilium s disclosed risk factors in its securities filings, which were most recently included on its Form 10-K filed on February 26, 2009.

DFB is not a publicly traded company and therefore we have little information about its business and future prospects. Although we cannot be certain, we presume that many of the risk factors affecting Auxilium s business may have some bearing in evaluating DFB s ability to meet its payment obligations to us for technical assistance or to generate sufficient sales of topical collagenase products entitling us to receive any earn out payments.

Unstable market conditions may have serious adverse consequences on our business.

The recent economic downturn and market instability has made the business climate more volatile and more costly. Our general business strategy may be adversely affected by unpredictable and unstable market conditions. If the current equity and credit markets deteriorate further, or do not improve, it may make any necessary equity or debt financing more difficult, more costly, and more dilutive. While we believe we have adequate capital resources to meet our expected working capital and capital expenditure requirements until at least the first half of 2012, a radical economic downturn or increase in our expenses could require additional financing on less than attractive rates or on terms that are excessively dilutive to existing stockholders. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and stock price. There is a risk that one or more of our partners may encounter difficulties during challenging economic times, which could have an adverse effect on our business, results of operations and financial condition.

Risks Related to Limited Supply of Clinical Materials

The FDA s action in December 2005 to place on hold a clinical trial related to hypertrophic scarring being conducted on our behalf by an independent investigator, because of questions regarding certain of our clinical materials, may limit our ability to conduct other clinical trials and to obtain the associated option, milestone and contingent royalty payments under the Auxilium Agreement.

One of the independent investigators who has performed a clinical trial on hypertrophic scarring was notified by the FDA that a clinical hold has been placed on an investigational new drug (an IND) application for that indication. Prior to commencing clinical trials in U.S. interstate commerce, there must be an effective IND for each of our product candidates. As a result of the clinical hold, the independent investigators are not permitted to conduct a clinical trial for that indication under the IND until the FDA releases the hold. Although we believe that the clinical hold only applies to the use of our clinical materials in connection with the indication specified in the clinical hold notification, it is possible that the FDA might broaden the scope of the clinical hold to cover use of our clinical materials in clinical trials for other indications that we may want to pursue. If the FDA s hold also limits our ability to conduct clinical trials on other indications, it may make it difficult for us to conduct clinical trials on Additional Indications under the Auxilium Agreement. Consequently, it may limit our ability to obtain the option, milestone and contingent royalty payments under the Auxilium Agreement.

We have a limited supply of clinical material, which may limit our ability to conduct other clinical trials and to obtain the associated option, milestone and contingent royalty payments under our agreement with Auxilium.

Although we currently have our own clinical material, if this clinical material is damaged or otherwise becomes unusable, then we may have insufficient clinical material to conduct other clinical trials. Although Auxilium has

agreed to provide us with additional clinical material, there is no guaranty that Auxilium will do so. Consequently, the lack of availability of clinical material may limit our ability to obtain the option, milestone and contingent royalty payments under the Auxilium Agreement.

Risks Related to our Agreements with Auxilium and DFB

Our ability to conduct clinical trials and develop products for dermal formulations for topical or injectable administration of collagenase is limited by the agreements we have signed with Auxilium and DFB.

Under our agreements with Auxilium and DFB, we have sold, licensed, or granted options to certain of our rights to conduct clinical trials and develop products for dermal formulations for topical or injectable administration of collagenase. Under the terms of the Auxilium Agreement and our agreement with DFB, we have agreed to certain non-competition provisions, which limit our clinical development activities.

Risks Related to our Limited Financial and Employee Resources

Our limited financial and employee resources limit our ability to develop other indications or products.

We currently have only four employees and the sources of revenue described above. Because we have limited internal research capabilities, we are dependent upon independent investigators, pharmaceutical and biotechnology companies and other researchers to conduct clinical trials, sell or license products or technologies to us.

To end our reliance on Auxilium and DFB for the majority of our revenues, we would need to in-license, acquire, develop and market other products and product candidates. However, we may not be able to successfully identify any commercial products or product candidates to in-license, acquire or internally develop given our limited financial and employee resources. Moreover, negotiating and implementing an economically viable in-licensing arrangement or acquisition is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may, if we decide to follow this strategy, compete with us for the in-licensing or acquisition of product candidates and approved products. We may not be able to acquire or in-license the rights to additional product candidates and approved products on terms that we find acceptable, or at all. If we are unable to in-license or acquire additional commercial products or product candidates our ability to grow our business or increase our profits could be severely limited.

If we are unable to obtain option payments, milestone and earn out or contingent royalty payments from Auxilium or DFB or meet our needs for additional funding from other sources, we may be required to limit, scale back or cease our operations.

Our negative cash flows from operations are expected to continue for at least the foreseeable future. Our business strategy contains elements that we will not be able to execute if we do not receive the anticipated option, milestone, royalty or earn out payments from Auxilium or DFB, or secure additional funding from other sources. Specifically, we may need to raise additional capital to:

- acquire or in-license approved products or product candidates or technologies for development;
- fund our product development, including clinical trials relating to in-licensed technology and the remaining indications; and
- commercialize any resulting product candidates for which we receive regulatory approval.

We believe that our existing cash resources and interest on these funds will be sufficient to meet our anticipated operating requirements until at least the first half of 2012. Our future funding requirements will depend on many factors, including:

- DFB s ability to meet its payment obligations and to manufacture and commercialize topical collagenase products for which we would receive earn out payments;
- Auxilium s ability to manufacture and commercialize injectable product for which we would receive milestone and royalty payments;
- Pfizer s ability to develop and commercialize the product in the Pfizer Territory and Auxilium s receipt of milestone payments from Pfizer under the Pfizer Agreement for which we would receive a percentage of sublicense income and royalty payments (for more information regarding Auxilium s financial risks associated with Pfizer under the Pfizer Agreement, we refer you to the full text of Auxilium s disclosed risk factors in its securities filings, which were most recently included on its Form 10-K filed on February 26, 2009);
- The amount actually owed to Auxilium for lyophilization related costs;
- the scope, rate of progress, cost and results of our clinical trials on remaining Additional Indications, including lipomas and cellulite, and whether Auxilium exercises its option to acquire rights to them;
- the terms and timing of any future collaborative, licensing, co-promotion and other arrangements that we may establish; and

- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights or defending against any other litigation.

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 Auxilium or DFB, and are unable to secure additional financing, we may be required to cease operations.

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

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

Risks Related to the Age and Qualifications of the Members of Our Board of Directors

Because of the age of some of our independent Board members, we may have to find replacements shortly, and due to our financial condition and SEC compliance history this may be difficult, which could impact our ability to remain listed on Nasdaq.

The four independent members of our Board, who are also members of our audit committee (the Audit Committee), are eighty-eight, sixty-nine, sixty-eight and sixty years old, respectively, as of December 31, 2008. Upon the retirement, incapacity or death of one or more of our independent Board members, we would have to find replacements in a short period of time. In light of our financial condition and SEC compliance history, it may be difficult to find any replacements for our independent Board members. If we fail to find replacements in a timely manner, our ability to remain listed on the Nasdaq Global Market (Nasdaq) and our common stock price may be negatively impacted.

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, and the testing, development and manufacturing and distribution of any 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 any product candidates, as well as safe working conditions. Noncompliance with any applicable regulatory requirements can result in suspension or termination of any ongoing clinical trials of a product candidate or refusal of the government to approve product candidate for commercialization, criminal prosecution and fines, recall or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or refusal to allow the entering into of federal and state supply contracts. The FDA and comparable governmental authorities have the authority to suspend or terminate any ongoing clinical trials of a product candidate or withdraw product approvals that have been previously granted. 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.

Additionally, failure to comply with or changes to the regulatory requirements that are applicable, or may become applicable to us or any product candidates we may develop or obtain, may result in a variety of consequences, including the following:

- restrictions on our products or manufacturing processes;
- warning letters;
- withdrawal of a product candidate from the market;
- voluntary or mandatory recall of a product candidate;
- fines;
- suspension or withdrawal of regulatory approvals for a product candidate;
- 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;
- product seizure; and
- injunctions or the imposition of civil or criminal penalties against us.

We may be exposed to potential risks relating to our internal controls over financial reporting and our ability to have the operating effectiveness of our internal controls attested to by our independent auditors.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002 (SOX), or SOX 404, the SEC adopted rules requiring public companies to include a report of management on the company s internal controls over financial reporting in its annual reports, including Form 10-KSB. We were subject to this requirement commencing with our fiscal year ending December 31, 2007 and a report of our management is included under Item 9A(T) of this Report. In addition, SOX 404 requires the independent registered public accounting firm auditing a company s financial statements to also attest to and report on the operating effectiveness of such company s internal controls. However, this Report does not include an attestation report because under current securities laws, we are not subject to these requirements until our annual report for the fiscal year ending December 31, 2009. We can provide no assurance that we will comply with all of the requirements imposed thereby. There can be no assurance that we will receive a positive attestation from our independent auditors. In the event that we identify significant deficiencies or material weaknesses in our internal controls that we cannot remediate in a timely manner or we are unable to receive a positive attestation from our independent auditors with respect to our internal controls, investors and others may lose confidence in the reliability of our financial statements.

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

We are a small company and we rely heavily on third parties and outside consultants to conduct many important functions. 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 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, impede our ability to raise capital or list our securities on certain securities exchanges. The new rules could make it more difficult or more costly 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 of directors, our board 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.

Risks Related to Growth and Employees

Our failure to successfully in-license or acquire additional technologies, product candidates or approved products could impair our ability to grow or continue to operate.

We may decide to pursue other opportunities to in-license, acquire, develop and market additional products and product candidates so that we are not solely reliant on Auxilium and DFB sales for our revenues. Because we have limited internal research capabilities, we are dependent upon pharmaceutical and biotechnology companies and other researchers and independent investigators to sell or license products or technologies to us. The success of this strategy depends upon our ability to identify, select and acquire the right pharmaceutical product candidates, products and technologies.

We may not be able to successfully identify any commercial products or product candidates to in-license, acquire or internally develop. Moreover, negotiating and implementing an economically viable in-licensing arrangement or acquisition is a lengthy and complex process. Other companies, including those with substantially greater financial, marketing and sales resources, may compete with us for the in-licensing or acquisition of product candidates and approved products. We may not be able to acquire or in-license the rights to additional product candidates and approved products on terms that we find acceptable, or at all. If we are unable to in-license or acquire additional commercial products or product candidates we may be reliant solely on Auxilium and DFB sales for revenues. As a result, our ability to grow our business or increase our revenues could be severely limited.

If we are able to develop any product candidates for Additional Indications of injectable collagenase, we may not be able to obtain option, milestone or royalty payments under the Auxilium Agreement, which could impair our ability to grow and could cause a decline in the price of our common stock.

The process of conducting clinical trials and developing product candidates involves a high degree of risk and may take several years. 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 any unforeseen result;
- 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 or other factors may make our product candidates uneconomical; and
- the proprietary rights of others and their competing products and technologies may prevent product candidates from being effectively commercialized or to obtain 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. Currently, there is substantial congressional and administration review of the regulatory approval process for drug candidates in the U.S. Any changes to the U.S. regulatory approval process could significantly increase the timing or cost of regulatory approval for a product candidates making further development uneconomical or impossible. In addition, once Auxilium exercises its option with respect to any product candidate for any Additional Indications, further clinical trials, development, manufacturing, marketing and selling of such product is out of our control. Our interest is limited to receiving option, milestone and royalty payment, and the option in certain circumstances to manufacture according to particular specifications set by Auxilium.

Any product acquisition or development efforts also could result in large and immediate write-offs, incurrence of debt and contingent liabilities or amortization of expenses related to intangible assets, any of which could negatively impact our financial results.

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

If we decide to proceed with conducting clinical trials with respect to any Additional Indications, adverse events or lack of efficacy may force us to stop development of our product candidates or prevent regulatory approval of our product candidates, which could materially harm our business. In addition, any adverse events or lack of efficacy may force Auxilium to stop development of the products we have licensed to them or prevent regulatory approval of such products, which could materially impair all or a material part of the future revenue we hope to receive from Auxilium.

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

We face competition in our product development 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. Our competitors may succeed in developing products or intellectual property earlier than we do, entering into successful collaborations before us, obtaining approvals from the FDA or other regulatory agencies for such products before us, or developing products that are more effective than those we could develop. The success of any one competitor in these or other respects will have a material adverse effect on our business, our ability to receive option payments from Auxilium or ability to generate revenues from third party arrangements with respect to the Additional Indications (to the extent that Auxilium does not exercise its option with respect to an Additional Indication).

Because of the specialized nature of our business, 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 obtaining financing.

The competition for qualified personnel in the biotechnology field is intense, and we rely heavily on our ability to attract and contract with qualified independent scientific and medical investigators, and technical and managerial personnel. We face intense competition for qualified individuals from numerous pharmaceutical, biopharmaceutical and biotechnology companies, as well as academic and other research institutions. To the extent we are unable to attract and retain any of these individuals on favorable terms our business may be adversely affected.

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

We continue to have product liability exposure for topical product sold by us prior to the sale of our topical business to DFB. In addition, under the Auxilium Agreement, we are obligated to indemnify Auxilium and its affiliates for any harm or losses they suffered relating to any personal injury and other product liability resulting from our development, manufacture or commercialization of any injectable collagenase product. In addition, the clinical testing and, if approved, commercialization of our product candidates involves significant exposure to product liability claims. We have clinical trial and product liability insurance in the aggregate amount of $3 million dollars that covers us and the clinical trials of our other product candidates that we believe is adequate in both scope and amount and has been placed with what we believe are reputable insurers. Our current and future coverage may, however, not be adequate to protect us from all the liabilities that we may incur. If losses from product liability claims exceed our insurance coverage, we may incur substantial liabilities that exceed our financial resources. 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. 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 we are required to pay a product liability claim, we may not have sufficient financial resources and our business and results of operations may be harmed.

Risks Related to Intellectual Property Rights

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 any of the parties terminate their agreements, whether by their terms or due to a breach by us, our right to use their intellectual property may negatively affect our licenses to Auxilium or DFB and, in turn, their obligation to make option, milestone, contingent royalty or other payments to us.

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

Auxilium s, DFB s and our commercial success in developing and manufacturing collagenase products based on our patents is dependent on these products not infringing the patents or proprietary rights of third parties. While we currently believe that we, our licensees, licensors 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 in-license or license to others thereby, in effect, limiting the scope of our patent rights and those of our licensees, licensors or collaborators. We are obligated by our agreements with Auxilium and DFB 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 Auxilium or DFB 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 option, milestone 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, our licensees, licensors or our 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 acceptable terms or at all. Ultimately, we, our licensees, licensors 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 option, milestone and contingent royalty payments.

Risks Related to our Common Stock

Although we currently meet the listing requirements for Nasdaq, our common stock could be delisted from Nasdaq.

The National Association of Securities Dealers, Inc. has established certain standards for the continued listing of a security on Nasdaq, which are applicable to the continued listing of our common stock. In light of the current economic slowdown, Nasdaq has temporarily suspended certain of its continued listing requirements regarding minimum bid price and market value of publicly held shares. These rules will be reinstated on July 20, 2009. Nasdaq has not indicated any further suspension of those requirements beyond that date.

If we are unsuccessful in maintaining our Nasdaq listing, then we may pursue listing and trading of our common stock on the Over-The-Counter Bulletin Board or another securities exchange or association with different listing standards

than Nasdaq.

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

The trading market for our common stock will depend in part on research and reports that industry or financial analysts publish about us or our business. We are not currently covered by any research analysts. Furthermore, if the analysts who cover us in the future downgrade us or the industry in which we operate or the stock of any of our competitors, the price of our common stock will probably decline.

Future sales of our common stock could negatively affect our stock price.

If our common stockholders sell substantial amounts of common stock in the public market, or the market perceives that such sales may occur, the market price of our common stock could decline. In addition, we may need to raise additional capital in the future to fund our operations. If we raise additional funds by issuing equity securities, our stock price may decline and our existing stockholders may experience dilution of their interests. 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.

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 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:

- listing of our common stock on a securities exchange or market;
- results of our clinical trials;
- failure of any product candidates we have licensed to Auxilium or sold to DFB to achieve commercial success;
- 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 CEO or others;
- changes in the structure of healthcare payment systems, including developments in price control legislation;
- departure of key personnel;
- 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; and
- general economic, industry and market conditions.

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 have no current plan to pay dividends on our common stock and investors may lose the entire amount of their investment.

We have no current plans to pay dividends on our common stock. Therefore, 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 nor can we assure that investors will not lose the entire amount of their investment.

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

As of December 31, 2008, options to purchase 1,427,100 shares of common stock were outstanding. In addition, as of December 31, 2008 a total of 194,098 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.

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

Provisions of our certificate of incorporation, bylaws (as amended) and stockholder rights agreement 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 of directors;
- 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, during 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. 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 those of other stockholders.

As of March 2, 2009 our executive officers, directors and their affiliates, in the aggregate, beneficially owned shares representing approximately 34.9% of our common stock, although sales by the estate of Edwin H. Wegman, our former Chairman and CEO, may result in a change of control of certain of these shares. 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, these individuals, if they chose to act together, 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.

Changes in the expensing of stock-based compensation will result in unfavorable accounting charges and may require us to change our compensation practices. Any change in our compensation practices may adversely affect our ability to attract and retain qualified scientific, technical and business personnel.

In the past, we have relied on stock options to compensate existing directors, employees and attract new employees and consultants. The Financial Accounting Standards Board (FASB) has announced new rules for recording expense for the fair value of stock options. As a result of these new rules, commencing on January 1, 2006, we will expense the fair value of stock options, thereby increasing our operating expenses and reported losses. Although we may continue to include various forms of equity in our compensation plans, if the extent to which we use forms of equity in our plans is reduced due to the negative effects on earnings, it may be difficult for us to attract and retain qualified scientific, technical and business personnel.

Item IB. UNRESOLVED STAFF COMMENTS

None.

SUBSEQUENT EVENTS

On January 6, 2009 the Company announced that it will hold its 2009 Annual Meeting of Stockholders on June 17, 2009 at the New York offices of Bingham McCutchen LLP, located at 399 Park Avenue, New York, NY 10022 and that the deadline for stockholders to submit proposals to be included in our proxy statement with respect to the 2009 Annual Meeting of Stockholders was February 6, 2009.

On January 9, 2009 the Company s common became listed and commenced trading on the Nasdaq Global Market under the symbol BSTC.

On January 30, 2009, the Company received an upfront sublicense payment of $6.375 million from Auxilium in accordance with the terms of the Auxilium Agreement.

In a press release dated February 2, 2009, Auxilium announced that it has completed patient enrollment in its Phase IIb trial of XIAFLEX for the treatment of Peyronie s disease and that all patients have received their first injection of either XIAFLEX or placebo in accordance with the study design.

In a press release dated March 2, 2009, Auxilium announced that it filed a BLA for the treatment of Dupuytren s disease on February 27, 2009. Auxilium also announced that it has requested a Priority Review designation for the BLA submission from the FDA and that it expects to hear from the FDA on Priority Review designation within approximately 60 days of the filing date.

Item 2. DESCRIPTION OF PROPERTY.

As of December 31, 2007 we leased one facility in Lynbrook, New York. The New York facility is our administrative headquarters and contains approximately 3,500 square feet of office space and 11,500 square feet of laboratory, production, and storage facilities. As part of the agreement with DFB, DFB agreed to sublease a part of the New York facility for a period of one year, which expired on March 2, 2007, for an all inclusive monthly payment of $15,500. DFB extended its sublease until March 6, 2008 and paid $16,500 per month during this extended lease period. In April 2008, DFB extended its sublease until March 3, 2009 and paid $19,000 per month during the extended lease period. In accordance with the sublease extension, in July 2008 DFB provided notice of the termination of its obligations under the sublease, effective as of September 1, 2008. We lease this facility from WSC and are currently negotiating with WSC a reduction of the rent price of the facility but as of the date of this filing the parties have not reached an agreement regarding such reduction.

WSC was an affiliate of Edwin H. Wegman, our former Chairman and CEO, until Edwin H. Wegman s death. At the present time the ownership of WSC is unclear. However, our President, Thomas L. Wegman, is the senior most officer of WSC.

Item 3. LEGAL PROCEEDINGS.

None.

Item 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.

Our 2008 Annual Meeting of Stockholders was held on September 9, 2008 at the offices of Thelen LLP in New York, New York, in accordance with the Notice of Annual Meeting of Stockholders sent on or about August 14, 2008. The

tables below present the voting results of the matters voted upon by our stockholders at the meeting:

Proposal 1: Election of Directors

At the meeting, each of the nominees listed below was elected to our Board of Directors to serve as director until the end of his or her respective term and received the number votes set forth after their respective names below.

Nominee*	For	Number of Shares Against	Abstain
Toby Wegman	4,555,895	544,653	0
Dr. Mark Wegman	4,354,850	645,698	100,000

_____

* The Board is divided into three classes, each of which serves for a term of three years, with only one class of directors being elected in each year. Each director holds office for the term for which elected and until his or her successor shall be elected and shall qualify and be subject to such director s earlier death, resignation or removal. The term of office of the first class of directors, presently consisting of Thomas L. Wegman, Dr. Paul A. Gitman and Dr. Matthew Geller, is scheduled to expire at the 2009 Annual Meeting of Stockholders; the term of office of the second class of directors, presently consisting of Henry Morgan and Michael Schamroth is scheduled to expire on the date of the 2010 Annual Meeting of Stockholders; and the third class of directors, which was elected at our 2008 Annual Meeting of Stockholders, consisting of Toby Wegman and Dr. Mark Wegman is now scheduled to expire at the 2011 Annual Meeting of Stockholders. Dr. Matthew Geller was appointed to the Board on September 22, 2008 to serve in the first class until the end of the applicable term.

Proposal 2: Ratification of the selection of Tabriztchi & Co. CPA, P.C. as our independent registered public accounting firm for the fiscal year ending December 31, 2008.

At the meeting, our stockholders ratified by the vote set forth below the selection of Tabriztchi & Co. CPA, P.C. as our independent registered public accounting firm for the fiscal year ending December 31, 2008.

	Number of Shares		
For	Against	Abstain	Broker Non-Votes
4,661,430	245,713	193,405	0

The number of shares of our common stock eligible to vote as of the record date of July 23, 2008 was 5,950,801 shares.

PART II

Item 5. MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS.

Market Information

Our common stock currently trades under the symbol BSTC on the Nasdaq Global Market (Nasdaq). We were listing and commenced trading on Nasdaq on January 9, 2009. From January 29, 2008 through market close on January 8, 2009, our common stock was quoted and traded on the Over-The-Counter Bulletin Board (the OTCBB) under the symbol BSTC. Prior to January 29, 2008, our common stock was quoted on the Pink Sheets.

The table below sets forth the high and low closing sale prices for our common stock for each of the quarterly periods in 2008 and 2007 as reported by and as quoted in the OTCBB, on which we traded under the symbol BSTC.OB until we obtained listing on Nasdaq:

2008	HIGH	LOW

Fourth Quarter	$22.00	$11.75
Third Quarter	$22.50	$17.00
Second Quarter	$19.00	$11.00
First Quarter	$14.90	$9.50

2007	**HIGH**	**LOW**
Fourth Quarter	$10.25	$5.50
Third Quarter	$6.00	$4.50
Second Quarter	$4.70	$4.10
First Quarter	$4.65	$4.00

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

Holders

As of March 2, 2009, to the best of our knowledge, there were approximately 750 beneficial stockholders of our common stock.

Dividends

It is our current policy to retain potential earnings to finance the growth and development of our business and not 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 the Board may deem relevant.

Transfer Agent

Our common shares are issued in registered form. The registrar and transfer agent for our common shares is OTC Corporate Transfer Service Co., 52 Maple Run Drive, Jericho, New York 11753 (Telephone: 516-932-2080; Facsimile: 516-932-2078; Website: www.otccorporatetransferservice.com). We have no other exchangeable securities.

Equity Compensation Plan Information.

The following table provides information as of December 31, 2008 with respect to the shares of our common stock that may be issued under our existing equity compensation plans:

	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)]	1,427,100	$4.25	194,098
Equity compensation plans not approved by security holders	-	-	-
Total	1,427,100	$4.25	194,098

(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.

Performance Graph

Not applicable.

Recent Sales of Unregistered Securities

The Company engaged in multiple issuances of unregistered securities, as described below.

The Company sold shares of its common stock in the following transactions, in which its shares were offered and sold in reliance on Section 4(2) of the Securities Act of 1933 (the Act) as private placements of securities that are exempt from the registration requirements of the Act. In each of the following transactions the shares were sold to financially sophisticated investors who had access to the sort of information which registration under the Act would disclose. Additionally, no commissions were paid and no general solicitation was made to any person or entity in connection with the sale of the shares in any of the following transactions.

On January 14, 2008, the Company sold 200,000 shares of its common stock in a private placement offering to Apis Capital Advisors LLC on behalf of various funds advised by them at a purchase price of $10.50 per share, for aggregate proceeds to the Company of $2,100,000.

On May 30, 2008, the Company sold 100,000 shares of its common stock in a private placement offering to an investment fund at a purchase price of $13.00 per share, for aggregate proceeds to the Company of $1,300,000.

On June 9, 2008, the Company sold 100,000 shares of its common stock in a private placement offering to certain private investors at a purchase price of $15.00 per share, for aggregate proceeds to the Company of $1,500,000.

On August 19, 2008, the Company sold 50,000 shares of its common stock in a private placement offering to an investment fund at a purchase price of $22.50 per share, for aggregate proceeds to the Company of $1,125,000.

Item 6. SELECTED FINANCIAL DATA

Not applicable.

Item 7. MANAGEMENT S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

This annual report on Form 10-K (the Report) includes forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities and Exchange Act of 1934, as amended. All statements other than statements of historical facts are forward-looking statements for purposes of these provisions, including any projections of earnings, revenues or other financial items, any statements of the plans and objectives of management for future operations, any statements concerning proposed new products or licensing or collaborative arrangements, any statements regarding future economic conditions or performance, and any statement of assumptions underlying any of the foregoing. In some cases, forward-looking statements can be identified by the use of terminology such as may, will, expects, plans, anticipates, estimates, potential, or continue o thereof or other comparable terminology. Although we believe that the expectations reflected in the forward-looking statements contained in this report are reasonable, there can be no assurance that such expectations or any of the forward-looking statements will prove to be correct, and actual results could differ materially from those projected or assumed in the forward-looking statements. Our future financial condition and results of operations, as well as any forward-looking statements, are subject to inherent risks and uncertainties, including but not limited to the risk factors set forth above, and for the reasons described elsewhere in this report. All forward-looking statements and reasons why results may differ included in this report are made as of the date hereof, and we assume no obligation to update these forward-looking statements or reasons why actual results might differ.

Overview

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. (Auxilium) for injectable collagenase (which Auxilium has named XIAFLEX™ (formerly known as AA4500)) for clinical indications in Dupuytren s disease, Peyronie s disease and frozen shoulder (*adhesive capsulitis*), and Auxilium has an option to acquire additional indications that we may pursue, including cellulite and lipomas.

The most advanced indications are for the treatment of Dupuytren s disease, Peyronie s disease and frozen shoulder. On June 3, 2004, we entered into a development and license agreement with Auxilium, as amended on May 10, 2005 and December 15, 2005, respectively (the Prior Auxilium Agreement), pursuant to which we granted to Auxilium an exclusive worldwide license to develop products containing our injectable collagenase for the treatment of Dupuytren s disease, Peyronie's disease and frozen shoulder, as well as an exclusive option to develop and license the technology for use in additional indications other than dermal formulations labeled for topical administration.

On December 11, 2008, the parties amended and restated the development and license agreement (the Auxilium Agreement), which became effective on December 17, 2008 upon the execution and effectiveness of the Development, Commercialization and Supply Agreement, dated December 17, 2008 (the Pfizer Agreement) between Auxilium International Holdings, Inc., a wholly owned subsidiary of Auxilium, and Pfizer, Inc. (Pfizer), pursuant to which Pfizer will market XIAFLEX for the treatment of Dupuytren s disease and Peyronie s disease in Europe and various other territories. The Auxilium Agreement amends and restates in its entirety the Prior Auxilium Agreement.

The Auxilium Agreement and other licensing agreements are discussed more fully in Item 1, under the section titled Licensing and Marketing Agreements.

Outlook

We foresee the potential to generate income from limited sources in the next several years. Under the terms of our agreement with DFB, we are scheduled to receive certain contractual anniversary payments and, if DFB exceeds a certain sales target, we would be entitled to an earn out on sales. Under the terms of our agreement with Auxilium, we may receive milestone payments upon their achieving certain regulatory progress and if Auxilium elects to pursue additional indications for injectable collagenase (Additional Indications) as well as 8.5% of all sublicense income that Auxilium may receive from Pfizer under the Pfizer Agreement.

The Company sold shares of its common stock in the following transactions, in which its shares were offered and sold in reliance on Section 4(2) of the Securities Act of 1933 (the Act) as private placements of securities that are exempt from the registration requirements of the Act.

On January 14, 2008, the Company sold 200,000 shares of it common stock in a private placement offering to Apis Capital Advisors LLC on behalf of various funds advised by them at a purchase price of $10.50 per share, for aggregate proceeds to the Company of $2,100,000.

On May 30, 2008, the Company sold 100,000 shares of it common stock in a private placement offering to an investment fund at a purchase price of $13.00 per share, for aggregate proceeds to the Company of $1,300,000.

On June 9, 2008, the Company sold 100,000 shares of it common stock in a private placement offering to certain private investors at a purchase price of $15.00 per share, for aggregate proceeds to the Company of $1,500,000.

On August 19, 2008, the Company sold 50,000 shares of it common stock in a private placement offering to an investment fund at a purchase price of $22.50 per share, for aggregate proceeds to the Company of $1,125,000.

On February 1, 2008, the Estate of Edwin H. Wegman (the Estate) sold an aggregate of 344,114 shares of the Company's common stock, par value $0.001, at a purchase price of $12.00 per share to certain private investors. The Estate used certain of the proceeds of the transaction to repay the loan owed to the Company by Edwin H. Wegman, our former Chairman and CEO. The total loan repayment amount was $1,116,558, which represents the principal amount of $625,774 owed to the Company and accrued interest through January 31, 2008 of $490,784.

Additionally, on December 11, 2008 the Company and Auxilium entered into the Auxilium Agreement, which became effective on December 17, 2008 upon the execution and effectiveness of the Pfizer Agreement, pursuant to

which Pfizer will market XIAFLEX for the treatment of Dupuytren s disease and Peyronie s disease in Europe and various other territories. The Auxilium Agreement amends and restates in its entirety the Prior Auxilium Agreement. Under the Auxilium Agreement, we recognized in 2008 $6.375 million of the $75 million upfront payment paid to Auxilium by Pfizer and will receive 8.5% of the $410 million in potential additional milestone payments that may be made by Pfizer to Auxilium under the Pfizer Agreement. Of these additional milestones, $150 million are tied to regulatory milestones and $260 million are based on sales milestones.

Based on our current business model, we expect to have adequate cash reserves until at least the first half of 2012 depending on the amount actually owed to Auxilium, as discussed in Item 1A of this Report, Risk Factors. As a significant portion of our revenues is tied directly to the success of Auxilium in commercializing XIAFLEX, we cannot reasonably forecast our financial condition beyond this time.

Significant Risks

In recent history we have had operating losses and may not achieve sustained profitability. As of December 31, 2008 we had an accumulated deficit from continuing operations of $6,428,447.

We are dependent to a significant extent on third parties, and our principal licensee, Auxilium, may not be able to successfully develop products, obtain required regulatory approvals, manufacture products 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.

As of December 31, 2008, we held $0.9 million of taxable auction rate securities, or ARS, which are classified as short-term investments. In October 2008, the Company received notice from UBS of a solution that provided us the option to continue to hold our Auction Rate Securities (ARS) or sell the securities back to UBS at par value plus any accrued interest. On October 24, 2008 we accepted UBS s offer and instructed UBS that we would notify them if and when we want to exercise our rights and sell our ARS to UBS during the period January 2, 2009 through January 4, 2011. In early January 2009, we exercised our rights and instructed UBS to sell all our remaining ARS. On January 6, 2009, we received the remaining principal balance of our investment in auction rate securities of $0.9 million.

Critical Accounting Policies, Estimates and Assumptions

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and the reported amounts of revenues and expenses during the reporting period. These estimates are based on historical experience and on various other assumptions that we believe are reasonable under the circumstances. Actual results could differ from those estimates. While our significant accounting policies are described in more detail in the notes to our consolidated financial statements, we believe the following accounting policies to be critical to the judgments and estimates used in the preparation of our consolidated financial statements.

Revenue Recognition. We recognize revenues from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable, and payment is reasonably assured. We currently recognize revenues resulting from the licensing, sublicensing and use of our technology and from services we sometimes perform in connection with the licensed technology.

We enter into product development licenses, and collaboration agreements that may contain multiple elements, such as upfront license and sublicense fees, and milestones related to the achievement of particular stages in product development and royalties. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple-element arrangement should be treated as separate units of accounting for revenue recognition purposes, and if so, how the aggregate contract value should be allocated among the deliverable elements and when to recognize revenue for each element.

We recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete and, to the extent the milestone amount relates to our performance obligation, when our licensee confirms that we have met the requirements under the terms of the agreement, and when payment is reasonably assured. Changes in the allocation of the contract value between various deliverable elements might impact the timing of revenue recognition, but in any event, would not change the total revenue recognized on the contract.

For example, nonrefundable upfront product license fees, for product candidates where we are providing continuing services related to product development, are deferred and recognized as revenue over the development period.

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

Royalty/Earn-Out Revenue. We recognize royalties under the earn-out provision of the Asset Purchase Agreement with DFB. We have the right to receive earn out payments in the future based on sales of certain products. Generally, under this agreement we would receive royalty payments and a report within ninety (90) days from the end of each calendar year after the licensee has sold the royalty-bearing product. We recognize royalty revenues when we can reliably estimate such amounts and collectibility is reasonably assured.

Consulting and Technical Assistance Services. We recognize revenues from a consulting and technical assistance contracts primarily as a result of our agreements with DFB BioTech, Inc. (DFB) and Auxilium. Consulting revenues are recognized ratably over the term of the contract. The consulting obligations to DFB generally expire during March 2011.

Inventory and Warranty Provisions. Inventories are stated at the lower of cost or realizable market value. In assessing the ultimate realization of inventories, we are required to make judgments as to future demand requirements and compare that with the current inventory levels. In March 2006 we sold our topical collagenase business to DFB, including certain product inventory. As of a result of this sale our product inventory as of December 31, 2008 and 2007 was zero.

Reimbursable Third Party Development Costs. We accrue expenses to research and development and capitalize certain patent costs for estimated third party development costs that are reimbursable under our agreement with Auxilium. Estimates are based on contractual terms, historical development costs, reviewing third party data and expectations regarding future development for certain products. Further, we monitor the activities and clinical trials of our development partners.

If conditions or other circumstances change, we may take actions to revise our reimbursable third party development cost estimates. These revisions could result in an incremental increase in research and development costs. For example, the Auxilium Agreement provides that Auxilium and BioSpecifics will share equally in third party costs for the development of the lyophilization of the injection formulation and patent expenses.

In February 2009, we received an updated invoice from Auxilium for approximately $2.8 million which represents an increase of approximately $0.5 million in the total amount due that Auxilium believes is owed by us through year end 2008 under this provision. The increase in 2008 was primarily due to additional lyophilization costs for the development of the injection formulation of $86,106 and patent and related legal fees of $399,520. Based upon the updated invoice, we changed our estimates for reimbursable third party development and patent cost estimates from approximately $2.3 million to approximately $2.8 million.

Based on our preliminary review, we believe that only a portion of the amounts invoiced actually relates to the development of the lyophilization of the injection formulation as well as for patent and related legal fees, and therefore, reserve all rights related to this matter, including but not limited to our right to contest the amount charged by Auxilium.

Actual results have differed in the past, and may differ in the future, from our estimates and could impact our earnings in any period during which an adjustment is made.

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Stock Based Compensation. On January 1, 2006, we began accounting for employee stock-based compensation in accordance with SFAS 123(R). Under the provisions of SFAS 123(R), we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our common stock and the expected term of the award. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures) and the expected volatility. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change.

Further, SFAS 123(R) 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. Accordingly, in 2008 we recognized employee stock-based compensation as part of our operating expenses and allocated $37,789 to research and development expenses and $1,438,360 to general and administrative expenses.

We account for stock options granted to persons other than employees or directors at fair value using the Black-Scholes option-pricing model in accordance with EITF Issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Stock options granted to such persons and stock options that are modified and continue to vest when an employee has a change in employment status are subject to periodic revaluation over their vesting terms. We recognize the resulting stock-based compensation expense during the service period over which the non-employee provides services to us. The stock-based compensation expense related to non-employees for the year ended December 31, 2008 was $572,424.

RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2008 COMPARED WITH YEAR ENDED DECEMBER 31, 2007

Product Revenues, net

Product revenues include the sales of the API Enzyme recognized at the time it is shipped to customers. We had a small amount of revenue from the sale of collagenase for laboratory use. For the calendar years ended 2008 and 2007 product revenues were $37,343 and $34,357, respectively. This increase of $2,986 or 9% was primarily related to the amount of material required to perform testing and additional research by our customers.

Royalties/Earn-Out

We received all of our royalty revenues from DFB under the earn-out payment provision of the Asset Purchase Agreement. Total royalty revenues recognized under our agreement with DFB were $510,126 and 16,361 for the calendar year 2008 and 2007, respectively. This increase of $493,765 for the calendar year 2008 was due to certain sales levels achieved by DFB in connection with the sale of topical collagenase.

Licensing, Sublicensing and Milestone Revenues

We recognized as licensing, sublicensing and milestone revenue $7,440,125 and $1,157,116 in calendar years 2008 and 2007, respectively. This increase of $6,283,009 or 543% was due to a sublicense fee of $6,375,000 recognized in 2008 partially offset by slightly lower licensing revenue due to the extension of the development timeline for XIAFLEX in Peyronie s disease in connection with the Auxilium Agreement.

Under current accounting guidance, nonrefundable upfront sublicense fees for product candidates where we are not providing continuing services related to product development and have no ongoing performance obligations, are

recognized as revenue when payment can be reasonable assured according to contractual terms.

Nonrefundable upfront license fees for product candidates where we are providing continuing services related to product development, are deferred and recognized as revenue over the development period. The remaining balance will be recognized over the respective development periods or when we determine that we have no ongoing performance obligations.

Consulting Services

We recognize revenues from consulting and technical assistance contracts primarily as a result of the Asset Purchase Agreement and a consulting agreement signed in October 2007 with Auxilium. Consulting revenues are recognized ratably over the term of the contract. The consulting obligations under the Asset Purchase Agreement generally expire during March 2011. For the calendar years 2008 and 2007 consulting revenue recognized was $424,185 and $306,500, respectively. This increase of $117,685 or 38% in consulting revenues was primarily the result of the Auxilium consulting agreement which was completed in June 2008.

Research and Development Activities

Research and development expenses were $439,919 and $2,489,122 respectively, for the calendar years 2008 and 2007, a decrease in calendar year 2008 of $2,049,203 or 82%. The decrease in research and development expenses was primarily due to lower third party development costs in 2008.

General and Administrative Expenses

General and administrative expenses were $4,191,052 and $3,516,716 for the calendar years 2008 and 2007, respectively, which was an increase of $674,336 or 19%. The increase in general and administrative expenses was primarily due to employee stock-based compensation expense, third-party patent fees, legal fees, Nasdaq registration fees and investor relations partially offset by general and administrative personnel cost and consulting expenses.

Other Income and expense, net

Other income, net, for the calendar year 2008 was $262,811compared to other income, net of $1,040 for the 2007 period. Other income, net during the 2008 period was due to interest earned on our investments of $107,552, a reversal of accrued tax penalties of $103,203 and interest of $80,409 associated with our delinquent tax filings and a small gain from the sale of an asset of $5,527 partially offset by interest expense related to our delinquent tax filings of $33,880. Other income, net for the 2007 period was primarily due to interest earned on our investments of $126,821 partially offset by accrued penalties of $105,000 and interest of $20,000, associated with out delinquent tax filings.

Income Taxes

The income tax expense for 2008 was $299,212 as compared to $53,865 for 2007. We accrued approximately $494,234 associated with federal and state taxes based on our net income in 2008 which was partially offset by a tax benefit related to the exercise of stock options of $314,648. After finalizing our delinquent prior year tax filings in 2008, our estimated federal and state tax penalties and interest were reduced by $103,203 and $77,250, respectively, and we recognized a $195,022 tax benefit in connection with our 2007 net operating loss. We have postponed the recognition of a tax benefit of $220,000 for the 2007 period due to net operating loss carrybacks and will request that the Internal Revenue Service apply this amount to our 2008 federal taxes.

Liquidity and Capital Resources

To date, we have financed our operations primarily through product sales, debt instruments, licensing revenues under agreements with third parties and sales of our common stock. At December 31, 2008 and 2007 we had cash, cash equivalents in the aggregate of $3,494,150 and $68,564, respectively.

Continuing Operations

Net cash used in operating activities in the 2008 period was $3,101,055 as compared to net cash used in operating activities in the 2007 period of $3,125,488. In the 2008 period, the change in net cash used in operating activities as

compared to the 2007 period was primarily due to lower operating expenses, an increase in non-cash stock compensation expense, increases in accounts receivable related to revenue recognized from a sublicense fee and earn-out royalties under certain agreements not received until 2009 and accounts payable and accrued expenses.

Net cash used in investing activities in the 2008 period was $1,167,000 as compared to cash used in investing activities of $975,000 in the 2007 period. Net cash used in investing activities in the 2008 period reflect our investment in marketable securities of $2,000,000, a one-time cash payment related to our future royalty obligations for Peyronie's disease of $1,250,000 and by the sale or maturity of marketable securities of $2,075,000. Net cash provided by investing activities in the 2007 was due to purchases of short-term investments.

Net cash provided by financing activities for 2008 was $7,693,641 as compared to the 2007 period of $122,912. The increase in net cash provided by financing activities for the 2008 consisted of proceeds from the sale of our common stock of $6,007,047, repayment of an outstanding loan from our former Chairman and CEO of $1,116,558, $314,648 related to excess tax benefits from share-based payment arrangements and proceeds received from stock option exercises of $255,388. Net cash provided by financing activities in the 2007 period was from proceeds received from stock option exercises.

Discontinued Operations

Cash flow changes from discontinued operations are primarily due to the operating results of ABC-Curacao and certain operations of ABC-NY, which have been classified as discontinued operations.

Net cash used in operating activities from discontinued operations in the 2008 period was zero as compared to net cash provided by operating activities from discontinued operations in the 2007 period of $321,038. The net cash used in the 2007 period was primarily due to the payment of accrued payroll taxes from previous periods on our Curacao operations.

Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.

Not applicable.

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(T). CONTROLS AND PROCEDURES.

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

A material weakness is a control deficiency, or combination of control deficiencies (within the meaning of Public Company Accounting Oversight Board Auditing Standard No. 2), that results in there being more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis by employees in the normal course of their assigned functions. Management has identified the

following material weaknesses in our internal control over financial reporting as of December 31, 2008: certain non-executive employees of the Company sold shares of the Company s common stock prior to obtaining pre-clearance in accordance with the Company s insider trading policy. Management has taken steps to remind all of its non-executive employees that all transactions in the Company s securities must be pre-cleared, regardless of whether such transactions occur during an open trading window. Additionally, management has identified the following non-material weakness: the Company had not filed either its federal or state corporate tax returns since the calendar year 2002 but had paid the estimated franchise tax due to New York State. In September 2008, we filed our delinquent federal and state tax returns for the years ended 2003, 2004, 2005, 2006 and 2007.

Management s Annual Report on Internal Control Over Financial Reporting

Management of the Company 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 of directors 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, 2008. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in *Internal Control Integrated Framework*. We believe that, as of December 31, 2008, the Company s internal control over financial reporting is not effective based on this criteria, due to the material weakness identified by management and discussed above in Item 9A(T).

This Report does not include an attestation report of the Company s registered public accounting firm regarding internal control over financial reporting. Management s report was not subject to attestation by the Company s registered public accounting firm pursuant to temporary rules of the SEC that permit the Company to provide only management s report in this Report.

Changes in Internal Control Over Financial Reporting

There were no changes in the Company s internal control over financial reporting in the year ended December 31, 2008 that materially affected, or are reasonably likely to materially affect, the Company s internal control over financial reporting.

Item 9B. OTHER INFORMATION

On October 1, 2008, the Company entered into a change of control agreement with Dr. Matthew Geller, who was appointed to serve as an independent director of the Company on September 22, 2008. The agreement follows the Company s standard change of control agreement for independent directors. Dr. Matthew Geller s change of control agreement is filed as Exhibit 10.23 to this Form 10-K. The foregoing descriptions of the agreement do not purport to be complete and are qualified in their entirety by reference to the full text of the agreement.

PART III

Item 10. DIRECTORS AND EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT

The information required by this item is incorporated herein by reference to the sections captioned Directors and Executive Officers, Committees of the Board of Directors, and Section 16(a) Beneficial Ownership Reporting Compliance in our definitive Proxy Statement relating to our 2009 Annual Meeting of Stockholders.

We have adopted an Amended and Restated Code of Business Conduct and Ethics (Code of Ethics) that applies to all of our directors, officers and employees. Our Code of Ethics contains provisions that satisfy the standards for a code of ethics set forth in Item 406 of Regulation S-K of the rules and regulations of the SEC. Our Code of Conduct is available under the heading Investor Relations Corporate Governance on our Internet Web site, the address of which is www.biospecifics.com. The information contained on our Internet Web site is not incorporated by reference into

this Report and should not be considered part of this or any other report that we file with or furnish to the SEC.

To the extent that we amend any provision of our Code of Ethics or grant a waiver from any provision of our Code of Ethics that is applicable to any of our directors or our principal executive officer, principal financial officer, principal accounting officer or controller or persons performing similar functions, we intend to satisfy our disclosure obligations under applicable SEC rules by posting such information on our Internet Web site under the heading Investor Relations Corporate Governance.

Item 11. EXECUTIVE COMPENSATION.

The information required by this item is incorporated herein by reference to the section captioned Executive Compensation in our definitive Proxy Statement relating to our 2009 Annual Meeting of Stockholders.

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

The information required by this item is incorporated herein by reference to the sections captioned Security Ownership of Certain Beneficial Owners and Management and Equity Compensation Plan Information in our definitive Proxy Statement relating to our 2009 Annual Meeting of Stockholders.

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

The information required by this item is incorporated herein by reference to the section captioned Certain Relationships and Related Transactions in our definitive Proxy Statement relating to our 2009 Annual Meeting of Stockholders.

Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item is incorporated herein by reference to the section captioned Ratification of Selection of Independent Registered Public Accounting Firm in our definitive Proxy Statement relating to our 2009 Annual Meeting of Stockholders.

PART IV

Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.

(a) The following documents are filed as part of this 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.

BIOSPECIFICS TECHNOLOGIES CORP.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2008

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have audited the accompanying balance sheets of BioSpecifics Technologies Corp. (the Company) as of December 31, 2008 and 2007, and the related statements of operations, stockholders' equity (deficit), and cash flows for each of the two years in the period ended December 31, 2008. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2008 and 2007, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

/s/Tabriztchi & Co., CPA, P.C.
Garden City, NY March 25, 2009

7 Twelfth Street Garden City, NY 11530 Tel: 516-746-4200 Fax: 516-746-7900
Email:Info@Tabrizcpa.com www.Tabrizcpa.com

BioSpecifics Technologies Corp.
Consolidated Balance Sheet
December 31,

	2008	2007
Assets		
Current assets:		
Cash and cash equivalents	$ 3,494,150	$ 68,564
Short term investments	900,000	975,000
Accounts receivable, net	6,952,781	108,809
Prepaid expenses and other current assets	67,709	73,158
Total current assets	**11,414,640**	**1,225,531**
Deferred royalty buy-down	1,250,000	-
Property, plant and equipment, net	2,297	35,680
Patent costs, net	164,424	-
Total assets	**12,831,361**	**1,261,211**
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable and accrued expenses	642,465	873,460
Accrued tax liability	-	453,553
Deferred revenue	1,271,792	1,437,116
Accrued liabilities of discontinued operations	78,138	78,138
Total current liabilities	**1,992,395**	**2,842,267**
Accrued third party development expenses	2,758,595	2,272,969
Deferred revenue - license fees	1,901,832	2,881,633
Stockholders' equity (deficit):		
Series A Preferred stock, $.50 par value, 700,000 shares authorized;		
none outstanding	-	-
Common stock, $.001 par value; 10,000,000 shares authorized;		
6,140,068 and 5,480,768 shares issued and outstanding at December 31, 2008 and 2007, respectively	6,140	5,481
Additional paid-in capital	13,294,803	4,751,447
Accumulated deficit	(6,428,447)	(10,172,855)
Treasury stock, 131,267 shares at cost as of December 31, 2008 and 2007	(693,957)	(693,957)
Notes receivable from former Chairman and CEO and other related party	-	(625,774)
Total stockholders' equity (deficit)	**6,178,539**	**(6,735,658)**
Total liabilities and stockholders equity (deficit)	**$ 12,831,361**	**$ 1,261,211**

BioSpecifics Technologies Corp.
Consolidated Statements of Operations
Years Ended December 31,

		2008		2007
Revenues:				
Net sales	$	37,343	$	34,357
Royalties		510,127		16,361
Licensing fees		7,440,125		1,157,116
Consulting fees		424,185		306,500
Total revenues		8,411,780		1,514,334
Costs and expenses:				
Research and development		439,919		2,489,122
General and administrative		4,191,052		3,516,716
Total costs and expenses		4,630,971		6,005,838
Operating income (loss)		**3,780,809**		**(4,491,504)**
Other income (expense):				
Interest income		107,552		126,821
Interest expense		(33,880)		(781)
Other income (expense)		189,139		(125,000)
		262,811		1,040
Income (loss) before expense for income tax		4,043,620		(4,490,464)
Income tax expense		(299,212)		(53,865)
Net income (loss)	**$**	**3,744,408**	**$**	**(4,544,329)**
Basic net income (loss) per share	**$**	**0.64**	**$**	**(0.86)**
Diluted net income (loss) per share	**$**	**0.55**	**$**	**(0.86)**
Shares used in computation of basic net income (loss) per share		**5,854,836**		**5,291,506**
Shares used in computation of diluted net income (loss) per share		**6,836,911**		**5,291,506**

BioSpecifics Technologies Corp.
Consolidated Statements of Cash Flows
Years Ended December 31,

	2008	2007
Cash flows from operating activities:		
Net income (loss)	**$ 3,744,408**	**$ (4,544,329)**
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	55,774	32,144
Gain on disposal of fixed assets	(5,535)	-
Stock-based compensation expense	1,476,148	650,160
Changes in operating assets and liabilities:		
Accounts receivable	(6,843,974)	(57,685)
Prepaid expenses and other current assets	5,449	(28,745)
Accounts payable and accrued expenses	(388,200)	1,885,084
Deferred revenue	(1,145,125)	(1,062,117)
Net cash used in operating activities from continuing operations	**(3,101,055)**	**(3,125,488)**
Net cash used in discontinued operations	**-**	**(321,038)**
Cash flows from investing activities:		
Maturities of marketable securities	2,075,000	-
Purchases of marketable securities	(2,000,000)	(975,000)
Payment for royalty buy down	(1,250,000)	-
Proceeds from sale of fixed asset	8,000	-
Net cash used in investing activities from continuing operations	**(1,167,000)**	**(975,000)**
Cash flows from financing activities:		
Proceeds from issuance of capital stock	6,007,047	-
Proceeds from stock option exercises	255,388	122,912
Excess tax benefits from share-based payment arrangements	314,648	-
Proceeds from pay-off of notes receivable from former CEO and Chairman	1,116,558	-
Net cash provided by financing activities from continuing operations	**7,693,641**	**122,912**
Increase (decrease) in cash and cash equivalents	3,425,586	(4,298,614)
Cash and cash equivalents at beginning of year	68,564	4,367,178
Cash and cash equivalents at end of year	**$ 3,494,150**	**$ 68,564**
Supplemental disclosures of cash flow information:		
Cash paid during the year for:		
Interest	$ 33,880	$ 781
Taxes	$ 225,824	$ 3,600

Supplemental disclosures of non-cash transactions:

Under our agreement with Auxilium certain patent costs paid by Auxilium on behalf of the Company are creditable against future royalties. As of December 31, 2008 we accrued $189,280 related to this issue of which $24,856 was amortized in the 2008 period.

In March 2007, in full repayment of the $304,398 loan owed to the Company by Wilbur Street Corporation (WSC), WSC offset $304,398 in back rent due from the Company. The transaction was recorded by reducing the rent payable by $304,398 and the receivable from the former CEO and Chairman by $98,253 and increasing additional paid in capital by $206,145.

See accompanying notes to consolidated financial statements

BioSpecifics Technologies Corp.
Consolidated Statements of Stockholders' Equity (Deficit)

	Shares	Amount	Additional Paid in Capital	Accumulated Deficit
Balances - December 31, 2006	**5,365,816**	**$ 5,366**	**$ 3,772,345**	**$ (5,628,526)**
Issuance of common stock under stock option plans	114,952	115	122,797	-
Stock compensation expense	-	-	650,160	-
Offset of former CEO and Chairman loan principal and interest	-	-	206,145	-
Net loss	-	-	-	(4,544,329)
Balances - December 31, 2007	**5,480,768**	**$ 5,481**	**$ 4,751,447**	**$ (10,172,855)**
Issuance of common stock at $10.50 to a private investor, net of issuance costs	200,000	200	2,093,450	-
Issuance of common stock at $13.00 to a private investor, net of issuance costs	100,000	100	1,299,900	-
Issuance of common stock at $15.00 to a private investor, net of issuance costs	100,000	100	1,488,929	-
Issuance of common stock at $22.50 to a private investor, net of issuance costs	50,000	50	1,124,318	-
Issuance of common stock under stock option plans	209,300	209	255,178	
Tax benefit from exercised stock options	-	-	314,648	-
Stock compensation expense	-	-	1,476,149	-
Payment from former CEO and Chairman loan principal and interest	-	-	490,784	-
Net income	-	-	-	3,744,408
Balances - December 31, 2008	**6,140,068**	**$ 6,140**	**$ 13,294,803**	**$ (6,428,447)**

	Treasury Stock	Due from former Chairman and CEO	Shareholder Equity (Deficit) Total
Balances - December 31, 2006	**(693,957)**	**$ (724,027)**	**$ (3,268,799)**
Issuance of common stock under stock option plans	-	-	122,912
Stock compensation expense	-	-	650,160
Offset of former CEO and Chairman loan principal and interest	-	98,253	304,398
Net loss	-	-	(4,544,329)
Balances - December 31, 2007	**(693,957)**	**$ (625,774)**	**$ (6,735,658)**
Issuance of common stock at $10.50 to a private investor, net of issuance costs	-	-	2,093,650
Issuance of common stock at $13.00 to a private investor, net of issuance costs	-	-	1,300,000
Issuance of common stock at $15.00 to a private investor, net of issuance costs	-	-	1,489,029
Issuance of common stock at $22.50 to a private investor, net of issuance costs	-	-	1,124,368
Issuance of common stock under stock option plans	-	-	255,387
Tax benefit of exercised stock options	-	-	314,648
Stock compensation expense	-	-	1,476,149
Payment from former CEO and Chairman loan principal and interest	-	625,774	1,116,558
Net income	-	-	3,744,408
Balances - December 31, 2008	**(693,957)**	**$ -**	**$ 6,178,539**

BIOSPECIFICS TECHNOLOGIES CORP.

Notes to Consolidated Financial Statements
December 31, 2008 and 2007

1. ORGANIZATION AND DESCRIPTION OF BUSINESS

We are a biopharmaceutical company involved in the development of an injectable collagenase for multiple indications. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. (Auxilium) for injectable collagenase (which Auxilium has named XIAFLEX™ (formerly known as AA4500)) for clinical indications in Dupuytren s disease, Peyronie s disease and frozen shoulder (*adhesive capsulitis*), and Auxilium has an option to acquire additional indications that we may pursue, including cellulite and lipomas.

The most advanced indications are for the treatment of Dupuytren s disease, Peyronie s disease and frozen shoulder. On June 3, 2004, we entered into a development and license agreement with Auxilium, as amended on May 5, 2005 and December 15, 2005, respectively (the Prior Auxilium Agreement), pursuant to which we granted to Auxilium an exclusive worldwide license to develop products containing our injectable collagenase for the treatment of Dupuytren s disease, Peyronie's disease and frozen shoulder, as well as an exclusive option to develop and license the technology for use in additional indications other than dermal formulations labeled for topical administration.

On December 11, 2008, the parties amended and restated the development and license agreement (the Auxilium Agreement), which became effective on December 17, 2008 upon the execution and effectiveness of the Development, Commercialization and Supply Agreement, dated December 17, 2008 (the Pfizer Agreement) between Auxilium International Holdings, Inc., a wholly owned subsidiary of Auxilium, and Pfizer, Inc. (Pfizer), pursuant to which Pfizer will market XIAFLEX for the treatment of Dupuytren s disease and Peyronie s disease in Europe and various other territories. The Auxilium Agreement amends and restates in its entirety the Prior Auxilium Agreement.

DISCONTINUED OPERATIONS

Prior to March 2006, we were a party to an exclusive license agreement with Abbott Laboratories, Inc. and its subsidiaries (Abbott), for the production of the active pharmaceutical ingredient (API or API Enzyme) for topica collagenase. In March 2006 we sold our topical collagenase business to DFB Biotech, Inc. and its affiliates (DFB), including all rights to the exclusive license agreement and we were released of any obligations thereunder.

In addition, DFB acquired all of the issued and outstanding shares of ABC-Curacao, pursuant to an asset purchase agreement between us, DFB and ABC-NY (the Asset Purchase Agreement). ABC-Curacao manufactured the API Enzyme, which in its final formulation was marketed by Abbott. The operating results of ABC-Curacao and certain operations of ABC-NY have been classified as discontinued operations in the Consolidated Financial Statements for all periods presented.

In addition, at the closing of the Asset Purchase Agreement, DFB (i) acquired from us certain inventory and manufacturing equipment used in the topical collagenase business, (ii) was granted a perpetual royalty free license to use, solely in connection with the topical collagenase business, certain intangible assets retained by us and (iii) was granted the right (for a limited period of time which was subsequently extended in April 2008) to use, solely in connection with the topical collagenase business, certain tangible assets retained by us. As part of the sale, we transferred to DFB our FDA manufacturing license.

As consideration for the purchased assets we received $8 million in cash, DFB s assumption of certain liabilities, and the right to receive earn out payments in the future based on sales of certain products. In connection with the closing of the Asset Purchase Agreement, we agreed to provide certain technical assistance and certain transition services to DFB in consideration of fees and costs totaling over $1.4 million. At the closing, DFB paid to us a partial payment of

$400,000 in respect of the technical assistance to be provided by us. As of December 31, 2008, we have received a total of $1,000,000 payments from DFB. The consulting obligations generally expire during March 2011.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The audited consolidated financial statements include the accounts of the Company and its subsidiary, ABC-NY. Due to the sale of ABC-Curacao in March 2006 to DFB all accounts of this former subsidiary and certain operations of ABC-NY are classified as discontinued operations in all periods presented.

Management Estimates

The preparation of consolidated financial statements in conformity with accounting principles generally accepted in the U.S. requires the use of management s estimates and assumptions that affect the amounts reported in the consolidated financial statements and accompanying notes. Actual results could differ from those estimates.

Cash, Cash Equivalents and Short-term Investments

Cash, cash equivalents and short-term investments are stated at market value. Cash equivalents include only securities having a maturity of three months or less at the time of purchase. The Company limits its credit risk associated with cash, cash equivalents and short-term investments by placing its investments with banks it believes are highly creditworthy and with highly rated money market funds, U.S. government securities, or short-term commercial paper.

Fair Value Measurements

SFAS 157 requires expanded disclosures about fair value measurements. SFAS 157 applies to other accounting pronouncements that require or permit fair value measurements, but does not require any new fair value measurements. We adopted the provisions of SFAS 157 relating to assets and liabilities recognized or disclosed in the financial statements at fair value on a recurring basis on January 1, 2008. The adoption of these provisions did not have a material effect on our consolidated financial statements.

SFAS 157 clarifies that fair value is an exit price, representing the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants based on the highest and best use of the asset or liability. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. SFAS 157 requires us to use valuation techniques to measure fair value that maximize the use of observable inputs and minimize the use of unobservable inputs. These inputs are prioritized as follows:

- Level 1: Observable inputs such as quoted prices for identical assets or liabilities in active markets
- Level 2: Other inputs that are observable directly or indirectly, such as quoted prices for similar assets or liabilities or market-corroborated inputs
- Level 3: Unobservable inputs for which there is little or no market data and which require us to develop our own assumptions about how market participants would price the assets or liabilities

The following table sets forth the fair value of our financial assets that were measured on a recurring basis as of December 31, 2008:

	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 3,494,150	-	-
Auction rate securities	$ 900,000	-	-

Auction Rate Securities

As of December 31, 2008, we held $0.9 million of taxable auction rate securities, or ARS, which are classified as short-term investments. In October 2008, the Company received notice from UBS of a solution that provided us the option to continue to hold our Auction Rate Securities (ARS) or sell the securities back to UBS at par value plus any accrued interest. On October 24, 2008 we accepted UBS s offer and instructed UBS that we would notify them if and when we want to exercise our rights and sell our ARS to UBS during the period January 2, 2009 through January 4, 2011. In early January 2009, we exercised our rights and instructed UBS to sell all our remaining ARS. On January 5, 2009, we received the remaining principal balance of our investment in auction rate securities of $0.9 million.

Revenue Recognition

We currently recognize revenues resulting from product sales and royalties from licensing, sublicensing and use of our technology, and from other services we sometimes perform in connection with the licensed technology under the guidance of Staff Accounting Bulletin (SAB) No. 104, Revenue Recognition.

If we determine that separate elements exist in a revenue arrangement under Emerging Issues Task Force Issue No. 00-21, Revenue Arrangements with Multiple Deliverables (EITF 00-21), we recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete, when payment is reasonably assured and, to the extent the milestone amount relates to our performance obligation, when our customer confirms that we have met the requirements under the terms of the agreement.

Revenues, and their respective treatment for financial reporting purposes, are as follows:

Product Sales

We recognize revenue from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed or determinable and collectability is reasonably assured. No right of return exists for our products except in the case of damaged goods. To date, we have not experienced any significant returns of our products.

Net sales include the sales of the API Enzyme that are recognized at the time the product is shipped to customers for laboratory use.

Royalty/Earn-Out Revenue

We recognize royalties under the earn-out provision of the Asset Purchase Agreement with DFB. We have the right to receive earn out payments in the future based on sales of certain products. Generally, under this agreement we would receive royalty payments and a report within ninety (90) days from the end of each calendar year after the licensee has sold the royalty-bearing product. We recognize royalty revenues when we can reliably estimate such amounts and collectability is reasonably assured.

License and Sublicense Fees

We include revenue recognized from upfront licensing, sublicensing and milestone payments in License Fees in our consolidated statements of operations in this Report.

Upfront License and Sublicensing Fees

We generally recognize revenue from upfront licensing and sublicensing fees when the agreement is signed, we have completed the earnings process and we have no ongoing performance obligation with respect to the arrangement. Nonrefundable upfront technology license for product candidates for which we are providing continuing services related to product development are deferred and recognized as revenue over the development period.

Milestones

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

revenue in a manner similar to that of an upfront license fee.

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

Accounts receivable and Allowance for Doubtful Accounts

The Company performs ongoing credit evaluations of its customers and maintains allowances for potential credit losses which when realized have been within the range of management s expectations. Our policy is to write off bad debts as uncollectible when it is determined that they cannot be collected.

As of December 31, 2008, accounts receivables include $6,375,000 due from Auxilium in accordance with the terms of the Auxilium Agreement for an upfront sublicense fee.

Reimbursable Third Party Development Costs

We accrue expenses to research and development for estimated third party development costs and capitalize certain patent costs that are reimbursable under our agreement with Auxilium. Estimates are based on contractual terms, historical development costs, reviewing third party data and expectations regarding future development for certain products. Further, we monitor the activities and clinical trials of our development partners.

If conditions or other circumstances change, we may take actions to revise our reimbursable third party development cost estimates. These revisions could result in an incremental increase in research and development costs. For example, the Auxilium Agreement provides that Auxilium and BioSpecifics will share equally in third party costs for the development of the lyophilization of the injection formulation and certain patent fees.

In February 2009, we received an updated invoice from Auxilium for approximately $2.8 million which represents an increase of approximately $0.5 million in the total amount due that Auxilium believes is owed by us through year end 2008 under this provision. The increase in 2008 was primarily due to additional lyophilization costs for the development of the injection formulation of $86,106 and patent and related legal fees of $399,520. Based upon the updated invoice, we changed our estimates for reimbursable third party development and patent cost estimates from approximately $2.3 million to approximately $2.8 million.

Based on our preliminary review, we believe that only a portion of the amount charged actually relates to the development of the lyophilization of the injection formulation as well as for patent and related legal fees and, therefore, reserve all rights related to this matter, including but not limited to our right to contest the amount charged by Auxilium.

Actual results have differed in the past, and may differ in the future, from our estimates and could impact our earnings in any period during which an adjustment is made.

Research and Development Expenses

Our research and development (R&D) costs are expensed as incurred. R&D includes, but is not limited to, internal costs, such as salaries and benefits, costs of materials, lab expense, facility costs and overhead. R&D also consists of

third party costs, such as medical professional fees, contract manufacturing costs for material used in clinical trials, consulting fees and costs associated with clinical study R&D arrangements. We fund R&D at medical research institutions under agreements that are generally cancelable. All of these costs are charged to R&D as incurred, which may be measured by percentage of completion, contract milestones, patient enrollment, or the passage of time.

Clinical Trial Expenses

Our cost accruals for clinical trials are based on estimates of the services received and efforts expended pursuant to contracts with various clinical trial centers and clinical research organizations. In the normal course of business we contract with third parties to perform various clinical trial activities in the ongoing development of potential drugs. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, the completion of portions of the clinical trial, or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual cost of services received and efforts expended. As such, expenses related to each patient enrolled in a clinical trial are recognized ratably beginning upon entry into the trial and over the course of the patient s continued participation in the trial. In the event of early termination of a clinical trial, we accrue an amount based on our estimate of the remaining non-cancelable obligations associated with the winding down of the clinical trial. Our estimates and assumptions could differ significantly from the amounts that may actually be incurred.

Stock Based Compensation

The Company has two stock-based compensation plans in effect which are described more fully in Note 12. Effective January 1, 2006, we adopted SFAS No. 123, Share-Based Payment (Revised 2004) (SFAS 123(R)), which supersedes our previous accounting under Accounting Principles Board Opinion No. 25, Accounting for Stock Issued to Employees (APB 25), and related interpretations. SFAS 123(R) requires the recognition of compensation expense, using a fair-value based method, for costs related to all share-based awards including stock options and common stock issued to our employees and directors under our stock plans. It requires companies to estimate the fair value of share-based awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense on a straight-line basis over the requisite service periods in our Consolidated Statements of Operations.

Under the provisions of Statement SFAS 123(R), we estimate the fair value of our employees and directors stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our common stock and the expected term of the award. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures) and the expected volatility. As required under the accounting rules, we review our valuation assumptions at each grant date and, as a result, our valuation assumptions used to value employee stock-based awards granted in future periods may change. The ranges of valuation assumptions used were as follows:

	Year Ended December 31, 2008	Year Ended December 31, 2007
Stock Option Plans		
Expected life, in years	5.0	5.0
Risk free interest rate	1.9%-2.9%	4.9%
Volatility	61% - 80%	62% - 151%
Dividend yield		

Further, SFAS 123(R) 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 SFAS 123(R) was as follows:

	December 31,	
	2008	**2007**
Research and development	$ 37,789	$ 14,197
General and administrative	865,936	409,422
Total stock-based compensation expense	**$ 903,725**	**$ 423,619**

We account for stock options granted to persons other than employees or directors at fair value using the Black-Scholes option-pricing model in accordance with EITF Issue No. 96-18, Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services. Stock options granted to such persons and stock options that are modified and continue to vest when an employee has a change in employment status are subject to periodic revaluation over their vesting terms. We recognize the resulting stock-based compensation expense during the service period over which the non-employee provides services to us. The stock-based compensation expense related to non-employees for the years ended December 31, 2008 and 2007 was $572,424 and $226,541, respectively.

Property, Plant and Equipment

Property, plant and equipment are stated at cost, less accumulated depreciation. Machinery and equipment, furniture and fixtures, and autos are depreciated on the straight-line basis over their estimated useful lives of 5 to 10 years. Leasehold improvements are being amortized over the lesser of their estimated useful lives or the life of the lease, which is approximately 8 to 10 years.

Patent Costs

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 5 to 13 years, and review for impairment on a quarterly basis and when events or changes in circumstances indicate that the carrying amount of such assets may not be recoverable.

As of December 31, 2008, the Company capitalized certain patent costs, paid by Auxilium on behalf of the Company. These costs are reimbursable to Auxilium under our agreement and are creditable against future royalty revenues. At December 31, patent costs consisted of:

	2008	**2007**
Patents	$ 164,424	$ -

The amortization expense for patents was $24,856, for the year ended December 31, 2008. The estimated aggregate amortization expense for each of the next five years is as follows:

2009	$ 24,856
2010	24,856
2011	24,856
2012	23,033
2013	21,209

Income Taxes

The Company uses the liability method of accounting for income taxes, as set forth in Statement of Financial Accounting Standards No. 109, Accounting for Income Taxes. Under this method, deferred income taxes, when required, are provided on the basis of the difference between the financial reporting and income tax bases of assets and liabilities at the statutory rates enacted for future periods.

Recent Accounting Pronouncements

In February 2007, the FASB issued SFAS No. 159, The Fair Value Option for Financial Assets and Financial Liabilities, or SFAS 159, which provides companies with an option to report selected financial assets and liabilities at fair value. SFAS 159 establishes presentation and disclosure requirements designed to facilitate comparisons between companies that choose different measurement attributes for similar types of assets and liabilities and highlights the effect of a company s choice to use fair value on its earnings. It also requires a company to display the fair value of those assets and liabilities for which it has chosen to use fair value on the face of the balance sheet. SFAS 159 was effective for us beginning January 1, 2008 and did not have an impact on our consolidated financial statements as we did not choose to use the fair value option.

In June 2007, the FASB ratified Emerging Issues Task Force, or EITF, Issue No. 07-3, Accounting for Non-Refundable Advance Payments for Goods or Services to be Used in Future Research and Development Activities, or EITF 07-3, which provides that non-refundable advance payments for future research and development activities should be deferred and capitalized until the related goods are delivered or the related services are performed. EITF 07-3 was effective for us on a prospective basis beginning January 1, 2008 and did not have a material impact on our consolidated financial statements.

In December 2007, the FASB ratified EITF Issue No. 07-1, Accounting for Collaborative Arrangements Related to the Development and Commercialization of Intellectual Property, or EITF 07-1, which provides guidance on how the parties to a collaborative agreement should account for costs incurred and revenue generated on sales to third parties, how sharing payments pursuant to a collaboration agreement should be presented in the income statement and certain related disclosure requirements. EITF 07-1 will be effective for us beginning January 1, 2009 on a retrospective basis. We currently do not expect that the adoption of EITF 07-1 will have a material impact on our consolidated financial statements.

In December 2007, the FASB issued SFAS No. 141R, Business Combinations, or SFAS 141R, which replaces FASB Statement No. 141, Business Combinations, and requires an acquirer to recognize the assets acquired, the liabilities assumed and any noncontrolling interest in the acquiree at the acquisition date, measured at their fair values as of that date, with limited exceptions specified in SFAS 141R. SFAS 141R amended SFAS No. 109, Accounting for Income Taxes, or SFAS 109, and FASB Interpretation No. 48, Accounting for Uncertainty in Income Taxes an Interpretation of FASB Statement No. 109, or FIN 48. Previously, SFAS 109 and FIN 48, respectively, generally required post-acquisition adjustments to a business combination related deferred tax asset valuation allowance and liabilities related to uncertain tax positions to be recorded as an increase or decrease to goodwill. SFAS 141R does not permit this accounting and generally will require any such changes to be recorded in current period income tax expense. Thus, after SFAS 141R is adopted, all changes to valuation allowances and liabilities related to uncertain tax positions from an acquisition (whether the combination was accounted for under SFAS 141 or SFAS 141R) must be recognized in current period income tax expense. SFAS 141R is effective prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. SFAS 141R is effective for us beginning January 1, 2009 and we will account for future business combinations in accordance with its provisions, in addition to adopting its provisions related to post-acquisition adjustments to taxes.

In December 2007, the FASB issued SFAS No. 160, Noncontrolling Interests in Consolidated Financial Statements, an Amendment of ARB No. 51, or SFAS 160, which changes the accounting for and reporting of noncontrolling interests (formerly known as minority interests) in consolidated financial statements. It is effective for financial statements issued for fiscal years and interim periods beginning after December 15, 2008, with early adoption prohibited. Upon implementation, prior periods will be recast for the changes required by SFAS 160. We currently do not expect that the adoption of SFAS 160 will have a material impact on our consolidated financial statements.

In March 2008, the FASB issued SFAS No. 161, Disclosures about Derivative Instruments and Hedging Activities, or SFAS 161, which is intended to improve financial reporting about derivative instruments and hedging activities by requiring enhanced disclosures to enable investors to better understand their effects on an entity s financial position, financial performance and cash flows. It is effective for financial statements issued for fiscal years and interim periods beginning after November 15, 2008, with early adoption encouraged. SFAS 161 is effective for us during the interim period beginning January 1, 2009 and we will adopt the disclosure provisions in our financial statements as of March 31, 2009.

In April 2008, the FASB issued FASB Staff Position, or FSP, No. FAS 142-3, Determination of the Useful Life of Intangible Assets, or FSP FAS 142-3. FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, Goodwill and Other Intangible Assets. FSP FAS142-3 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. We currently do not expect that the adoption of FSP FAS 142-3 will have a material impact on our consolidated financial statements.

In May 2008, the FASB issued FSP No. APB 14-1, Accounting for Convertible Debt Instruments That May Be Settled in Cash upon Conversion (Including Partial Cash Settlement), or FSP APB 14-1, which requires separate accounting for the debt and equity components of convertible debt issuances that have a cash settlement feature permitting settlement partially or fully in cash upon conversion. A component of such debt issuances representative of the approximate fair value of the conversion feature at inception should be bifurcated and recorded to equity, with the resulting debt discount amortized to interest expense in a manner that reflects the issuer s nonconvertible, unsecured debt borrowing rate. The requirements for separate accounting must be applied retrospectively to previously issued convertible debt issuances as well as prospectively to newly issued convertible debt issuances, negatively affecting both net income and earnings per share, in financial statements issued for fiscal years beginning after December 15, 2008. The adoption of FSP APB 14-1 will not have any impact on our consolidated financial statements.

In May 2008, the FASB issued SFAS No. 162, The Hierarchy of Generally Accepted Accounting Principles or SFAS No. 162. SFAS No. 162 identifies the sources of accounting principles and the framework for selecting the principles used in the preparation of financial statements of nongovernmental entities that are presented in conformity with GAAP. This statement shall be effective 60 days following the Securities and Exchange Commission s (SEC or the Commission) approval of the Public Company Accounting Oversight Board amendments to AU Section 411, The Meaning of Present Fairly in Conformity With Generally Accepted Accounting Principles. The Company does not believe that implementation of this standard will have a material impact on its consolidated financial position, results of operations or cash flows.

In June 2008, the FASB issued FSP EITF No. 03-6-1, Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities, or FSP EITF 03-6-1. The FSP addresses whether instruments granted in share-based payment transactions are participating securities prior to vesting and therefore need to be included in the earnings allocation in calculating earnings per share under the two-class method described in SFAS No. 128, Earnings per Share. The FSP requires companies to treat unvested share-based payment awards that have non-forfeitable rights to dividends or dividend equivalents as a separate class of securities in calculating earnings per share. The FSP is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. The adoption of FSP EITF 03-6-1 will not have any impact on our consolidated financial statements.

In October 2008, the FASB issued FSP No. FAS 157-3, Determining the Fair Value of a Financial Asset When the Market for That Asset Is Not Active, or FSP FAS 157-3. The FSP clarifies the application of FASB Statement No. 157 in a market that is not active and provides an example to illustrate key considerations in determining the fair value of a financial asset when the market for that financial asset is not active. The FSP was effective upon issuance, including prior periods for which financial statements have not been issued and did not have a material impact on our financial statements.

In November 2008, the FASB ratified EITF Issue No. 08-6, Equity Method Investment Accounting Considerations, or EITF 08-6, which clarifies the accounting for certain transactions and impairment considerations involving equity method investments. EITF 08-6 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. We currently do not expect that the adoption of EITF 08-6 will have a material impact on our consolidated financial statements.

In November 2008, the FASB ratified EITF Issue No. 08-7, Accounting for Defensive Intangible Assets, or EITF 08-7, which clarifies the accounting for certain separately identifiable intangible assets which an acquirer does not

intend to actively use but intends to hold to prevent its competitors from obtaining access to them. EITF 08-7 requires an acquirer in a business combination to account for a defensive intangible asset as a separate unit of accounting which should be amortized to expense over the period the asset diminishes in value. EITF 08-7 is effective for fiscal years beginning after December 15, 2008, with early adoption prohibited. It is effective prospectively for intangible assets acquired on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. EITF 08-7 is effective for us beginning January 1, 2009 and we will account for defensive intangible assets acquired in future business combinations in accordance with its provisions.

4. EARNINGS PER SHARE

Basic earnings per share is computed by dividing net income (loss) 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. In periods in which there is a net loss, potentially dilutive common shares are excluded from the computation of diluted earnings per share as their effect would be anti-dilutive.

	2008	2007
Net income (loss) for diluted computation	$ 3,744,408	$ (4,544,329)
Weighted average shares:		
Basic	5,854,836	5,291,506
Effect of dilutive securities:		
Stock options	982,075	-
Diluted	6,836,911	5,291,506
Net Income (Loss) Per Share:		
Basic	**$ 0.64**	**$ (0.86)**
Diluted	**$ 0.55**	**$ (0.86)**

For the year ended December 31, 2007, 1,409,700 of potential common shares were excluded from the diluted loss per share calculation because their effect was anti-dilutive as a result of the Company s 2007 net loss.

5. INVENTORIES, NET

None.

6. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment from continuing operations consist of:

	December 31,	
	2008	**2007**
Machinery and equipment	$ 562,610	$ 575,069
Furniture and fixtures	91,928	91,928
Leasehold improvements	1,185,059	1,185,059
	1,839,597	1,852,056
Less accumulated depreciation and amortization	(1,837,300)	(1,816,376)
	$ 2,297	$ 35,680

Total depreciation expense amounted to $30,919 and $32,143 for calendar years 2008 and 2007, respectively.

7. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following:

	December 31,	
	2008	**2007**
Trade accounts payable and accrued expenses	$ 409,433	$ 686,742
Accrued legal and other professional fees	117,837	98,438
Accrued payroll and related costs	115,195	88,280
	$ 642,465	$ 873,460

8. INCOME TAXES

The income tax expense for 2008 was $299,212 as compared to $53,865 for 2007. We accrued approximately $494,234 associated with federal and state taxes based on our net income in 2008 which was partially offset by a tax benefit related to the exercise of stock options of $314,648. After finalizing our delinquent prior year tax filings in 2008, our estimated federal and state tax penalties and interest were reduced by $103,203 and $77,250, respectively, and we recognized a $195,002 tax benefit in connection with our 2007 net operating loss. We have postponed the recognition of a tax benefit of $220,000 for the 2007 period due to net operating loss carrybacks and will request that the Internal Revenue Service apply this amount to our 2008 federal taxes.

The provision for income taxes consist of the following:

	Year ended December 31,	
	2008	**2007**
Current:		
Federal	$ 172,186	$ -
State	7,400	3,600
	179,586	3,600
Deferred:		
Federal	-	-
State	-	-
Total	$ 179,586	$ 3,600

The effective income tax rate of the Company differs from the federal statutory tax rate of 34% due to the following items:

	Year ended December 31,	
	2008	**2007**
Computed tax expense at statutory rate	34.0%	34.0%
State income taxes, net of federal tax benefit	0.1%	0.1%
Deferred revenues	(9.0%)	(25.7%)
Tax benefit of exercised options and warrant	(6.4%)	(0.4%)
Orphan drug and other tax credits	(2.2%)	-
Stock-based compensation	12.4%	14.3%
Tax benefit of NOL	(14.7%)	-
Depreciation and amortization	(8.4%)	-
Other	(1.4%)	0.2%
Increase (decrease) in valuation allowance	-	(22.5%)
	4.4%	-%

The significant components of the Company's deferred tax assets, pursuant to SFAS No. 109, are summarized as follows:

	Year ended December 31, 2008	2007
Tax Credit carryforward	$ 1,039,390	$ 1,128,724
Deferred revenues	1,231,287	1,673,314
Other	37,736	117,308
Options	815,686	381,882
Net operating loss carryforward	128,775	1,831,764
Net deferred tax assets before valuation allowance	3,252,874	5,132,992
Valuation allowance	(3,252,874)	(5,132,992)
Net deferred tax asset	$ -	$ -

SFAS No. 109 requires a valuation allowance against deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. The Company decreased the valuation allowance by $2,008,893 during the year ending December 31, 2008. The decrease in the valuation allowance was primarily to the realization of net income for the reporting period. The net deferred tax asset has been fully reserved due to the uncertainty of the Company's ability to generate taxable income under the more likely than not criteria of FAS 109.

At December 31, 2008, the Company had $1,717,000 of state and zero of federal net operating loss carryforward. As of December 2008, the Company had approximately $1,020,626 of orphan drug tax credit that can be carried forward and used indefinitely.

9. STOCKHOLDERS EQUITY

Stock Option Plans

In July 1994, the Company's stockholders approved a stock option plan for eligible key employees, directors, independent agents, and consultants who make a significant contribution toward the Company's success and development and to attract and retain qualified employees (the 1993 Plan), which expired in July 2004. Under the 1993 Plan, qualified incentive stock options and non-qualified stock options may be granted to purchase up to an aggregate of 200,000 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 Board, at its discretion, may provide for different vesting schedules. The options expire ten years (five years for qualified incentive stock options granted to stockholders owning at least 10% of common shares) after such date. In accordance with terms of the 1993 Plan, no options were granted ten years after the effective date of the 1993 Plan, or July 2004. As of December 31, 2008 there were zero options outstanding under the 1993 Plan.

In July 1997, the Company's stockholders approved a stock option plan (the 1997 Plan) with terms identical to the 1993 Plan. The 1997 Plan authorizes the granting of awards of up to an aggregate of 500,000 shares of the Company's common stock, subject to certain anti-dilution provisions. In accordance with terms of the 1997 Plan, no options were granted ten years after the effective date of the 1997 Plan or July 2007. In July 2007, approximately 231,000 stock options expired unissued. As of December 31, 2008 there were 147,250 options outstanding under the 1997 Plan.

In August 2001, the Company's stockholders approved a stock option plan (the 2001 Plan), with terms similar to the 1997 Plan. The 2001 Plan authorizes the granting of awards of up to an aggregate of 750,000 shares of the Company's common stock, subject to certain anti-dilution provisions. On December 16, 2003, stockholders approved an amendment to the 2001 Plan, which increased the number of shares authorized for grant from 750,000 shares to 1,750,000 shares, an increase of 1,000,000 shares. A total of 1,750,000 shares of common stock are now authorized for issuance under the amended 2001 Plan. The 2001 Plan, as amended expires in August 2011. The Company filed a Registration Statement on Form S-8 for the 2001 Plan with the Commission on October 5, 2007 to register these securities. As of December 31, 2008 there were 1,279,850 options outstanding and a total of 194,098 shares available for grant remaining under the 2001 Plan.

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

	December 31,					
	2008			2007		
	Shares		Weighted Average Exercise Price	Shares		Weighted Average Exercise Price
Outstanding at beginning of year	1,409,700	$	1.86	1,281,125	$	1.17
Options granted	232,500		16.00	277,000		4.68
Options exercised	(209,300)		1.22	(104,952)		1.06
Options canceled or expired	(5,800)		4.18	(43,473)		1.95
Outstanding at end of year	1,427,100		4.25	1,409,700		1.86
Options exercisable at year end	1,220,850		3.12	1,226,700		1.57
Shares available for future grant	194,098		--	426,598		--

During 2008, the Company granted 232,500 options to Board members, employees and consultants on various dates. Of the 232,500 options granted in 2008, 200,000 options granted to our Board members vest over one year, 30,000 options granted to our employees vest over four years, 2,500 options granted to our employees vested immediately and 50,000 options granted to a consultant vested immediately. During 2007, the Company granted 277,000 options to Board members, employees and consultants on various dates. Of the 277,000 options granted in 2007, 147,000 options granted to our Board members vest over one year, 30,000 options granted to our employees vest over four years and 100,000 options granted to a consultant vests upon the achievement of certain milestones. The options granted in 2008 and 2007 were granted at exercise prices ranging from $4.00 to $20.00 per share.

The following table summarizes information relating to stock options by exercise price at December 31, 2008:

Outstanding				Exercisable		
Option Exercise Price	Shares	Weighted Average Life (years)		Weighted Average Exercise Price	Shares	Weighted Average Option Price
$0.83-1.99	867,600	5.67	$	1.06	817,600	$ 1.07
2.00-2.99	30,000	1.40		2.67	30,000	2.67
3.00-3.99	20,000	0.52		3.00	20,000	3.00
4.00-4.99	182,000	8.25		4.34	159,500	4.30
5.00-5.99	95,000	8.75		5.33	85,000	5.31
13.00-13.99	125,000	9.38		13.51	72,500	13.60
17.00-17.99	30,000	9.48		17.00	15,000	17.00
19.00-20.00	77,500	9.70		19.61	21,250	19.65
	1,427,100	6.67	$	4.25	1,220,850	$ 4.82

The weighted-average grant-date fair value for options granted during 2008 was $16.00 per share and $4.50 per share in 2007. During the 2008 and 2007, $255,388 and $122,912 were received from stock options exercised by employees, respectively.

During 2008, the exercise of 70,300 stock options resulted in a realized benefit of $314, 647 in tax return deductions, in excess of compensation cost recognized and is accounted for as a reduction of the Company s tax liability and an increase in additional paid-in capital.

Under FASB Statement No. 95, *Statement of Cash Flows,* as amended, the realized tax benefit related to the excess of the deductible amount over the compensation cost recognized is classified as a cash inflow from financing activities and a cash outflow from operating activities in the statement of cash flows.

10. COMMITMENTS AND CONTINGENCIES

Lease Agreements

The Company's operations are principally conducted on leased premises. Future minimum annual rental payments required under non-cancelable operating leases are approximated as follows:

Year ending December 31,

2009	$ 152,000
2010	75,000
thereafter	-0-

Rent expense under all operating leases amounted to approximately $150,000 for each calendar year 2008 and 2007. Wilbur Street Corporation (WSC) owns and has leased to ABC-NY a building that serves as a manufacturing facility and our headquarters in Lynbrook, New York for over 30 years. The building also serves as the Company s administrative headquarters. Edwin H. Wegman, the Company's former Chairman and CEO, was the President of WSC.

In January 1998, WSC, the Company and ABC-NY entered into a triple net lease agreement that provides for an annual rent starting at $125,000, which can increase annually by the amount of the annual increase in the consumer price index for the greater New York metropolitan region. The lease term was 7 years and expired on January 31, 2005. The Company paid and accrued approximately $220,000 and $220,000 representing rent, real estate taxes and insurance to WSC in 2008 and 2007, respectively. Without Board approval, the lease was renewed (a related party transaction) in July 2005 for an additional 5 years, expiring on June 30, 2010. The extension of the lease may thus not be valid. The annual base rent, exclusive of taxes and related insurance, is $150,000 ($10 per square foot) per annum commencing in February 2006. Our rent may increase annually by the amount of the annual increase in the consumer price index for the greater New York metropolitan region. As part of the agreement with DFB, DFB agreed to sublease a part of the New York facility for a period of one year, which expired on March 2, 2007, for an all inclusive monthly payment of $15,500. DFB extended its sublease until March 6, 2008 and paid $16,500 per month during this extended lease period. In April 2008, DFB extended its sublease until March 3, 2009 and paid $19,000 per month during the extended lease period. In accordance with the sublease extension, in July 2008 DFB provided notice of the termination of its obligations under the sublease, effective as of September 1, 2008. We are currently negotiating with WSC a reduction of the rent price of the facility but as of the date of this filing the parties have not reached an agreement regarding such reduction.

Receivables and Deferred Revenue

Under our agreement with DFB, we agreed to provide certain technical assistance and certain transition services to DFB in consideration of fees and costs totaling over $1.4 million. At the closing, DFB paid to us a partial payment of

$400,000 in respect of the technical assistance to be provided by us. As of December 31, 2008, we have received a total of $1,000,000 in payments from DFB. The consulting obligations generally expire during March 2011. As of December 31, 2008, the remaining accounts receivable balance due was $400,000 for future services and was offset by the associated deferred revenues to be recognized in future periods of $400,000.

Potential Product Liability

The sale of our topical collagenase product, as well as the development and marketing of any potential products of the Company, exposes us to potential product liability claims both directly from patients using the product or products in development, as well as from our agreement to indemnify certain distributors of the product for claims made by others. We have product liability insurance, which covers the use of our licensed topical collagenase product and clinical experiments of potential products in the U.S. No known claims are pending against us at the current time. Our insurance policy has a limit of $3 million and is renewed annually during the month of February.

11. RELATED PARTY TRANSACTIONS

As of December 31, 2007 we leased one facility in Lynbrook, New York. The New York facility is our administrative headquarters and contains approximately 3,500 square feet of office space and 11,500 square feet of laboratory, production, and storage facilities. As part of the agreement with DFB, DFB agreed to sublease a part of the New York facility for a period of one year, which expired on March 2, 2007, for an all inclusive monthly payment of $15,500. DFB extended its sublease until March 6, 2008 and paid $16,500 per month during this extended lease period. In April 2008, DFB extended its sublease until March 3, 2009 and paid $19,000 per month during the extended lease period. In accordance with the sublease extension, in July 2008 DFB provided notice of the termination of its obligations under the sublease, effective as of September 1, 2008. We lease this facility from WSC and are currently negotiating with WSC a reduction of the rent price of the facility but as of the date of this filing the parties have not reached an agreement regarding such reduction.

WSC was an affiliate of Edwin H. Wegman, our former Chairman and CEO, until Edwin H. Wegman s death. At the present time the ownership of WSC is unclear. However, our President, Thomas L. Wegman, is the senior most officer of WSC.

In January 2007, we entered into two amended and restated demand promissory notes with each of Edwin H. Wegman and WSC reflecting the prior outstanding principal amounts of the loans and compounded interest (collectively, the Notes). Upon the death of Edwin H. Wegman on February 16, 2007, his Notes became the obligation of his estate. As of December 31, 2007, the aggregate principal amounts, including compounded interest, owed to us by Edwin H. Wegman and WSC were $1,108,088 and $304,397, respectively. Under the Notes, the respective principal amounts remaining unpaid at any time shall each bear interest at the rate of nine percent (9%) per annum compounded annually. The loans were secured by a pledge of 100% of the shares of the Company owned by The S.J. Wegman Company. At December 31, 2007 the total number of shares pledged, 1,843,327, had a current market value of $3.80 per share. In March 2007, in full repayment of the loan made by the Company to WSC, WSC offset $304,397 in back rent due from the Company in full repayment of the loan.

Edwin H. Wegman was the sole general partner of The S.J. Wegman Company, a limited partnership which owned over 20% of the issued and outstanding common stock of the Company. Upon his death on February 16, 2007, The S.J. Wegman Company was legally dissolved. The dissolution of The S.J. Wegman Company constituted an event of default under the above mentioned pledge agreement, which gave the Board the right to vote the pledged shares.

As of December 31, 2007, the Company had an outstanding loan to the Company s former Chairman and CEO, Edwin H. Wegman. The principal amount owed was $625,774 and the accrued interest amount through December 31, 2007 was $482,314 for an aggregate amount of $1,108,088. The loan was in the form of a demand promissory note, bearing interest at a rate of 9% per annum. For financial statement purposes, this loan is classified as components of stockholders equity in the balance sheet and appear as Notes due from former Chairman and CEO and other related party.

Notwithstanding the dissolution of The S.J. Wegman Company, upon the death of Edwin H. Wegman, the loan continued to be secured by The S.J. Wegman Company pledge. Interest income accrued for these loans, but not

recognized for financial statement purposes, aggregated approximately $8,470 and $91,500, for the calendar years 2008 and 2007, respectively.

On February 1, 2008, the Estate of Edwin H. Wegman (the Estate) sold an aggregate of 344,114 shares of the Company's common stock, par value $0.001, at a purchase price of $12.00 per share to certain private investors. The Estate used certain of the proceeds of the transaction to repay the loan owed to the Company by Edwin H. Wegman, our former Chairman and CEO. The total loan repayment amount was $1,116,558, which represents the principal amount of $625,774 owed to the Company and accrued interest through January 31, 2008 of $490,784.

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 calendar years 2008 or 2007.

13. SUBSEQUENT EVENTS

On January 5, 2009, we received the entire outstanding principal balance of our investment in auction rate securities of $0.9 million.

On January 6, 2009 the Company announced that it will hold its 2009 Annual Meeting of Stockholders on June 17, 2009 at the New York offices of Bingham McCutchen LLP, located at 399 Park Avenue, New York, NY 10022 and that the deadline for stockholders to submit proposals to be included in our proxy statement with respect to the 2009 Annual Meeting of Stockholders was February 6, 2009.

On January 9, 2009 the Company s common stock became listed and commenced trading on the Nasdaq Global Market under the symbol BSTC.

On January 30, 2009, the Company received an upfront sublicense payment of $6.375 million from Auxilium in accordance with the terms of the Auxilium Agreement.

In a press release dated February 2, 2009, Auxilium announced that it has completed patient enrollment in its Phase IIb trial of XIAFLEX for the treatment of Peyronie s disease and that all patients have received their first injection of either XIAFLEX or placebo in accordance with the study design.

In a press release dated March 2, 2009, Auxilium announced that it filed a BLA for the treatment of Dupuytren s disease on February 27, 2009. Auxilium also announced that it has requested a Priority Review designation for the BLA submission from the FDA and that it expects to hear from the FDA on Priority Review designation within approximately 60 days of the filing date.

EXHIBIT INDEX

The documents listed below are being filed or have previously been filed on behalf of the Company and are incorporated herein by reference from the documents indicated and made a part hereof. Exhibits not identified as previously filed are filed herewith:

Exhibit Number	*Description*
3.1	Registrant s Certificate of Incorporation, as amended (incorporated by reference to Exhibit 3.1 of the Registrant s Form 10-KSB filed with the Commission on March 2, 2007)
3.2	Registrant s Amended and Restated By-laws (incorporated by reference to Exhibit 3.2 of the Registrant s Form 10-KSB filed with the Commission on March 2, 2007)
10.1	Copy of Promissory Note, dated January 1, 2007, executed by Edwin H. Wegman in favor of the Company (incorporated by reference to Exhibit 10.1 of the Registrant s Form 10-KSB filed with the Commission on March 2, 2007)
10.2	Copy of Promissory Note, dated January 1, 2007, executed by Wilbur Street Corporation in favor of the Company (incorporated by reference to Exhibit 10.2 of the Registrant s Form 10- KSB filed with the Commission on March 2, 2007)
10.3	Copy of Pledge Agreement, dated January 1, 2007, executed by The S.J. Wegman Company in favor of the Company (incorporated by reference to Exhibit 10.3 of the Registrant s Form 10- KSB filed with the Commission on March 2, 2007)
10.4	Copy of Lease, dated January 30, 1998, between the Company and the Wilbur Street Corporation (incorporated by reference to Exhibit 10.14 of the Registrant s Form 10-KSB filed with the Commission on May 7, 1998)
10.5	Copy of Extension and Modification Agreement, dated July 1, 2005, between the Company and the Wilbur Street Corporation (incorporated by reference to Exhibit 10.5 of the Registrant s Form 10-KSB filed with the Commission on March 2, 2007)
10.6	Asset Purchase Agreement between the Company, ABC-NY and DFB dated March 3, 2006 (incorporated by reference to Exhibit 2.1 of the Registrant s Form 8-K filed with the Commission on March 9, 2006)
10.7	Amendment to Asset Agreement between the Company, ABC-NY and DFB dated January 8, 2007 (incorporated by reference to Exhibit 10.1 of the Registrant s Form 8-K filed with the Commission on January 12, 2007)
10.8	Dupuytren s License Agreement dated November 21, 2006 between the Company and the Research Foundation (incorporated by reference to Exhibit 10.1 of the Registrant s Form 8-K filed with the Commission on November 28, 2006)
10.9	Frozen Shoulder License Agreement dated November 21, 2006 between the Company and the Research Foundation (incorporated by reference to Exhibit 10.2 of the Registrant s Form 8-K filed with the Commission on November 28, 2006)
10.10	Form of 1993 Stock Option Plan of Registrant (incorporated by reference as Exhibit 10.2 of the Registrant s Form S-8 filed with the Commission on July 27, 1995)
10.11	Form of 1997 Stock Option Plan of Registrant (incorporated by reference as Exhibit 4.1 of the Registrant s Form S-8 filed with the Commission on September 26, 1997)
10.12	Form of 2001 Stock Option Plan of Registrant (incorporated by reference as Exhibit 10.15 of the Registrant s Form 10-KSB filed with the Commission on May 17, 2001)
10.13	Amendment to 2001 Stock Option Plan of Registrant (incorporated by reference to the Registrant s Form 14A filed with the Commission on November 12, 2003)
10.14	Warrant to purchase common stock of the Company dated March 12, 2003 between the Company and David Geller (incorporated by reference to Exhibit 10.17 of the Registrant s Form 10-KSB filed with the Commission on March 2, 2007)
10.15	Rights Agreement dated as of May 14, 2002 (incorporated by reference as Exhibit 1 to the Registrant s Form 8-A filed with the Commission on May 30, 2002)

10.16	Amendment No.1 to Rights Agreement, dated June 19, 2003 (incorporated by reference to Exhibit 10.19 of the Registrant s Form 10-KSB filed with the Commission on March 2, 2007)
10.17	Change of Control Agreement, dated June 18, 2007 between the Company and Henry Morgan (incorporated by reference to Exhibit 10.21 of the Registrant s Form 10-KSB filed with the Commission on September 26, 2007)
10.18	Change of Control Agreement, dated June 18, 2007 between the Company and Michael Schamroth (incorporated by reference to Exhibit 10.22 of the Registrant s Form 10-KSB filed with the Commission on September 26, 2007)
10.19	Change of Control Agreement, dated June 18, 2007 between the Company and Dr. Paul Gitman (incorporated by reference to Exhibit 10.23 of the Registrant s Form 10-KSB filed with the Commission on September 26, 2007)
10.20	Agreement dated August 27, 2008 (incorporated by reference to Exhibit 10.1 of the Registrant s Form 8-K filed with the Commission on September 5, 2008)
10.21	Amended and Restated Development and License Agreement dated December 11, 2008 and effective December 17, 2008 between the Company and Auxilium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 of the Registrant s Form 8-K filed with the Commission on December 19, 2008)
10.22	Executive Employment Agreement, dated August 5, 2008 between the Company and Thomas L. Wegman (incorporated by reference to Exhibit 10.1 of the Registrant s Form 8-K filed with the Commission on August 8, 2008)
10.23*	Change of Control Agreement, dated October 1, 2008 between the Company and Dr. Matthew Geller
14	Amended and Restated Code of Business Conduct and Ethics (incorporated by reference to Exhibit 14.1 of the Registrant s Form 10-KSB filed with the Commission on March 2, 2007)
21	Subsidiaries of the Registrant (incorporated by reference to Exhibit 21.1 of the Registrant s Form 10-KSB filed with the Commission on March 2, 2007)
23*	Consent of Tabriztchi & Co. CPA, P.C.*
31*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*
32*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*

* filed herewith

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: March 30, 2009

BIOSPECIFICS TECHNOLOGIES CORP.

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

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/ Thomas L. Wegman Name: Thomas L. Wegman Date: March 30, 2009	President, Director, Principal Executive Officer and Principal Financial Officer)
/s/ Henry Morgan Name: Henry Morgan Date: March 30, 2009	Director
/s/ Dr. Paul Gitman Name: Dr. Paul Gitman Date: March 30, 2009	Director
/s/ Dr. Mark Wegman Name: Dr. Mark Wegman Date: March 30, 2009	Director

/s/ Dr. Matthew Geller Name: Dr. Matthew Geller Date: March 30, 2009	Director
/s/ Michael Schamroth Name: Michael Schamroth Date: March 30, 2009	Director