BIOSPECIFICS TECHNOLOGIES CORP
Form 10-K
March 13, 2012

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

FORM 10-K

(Mark One)

x ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2011

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

Commission File Number: 001-34236

BIOSPECIFICS TECHNOLOGIES CORP.
(Exact name of registrant as specified in its charter)

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

Registrant's telephone number, including area code: 516.593.7000

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

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

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
¨Yes þNo

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 þNo

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.
þYes ¨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.

i

Large accelerated filer ¨ Accelerated filer þ

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).
¨Yes þNo
The aggregate market value of voting and non-voting common stock held by non-affiliates of the Registrant as of June 30, 2011, the last business day of the registrant's most recently completed second fiscal quarter, was approximately $112 million.

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 9, 2012 is 6,336,139.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2012 Annual Meeting of Stockholders scheduled to be held on June 15, 2012, 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, 2011, 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 2012 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.

TABLE OF CONTENTS

		Page
PART I		2
	Item 1. DESCRIPTION OF BUSINESS.	2
	Item IB. UNRESOLVED STAFF COMMENTS	26
	Item 2. DESCRIPTION OF PROPERTY.	26
	Item 3. LEGAL PROCEEDINGS.	26
	Item 4. (REMOVED AND RESERVED).	26
PART II		26
	Item 5. MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS.	26
	Item 6. SELECTED FINANCIAL DATA	29
	Item 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION	30
	Item 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK.	42
	Item 8. FINANCIAL STATEMENTS.	43
	Item 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.	43
	Item 9A. EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES.	43
	Item 9B. OTHER INFORMATION	44
PART III		44
	Item 10. DIRECTORS AND EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT	44
	Item 11. EXECUTIVE COMPENSATION.	44
	Item 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.	44
	Item 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.	44
	Item 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.	44
PART IV		44
	Item 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES.	44

Table of Content

Introductory Comments – Terminology

Throughout this annual report on Form 10-K (this “Report”), the terms “BioSpecifics,” “Company,” “we,” “our,” and “us” re
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, and made pursuant to the safe harbor provisions of, the Private Securities Litigation Reform Act of 1995. All statements other than statements of historical fact, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, expected revenue growth, and the assumptions underlying or relating to such statements, are “forward-looking statements”. In some cases, you can identify these statements by forward-looking words such as “believe,” “expect,” “anticipate,” “plan,” “estimate,” “likely,” “may,” “will,” “co “continue,” “project,” “predict,” “goal,” the negative or plural of these words, and other similar expressions. Our forward-looking statements are predictions based on our current expectations and our projections about future events. There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements, including the statements made by us or by our partner Auxilium Pharmaceuticals, Inc. regarding progress toward achievement of its objectives for the sale and marketing of XIAFLEX® for Dupuytren’s contracture in the U.S., including, among other things, developments in the reimbursement process; the ability of Pfizer, Inc. to achieve its objectives for XIAPEX® in Europe; the ability of Asahi Kasei Pharma Corporation to achieve its objectives for XIAFLEX in Japan; the ability of Actelion Pharmaceuticals Ltd. to achieve its objectives for XIAFLEX in Canada, Australia, Brazil and Mexico; the success of the Phase III trials for XIAFLEX for the treatment of Peyronie’s disease; the potential market for XIAFLEX in a given indication; the initiation and outcome of clinical trials for additional indications including frozen shoulder, cellulite, human lipoma and canine lipoma, all of which will determine the amount of milestone, royalty and sublicense income we may receive; the potential of XIAFLEX to be used in additional indications; the timing of results of any clinical trials; the timing of regulatory filings and action; the receipt of any applicable milestone payments from Auxilium Pharmaceuticals, Inc.; whether royalty payments we are entitled to receive will exceed set-offs; and other risk factors set forth in Part I, Item 1A of this Report under the heading "Risk Factors". All forward-looking statements included in this Report are made as of the date hereof, and we assume no obligation to update these forward-looking statements.

Table of Content

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® (collagenase clostridium histolyticum)) for clinical indications in Dupuytren's contracture, Peyronie's disease and frozen shoulder (adhesive capsulitis). Auxilium has an option to acquire additional indications that we may pursue, including cellulite, for which we have granted Auxilium the right to initiate early development studies at its cost, and human and canine lipoma. Auxilium is currently selling XIAFLEX in the U.S. for the treatment of Dupuytren's contracture. Auxilium has an agreement with Pfizer, Inc. ("Pfizer") pursuant to which Pfizer has the right to market XIAFLEX for Dupuytren's contracture and Peyronie's disease in Europe and certain Eurasian countries, and will do so under the registered trademark XIAPEX® (collagenase clostridium histolyticum). Pfizer is currently selling XIAPEX in nine countries in Europe, including the United Kingdom, Germany and Spain. In addition, Auxilium has an agreement with Asahi Kasei Pharma Corporation ("Asahi") pursuant to which Asahi has the right to commercialize XIAFLEX for the treatment of Duputyren's contracture and Peyronie's disease in Japan. Auxilium also has an agreement with Actelion Pharmaceuticals Ltd. ("Actelion") pursuant to which Actelion has the right to commercialize XIAFLEX for the treatment of Duputyren's contracture and Peyronie's disease in Canada, Australia, Brazil and Mexico.

Operational Highlights

As previously reported, on August 31, 2011, we and Auxilium announced the dismissal of all pending litigation between us in accordance with a settlement agreement. Pursuant to the settlement agreement, among other things, we became a co-owner with Auxilium of U.S. Patent No. 7,811,560 and any continuations and divisionals of that patent. Also on August 31, 2011, we amended and restated our development and license agreement with Auxilium to clarify and change certain of our and Auxilium's rights and responsibilities. We clarified, for example, that we retain the right to conduct trials, studies or development work for: indications in canine lipomas and human lipomas; additional indications upon approval by the parties' joint development committee; tissue disassociation research and development; and in vitro research and development. In addition, on August 31, 2011, we announced with Auxilium plans to move XIAFLEX forward in the clinic for cellulite and human and canine lipoma as well as to collaborate on the initiation of further studies for XIAFLEX for additional indications. A phase Ib trial of XIAFLEX for the treatment of cellulite is currently underway by Auxilium. Auxilium expects top line study results in the fourth quarter of 2012. In addition, as announced by Auxilium on December 1, 2011, Auxilium currently has underway a phase IIa, open-label, controlled dose-ranging study to assess the safety and efficacy of XIAFLEX for the treatment of Frozen Shoulder syndrome in comparison to an exercise-only control group. Auxilium expects topline study results in the first half of 2013.

Auxilium continues to market XIAFLEX in the U.S. for the treatment of adult Dupuytren's contracture patients with a palpable cord. On November 2, 2011, it announced that the American Medical Association (the "AMA") has issued two new Category I Current Procedural Terminology ("CPT") Codes that will be used with XIAFLEX for the treatment of adult Dupuytren's contracture patients with a palpable cord beginning January 1, 2012. CPT codes are the most widely accepted form of medical nomenclature used to report medical procedures and services under public and private health insurance programs in the U.S. The new CPT codes are 20527 for the XIAFLEX injection procedure and 26341 for the finger extension or manipulation procedure administered 24 hours after the XIAFLEX injection, in accordance with the label. According to the November 2, 2011 press release, "The CPT codes will apply to the procedures only, and leave in place the separate J code for reimbursement" of XIAFLEX.

In December 2011, we announced the appointment of George Gould, Esq., to our board of directors. Mr. Gould brings considerable expertise in pharmaceutical and biotechnology intellectual property law and has served as an expert witness in patent cases.

Auxilium has also recently announced leadership changes including a new Chief Executive Officer, Adrian Adams in December 2011, a new Executive Vice President, Chief Administrative Officer and General Counsel, Andrew I. Koven and a new Senior Vice President, Sales, Mark A. Glickman, in February 2012. In the press release announcing Mr. Adams' appointment as CEO, the Chairman of Auxilium's board of directors, Rolf Classon, stated "We believe that [Adrian's] visionary leadership and operational expertise will lead Auxilium to profitability and success as we seek to maximize the value of XIAFLEX . . . while delivering on our current pipeline."

Table of Content

In a February 23, 2012 press release, Auxilium announced that it had entered into a Collaboration Agreement with Actelion pursuant to which Actelion has the right to develop and commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Canada, Australia, Brazil and Mexico. According to the release, XIAFLEX for the treatment of Dupuytren's contracture has been accepted for review by Health Canada and regulatory action is expected in the second half of 2012. Additionally, Actelion expects to file for approval of XIAFLEX for the treatment of Dupuytren's contracture in Australia, Brazil and Mexico over the next 12 months. Under the terms of the agreement with Actelion, Auxilium is to receive a $10 million upfront payment from Actelion, as well as up to $16 million in potential regulatory, pricing, and reimbursement milestone payments and $42.5 million in potential sales milestone payments. Under the terms of our development and license agreement with Auxilium, we will receive a certain percentage from Auxilium in connection with the upfront payment by Actelion, and a specified percentage of any additional milestones received by Auxilium. We will also receive from Auxilium royalties from net sales and payments on costs of goods sold in Canada, Australia, Brazil and Mexico, which will be a specified percentage of what Auxilium is entitled to receive from Actelion without regard to any offset that Actelion may have with respect to Auxilium.

Research and Development of Injectable Collagenase for Multiple Indications

On June 3, 2004, we entered into, and later amended, a development and license agreement with Auxilium pursuant to which we granted to Auxilium an exclusive worldwide license to develop, market and sell products containing our injectable collagenase for the treatment of Dupuytren's contracture, 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. We have amended and restated that agreement twice, once on December 11, 2008 in connection with the Development, Commercialization and Supply Agreement, dated December 17, 2008 between an Auxilium subsidiary and Pfizer, and more recently on August 31, 2011 (the "Auxilium Agreement"). The Auxilium Agreement and other licensing agreements are discussed more fully throughout this Item 1, in particular under the section titled "Licensing and Marketing Agreements."

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.

Collagenase is widely used for cell dispersion for tissue disassociation and cell culture because it does not damage the cell membrane. Since the main component of scar tissue is collagen, collagenase has been used in a variety of clinical investigations to remove scar tissue without surgery. Histological and biochemical studies have shown that the tissue responsible for the deformities associated with Dupuytren's contracture and Peyronie's disease is primarily composed of collagen. Surgical removal of scar tissue has the potential to result in complications including increased scar formation. Due to the highly specific nature of the Clostridial collagenase enzyme, we consider its use to be more desirable for the removal of unwanted tissue than the application of general proteolytic enzymes. Treatment with injectable collagenase for removal of excessive scar tissue represents a first in class non-invasive approach to this unmet medical need. The lead indications involving our injectable collagenase are Dupuytren's contracture, Peyronie's disease and frozen shoulder. New clinical indications involving the therapeutic application of Clostridial collagenase

to supplement the body’s own natural enzymes are continuously being proposed to us by specialists in the medical community.

Table of Content

Collagenase for Treatment of Dupuytren's Contracture

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

XIAFLEX is the only drug approved by the U.S. Food and Drug Administration (the "FDA") for the treatment of Dupuytren's contracture. Prior to FDA approval of XIAFLEX, the only proven treatment for Dupuytren's contracture was surgery. Recurrence rates after surgery can be as high as 30% the first two years after surgery and 55% within ten years of surgery. In addition, as reported by Auxilium in its February 2012 presentation (the "Auxilium Presentation"), XIAFLEX is a "minimally invasive treatment," requires only "simple injection and manipulation procedure", is an "efficient use of surgeon's time," does not require active physical therapy and provides a "long protection period." In Auxilium's Annual Report on 10-K filed with the Securities and Exchange Commission (the "SEC") on February 29, 2012 (the "Auxilium 10-K"), Auxilium cited the following reasons that "treatment with XIAFLEX offers benefits compared to surgery". It:

- "delivers improvement to 0 to 5 degrees of normal joint contracture without surgery for a majority of patients;
- safeguards patients from the complications commonly associated with surgery;
- simplifies treatment by offering a convenient in-office procedure alternative;
- streamlines recovery for a rapid return to daily activities; and
- significantly reduces costly and time-consuming physical therapy associated with surgery."

Commercialization of XIAFLEX for Dupuytren's Contracture in the United States

Auxilium has been marketing XIAFLEX for the treatment of adult Dupuytren's contracture patients with a palpable cord since it became available by prescription in March 2010, following Auxilium's receipt of marketing approval from the FDA. The prescribing information for XIAFLEX made available by Auxilium lists "tendon rupture or other serious injury to the injected extremity," as well as "pulley rupture, ligament injury, complex regional pain syndrome, and sensory abnormality of the hand," as reported serious adverse reactions to XIAFLEX. The prescribing information for XIAFLEX also states that the most frequently reported adverse drug reactions in XIAFLEX clinical trials included swelling of the injected hand, contusion, injection site reaction, injection site hemorrhage, and pain in the treated extremity. The prescribing information notes that adverse reaction rates observed in clinical trials of a drug may not reflect those observed in practice because such trials "are conducted under widely varying conditions." As a condition of its approval of XIAFLEX, the FDA required a risk evaluation and mitigation strategy ("REMS") program for XIAFLEX, which consists of a communication plan and a medication guide. This REMS program is designed (1) to evaluate and mitigate known and potential risks and serious adverse events; (2) to inform healthcare providers about how to properly inject XIAFLEX and perform finger extension procedures; and (3) to inform patients about the serious risks associated with XIAFLEX.

According to the Auxilium Presentation, Auxilium is working to establish XIAFLEX as the standard of care for Dupuytren's contracture with the following highlighted strategies: "streamline reimbursement", "motivate physicians" and

“activate patients”. In terms of streamlining reimbursement, Auxilium noted that it has had “additional wins with managed care - 96% of covered lives have access to XIAFLEX” and that “2012 XIAFLEX growth should be helped modestly by [the] new CPT codes”. Auxilium highlighted the following for purposes of motivating physicians “compelling clinical efficacy and safety data, facilitat[ing] peer to peer dialogue, activat[ing] a critical mass of experienced prescribers, a sample program for XIAFLEX-naïve physicians, and the multi-cord phase IV clinical study [that Auxilium has] initiated”. In terms of activating patients, Auxilium highlighted a patient copay assistance program and a “direct response TV campaign in 12 ready markets”.

Table of Content

Status of Regulatory Approval of XIAFLEX for Dupuytren's Contracture in Europe

Pursuant to Auxilium's agreement with Pfizer (the "Pfizer Agreement"), Pfizer has the right to market XIAFLEX for Dupuytren's contracture and Peyronie's disease in Europe and certain Eurasian countries, and will do so under the registered trademark XIAPEX® (collagenase clostridium histolyticum). The European Commission granted XIAPEX marketing authorization for the treatment of Dupuytren's contracture in adult patients with a palpable cord in the first quarter of 2011. To date, XIAPEX has been launched in nine countries in Europe, including the United Kingdom, Germany and Spain.

Collagenase for Treatment of Peyronie's Disease

Peyronie's disease is characterized by the presence of a collagen plaque on the shaft of the penis, which can distort an erection and make intercourse difficult or impossible in advanced cases. In some mild cases, the plaque can resolve spontaneously without medical intervention. In severe cases, the penis can be bent at a 90-degree angle during erection. Significant psychological distress has been noted in patients with 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 contracture, 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.

Currently, there are no FDA approved pharmaceutical products that are labeled as effective for use in Peyronie's disease. As Auxilium reported in the Auxilium Presentation, "surgery is a treatment of last resort and most patients are treated first-line with unapproved medical therapy."

Development Status

As described in more detail below, Auxilium currently has underway phase III studies of XIAFLEX for the treatment of Peyronie's disease. These double-blind, placebo-controlled phase III studies reached target enrollment in the first quarter of 2011, and the active dosing phase of the studies is complete. According to the Auxilium Presentation, Auxilium expects to announce top-line results late in the second quarter of 2012.

Phase IIb Trial

On December 16, 2009, Auxilium announced top-line efficacy and safety results from a phase IIb trial of XIAFLEX for the treatment of Peyronie's disease. According to the Auxilium 10-K, the phase IIb trial was a "randomized, double-blind, placebo-controlled study 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. The study was conducted at 12 sites throughout the U.S., and patients were monitored for 36 weeks following the first injection. The trial was designed to validate a proprietary Peyronie's Disease Questionnaire ("PDQ") which measures several domains of patients' sexual quality of life over a 36 week period. The four domains measured by the PDQ are penile pain, Peyronie's bother, intercourse discomfort and intercourse constraint. Patients had to have a penile contracture between 30 and 90 degrees to be included in the study. Patients were stratified by the degree of penile curvature (i.e. 30 degrees to 60 degrees versus 60 to 90 degrees) and then randomized into four treatment groups to receive either XIAFLEX or placebo with or without modeling of the penile plaque. Modeling refers to massaging of the plaque after the second injection of a treatment series and is intended to maximize the enzymatic effect of the XIAFLEX injection in the plaque. Patients were randomized in a 3:1 ratio of XIAFLEX to placebo and a 1:1 ratio to receive penile plaque modeling or no modeling."

5

Table of Content

In addition, the Auxilium 10-K stated that "Data demonstrated that XIAFLEX improved penile curvature when compared to placebo with a mean improvement of 29.7% vs. 11%, respectively (P=0.001). In addition, the PDQ domain of Peyronie's symptom bother was significantly improved in XIAFLEX treated subjects compared to placebo. The use of modeling also demonstrated significant improvement in XIAFLEX subjects compared to placebo, 32.4% improvement in curvature compared to a 2.5% worsening of curvature in placebo subjects (p<0.001). In the no-modeling group, XIAFLEX subjects experienced a 27.1% mean improvement in penile curvature, which was not statistically different from the 27.9% mean improvement for subjects receiving the placebo. The most common adverse events reported in the phase IIb trial were injection site bruising, injection site pain, injection site edema, contusion, penile edema and penile pain. There was a total of five (3.4%) subjects who experienced eight non-fatal serious adverse events, none of which were considered to be related to XIAFLEX. [Auxilium] sought to accomplish two goals with this study. First, [Auxilium] wanted to validate the PDQ as a tool for use in future pivotal studies. Second, [Auxilium] aimed to establish an acceptable primary endpoint related to the PDQ for use in pivotal phase III trials."

Phase III

In the Auxilium 10-K, Auxilium stated that "[f]ollowing discussions with the FDA where [Auxilium] achieved agreement that the PDQ was a valid tool for use in a pivotal phase III trial and the appropriate endpoint for such trials, [Auxilium] commenced its phase III studies." Auxilium "completed enrollment in [its] Phase III trial in March 2011 and, in August 2011, [Auxilium] announced that dosing had been completed." Also in the Auxilium 10-K, Auxilium noted its phase III plan "consists of four clinical studies and is known by the acronym IMPRESS – The Investigation for Maximal Peyronie's Reduction Efficacy and Safety Studies. There are two randomized, double-blind, placebo-controlled phase III studies, which enrolled over 800 patients at approximately 70 sites in the U.S. and Australia, with a 2:1 ratio of XIAFLEX to placebo. There is one open label study, which enrolled at least 250 patients, at approximately 30 sites in the U.S., EU and New Zealand, and one pharmacokinetic study, which enrolled approximately 16 patients in the U.S. XIAFLEX was administered two times a week every six weeks for up to four treatment cycles (2 x 4). Each treatment cycle was followed by a penile modeling procedure. Patients will be followed for 52 weeks post-first injection in the double-blind studies and for 36 weeks in the open label trial. The trials' co-primary endpoints are the mean change from baseline in the Peyronie's disease bother domain of the PDQ compared to placebo and mean percent improvement from baseline in penile curvature compared to placebo. The remaining domains of the PDQ will be considered secondary endpoints. Safety measurements will include adverse event monitoring, immunogenicity testing and clinical labs."

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 20 to 50 million people worldwide 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. As noted in the Auxilium Presentation, there are currently no FDA approved non-surgical therapies for frozen shoulder syndrome.

According to the Auxilium Presentation, current treatment options for frozen shoulder syndrome have limited results and "manipulation of the shoulder under anesthesia, long-term intensive physical therapy or arthroscopic surgery can disrupt the frozen capsule". In addition, Auxilium "believe[s] that XIAFLEX may act by thinning the thickened collagen capsule allowing improved range of motion of the affected shoulder".

We initiated, monitored and supplied requisite study drug for a Phase II clinical trial using our injectable collagenase in the treatment of frozen shoulder. Three different doses of injectable collagenase were compared to placebo in this

double-blind, randomized trial in 60 patients. Results of this Phase II clinical trial were presented at the annual meeting of the American Academy of Orthopaedic Surgeons in March 2006. Based on its prior review of the data contained in the oral presentation, Auxilium elected to exercise its option to develop and commercialize this additional indication for collagenase injection in December 2005. In a press release dated December 20, 2005 and issued concurrently with the exercise of its option, Auxilium stated its belief that "the addition of a third indication for this development program enhances the commercial potential of AA4500" (now known as XIAFLEX).

Phase IIa

Auxilium currently has underway a phase IIa open-label, controlled dose-ranging study designed to assess the safety and efficacy of XIAFLEX for the treatment of Frozen Shoulder syndrome in comparison to an exercise-only control group. The study will involve approximately 50 adult men and women at approximately nine sites throughout the U.S. Topline study results are expected in the first half of 2013.

Table of Content

According to a December 1, 2011 press release in which Auxilium announced that the first patient has been dosed in this phase IIa trial, "[t]o qualify for the Frozen Shoulder syndrome study, patients must have unilateral idiopathic adhesive capsulitis of the shoulder with restricted range of motion in the affected shoulder for at least three months, but not more than 12 months. Following screening and determination of study eligibility, subjects will be assigned to four groups that vary in dosing (injection volume and concentration) or a fifth group receiving shoulder exercises only. Patients may receive up to three ultrasound-guided injections of varying doses of XIAFLEX (ranging from 0.29 mg to 0.58 mg in varying concentrations) separated by a minimum of 21 days and all patients will be instructed to perform home shoulder exercises. The study's primary endpoint is the change (degrees) from baseline to the day 92 follow-up in forward flexion (active) in the affected shoulder. Safety assessments, including immunogenicity testing, will be made during all study visits. More information on the study, including study sites participating in this trial, can be found at clinicaltrials.gov."

Collagenase For Treatment of Cellulite (Edematous Fibrosclerotic Panniculopathy)

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.

In the Auxilium 10-K, Auxilium noted that "[c]ellulite has been reported to occur in 85-98% of post-pubertal females and rarely in men. The condition is prevalent in women of all races." In the Auxlium Presentation, Auxilium noted that there are no FDA-approved medical therapies for cellulite, that current non-surgical options have not shown benefit, that surgical approaches have shown some benefit but are invasive and that it "believes [that] XIAFLEX may enable physicians to enzymatically and specifically lyse the connective septae, in a more targeted fashion than subscision, possibly resulting in a smoother appearance to the skin surface."

Under the Auxilium Agreement, we have granted Auxilium the right to initiate early development studies for cellulite, and Auxilium will be responsible for all costs associated with such development. Auxilium has the option, upon completion of such early stage development and upon its payment to us of a one-time fee of $500,000, to add the treatment of cellulite as an Auxilium exercised indication under the Auxilium Agreement, in which case we would receive milestone payments, low double digit royalties and a mark-up on cost of goods for sales in cellulite.

Auxilium currently has underway a single site, phase Ib, open-label dose escalation study of XIAFLEX for the treatment of cellulite. The study is targeted to enroll 63 women between 21 and 60 years of age. The study's objectives are to assess the safety, effectiveness and pharmacokinetics of XIAFLEX for the treatment of cellulite. Auxilium expects topline results in the fourth quarter of 2012. According to a January 26, 2012 press release in which Auxilium announced that the first cohort of patients had been dosed, "[t]o qualify for the study, participants must have EFP in the posterolateral thighs and/or buttocks for at least 12 months prior to a screening visit. Following screening and determination of eligibility, study participants will be assigned to one of seven groups that vary in treatment dose, injection concentration and volume. Subjects will receive 10 concurrent injections (0.1 or 0.5 mL per injection) of XIAFLEX via a standardized template over a targeted area (8 cm x 10 cm) of EFP. The total dose of XIAFLEX that will be administered into the targeted area will range between 0.0029 mg and 0.116 mg; these doses represent between 0.5% and 20% of the dose used in a single injection for Dupuytren's contracture (0.58 mg). Safety will be evaluated through the collection of adverse events, as well as a targeted assessment of local reactions to the treatment. The treatment effectiveness will be evaluated by investigator and patient assessments, as well as 3-D photographic imaging techniques. More information on the study will be posted at www.clinicaltrials.gov".

7

Table of Content

Additional Clinical Indications For Collagenase

Human Lipoma

Lipomas are benign fatty tumors that occur as bulges under the skin and affect humans and canines. It is estimated that lipomas are the primary diagnosis in 575,000 patients in the U.S. annually. The only proven therapy for lipoma treatment is surgery, which is often not practical for patients with multiple lipomas. Based on observations made during preclinical studies that a collagenase injection decreased the size of fat pads in animals, we initiated, monitored and supplied the requisite study drug for a Phase I open label clinical trial for the treatment of human lipomas with a single injection of collagenase. Favorable initial results (10 out of 12 patients had a 50-90% reduction in the size of the lipomas) from this trial for the treatment of lipomas were presented at a meeting of the American Society of Plastic Surgeons.

We have designed a phase II dose escalation clinical study of XIAFLEX for the treatment of human lipomas. The study consists of 14 patients and four dosage groups for the treatment of benign subcutaneous lipomas. We have received FDA clearance to initiate the clinical trial and plan to do so during the first half of 2012.

Canine Lipoma

Based on the encouraging results reported in the clinical investigations in human lipoma, we began clinical trials in canine lipoma. Lipomas are found in 2.3% of canines, and there may be as many as 1.7 million canines affected with skin lipomas in the U.S. Lipomas in older canines are very common, and lipomas that restrict motion in older canines are a serious problem. The only proven therapy for this condition is surgical excision of the lipoma, which necessarily involves the use of general anesthesia. It has been estimated that up to 2% of sick canines die as a complication of general anesthesia (See Brodbelt Vet J 2009 Dec; 182 (3): 375-6). We surveyed 77 veterinarians which included participants from the academic field and others that are in private practice. The participants indicated that on average they perform 25 lipoma excision surgeries per year at an average cost of $530 for the surgical procedure. It is conservatively estimated that 47,000 veterinarians are in active practice in the U.S.

Chien-801 and Chien-802 Clinical Trials

Chien-801 was a pilot study conducted for the purpose of evaluating the use of purified collagenase for the non-surgical treatment of lipoma in six canines. The study evaluated the appropriate dosage and frequency of injections necessary to significantly reduce the size of the lipoma. The dose administered ranged from 0.012 to 0.021 mg/ cm2 which was approximately ½ to ¾ of the dose used in previous human clinical trials. Based on this dose escalation study the Company selected the dose for Chien-802.

Chien-802 was designed to evaluate the efficacy of injectable collagenase in canine lipoma in four healthy canines with subcutaneous lipomas. Inclusion criteria required the lipoma to be benign, superficial and easily measureable. All canines had a second lipoma that was untreated and used as a control. At 90 days post injection, in the three evaluable canines, the lipoma size was 0%, 0% or 7% of the original size as measured by a CT scan. By contrast, the untreated lipomas were 129%, 113% and 128% of the original size at day 90. Thus, the treated lipomas showed a 97% reduction in the size of the lipoma and an increase in the size of the untreated controls of 23%.

Chien-803

Based on the positive results from Chien-802, we announced on January 6, 2011 that we had begun enrollment in a randomized, double-blind, placebo-controlled study designed to evaluate the efficacy of purified collagenase for injection for the treatment of canine lipomas. The trial was to enroll 25 canines, each having two or more lipomas. To

meet the primary endpoint, an animal would have to have achieved at least a 50% decrease in the drug-treated lipoma volume relative to baseline as measured by CT scan at 3 months post injection. We subsequently discontinued this study and designed a new clinical trial, Chien 804, following our settlement and amended and restated development and license agreement with Auxilium in August 2011.

Chien-804

We have designed a placebo controlled randomized study to evaluate the efficacy of XIAFLEX for the treatment of subcutaneous benign lipomas in canines. The study will consist of 32 canines randomized at 1:1 XIAFLEX or placebo. The treatment is a single injection of XIAFLEX or placebo. We have received clearance from the FDA's Center for Veterinary Medicine to begin the study and expect to do so during the first half of 2012.

Table of Content

Other Clinical Indications

Other clinical indications for which our collagenase injection has been tested include keloids, hypertrophic scars, scarred tendons, glaucoma, herniated intervertebral discs, and as an adjunct to vitrectomy.

LICENSING AND MARKETING AGREEMENTS

Topical Collagenase Agreement

In connection with a March 2006 agreement (the "DFB Agreement"), pursuant to which we sold our topical collagenase business to DFB Biotech, Inc. and its affiliates ("DFB"), until March 2011 we received payments for certain technical assistance and certain transition services that we provided to DFB. Pursuant to the DFB Agreement, we continue to receive earn out payments based on the sales of certain products. Our right to receive earn out payments with respect to the marketed topical product sold to DFB expires in June 2013, but earn out payments for second generation collagenase products, if any, continue indefinitely.

In 2011, we received $46,667 of technical assistance related payments, and as of December 31, 2011, we have received a total of $1.4 million in consulting fees. In addition, we have recognized $2.3 million in earn out payments from DFB in connection with the net sales of topical collagenase in 2011.

Auxilium Agreement

Under the Auxilium Agreement, we granted to Auxilium exclusive worldwide rights to develop, market and sell certain products containing our injectable collagenase. Currently its licensed rights cover the indications of Dupuytren's contracture, Peyronie's disease and frozen shoulder. We also granted Auxilium the right to initiate early stage development of cellulite, and Auxilium is responsible for all costs associated with that development. Auxilium may further expand the Auxilium Agreement, at its exclusive option, to develop and license our injectable collagenase for use in additional indications. Auxilium has partnered with Pfizer pursuant to the Pfizer Agreement, and Pfizer is responsible for marketing XIAPEX for the treatment of both Dupuytren's contracture and Peyronie's disease in Europe and certain Eurasian countries (the "Pfizer Territory") and is primarily responsible for regulatory activities for XIAPEX in the Pfizer Territory. Auxilium has granted to Asahi the exclusive right to develop and commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Japan. Auxilium has granted to Actelion the exclusive right to develop and commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Canada, Australia, Brazil and Mexico.

Through December 31, 2011, Auxilium has paid us up-front licensing and sublicensing fees and milestone payments under the Auxilium Agreement of $22.2 million, including amounts in connection with the Pfizer Agreement and Auxilium's agreement with Asahi. In addition to the payments already received by us and to be received by us with respect to the Dupuytren's contracture indication, Auxilium will be obligated to make contingent milestone payments, with respect to each of the Peyronie's disease and frozen shoulder indications, upon the acceptance of the regulatory filing and receipt by Auxilium, its affiliate or sublicensee of regulatory approval. Auxilium will also be obligated to make sublicense fee payments to us if it out-licenses to third parties the right to market and sell XIAFLEX for the treatment of frozen shoulder. Additional milestone obligations will be due if Auxilium exercises its option to develop and license XIAFLEX for additional indications.

In addition to the milestone payments from Auxilium, the Company is entitled to 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. Under the Pfizer Agreement, Auxilium received a $30 million milestone payment from Pfizer following the first sale of XIAPEX in the United Kingdom, which was the first

major market country in which Pfizer sold XIAPEX, and we received from Auxilium $2.5 million in connection with that first sale. For each additional major market country in which XIAPEX is launched, Auxilium is eligible to receive an additional $7.5 million. In connection with the launch of XIAPEX in each of Germany and Spain, we received from Auxilium 8.5% of each of the $7.5 million milestone payments from Pfizer to Auxilium, or $637,500. We will receive 8.5% of the $350 million, or $29.8 million, in potential additional milestone payments that may be made by Pfizer to Auxilium under the Pfizer Agreement. As of January 25, 2012, we have received $11.4 million in milestones related to the Pfizer Agreement. In 2011, we received $750,000 of the $15 million upfront payment Auxilium received from Asahi. Auxilium has reported that it is to receive a $10 million upfront payment from Actelion in connection with their recently announced agreement, and we will receive a specified percentage from Auxilium in connection with such payment. To the extent Auxilium enters into an agreement or agreements related to other territories, the percentage of sublicense income that Auxilium would pay us will depend on the stage of development and approval of XIAFLEX for the particular indication at the time such other agreement or agreements are executed.

Table of Content

Auxilium must pay us on a country-by-country and product-by-product basis a low double digit royalty as a percentage of net sales for products covered by the Auxilium Agreement and sold in the United States, the Pfizer Territory and Japan. In the case of products covered by the Auxilium Agreement and sold in other countries (the "Rest of the World"), Auxilium must pay us on a country-by-country and product-by-product basis a specified percentage of the royalties it is entitled to receive from a partner or partners with whom it has contracted for such countries (a "Rest of the World Partner"), which in the case of Canada, Australia, Brazil and Mexico is Actelion. The royalty rate is independent of sales volume and clinical indication in the United States, the Pfizer Territory and Japan, but is subject to set-off in those countries and the Rest of the World for certain expenses we owe to Auxilium relating to certain development and patent costs. In addition, the royalty percentage may be reduced if (i) market share of a competing product exceeds a specified threshold; or (ii) 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, although Auxilium has confirmed to us that no license from a third party is required. 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.

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

On top of 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 in the United States, the Pfizer Territory or Japan. For products sold in the Rest of the World, Auxilium must pay to us a specified percentage of the mark-up of the cost of goods sold it is entitled to receive from a Rest of the World Partner, including Actelion, without regard to any set-offs that the Rest of the World Partner may have with respect to Auxilium.

Auxilium is generally responsible, at its own cost and expense, for developing the formulation and finished dosage form of products and arranging for the clinical supply of products. Auxilium is generally responsible for all clinical development and regulatory costs for Peyronie's disease, Dupuytren's contracture, frozen shoulder and all additional indications for which it exercises its options. In addition, Auxilium is responsible for all costs associated with its early stage development for cellulite.

A redacted copy of the Auxilium Agreement was filed on Form 8-K with the SEC on September 1, 2011. 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 Auxilium 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 Contracture

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 contracture.

Table of Content

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 contracture (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 Office of Orphan Products Development ("OOPD") with respect to the Dupuytren's Licensed Product; or (iii) June 3, 2016.

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

Peyronie's Disease

On August 27, 2008, we entered into an agreement 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 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 under that agreement will continue in effect until the termination of our royalty obligations. After

that, all licenses granted to us under the Frozen Shoulder License Agreement will become fully paid, irrevocable exclusive licenses.

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

Table of Content

Other Indications

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

COMPETITION

We and our licensees face worldwide competition from larger pharmaceutical companies, specialty pharmaceutical companies and biotechnology firms, universities and other research institutions and government agencies that are developing and commercializing pharmaceutical products. Many of our competitors have substantially greater financial, technical and human resources than we have and may subsequently develop products that are more effective, safer or less costly than any products that we have developed, are developing or will develop, or that are generic products. Our success will depend on our ability to acquire, develop and commercialize products and our ability to establish and maintain markets for our products that receive marketing approval.

COST OF RESEARCH AND DEVELOPMENT ACTIVITIES

During fiscal years 2011 and 2010, the Company invested $972,078 and $1,223,931, respectively, in research and development activities.

GOVERNMENT REGULATION

Any product labeled for use in humans requires regulatory approval by government agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials to demonstrate 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 and 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, we or our partners may suspend or terminate clinical trials at any time for various reasons, including a finding that the subjects or patients are being exposed to an unacceptable health risk. The 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 an 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.

Table of Content

Before approving an NDA or BLA, the FDA will inspect the facility or facilities where the product is manufactured. The FDA will not approve the NDA or BLA unless cGMP compliance is satisfactory. The FDA will issue an approval letter if it determines that the NDA or BLA, manufacturing process and manufacturing facilities are acceptable. If the FDA determines that the NDA or BLA, 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 NDA or BLA does not satisfy the regulatory criteria for approval and refuse to approve the NDA or BLA 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 or our partners may encounter difficulties or unanticipated costs in our or their efforts to secure necessary governmental approvals, which could delay or preclude us or them from marketing our products. Furthermore, the FDA may prevent a 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 and any other requirements set forth in the FDA’s approval (such as the REMS program, which the FDA has required for XIAFLEX and consists of a communication plan and a medication guide). 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 impose 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 regulatory requirements. 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/BLA and FDA approval of the new labeling claims. The purpose of these trials and studies is to broaden the application and use of the 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, at the facilities of our contract manufacturers or at those of our partners 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

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.

Table of Content

Patents

We are the assignee or licensee of various U.S. patents, which have received patent protection in various foreign countries. Pursuant to our August 31, 2011 settlement agreement with Auxilium, we are now co-owners of U.S. Patent No. 7,811,560 and any continuations and divisionals thereof. Auxilium expects this patent will expire in July 2028. In addition, we have licenses to other pending patent applications. Although we believe these patent applications, if they issue as patents, will provide a competitive advantage, the scope of the patent positions of pharmaceutical firms involves complex legal, scientific and factual questions and, as such, is generally uncertain. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of our current patent applications, or the products or product candidates we develop, acquire or license will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection, will be of any value to us or will be challenged, circumvented or invalidated by our competitors or otherwise.

While we attempt to ensure that our product candidates and the methods we employ to manufacture them do not infringe other parties' patents and proprietary rights, competitors or other parties may assert that we infringe on their proprietary rights. Because patent applications in the U.S. and some other jurisdictions can proceed in secrecy until patents issue, third parties may obtain other patents without our knowledge prior to the issuance of patents relating to our product candidates, which they could attempt to assert against us. Also, since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office (the "USPTO") to determine priority of invention, or in opposition proceedings in the USPTO, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. In the U.S., issued patents may be broadened, narrowed or even canceled as a result of post-issuance procedures instituted by us or third parties, including reissue, reexamination and the new supplemental examination procedure enacted as part of the Leahy-Smith America Invents Act. 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 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, assigned or licensed to us or to determine the scope and validity of other parties' proprietary rights, we may also become involved in litigation or in interference proceedings declared by the 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 licensed to Auxilium our injectable collagenase for the treatment of Dupuytren's contracture, Peyronie's disease, and frozen shoulder and have given a development license to Auxilium with respect to cellulite. We have two use patents in the U.S. covering the enzyme underlying our injectable collagenase, one for the treatment of Dupuytren's contracture, 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 contracture and Peyronie's disease within certain dose ranges. An application to extend the term of the Dupytren's patent to August 22, 2019 based upon regulatory delay in granting approval to sell XIAFLEX was filed in the USPTO on April 1, 2010. The

USPTO has not taken any action on the request for extension, and we cannot be certain how much of an extension, if any, will be granted by the USPTO.

Table of Content

Orphan Drug Designations

Two indications, Dupuytren's contracture and Peyronie's disease, have received orphan drug designation from the OOPD. These indications did not receive the European equivalent of orphan drug designation.

The OOPD administers the major provisions of the Orphan Drug Act, an innovative program that provides incentives for sponsors to develop products for rare diseases. The incentives for products that qualify under the Orphan Drug Act include seven-year exclusive marketing rights post-FDA approval (which means, with respect to Dupuytren's contracture, exclusivity until February 2, 2017), 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.

In the Auxilium 10-K, Auxilium stated that "[w]hile 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 believe the product will benefit from ten years of market exclusivity and eight 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." Our royalty term, however, is not extended by any period of marketing exclusivity as contrasted with any period of orphan drug status or foreign equivalent thereof.

Trade Secrets

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

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

EMPLOYEES

The Company currently has five employees, 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 telephone number is 516-593-7000. Our corporate headquarters are currently located at 35 Wilbur St., Lynbrook, NY 11563, as further described in this Report under “Item 2 - Description of Property.”

Table of Content

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 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) contingent earn out payments from DFB and (iii) the sale of small amounts of collagenase for laboratory research.

As described in Item 1 above, under the Auxilium Agreement, in exchange for the right to receive royalties and other payments, 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 contracture, Peyronie's disease, and frozen shoulder. However, we have no control over Auxilium's ability to successfully market, sell and manufacture candidate products for the treatment of Dupuytren's contracture, or, in the case of Peyronie's disease and frozen shoulder, to pursue commercialization, and we may receive limited, if any, royalty payments from Auxilium.

In addition, there is no guarantee that the XIAFLEX-specific CPT codes for the injection procedure and the finger extension or manipulation procedure administered after the injection will meet the expectations of physicians or significantly or quickly increase sales of XIAFLEX. Moreover, under the Auxilium Agreement, royalty payments are subject to set-off for certain expenses we owe Auxilium related to development and patent costs. We received our first royalty payment from Auxilium in November 2011 because the amount of royalties exceeded accrued set-off expenses for the first time. We anticipate that the amount of royalties due to us will exceed the amount of any set-offs on a going forward basis. 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 candidate products, but we have no control over Auxilium's ability to achieve the milestones. Additionally, we have received in the past, and are entitled to receive in the future, 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 granted to Auxilium the right to initiate early stage development of XIAFLEX for the treatment of cellulite, and Auxilium will be responsible for all costs associated with such early stage development. Auxilium has the option, upon completion of such early stage development and upon its payment to us of a one-time fee of $500,000, to add the treatment of cellulite to the list of Auxilium exercised indications, in which case we would receive milestone payments and royalties for further cellulite development. Even if Auxilium exercises its option with respect to cellulite, its obligations to develop the product for such indication are limited to initiating Stage II Development (as defined in the Auxilium Agreement) for such indication within one year of exercising the option as to such indication.

In addition, we have granted to Auxilium an option to expand its license and development rights to one or more additional indications for injectable collagenase not currently licensed to Auxilium, including for the treatment of human and canine lipoma. If Auxilium exercises its option with respect to an additional indication, we are entitled to receive a one-time license fee for the rights to, as well as potential milestone, royalty and other payments with respect to, such new indication. If 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 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. Even if Auxilium exercises its option as to any additional indication, its obligations to develop the product for such indication are limited to initiating Stage II Development (as defined in the Auxilium Agreement) for such additional indication within one year of exercising the option as to such indication.

Table of Content

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 the manufacture and commercialization of such products and its ability to achieve certain sales thresholds.

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. These obligations expired during March 2011.

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 in the Auxilium 10-K.

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 generate sufficient sales of topical collagenase products to entitle us to receive any earn out payments.

If we are unable to obtain option, milestone, earn out and 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 business strategy contains elements that we will not be able to implement 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. While we anticipate being profitable on an ongoing, annual basis, 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 until June 2013, when DFB's obligations to us terminate, absent the introduction of a second generation product as defined in the DFB Agreement;

Auxilium's ability to manufacture and commercialize XIAFLEX for which we would receive milestone and royalty payments;

Pfizer's ability to develop and commercialize XIAPEX 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 in the Auxilium 10-K);

the amount actually owed to Auxilium for certain patent costs;

the scope, rate of progress, cost and results of our clinical trials on additional indications, including human and canine lipoma, for which Auxilium could exercise its option to acquire rights to them, and whether Auxilium exercises the option;

the rate of progress and results of Auxilium's development of XIAFLEX for the treatment of cellulite, for which we granted Auxilium the right to initiate clinical studies and Auxilium is responsible for development costs, and whether Auxilium pursues development beyond the early stages;

Table of Content

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.

If we breach our agreements with third parties, our business could be materially harmed.

Our agreements with third parties impose on us various obligations, such as those related to intellectual property rights, non-competition, and development of products, as described throughout this Item 1A of this Report. If we fail to comply with such obligations, or a counterparty to our agreements believes that we have failed to comply with such obligations, we may be sued and the costs of the resulting litigation could materially harm our business.

Risks Related to Clinical Trials and Development of Drug Candidates

Our ability to conduct clinical trials may be limited by the Auxilium Agreement.

Under the Auxilium Agreement, we have the right to conduct trials, studies or development work for, among other things, indications in canine lipomas and human lipomas, and, upon approval by the parties' joint development committee ("JDC"), additional indications. Auxilium has pre-approved our protocols for canine lipomas and human lipomas. However, certain material changes to the protocols must be approved by the JDC, and the JDC may decide not to approve such changes if the JDC has reasonable safety concerns. In addition, the JDC has the right to stop a study or trial in canine lipomas and human lipomas if the rate of serious adverse events exceeds certain thresholds. If the JDC fails to approve changes to our protocols for canine lipomas and human lipomas or if the JDC stops our studies or trials in canine lipomas and human lipomas due to safety concerns, our ability to obtain option, milestone and royalty payments with respect to those indications would be limited. We may only conduct trials, studies or development work for additional indications beyond the pre-approved indications upon submission to and approval by the JDC of our development plan. In the case of indications in keloids, capsular contraction after breast augmentation, arthrofibrosis following total joint replacement in humans and equine suspensory ligament desmitis, the JDC may reject our submission only for reasonable safety concerns. The JDC may reject our submission for any other additional indications for safety or commercial concerns. If the JDC rejects our submissions in any additional indications, our ability to obtain option, milestone and royalty payments with respect to those additional indications would be limited.

18

Table of Content

We are dependent on Auxilium for access to XIAFLEX, which may limit our ability to conduct clinical trials and to obtain the associated option, milestone and contingent royalty payments under the Auxilium Agreement.

Under the Auxilium Agreement, we have agreed to buy at cost plus a mark-up XIAFLEX from Auxilium for conducting our trials, studies and development work. If Auxilium does not supply XIAFLEX to us, our ability to conduct clinical trials using XIAFLEX would be limited because we do not have the right to make XIAFLEX or to purchase it from third parties. Moreover, our ability to use our own clinical material may be limited both by lack of availability and by certain potential regulatory restrictions. Without adequate supply of clinical material our ability to obtain additional option, milestone and royalty payments under the Auxilium Agreement would be limited.

If clinical trials in humans or veterinarian trials for our potential new indications are delayed, we may not be able to obtain option, milestone or royalty payments under the Auxilium Agreement for new indications.

Clinical trials that we or our investigators may conduct may not begin on time or may need to be restructured or temporarily suspended after they have begun. Clinical trials can be delayed or may need to be restructured for a variety of reasons, including delays or restructuring related to:

- changes to the regulatory approval process for product candidates;
- obtaining regulatory approval to commence a clinical trial;
- timing of responses required from regulatory authorities;
- negotiating acceptable clinical trial agreement terms with prospective investigators or trial sites;
- obtaining institutional review board, or equivalent, approval to conduct a clinical trial at a prospective site;
- recruiting subjects to participate in a clinical trial;
- competition in recruiting clinical investigators;
- shortage or lack of availability of clinical trial supplies from external and internal sources;
- the need to repeat clinical trials as a result of inconclusive results or poorly executed testing;
- failure to validate a patient-reported outcome questionnaire;
- the placement of a clinical hold on a study;
- the failure of third parties conducting and overseeing the operations of our clinical trials to perform their contractual or regulatory obligations in a timely fashion; and
- exposure of clinical trial subjects to unexpected and unacceptable health risks or noncompliance with regulatory requirements, which may result in suspension of the trial.

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

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

clinical trials may show product candidates to be ineffective or not as effective as anticipated or to have harmful side effects or 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 from obtaining exclusivity.

Table of Content

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

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

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

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

- the nature, timing and estimated costs of the efforts necessary to complete the development of our drug candidate projects;
- the anticipated completion dates for our drug candidate projects;
- the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future with respect to our drug candidate projects;
- the scope, rate of progress of our preclinical studies and other research and development activities related to our drug candidate projects;
- clinical trial results for our drug candidate projects;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our drug candidate projects;
- the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our drug candidate projects;
- the cost and timing of regulatory approvals with respect to our drug candidate projects; and
- the cost of establishing clinical supplies for our drug candidate projects.

Risks Related to Our Agreements with Auxilium and DFB

Our ability to conduct clinical trials and develop products for injectable administration of collagenase is limited by the Auxilium Agreement.

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

Our ability to conduct clinical trials and develop products for topical administration of collagenase is limited by the agreement we have signed with DFB.

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

Table of Content

Risks Related to Regulatory Requirements

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

Conducting clinical trials for human drugs and, in certain circumstances, veterinarian trials for animal drugs, and the testing, development and manufacturing and distribution of product candidates are subject to regulation by numerous governmental authorities in the U.S. and other jurisdictions, if we desire to export the resulting products to such other jurisdictions. These regulations govern or affect the testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, advertising and promotion of product candidates, as well as safe working conditions. 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 a 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. Even after a product candidate has been approved, the FDA and comparable governmental authorities subject such product to continuing review and regulatory requirements including, for example, requiring the conducting and reporting of the results of certain clinical studies or trials and commitments to voluntarily conduct additional clinical trials. In addition, regulatory approval could impose limitations on the indicated or intended uses for which product candidates may be marketed. With respect to its approval of XIAFLEX for the treatment of adult Dupuytren's contracture patients with a palpable cord, for example, the FDA has required a REMS program consisting of a communication plan and a medication guide. 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 applicable regulatory requirements may result in a variety of consequences, including the following:

restrictions on our products or manufacturing processes;

warning letters;

withdrawal of a product from the market;

voluntary or mandatory recall of a product;

fines;

suspension or withdrawal of regulatory approvals for a product;

refusal to permit the import or export of our products;

refusal to approve pending applications or supplements to approved applications that we submit;

denial of permission to file an application or supplement in a jurisdiction;

product seizure; and

injunctions or the imposition of civil or criminal penalties against us.

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

Table of Content

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 the Sarbanes-Oxley Act of 2002 ("SOX"), some of which have only recently been revised or adopted. We cannot assure you that we are or will be in compliance with all potentially applicable laws and regulations. Failure to comply with all potentially applicable laws and regulations could lead to the imposition of fines, cause the value of our common stock to decline, impede our ability to raise capital or list our securities on certain securities exchanges. 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.

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

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

Risks Related to Growth and Employees

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

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

Auxilium reported in the Auxilium 10-K that the most common adverse events in the Peyronie's phase IIb clinical trial were "injection site bruising, injection site pain, injection site edema, contusion, penile edema and penile pain."

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 it 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. Even if our product candidates receive regulatory approval, new safety issues may be reported and we or our partners may be required to amend the conditions of use for a product.

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

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

Table of Content

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/or 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 suffer 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 $5 million dollars that we believe is adequate in both scope and amount and has been placed with what we believe are reputable insurers. We may not be able to maintain our clinical trial and product liability insurance at an acceptable cost, if at all, and this insurance may not provide adequate coverage against potential claims or losses. If losses from product liability claims exceed our insurance coverage, we may incur substantial liabilities that exceed our financial resources, and our business and results of operations may be harmed. Whether or not we are ultimately successful in product liability litigation, such litigation could consume substantial amounts of our financial and managerial resources, and might result in adverse publicity, all of which could impair our business.

If we are unable to negotiate a new lease for our corporate headquarters or relocate, our existing operations and our operating results could be adversely affected.

As described in this Report under “Item 2 - Description of Property”, we are holding over in our current premises on a month-to-month basis. If we are unable to negotiate a new lease for our current premises or relocate to other premises, our existing operations and operating results could be adversely affected.

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 terminates its agreement, whether by its terms or due to our breach, our right to use the party’s 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 our 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.

Table of Content

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, which could, in effect, limit the scope of our patent rights and those of our licensees, licensors or collaborators. Our agreements with Auxilium and DFB require us to indemnify them against any claims for infringement based on the use of our technology. If we become involved in any litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. If 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 is 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

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 The Nasdaq Global Market ("Nasdaq") and is thinly traded.

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

results of our clinical trials;

failure of any product candidates we have licensed to 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.

Table of Content

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. In addition, purchases of our common stock pursuant to our stock repurchase program may, depending on the timing and volume of such repurchases, result in our stock price being higher than it would be in the absence of such repurchases. If repurchases pursuant to the program are discontinued, our stock price may fall.

We may become subject to stockholder activism efforts that could cause material disruption to our business.

Certain influential institutional investors, hedge funds and other stockholders have taken steps to involve themselves in the governance and strategic direction of certain companies due to governance or strategic related disagreements between such companies and such stockholders. If we become subject to such stockholder activism efforts, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and adversely affect the market price of our common stock.

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, 2011, options to purchase 1,261,425 shares of common stock were outstanding. In addition, as of December 31, 2011 a total of 269,098 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.

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

The trading market for our common stock will depend in part on research reports that industry or financial analysts publish about us or our business. If analysts downgrade us or any of our licensees, or other research analysts downgrade the industry in which we operate or the stock of any of our competitors or licensees, the price of our common stock will probably decline.

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

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

provide for a classified board 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.

Table of Content

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. The Board amended the Poison Pill in February 2011 to increase the threshold from 15% to 18% and extended the expiration date of the Poison Pill for an additional two years, to May 31, 2014. 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 12, 2012 our executive officers, directors and their affiliates, in the aggregate, beneficially owned shares representing approximately 29.6% of our common stock. Beneficial ownership includes shares over which an individual or entity has investment or voting power and includes shares that could be issued upon the exercise of options within 60 days. As a result, if these stockholders were to choose to act together, they may be able to control all matters submitted to our stockholders for approval, as well as our management and affairs. For example, 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.

Item IB. UNRESOLVED STAFF COMMENTS

None.

Item 2. DESCRIPTION OF PROPERTY.

Our corporate headquarters are currently located at 35 Wilbur St., Lynbrook, NY 11563. As previously reported, we are currently holding over in our premises on a month-to-month basis.

Item 3. LEGAL PROCEEDINGS.

None.

Item 4. (REMOVED AND RESERVED).

PART II

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

Market Information

Our common stock currently trades under the symbol BSTC on Nasdaq.

The table below sets forth the high and low closing sale prices for our common stock for each of the quarterly periods in 2011 and 2010 as reported by and as quoted by Nasdaq, as applicable:

2011	HIGH	LOW
Fourth Quarter	$ 19.08	$ 13.36
Third Quarter	$ 25.04	$ 14.80
Second Quarter	$ 25.52	$ 22.40
First Quarter	$ 26.88	$ 23.00

2010	HIGH	LOW
Fourth Quarter	$ 27.86	$ 20.71
Third Quarter	$ 27.36	$ 18.80
Second Quarter	$31.72	$19.02
First Quarter	$29.98	$26.53

Table of Content

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

Holders of Record

As of March 1, 2012, there were approximately 75 holders of record of our common stock. Because many of such shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of stockholders represented by these record holders.

Dividends

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

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2011 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)	1,261,425	$ 8.27	269,098
Equity compensation plans not approved by security holders	-	-	-
Total	1,261,425	$ 8.27	269,098

(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.

Recent Sales of Unregistered Securities

For the year ended December 31, 2011, we did not issue any unregistered shares of securities.

Table of Content

Issuer Purchases of Equity Securities (1)

Month	Total Number of Shares Purchased During Quarter (2)	Average Price Paid Per Share (3)	Total Number of Shares Purchased as Part of Publicly Announced Plan	Maximum Dollar Value of Shares that may yet be Purchased under the Plan (4)	
January 1, 2011 – March 31, 2011	-	-	20,608	$ 1,541,999	
April 1, 2011 – June 30, 2011	8,777	$ 23.51	29,385	$ 1,335,651	
				$ 2,000,000	(5)
July 1, 2011 – September 30, 2011	8,981	$ 17.18	38,366	$ 1,845,900	
October 1, 2011 to December 31, 2011	24,971	$ 15.18	63,337	$ 1,466,796	
Total	42,729				

(1) On June 4, 2010, we announced that our board of directors authorized a stock repurchase program under Rule 10b-18 of the Exchange Act of up to $2.0 million of our outstanding common stock over a period of 12 months. On June 20, 2011, we announced that our Board of Directors had reauthorized this stock repurchase program.

(2) The purchases were made in open-market transactions.

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

(4) Represents the difference between the reauthorized $2.0 million of stock repurchases by our board of directors on June 20, 2011 less the value of the stock repurchased for the indicated period.

(5) On June 20, 2011, our board of directors reauthorized the repurchase of up to $2.0 million of our common stock under the stock repurchase program.

Performance Graph

The graph below compares the cumulative total stockholder return on our common stock with the cumulative total stockholder return of (i) the NASDAQ Biotechnology Index, and (ii) the NASDAQ Composite Index, assuming an investment of $100 on December 31, 2006, in each of our common stock; the stocks comprising the NASDAQ Composite Index; and the stocks comprising the NASDAQ Biotechnology Index.

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

	12/31/2006	12/31/2007	12/31/2008	12/31/2009	12/31/2010	12/31/2011
Biospecifics Technologies Corp	$100.00	$263.16	$563.16	$772.37	$673.68	$437.37
Nasdaq Biotechnology Index	$100.00	$104.58	$91.38	$105.63	$121.52	$135.86
Nasdaq Composite Index	$100.00	$109.81	$65.29	$93.95	$109.84	$107.86

Table of Content

*Total return assumes $100 invested on December 31, 2006 in our common stock, the NASDAQ Composite Index, and the NASDAQ Biotechnology Index and reinvestment of dividends through fiscal year ended December 31, 2011.

Item 6. SELECTED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes appearing elsewhere in this Report. The consolidated statements of operations data for the years ended December 31, 2011, 2010 and 2009 and the consolidated balance sheet data as of December 31, 2011 and 2010 have been derived from our audited consolidated financial statements and related notes, which are included elsewhere in this Report. The consolidated statement of operations data for the years ended December 31, 2008 and 2007 and the consolidated balance sheet data as of December 31, 2009, 2008 and 2007 have been derived from audited financial statements which do not appear in this Report. The historical results presented are not necessarily indicative of results to be expected in any future period.

	Years Ended December 31,				
Consolidated Statement of Operations Data	2011	2010	2009	2008	2007
Net revenues	$11,395,726	$5,661,348	$3,155,757	$8,411,780	$1,514,334
Operating expenses:					
Research and development	972,078	1,223,931	488,646	439,919	2,489,122
General and administrative	5,231,881	6,470,449	4,832,019	4,191,052	3,516,716
Total operating expenses	6,203,959	7,694,380	5,320,665	4,630,971	6,005,838
Operating income (loss)	5,191,767	(2,033,032)	(2,164,908)	3,780,809	(4,491,504)
Other income (expense):					
Interest income	55,780	86,310	55,693	107,552	126,821
Interest expense	-	-	(39)	46,529	(781)
Other	15,823	13,130	(8,863)	108,730	(125,000)
Qualifying Therapeutic Credit	-	426,403	-	-	-
	71,603	525,843	46,791	262,811	1,040
Income (loss) before income tax	5,263,370	(1,507,189)	(2,118,117)	4,043,620	(4,490,464)
Income tax benefit (expense)	1,338,256	(1,351)	161,574	(299,212)	(53,865)
Net income (loss)	$6,601,626	$(1,508,540)	$(1,956,543)	$3,744,408	$(4,544,329)
Basic net income (loss) per share	$1.04	$(0.24)	$(0.32)	$0.64	$(0.86)
Diluted net income (loss) per share	$0.95	$(0.24)	$(0.32)	$0.55	$(0.86)
Shares used in computation of basic net income (loss) per share	6,340,648	6,261,214	6,065,939	5,854,836	5,291,506
Shares used in computation of diluted net income (loss) per share	6,952,386	6,261,214	6,065,939	6,836,911	5,291,506

	Years Ended December 31,				
Consolidated Balance Sheet Data:	2011	2010	2009	2008	2007
Cash and cash equivalents	$3,196,831	$2,470,852	$3,950,389	$3,494,150	$68,564
Short-term investments	5,000,000	5,360,970	4,548,541	900,000	975,000
Total assets	16,265,073	11,518,701	11,748,478	12,831,361	1,261,211
Total stockholders' equity (deficit)	14,872,314	6,700,723	6,092,107	6,178,539	(6,735,658)

Table of Content

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

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

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 for injectable collagenase (which Auxilium has named XIAFLEX® (collagenase clostridium histolyticum)) for clinical indications in Dupuytren's contracture, Peyronie's disease and frozen shoulder (adhesive capsulitis). Auxilium has an option to acquire additional indications that we may pursue, including cellulite, for which we have granted Auxilium the right to initiate early development studies at its cost, and human and canine lipoma. Auxilium is currently selling XIAFLEX in the U.S. for the treatment of Dupuytren's contracture. Auxilium has an agreement with Pfizer pursuant to which Pfizer has the right to market XIAFLEX for Dupuytren's contracture and Peyronie's disease in Europe and certain Eurasian countries, and will do so under the registered trademark XIAPEX® (collagenase clostridium histolyticum). Pfizer is currently selling XIAPEX in nine countries in Europe, including the United Kingdom, Germany and Spain. In addition, Auxilium has an agreement with Asahi pursuant to which Asahi has the right to commercialize XIAFLEX for the treatment of Duputyren's contracture and Peyronie's disease in Japan. Auxilium also has an agreement with Actelion pursuant to which Actelion has the right to commercialize XIAFLEX for the treatment of Duputyren's contracture and Peyronie's disease in Canada, Australia, Brazil and Mexico

Operational Highlights

As previously reported, on August 31, 2011, we and Auxilium announced the dismissal of all pending litigation between us in accordance with a settlement agreement. Pursuant to the settlement agreement, among other things, we became a co-owner with Auxilium of U.S. Patent No. 7,811,560 and any continuations and divisionals of that patent. Also on August 31, 2011, we amended and restated our development and license agreement with Auxilium to clarify and change certain of our and Auxilium's rights and responsibilities. We clarified, for example, that we retain the right to conduct trials, studies or development work for: indications in canine lipomas and human lipomas; additional indications upon approval by the parties' joint development committee; tissue disassociation research and development; and in vitro research and development. In addition, on August 31, 2011, we announced with Auxilium plans to move XIAFLEX forward in the clinic for cellulite and human and canine lipoma as well as to collaborate on the initiation of further studies for XIAFLEX for additional indications. A phase Ib trial of XIAFLEX for the treatment of cellulite is currently underway by Auxilium. Auxilium expects top line study results in the fourth quarter of 2012. In addition, as announced by Auxilium on December 1, 2011, Auxilium currently has underway a phase IIa, open-label, controlled dose-ranging study to assess the safety and efficacy of XIAFLEX for the treatment of Frozen Shoulder syndrome in comparison to an exercise-only control group. Auxilium expects topline study results in the first half of 2013.

Auxilium continues to market XIAFLEX in the U.S. for the treatment of adult Dupuytren's contracture patients with a palpable cord. On November 2, 2011, it announced that the AMA has issued two new CPT Codes that will be used with XIAFLEX for the treatment of adult Dupuytren's contracture patients with a palpable cord beginning January 1, 2012. CPT codes are the most widely accepted form of medical nomenclature used to report medical procedures and

services under public and private health insurance programs in the U.S. The new CPT codes are 20527 for the XIAFLEX injection procedure and 26341 for the finger extension or manipulation procedure administered 24 hours after the XIAFLEX injection, in accordance with the label. According to the November 2, 2011 press release, “The CPT codes will apply to the procedures only, and leave in place the separate J code for reimbursement” of XIAFLEX.

Table of Content

In December 2011, we announced the appointment of George Gould, Esq., to our board of directors. Mr. Gould brings considerable expertise in pharmaceutical and biotechnology intellectual property law and has served as an expert witness in patent cases.

Auxilium has also recently announced leadership changes including a new Chief Executive Officer, Adrian Adams in December 2011, a new Executive Vice President, Chief Administrative Officer and General Counsel, Andrew I. Koven and a new Senior Vice President, Sales, Mark A. Glickman, in February 2012. In the press release announcing Mr. Adams' appointment as CEO, the Chairman of Auxilium's board of directors, Rolf Classon, stated "We believe that [Adrian's] visionary leadership and operational expertise will lead Auxilium to profitability and success as we seek to maximize the value of XIAFLEX . . . while delivering on our current pipeline."

In a February 23, 2012 press release, Auxilium announced that it had entered into a Collaboration Agreement with Actelion pursuant to which Actelion has the right to develop and commercialize XIAFLEX for the treatment in humans of Dupuytren's contracture and Peyronie's disease in Canada, Australia, Brazil and Mexico. According to the release, XIAFLEX for the treatment of Dupuytren's contracture has been accepted for review by Health Canada and regulatory action is expected in the second half of 2012. Additionally, Actelion expects to file for approval of XIAFLEX for the treatment of Dupuytren's contracture in Australia, Brazil and Mexico over the next 12 months. Under the terms of the agreement with Actelion, Auxilium is to receive a $10 million upfront payment from Actelion, as well as up to $16 million in potential regulatory, pricing, and reimbursement milestone payments and $42.5 million in potential sales milestone payments. Under the terms of our development and license agreement with Auxilium, we will receive a certain percentage from Auxilium in connection with the upfront payment by Actelion, and a certain percentage of any additional milestones received by Auxilium. We will also receive from Auxilium royalties from net sales and payments on costs of goods sold in Canada, Australia, Brazil and Mexico, which will be a specified percentage of what Auxilium is entitled to receive from Actelion without regard to any offset that Actelion may have with respect to Auxilium.

Outlook

In connection with the DFB Agreement, pursuant to which we sold our topical collagenase business to DFB, until March 2011 we received payments for certain technical assistance and certain transition services that we provided to DFB. Pursuant to the DFB Agreement, we continue to receive earn out payments based on the sales of certain products. Our right to receive earn out payments with respect to the marketed topical product sold to DFB expires in June 2013, but earn out payments for second generation collagenase products, if any, continue indefinitely.

In 2011, we received $46,667 of technical assistance related payments, and as of December 31, 2011, we have received a total of $1.4 million in consulting fees. In addition, we have recognized $2.3 million in earn out payments from DFB in connection with the net sales of topical collagenase in 2011.

Under the Auxilium Agreement, we granted to Auxilium exclusive worldwide rights to develop, market and sell certain products containing our injectable collagenase. Currently its licensed rights cover the indications of Dupuytren's contracture, Peyronie's disease and frozen shoulder. We also granted Auxilium the right to initiate early stage development of cellulite, and Auxilium is responsible for all costs associated with that development. Auxilium may further expand the Auxilium Agreement, at its exclusive option, to develop and license our injectable collagenase for use in additional indications. Auxilium has partnered with Pfizer pursuant to the Pfizer Agreement, and Pfizer is responsible for marketing XIAPEX for the treatment of both Dupuytren's contracture and Peyronie's disease in the Pfizer Territory and is primarily responsible for regulatory activities for XIAPEX in the Pfizer Territory. Auxilium has granted to Asahi the exclusive right to develop and commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Japan. Auxilium has granted to Actelion the exclusive right to develop and commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Canada, Australia,

Brazil and Mexico.

Through December 31, 2011, Auxilium has paid us up-front licensing and sublicensing fees and milestone payments under the Auxilium Agreement of $22.2 million, including amounts in connection with the Pfizer Agreement and Auxilium's agreement with Asahi. In addition to the payments already received by us and to be received by us with respect to the Dupuytren's contracture indication, Auxilium will be obligated to make contingent milestone payments, with respect to each of the Peyronie's disease and frozen shoulder indications, upon the acceptance of the regulatory filing and receipt by Auxilium, its affiliate or sublicensee of regulatory approval. Auxilium will also be obligated to make sublicense fee payments to us if it out-licenses to third parties the right to market and sell XIAFLEX for the treatment of frozen shoulder. Additional sublicense fees and milestone obligations will be due if Auxilium exercises its option to develop, license and sublicense XIAFLEX for additional indications.

Table of Content

In addition to the milestone payments from Auxilium, the Company is entitled to 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. Under the Pfizer Agreement, Auxilium received a $30 million milestone payment from Pfizer following the first sale of XIAPEX in the United Kingdom, which was the first major market country in which Pfizer sold XIAPEX, and we received from Auxilium $2.5 million in connection with that first sale. For each additional major market country in which XIAPEX is launched, Auxilium is eligible to receive an additional $7.5 million. In connection with the launch of XIAPEX in each of Germany and Spain, we received from Auxilium 8.5% of each of the $7.5 million milestone payments from Pfizer to Auxilium, or $637,500. We will receive 8.5% of the $350 million, or $29.8 million, in potential additional milestone payments that may be made by Pfizer to Auxilium under the Pfizer Agreement. As of January 25, 2012, we have received $11.4 million in milestones related to the Pfizer Agreement. In 2011, we received $750,000 of the $15 million upfront payment Auxilium received from Asahi. Auxilium has reported that it is to receive a $10 million upfront payment from Actelion in connection with their recently announced agreement, and we will receive a specified percentage from Auxilium in connection with such payment. To the extent Auxilium enters into an agreement or agreements related to other territories, the percentage of sublicense income that Auxilium would pay us will depend on the stage of development and approval of XIAFLEX for the particular indication at the time such other agreement or agreements are executed.

Auxilium must pay us on a country-by-country and product-by-product basis a low double digit royalty as a percentage of net sales for products covered by the Auxilium Agreement and sold in the United States, the Pfizer Territory and Japan. In the case of products covered by the Auxilium Agreement and sold in the Rest of the World, Auxilium must pay us on a country-by-country and product-by-product basis a specified percentage of the royalties it is entitled to receive from a Rest of the World Partner, which in the case of Canada, Australia, Brazil and Mexico is Actelion. The royalty rate is independent of sales volume and clinical indication in the United States, the Pfizer Territory and Japan, but is subject to set-off in those countries and the Rest of the World for certain expenses we owe to Auxilium relating to certain development and patent costs. In addition, the royalty percentage may be reduced if (i) market share of a competing product exceeds a specified threshold; or (ii) 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, although Auxilium has confirmed to us that no license from a third party is required. 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.

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

On top of 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 in the United States, the Pfizer Territory or Japan. For products sold in the Rest of the World, Auxilium must pay to us a specified percentage of the mark-up of the cost of goods sold it is entitled to receive from a Rest of the World Partner, including Actelion, without regard to any set-offs that the Rest of the World Partner may have with respect to Auxilium.

Auxilium is generally responsible, at its own cost and expense, for developing the formulation and finished dosage form of products and arranging for the clinical supply of products. Auxilium is generally responsible for all clinical development and regulatory costs for Peyronie's disease, Dupuytren's contracture, frozen shoulder and all additional

indications for which it exercises its options. In addition, Auxilium is responsible for all costs associated with its early stage development for cellulite.

Table of Content

A redacted copy of the Auxilium Agreement was filed on Form 8-K with the SEC on September 1, 2011. 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 Auxilium Agreement.

Significant Risks

In recent history we have had operating losses and may not achieve sustained profitability. As of December 31, 2011, we had an accumulated deficit from continuing operations of approximately $3.3 million.

We are dependent to a significant extent on third parties, and our principal licensee, Auxilium, may not be able to continue successfully commercializing XIAFLEX for Dupuytren's contracture, successfully develop XIAFLEX for additional indications, obtain required regulatory approvals, manufacture XIAFLEX at an acceptable cost, in a timely manner and with appropriate quality, or successfully market products or maintain desired margins for products sold, and as a result we may not achieve sustained profitable operations.

Critical Accounting Policies, Estimates and Assumptions

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles 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, milestones related to the achievement of particular stages in product development and royalties. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple-element arrangement should be treated as separate units of accounting for revenue recognition purposes, and if so, how the aggregate contract value should be allocated among the deliverable elements and when to recognize revenue for each element.

We recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete and, to the extent the milestone amount relates to our performance obligation, when our licensee confirms that we have met the requirements under the terms of the agreement, and when payment is reasonably assured. Changes in the allocation of the contract value between various deliverable elements might impact the timing of revenue recognition, but in any event, would not change the total revenue recognized on the contract. For example, nonrefundable upfront product license fees, for product candidates for which we are providing continuing services related to product development, are deferred and recognized as revenue over the development period.

Milestones, in the form of additional license fees, typically represent nonrefundable payments to be received in conjunction with the achievement of a specific event identified in a contract, such as completion of specified clinical

development activities and/or regulatory submissions and/or approvals. We believe that a milestone represents the culmination of a distinct earnings process when it is not associated with ongoing research, development or other performance on our part. We recognize such milestones as revenue when they become due and payment is reasonably assured. When a milestone does not represent the culmination of a distinct earnings process, we recognize revenue in a manner similar to that of an upfront product license fee.

Table of Content

Royalty/ Mark-up on Cost of Goods Sold / Earn-Out Revenue

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

Under the Auxilium Agreement, we do not participate in the selling, marketing or manufacturing of products for which we receive royalties and a mark-up of the cost of goods sold revenues. The royalty, mark-up on cost of goods sold revenues will generally be recognized in the quarter that Auxilium provides the written reports and related information to us, that is, royalty and mark-up on cost of goods sold revenues are generally recognized one quarter following the quarter in which the underlying sales by Auxilium occurred. The royalties payable by Auxilium to us are subject to set-off for certain third party development and patent costs.

Under the DFB Agreement, pursuant to which we sold our topical collagenase business to DFB, we have the right to receive earn-out payments in the future based on sales of certain products. Generally, under the DFB Agreement we would receive payments and a report within ninety (90) days from the end of each calendar year after DFB has sold the royalty-bearing product. Currently, DFB is providing us earn-out reports on a quarterly basis.

Consulting and Technical Assistance Services. We recognize revenues from consulting and technical assistance contracts primarily as a result of the DFB Agreement. Consulting revenues are recognized ratably over the term of the contract. The consulting and technical assistance obligations to DFB expired during March 2011.

Reimbursable Third Party Development Costs. We accrued expenses for research and development that are reimbursable by us under the Auxilium Agreement. We capitalize certain patent costs related to estimated third party development costs that are reimbursable under the Auxilium Agreement. In August 2011, through the amendment and restatement of our development and license agreement with Auxilium, we have clarified the rights and responsibilities of the joint development of XIAFLEX. We resolved what had been an on-going dispute with Auxilium concerning the appropriate amount of creditable third party development expenses related to the lyophilization of the injection formulation and certain patent expenses for research and development costs that are reimbursable under the Auxilium Agreement. We agreed to reimburse Auxilium by offsetting future royalties payable for the amount invoiced us for third party development costs related to the development of the lyophilization of the injection formulation.

As of December 31, 2011 our net reimbursable third party development and certain patent costs accrual is zero.

Receivables and Deferred Revenue. Under the DFB Agreement, we agreed to provide certain technical assistance and transitional services in consideration of fees and costs totaling over $1.4 million. At the closing of the DFB Agreement, DFB made a partial payment to us of $400,000 in respect of the technical assistance to be provided by us. To date, we have received a total of $1.4 million in payments from DFB. The consulting and technical assistance obligations expired during March 2011.

Royalty Buy-Down. In August 2008, we signed an agreement to significantly 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. We modified our agreement to lower future royalties payable on net sales of injectable collagenase, XIAFLEX, for Peyronie’s disease. In addition, we agreed to pay certain development milestones, if achieved.

As of December 31, 2011, we capitalized $1,250,000 which will be amortized over approximately five years beginning on the date of the first commercial sale of XIAFLEX for the treatment of Peyronie's disease, which represents the period estimated to be benefited using the straight-line method. In accordance with Accounting Standards Codification 350, Intangibles, Goodwill and Other, the Company amortizes intangible assets with finite lives in a manner that reflects the pattern in which the economic benefits of the assets are consumed or otherwise used up. If that pattern cannot be reliably determined, the assets are amortized using the straight-line method.

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

Table of Content

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

RESULTS OF OPERATIONS

YEAR ENDED DECEMBER 31, 2011 COMPARED WITH YEAR ENDED DECEMBER 31, 2010

Net revenues

Net revenues for the two years ended December 31, 2011 and 2010 comprise the following:

	Year Ended December 31			
	2011	2010	Change	% Change
Net sales	$ 21,998	$ 34,508	$ (12,510)	(36)%
Royalties	6,314,959	2,320,729	3,994,230	172 %
Licensing revenue	5,012,102	3,026,111	1,985,991	66 %
Consulting fees	46,667	280,000	(233,333)	(83)%
Total net revenues	$ 11,395,726	$ 5,661,348	$ 5,734,378	101 %

Product Revenues, net

Product revenues include the sales of the collagenase for laboratory use 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 2011 and 2010 product revenues were $21,998 and $34,508, respectively. This decrease of $12,510 or 36% was primarily related to the amount of material required to perform testing and additional research by our customers.

Royalties

Royalties consist of royalties and the mark-up on cost of goods sold under the Auxilium Agreement and earn-out revenues associated with the DFB Agreement. Total royalty, mark-up on cost of goods sold and earn-out revenues for year ended December 31, 2011 were $6,314,959 as compared to $2,320,729 in the 2010 period, an increase of $3,994,230 or 172%. Royalty and the mark-up on cost of goods sold revenues recognized under the Auxilium Agreement were $4,028,623 for the 2011 period and $710,182 for the 2010 period. The increase was due to increased net sales of XIAFLEX during 2011 reported to us by Auxilium. Auxilium launched XIAFLEX in March 2010.

We receive earn-out revenues from DFB under the earn-out payment provision of the DFB Agreement after certain net sales levels are achieved. Revenues recognized under the DFB Agreement were $2,286,336 for the year ended December 31, 2011 and $1,610,548 for the same period in 2010. This increase of $675,788 or 42% is mainly related to the increase in net sales during the 2011 period reported to us by DFB.

Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. For the years ended December 31, 2011 and 2010, we recognized total licensing and milestone revenue of $5,012,102 and $3,026,111, respectively, an increase of $1,985,991 or 66%. Certain licensing revenues recognized are related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period. Licensing revenue recognized for the years ended December 31, 2011 and 2010 were $437,102 and $751,111, respectively. The decrease of $314,009, or 42%, was mainly due to the completed recognition of licensing revenue associated with the Dupuytren’s contracture indication during the first quarter of 2010. Sublicensing fees recognized in 2011 were $750,000 compared to zero in the same period in 2010. We recognized $750,000 of the $15.0 million paid to Auxilium by Asahi for the rights to commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Japan.

Table of Content

Milestone revenue recognized for the years ended December 31, 2011 and 2010 were $3.825 million and $2.275 million, respectively. In the 2011 period, we recognized milestones related to the first sale of XIAFLEX in Europe of $2.550 million, the first sale of XIAFLEX in Germany of $637,500 and the first sale of XIAFLEX in Spain of $637,500. In the comparable 2010 period, we received and recognized $1.275 million of the $15 million paid to Auxilium by Pfizer for the scientific/technical review procedure of the Marketing Authorization Application for XIAFLEX for Dupuytren's contracture in Europe. We also received and recognized in the 2010 period a milestone of $1.0 million related to the FDA's approval of XIAFLEX for Dupuytren's contracture in February 2010 and our notification to Auxilium in June 2010 of our election not to commercially manufacture XIAFLEX.

Under current accounting guidance, nonrefundable upfront license fees for product candidates for which we are providing continuing services related to product development are deferred and recognized as revenue over the development period. 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 DFB Agreement. We recognize consulting revenues ratably over the term of the contract. For calendar years 2011 and 2010 we recognized $46,667 and $280,000 respectively. The decrease in revenues resulting from consulting and technical assistance contracts is due to the expiration in March 2011 of our consulting obligations under the DFB Agreement.

Research and Development Activities

Research and development expenses include, but are not limited to, internal costs, such as salaries and benefits, costs of materials, lab expense, facility costs and overhead. Research and development expenses also consist of third party costs, such as medical professional fees, product costs used in clinical trials, consulting fees and costs associated with clinical study arrangements. Research and development expenses were $972,078 and $1,223,931, respectively, for calendar years 2011 and 2010, representing a decrease in 2011 of $251,853, or 21%. This decrease in research and development expenses was primarily due to third party development costs that are reimbursable under the Auxilium Agreement partially offset by increased clinical development expenses.

We are currently working to develop XIAFLEX for the treatment of human and canine lipoma. We have designed a placebo controlled randomized study to evaluate the efficacy of XIAFLEX for the treatment of subcutaneous benign lipomas in canines. The study will consist of 32 canines randomized at 1:1 XIAFLEX or placebo. The treatment is a single injection of XIAFLEX or placebo. We have received clearance from the FDA's Center for Veterinary Medicine to begin the study and expect to do so in the first half of 2012. Also, we have designed a phase II dose escalation clinical study of XIAFLEX for the treatment of human lipomas. The study consists of 14 patients and four dosage groups for the treatment of benign subcutaneous lipomas. We have received FDA clearance to initiate the clinical trial and plan to do so during the first half of 2012.

The following table summarizes our research and development expenses related to our clinical development programs. Please refer to Part I, Item 1, "Description of Business", for a more detailed description of each of these programs:

Program	Year Ended December 31, 2011	Year Ended December 31, 2010	Accumulated Expenses Since January 1, 2010

Canine Lipoma	$ 332,217	$ 198,030	$ 530,247
Human Lipoma	110,800	125,191	235,991

Table of Content

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

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

- the nature, timing and estimated costs of the efforts necessary to complete the development of our drug candidate projects;
- the anticipated completion dates for our drug candidate projects;
- the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future with respect to our drug candidate projects;
- the scope, rate of progress of our preclinical studies and other research and development activities related to our drug candidate projects;
- clinical trial results for our drug candidate projects;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our drug candidate projects;
- the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our drug candidate projects;
- the cost and timing of regulatory approvals with respect to our drug candidate projects; and
- the cost of establishing clinical supplies for our drug candidate projects.

Our current resources and liquidity are sufficient to advance our significant current research and development projects and, Auxilium will have the option to exclusively license the canine and human lipoma indications upon completion of the appropriate opt-in study.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel, consultant costs, legal fees, investor relations, professional fees and overhead costs. General and administrative expenses were $5,231,881 and $6,470,449 for calendar years 2011 and 2010, respectively, a decrease of $1,238,568, or 19%, from 2010. The decrease in general and administrative expenses was due to lower stock based compensation, consulting services, general legal fees and services related to investor relations partially offset by increases in patent costs and director fees.

Other Income and expense

Other income for calendar year 2011 was $71,603 compared to $525,843 for calendar year 2010. For calendar year 2011, other income consisted of interest earned on our investments of $55,780 (compared to $86,310 for the 2010 period) and a reversal of accrued tax penalties associated with our delinquent tax filings in previous years of $15,823 (compared to $13,130 for the 2010 period). Other income for the calendar year 2010, unlike the comparable 2011 period, included revenue in connection with a $426,000 grant under the Qualifying Therapeutic Discovery Project Program. Although we received $324,000 of this grant in 2011, we did not recognize revenues related to it in 2011 because we had recognized the full amount of the grant during the 2010 period and had incurred all of the qualifying expenses prior to 2011. We elected to classify this revenue as other income in the Consolidated Statement of Operations since this program is non-recurring,

Income Taxes

Our deferred tax liabilities, deferred tax assets and related valuation allowances are impacted by events and transactions arising in the ordinary course of business, research and development activities, vesting of nonqualified options, deferred revenues and other items. Deferred tax assets are affected by the valuation allowance which is dependent upon several factors, including estimates of the realization of deferred income tax assets, and the impact of estimated future taxable income. Significant judgment is required to determine the estimated amount of valuation allowance to record. Changes in the estimate of the valuation allowance could materially increase or decrease our provision for income taxes in future periods.

Table of Content

In 2011, 2010 and 2009. we had $0.7 million, $2.0 million and $1.9 million of unutilized tax deductible expenses from the exercise of non-qualified and disqualified disposition of incentive stock options, respectively. Based on the results of our operations over the last two years, the growth in the market for XIAFLEX. and the trend in actual and anticipated royalty income, we have determined that is was more likely than not that the benefit of our deferred tax assets will be realized. Consequently, we have eliminated our 2010 valuation allowance of $3.6 million and increased our deferred tax assets by $0.3 million to reflect the application of our state statutory rates of 7.1% to temporary differences.

Under the ASC 718-25-09. we recognized the tax effect of $4.6 million in disqualifying disposition of options and the exercise of nonqualified options in our financial statements for the year ended December 31, 2011. The exercise of nonqualified options and disposition of disqualified options lowered our taxes payable by $1.9 million, reduced our tax assets related to non-qualified options by $0.2 million and increased additional paid in capital and provision for income tax benefits by $1.7 million and $30,239. respectively. Additionally, we utilized tax assets from our federal and state net operating loss carryforwards of $0.3 million and deferred licensing revenue of $0.2 million to reduce our taxes payable. Because our state net operating losses exceeded our federal net operating losses we set up a valuation allowance of $0.2 million against our tax asset for our state net operating loss carryforwards.

In the 2010 period we had a tax expense of $1,351. The income tax expense for 2010 was the result of minimum New York State taxes.

YEAR ENDED DECEMBER 31, 2010 COMPARED WITH YEAR ENDED DECEMBER 31, 2009

Net revenues

Net revenues for the two years ended December 31, 2010 and 2009 comprise the following:

	Year Ended December 31			
	2010	2009	Change	% Change
Net sales	$ 34,508	$ 39,035	$ (4,527)	(12 %)
Royalties	2,320,729	1,271,597	1,049,132	83 %
Licensing revenue	3,026,111	1,565,125	1,460,986	93 %
Consulting fees	280,000	280,000	-	-
Total net revenues	$ 5,661,348	$ 3,155,757	$ 2,505,591	79 %

Product Revenues, net

Product revenues include the sales of the collagenase for laboratory use 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 2010 and 2009 product revenues were $34,508 and $39,035, respectively. This decrease of $4,527, or 12%, was primarily related to the amount of material required to perform testing and additional research by our customers.

Royalties

Royalties consist of royalties and the mark-up on cost of goods sold under the Auxilium Agreement and earn-out revenues associated with the DFB Agreement. Total royalty and earn-out revenues for year ended December 31, 2010 were $2,320,729 as compared to $1,271,597 in the 2009 period, an increase of $1,049,132, or 83%. We receive royalty revenues from DFB under the earn-out payment provision of the DFB Agreement, after certain net sales levels are achieved. Royalty revenues recognized under the DFB Agreement were $1,610,548 for the year ended December

31, 2010 and $1,271,597 for the same period in 2009. This increase of $338,950, or 27%, is mainly related to the increase in net sales during the 2010 period reported to us by DFB.

In 2010, we began to recognize royalties and the mark-up on cost of goods sold due to us under the terms of the Auxilium Agreement. Under the Auxilium Agreement, royalties to which we are entitled are subject to set-off for certain expenses we owe to Auxilium relating to certain development and patent costs. Royalty and the mark-up on cost of goods sold revenues recognized under the Auxilium Agreement were $682,160 for the 2010 period and zero in the comparable period of 2009. The increase was due to the net sales of XIAFLEX during 2010 reported to us by Auxilium. Auxilium launched XIAFLEX in March 2010.

Table of Content

Licensing Revenue

Licensing revenue consists of licensing fees, sublicensing fees and milestones. For the years ended December 31, 2010 and 2009, we recognized total licensing and milestone revenue of $3,026,111 and $1,565,125, respectively, an increase of $1,490,986, or 93%. Licensing revenues recognized are related to the cash payments received under the Auxilium Agreement in prior years and amortized over the expected development period. Licensing revenue recognized for the years ended December 31, 2010 and 2009 were $751,111 and $1,065,125, respectively. The decrease of $314,014, or 29%, was mainly due to the completed recognition of licensing revenue associated with the Dupuytren's contracture indication during the first quarter of 2010.

Milestone revenue recognized for the years ended December 31, 2010 and 2009 was $2.275 million and $0.5 million, respectively. In the 2010 period, we received and recognized $1.275 million of the $15 million paid to Auxilium by Pfizer for the scientific/technical review procedure of the Marketing Authorization Application for XIAFLEX for Dupuytren's contracture in Europe. We also received and recognized a milestone of $1.0 million related to the FDA's approval of XIAFLEX for Dupuytren's contracture in February 2010 and our notification to Auxilium in June 2010 of our election not to commercially manufacture XIAFLEX. In the comparable 2009 period, we recognized $500,000 related to a milestone received under the Auxilium Agreement for the filing and acceptance of a new drug application for Dupuytren's contracture.

Under current accounting guidance, nonrefundable upfront license fees for product candidates for which we are providing continuing services related to product development are deferred and recognized as revenue over the development period. 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 DFB Agreement. We recognize consulting revenues ratably over the term of the contract. The consulting and technical assistance obligations under the DFB Agreement expired during March 2011. For each of calendar years 2010 and 2009 we recognized $280,000 in consulting revenue.

Research and Development Activities

Research and development expenses include, but are not limited to, internal costs, such as salaries and benefits, costs of materials, lab expense, facility costs and overhead. Research and development expenses also consist of third party costs, such as medical professional fees, product costs used in clinical trials, consulting fees and costs associated with clinical study arrangements. Research and development expenses were $1,223,931 and $488,646, respectively, for calendar years 2010 and 2009, representing an increase in 2010 of $735,285, or 150%. This increase in research and development expenses was primarily due to third party development costs that are reimbursable under the Auxilium Agreement.

We are currently working to develop XIAFLEX for the treatment of human and canine lipoma. We have designed a placebo controlled randomized study to evaluate the efficacy of XIAFLEX for the treatment of subcutaneous benign lipomas in canines. The study will consist of 32 canines randomized at 1:1 XIAFLEX or placebo. The treatment is a single injection of XIAFLEX or placebo. We have received clearance from the FDA's Center for Veterinary Medicine to begin the study and expect to do so in the first half of 2012. Also, we have designed a phase II dose escalation clinical study of XIAFLEX for the treatment of human lipomas. The study consists of 14 patients and four dosage groups for the treatment of benign subcutaneous lipomas. We have received FDA clearance to initiate the clinical trial and plan to do so during the first half of 2012.

The following table summarizes our research and development expenses related to our clinical development programs. Please refer to Part I, Item 1, "Description of Business", for a more detailed description of each of these programs:

Table of Content

Program	Year Ended December 31, 2010	Accumulated Expenses Since January 1, 2010
Canine Lipoma	$ 198,030	198,030
Human Lipoma	125,191	125,191

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

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

- the nature, timing and estimated costs of the efforts necessary to complete the development of our drug candidate projects;
- the anticipated completion dates for our drug candidate projects;
- the scope, rate of progress and cost of our clinical trials that we are currently running or may commence in the future with respect to our drug candidate projects;
- the scope, rate of progress of our preclinical studies and other research and development activities related to our drug candidate projects;
- clinical trial results for our drug candidate projects;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights relating to our drug candidate projects;
- the terms and timing of any strategic alliance, licensing and other arrangements that we have or may establish in the future relating to our drug candidate projects;
- the cost and timing of regulatory approvals with respect to our drug candidate projects; and
- the cost of establishing clinical supplies for our drug candidate projects.

Our current resources and liquidity are sufficient to advance our significant current research and development projects and, Auxilium will have the option to exclusively license the canine and human lipoma indications upon completion of the appropriate opt-in study.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and other related costs for personnel, consultant costs, legal fees, investor relations, professional fees and overhead costs. General and administrative expenses were $6,470,449 and $4,832,019 for calendar years 2010 and 2009, respectively, an increase of $1,638,430, or 34%, from 2009. The increase in general and administrative expenses was due to legal fees, stock based compensation and services related to investor relations partially offset by lower patent costs.

Other Income and expense

Other income for calendar year 2010 was $525,843 compared to $46,791 for calendar year 2009. Other income during 2010 was due to interest of $83,310 earned on our investments (compared to $55,693 in the 2009 period), as well as a reversal of accrued tax penalties of $13,130 associated with our delinquent tax filings in previous years. Other income

during 2010 was also due to the Qualifying Therapeutic Discovery Project Program. In November 2010, we were notified that we had been awarded a total cash grant of approximately $426,000 under the Qualifying Therapeutic Discovery Project program administered under section 48D of the Internal Revenue Code, of which approximately $102,000 relates to qualifying expenses we had previously incurred during the 2009 fiscal year which was received during the fourth quarter of fiscal 2010. The remainder of the grant of approximately $324,000 was received in February 2011 based on qualifying expenses that we incurred during the 2010 fiscal year. We recognized the full $426,000 of the grant as of the November 2010 date of notification since we had already incurred all of the qualifying expenses. Since this program is non-recurring, we elected to classify this revenue as other income in the Consolidated Statement of Operations for the year ended December 31, 2010.

Table of Content

Income Taxes

The income tax expense for 2010 was $1,351 as compared to an income tax benefit of $161,574 for 2009. The income tax expense for 2010 was the result of minimum New York State taxes. In 2009, the Company utilized its current federal NOL to carry-back to the 2008 tax year to claim a refund of taxes paid of $198,239 which were partially offset by 2009 state tax of $1,784 and a $34,881 tax adjustment related to prior years' tax returns.

Liquidity and Capital Resources

To date, we have financed our operations primarily through product sales, debt instruments, licensing revenues and royalties under agreements with third parties and sales of our common stock. At December 31, 2011, 2010 and 2009, we had cash and cash equivalents and short-term investments in the aggregate of approximately $8.2 million, $7.8 million and $8.5 million, respectively.

Sources and Uses of Cash

Net Cash provided by (Used In) Operating Activities

Net cash provided by (used in) operating activities was $(0.7) million, $(0.9) million and $3.7 million for 2011, 2010 and 2009. Net cash used in operations for 2011 was mainly due to a decrease in accrued expenses, increases in deferred tax assets and accounts receivable partially offset by lower stock compensation expense. Cash used in operations for 2010 resulted primarily from operating losses, net of stock compensation expenses and other non-cash charges. At December 31, 2010, accounts receivable increased by $0.4 million, compared to December 31, 2009 primarily due to a higher receivable balance related to the DFB Agreement. Our deferred revenue at December 31, 2010 decreased by $0.8 million compared to December 31, 2009 primarily due to the amortization of previously received license payments under the Auxilium Agreement.

The majority of our cash expenditures in 2011, 2010, and 2009 were to fund research and development and our business activities.

Net Cash provided by (used in) Investing Activities

Net cash provided by investing activities was $0.4 million in 2011, compared to net cash used in investing activities of $0.8 million in 2010 and $3.6 million in 2009. In the 2011 period, maturities of $5.4 million exceeded purchases of $5.0 million. In 2010, purchases of marketable securities exceeded maturities by $0.8 million. In 2009, purchases of marketable securities exceeded maturities by $3.6 million.

Net Cash provided by Financing Activities

Net cash provided by financing activities for 2011 was $1.1 million, as compared to $0.2 million and $0.4 million for 2010 and 2009 periods. Net cash provided by financing activities was due to excess tax benefits related to share-based payments and stock option proceeds partly offset by the repurchase of our common stock under our 2010 Stock Repurchase Program Net cash provided by financing activities in 2010 was from proceeds from stock option exercises partly offset by the repurchase of our common stock under our 2010 Stock Repurchase Program. Net cash provided by financing activities in 2009 was from proceeds received from stock option exercises.

Contractual Commitments

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

Table of Content

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

Operating Leases

Our operating leases are principally for facilities and equipment. We currently lease approximately 15,000 square feet of space at our headquarters in Lynbrook, New York on a month to month basis. Additionally, we lease certain vehicle and certain office equipment which generally expire in 2014.

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

Year ending December 31,

2012	$8,000
2013	$8,000
2014	$3,000

Off-Balance Sheet Arrangements

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

Future Impact of Recently Issued Accounting Standards

In May 2011, the Financial Accounting Standards Board (the “FASB”) issued a new standard on fair value measurement and disclosure requirements. The new standard changes fair value measurement principles and disclosure requirements including measuring the fair value of financial instruments that are managed within a portfolio, the application of applying premiums and discounts in a fair value measurement, and additional disclosure about fair value measurements. The new standard is effective for interim and annual periods beginning after December 15, 2011. We do not expect a material impact with the adoption of this new standard.

In June 2011, the FASB issued a new standard on the presentation of comprehensive income. The new standard eliminated the current option to report other comprehensive income and its components in the statement of changes in equity. Under the new standard, companies can elect to present items of net income and other comprehensive income in one continuous statement or in two separate, but consecutive statements. The new standard is effective at the beginning of fiscal years beginning after December 15, 2011, and we will comply with this requirement in the first quarter 2012.

In September 2011, the FASB issued a new standard to simplify how an entity tests goodwill for impairment. The new standard allows companies an option to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining if it is necessary to perform the two-step quantitative goodwill impairment test. Under the new standard, a company is no longer required to calculate the fair value of a reporting unit unless the company determines, based on the qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount. The new standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. We do not expect a material impact with the adoption of this new standard.

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

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

Our investment portfolio is subject to interest rate risk, although limited given the nature of the investments, and will fall in value in the event market interest rates increase. All our cash and cash equivalents at December 31, 2011, amounting to approximately $3.2 million, were maintained in bank demand accounts and money market accounts. Our short-term investments of $5.0 million were maintained in certificates of deposit. We do not hedge our interest rate risks, as we believe reasonably possible near-term changes in interest rates would not materially affect our results of operations, financial position or cash flows.

Table of Content

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. EVALUATION OF DISCLOSURE CONTROLS AND PROCEDURES.

The Company, under the supervision and with the participation of Thomas L. Wegman, the Company’s President, Principal Executive Officer, Principal Financial Officer and Principal Accounting 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.

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, 2011. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control – Integrated Framework. We believe that, as of December 31, 2011, the Company’s internal control over financial reporting was effective based on this criteria.

Tabriztchi & Co, the independent registered public accounting firm that audited our Consolidated Financial Statements included in this Report, audited the effectiveness of our internal control over financial reporting as of December 31, 2011, as stated in their report which is included in Part IV, Item 15 of this Report.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting identified in connection with the evaluation of our controls performed during the year ended December 31, 2011 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Table of Content

Item 9B. OTHER INFORMATION

Not applicable.

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 2012 Annual Meeting of Stockholders.

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 2012 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 2012 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 2012 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 2012 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.

(b) Exhibits

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

Table of Content

BIOSPECIFICS TECHNOLOGIES CORP.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEAR ENDED DECEMBER 31, 2011

	Page
Report of Independent Registered Public Accounting Firm	F-2
Consolidated Balance Sheets	F-4
Consolidated Statements of Operations	F-5
Consolidated Statements of Cash Flows	F-6
Consolidated Statements of Stockholders' Deficit	F-7
Notes to Consolidated Financial Statements	F-8

Table of Content

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying consolidated balance sheets of BioSpecifics Technologies Corp. (the Company) as of December 31, 2011 and 2010, and the related consolidated statements of operations, stockholders' equity and cash flows for each of the years in the three-year period ended December 31, 2011. BioSpecifics Technologies Corp.'s management is responsible for these financial statements. 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 consolidated financial statements referred to above present fairly, in all material respects, the financial position of BioSpecifics Technologies Corp. as of December 31, 2011 and 2010, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2011 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), BioSpecifics Technologies Corp.'s internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 12, 2012 expressed an unqualified opinion.

/s/ Tabriztchi & Co., CPA, P.C.

Garden City, NY
March 12, 2012

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

Table of Content

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited BioSpecifics Technologies Corp.'s internal control over financial reporting as of December 31, 2011 based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). BioSpecifics Technologies Corp's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in the accompanying Management's Annual Report on Internal Control over Financial Reporting. Our responsibility is to express an opinion on the company's internal control over financial reporting based on our audit.

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

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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

In our opinion, BioSpecifics Technologies Corp. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2011, based on criteria established in Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the balance sheets and the related statements of income, stockholders' equity and cash flows of BioSpecifics Technologies Corp. and our report dated March 12, 2012 expressed an unqualified opinion.

/s/ Tabriztchi & Co., CPA, P.C.

Garden City, NY
March 12, 2012

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

Table of Content

BioSpecifics Technologies Corp.
Consolidated Balance Sheet

	December 31, 2011	2010
Assets		
Current assets:		
Cash and cash equivalents	$3,196,831	$2,470,852
Short term investments	5,000,000	5,360,970
Accounts receivable, net	3,236,917	1,986,125
Income tax receivable	244,720	185,386
Deferred tax asset	1,309,801	-
Prepaid expenses and other current assets	98,234	91,925
Total current assets	13,086,503	10,095,258
Deferred royalty buy-down	1,250,000	1,250,000
Deferred tax assets –long term	1,738,154	-
Patent costs, net	190,416	173,443
Total assetss	16,265,073	11,518,701
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	601,002	893,083
Accrued third party development expenses	-	2,649,369
Deferred revenue	437,099	483,769
Accrued liabilities of discontinued operations	78,138	78,138
Total current liabilities	1,116,239	4,104,359
Deferred revenue - license fees	276,520	713,619
Stockholders' equity:		
Series A Preferred stock, $.50 par value, 700,000 shares authorized; none outstanding	-	-
Common stock, $.001 par value; 10,000,000 shares authorized; 6,530,743 and 6,445,743shares issued at December 31, 2011 and 2010, respectively	6,531	6,446
Additional paid-in capital	20,049,196	17,739,765
Accumulated deficit	(3,291,904)	(9,893,530)
Treasury stock, 194,604 and 151,875 shares at cost as of December 31, 2011 and 2010	(1,891,509)	(1,151,958)
Total stockholders' equity	14,872,314	6,700,723
Total liabilities and stockholders’ equity	$16,265,073	$11,518,701

Table of Content

BioSpecifics Technologies Corp.
Consolidated Statements of Operations

	Years Ended December 31,		
	2011	2010	2009
Revenues:			
Net sales	$21,998	$34,508	$39,035
Royalties	6,314,959	2,320,729	1,271,597
Licensing revenue	5,012,102	3,026,111	1,565,125
Consulting fees	46,667	280,000	280,000
Total revenues	11,395,726	5,661,348	3,155,757
Costs and expenses:			
Research and development	972,078	1,223,931	488,646
General and administrative	5,231,881	6,470,449	4,832,019
Total costs and expenses	6,203,959	7,694,380	5,320,665
Operating income (loss)	5,191,767	(2,033,032)	(2,164,908)
Other income (expense):			
Interest income	55,780	86,310	55,693
Interest expense	-	-	(39)
Other	15,823	13,130	(8,863)
Qualifying Therapeutic Discovery Grant	-	426,403	-
	71,603	525,843	46,791
Income (loss) before benefit (expense) for income tax	5,263,370	(1,507,189)	(2,118,117)
Income tax benefit (expense)	1,338,256	(1,351)	161,574
Net income (loss)	$6,601,626	$(1,508,540)	$(1,956,543)
Basic net income (loss) per share	$1.04	$(0.24)	$(0.32)
Diluted net income (loss) per share	$0.95	$(0.24)	$(0.32)
Shares used in computation of basic net income (loss) per share	6,340,648	6,261,214	6,065,939
Shares used in computation of diluted net income (loss) per share	6,952,386	6,261,214	6,065,939

Table of Content

BioSpecifics Technologies Corp.
Consolidated Statements of Cash Flows

	Years Ended December 31,		
Cash flows from operating activities:	2011	2010	2009
Net income (loss)	$6,601,626	$(1,508,540)	$(1,956,543)
Adjustments to reconcile net income (loss) to net cash used in operating activities:			
Depreciation and amortization	50,685	18,949	35,669
Stock-based compensation expense	517,367	1,901,781	1,490,083
Deferred tax assets	(3,047,955)	-	-
Changes in operating assets and liabilities:			
Accounts receivable	(1,250,792)	(459,291)	5,616,601
Prepaid expenses and other current assets	(65,642)	(28,664)	(371,592)
Accounts payable and accrued expenses	(3,009,109)	24,394	55,658
Deferred revenue	(483,769)	(831,111)	(1,145,125)
Net cash provided by (used in) operating activities from continuing operations	(687,589)	(882,482)	3,724,751
Cash flows from investing activities:			
Maturities of marketable securities	5,360,970	4,548,541	2,799,754
Purchases of marketable securities	(5,000,000)	(5,360,970)	(6,448,295)
Net cash used in investing activities from continuing operations	360,970	(812,429)	(3,648,541)
Cash flows from financing activities:			
Proceeds from stock option exercises	82,450	673,375	380,029
Repurchases of common stock	(739,551)	(458,001)	-
Excess tax benefits from share-based payment arrangements	1,709,699	-	-
Net cash provided by financing activities from continuing operations	1,052,598	215,374	380,029
Increase (decrease) in cash and cash equivalents	725,979	(1,479,537)	456,239
Cash and cash equivalents at beginning of year	2,470,852	3,950,389	3,494,150
Cash and cash equivalents at end of year	$3,196,831	$2,470,852	$3,950,389
Supplemental disclosures of cash flow information:			
Cash paid during the year for:			
Interest	$-	$-	$-
Taxes	$190,000	$9,851	$214,467

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, 2011 we accrued $318,280 related to this issue of which $50,685, $36,041and $33,983 was amortized in the 2011, 2010 and 2009 periods, respectively. The net patent amortization expense for 2010 was $18,339 due to a reduction of reimbursable patents fees under our agreement with Auxilium from prior periods.

See accompanying notes to consolidated financial statements

F-6

Table of Content

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

	Shares	Amount	Additional Paid in Capital	Accumulated Deficit
Balances - December 31, 2008	6,140,068	$6,140	$ 13,294,803	$ (6,428,447)
Issuance of common stock under stock option plans	187,250	187	379,841	-
Stock compensation expense	-	-	1,490,083	-
Net loss	-	-	-	(1,956,543)
Balances - December 31, 2009	6,327,318	$6,327	$ 15,164,727	$ (8,384,990)
Issuance of common stock under stock option plans	118,425	119	673,257	-
Stock compensation expense	-	-	1,901,781	-
Repurchases of common stock	-	-	-	-
Net loss	-	-	-	(1,508,540)
Balances - December 31, 2010	6,445,743	$6,446	$ 17,739,765	$ (9,893,530)
Issuance of common stock under stock option plans	85,000	85	82,365	-
Stock compensation expense	-	-	517,367	-
Repurchases of common stock	-	-	-	-
Excess tax benefits from share-based payment arrangements	-	-	1,709,699	-
Net profit	-	-	-	6,601,626
Balances - December 31, 2011	6,530,743	$6,531	$ 20,049,196	$ (3,291,904)

	Treasury Stock	Shareholder Equity (Deficit) Total
Balances - December 31, 2008	$ (693,957)	$ 6,178,539
Issuance of common stock under stock option plans	-	380,028
Stock compensation expense	-	1,490,083
Net loss	-	(1,956,543)
Balances - December 31, 2009	$ (693,957)	$ 6,092,107
Issuance of common stock under stock option plans	-	673,376
Stock compensation expense	-	1,901,781
Repurchases of common stock	(458,001)	(458,001)
Net loss	-	(1,508,540)
Balances - December 31, 2010	$ (1,151,958)	$ 6,700,723
Issuance of common stock under stock option plans	-	82,450
Stock compensation expense	-	517,367
Repurchases of common stock	(739,551)	(739,551)
Excess tax benefits from share-based payment arrangements	-	1,709,699
Net profit	-	6,601,626
Balances - December 31, 2011	$ (1,891,509)	$ 14,872,314

Table of Content

BIOSPECIFICS TECHNOLOGIES CORP.

Notes to Consolidated Financial Statements
December 31, 2011, 2010 and 2009

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® (collagenase clostridium histolyticum)) for clinical indications in Dupuytren’s contracture, Peyronie’s disease and frozen shoulder (adhesive capsulitis). Auxilium has an option to acquire additional indications that we may pursue, including cellulite, for which we have granted Auxilium the right to initiate early development studies at its cost, and human and canine lipoma. Auxilium is currently selling XIAFLEX in the U.S. for the treatment of Dupuytren’s contracture. Auxilium has an agreement with Pfizer, Inc. (“Pfizer”) pursuant to which Pfizer has the right to market XIAFLEX for Dupuytren’s contracture and Peyronie’s disease in Europe and certain Eurasian countries, and will do so under the registered trademark XIAPEX® (collagenase clostridium histolyticum). Pfizer is currently selling XIAPEX in nine countries in Europe, including the United Kingdom, Germany and Spain. In addition, Auxilium has an agreement with Asahi Kasei Pharma Corporation (“Asahi”) pursuant to which Asahi has the right to commercialize XIAFLEX for the treatment of Duputyren’s contracture and Peyronie’s disease in Japan. Auxilium also has an agreement with Actelion Pharmaceuticals Ltd. (“Actelion”) pursuant to which Actelion has the right to commercialize XIAFLEX for the treatment of Duputyren’s contracture and Peyronie’s disease in Canada, Australia, Brazil and Mexico.

2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Principles of Consolidation

The audited consolidated financial statements include the accounts of the Company and its subsidiary, Advance Biofactures Corp. (“ABC-NY”).

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles 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

Management believes that the carrying amounts of the Company’s financial instruments, including cash, cash equivalents, short-term investments, accounts receivable, accounts payable and accrued expenses approximate fair value due to the short-term nature of those instruments.

Concentration of Credit Risk and Major Customers

The Company maintains bank account balances, which, at times, may exceed insured limits. The Company has not experienced any losses with these accounts and believes that it is not exposed to any significant credit risk on cash.

The Company maintains its investment in FDIC insured certificates of deposits with several banks.

At December 31, 2011, the accounts receivable balance of $3.3 million was primarily from two customers, comprising of $2.3 million (71% of total) from DFB Biotech, Inc. and $0.9 million (28% of total) from Auxilium Pharmaceutical, Inc.

The Company has been dependent in each year on a two customers who generate almost all its revenues. In the year ended December 31, 2011, the licensing and royalty revenues from Auxilium Pharmaceutical Inc. were $9.0 (79% of total) and royalties and consulting revenues from DFB Biotech, Inc. were $2.3 million (20% of total).

Revenue Recognition

We currently recognize revenues resulting from product sales, the licensing and sublicensing of the use of our technology and from services we sometimes perform in connection with the licensed technology under the guidance of Accounting Standards Codification 605, Revenue Recognition (“ASC 605”).

Table of Content

If we determine that separate elements exist in a revenue arrangement under ASC 605, we recognize revenue for delivered elements only when the fair values of undelivered elements are known, when the associated earnings process is complete, when payment is reasonably assured and, to the extent the milestone amount relates to our performance obligation, when our customer confirms that we have met the requirements under the terms of the agreement.

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

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 collagenase for laboratory use that are recognized at the time the product is shipped to customers for laboratory use.

Royalty/Mark-Up on Cost of Goods Sold / Earn-Out Revenue

Under our development and license agreement with Auxilium (as amended and restated on each of December 11, 2008 and August 31, 2011, the "Auxilium Agreement"), we do not participate in the selling, marketing or manufacturing of products for which we receive royalties and a mark-up of the cost of goods sold revenues, The royalty and mark-up on cost of goods sold revenues will generally be recognized in the quarter that Auxilium provides the written reports and related information to us, that is, royalty and mark up on cost of goods sold revenues are generally recognized one quarter following the quarter in which sales by Auxilium occurred. The royalties payable by Auxilium to us are subject to set-off for certain third party development and patent costs.

Under a March 2006 agreement (the "DFB Agreement"), pursuant to which we sold our topical collagenase business to DFB Biotech, Inc. and its affiliates ("DFB"), we have the right to receive earn-out payments in the future based on sales of certain products. Generally, under the DFB Agreement we would receive payments and a report within ninety (90) days from the end of each calendar year after DFB has sold the royalty-bearing product. Currently, DFB is providing us earn-out reports on a quarterly basis.

Licensing Revenue

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

Table of Content

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

Consulting and Technical Assistance Services

We recognize revenues from consulting and technical assistance contracts primarily as a result of our DFB Agreement and Auxilium Agreement. Consulting revenues are recognized ratably over the term of the contract. The consulting and technical assistance obligations to DFB expired in March 2011.

Treasury Stock

The Company accounts for treasury stock under the cost method and includes treasury stock as a component of stockholders' equity.

Accounts receivable and Allowance for Doubtful Accounts

Trade accounts receivable are stated at the amount the Company expects to collect. We maintain allowances for doubtful accounts for estimated losses resulting from the inability of its customers to make required payments. We consider the following factors when determining the collectability of specific customer accounts: customer credit-worthiness, past transaction history with the customer, current economic industry trends, and changes in customer payment terms. Our accounts receivable balance is typically due from its two large pharmaceutical customers. These companies have historically paid timely and have been financially stable organizations. Due to the nature of the accounts receivable balance, we believe the risk of doubtful accounts is minimal. If the financial condition of our customers were to deteriorate, adversely affecting their ability to make payments, additional allowances would be required. We provide for estimated uncollectible amounts through a charge to earnings and a credit to a valuation allowance. Balances that remain outstanding after we have used reasonable collection efforts are written off through a charge to the valuation allowance and a credit to accounts receivable. We recorded no material bad debt expense in each of the last three years. The allowance for doubtful accounts balance was $30,581 and $32,758, at December 31, 2011 and 2010, respectively.

As of December 31, 2011, accounts receivable of $3.2 million includes approximately $2.3 million due from DFB under the earn-out provision and approximately $0.9 million in royalties due from Auxilium in accordance with the terms of our agreements.

Reimbursable Third Party Development Costs

We accrued expenses for research and development that are reimbursable by us under the Auxilium Agreement. We capitalize certain patent costs related to estimated third party development costs that are reimbursable under the Auxilium Agreement. In August 2011, through the amendment and restatement of our development and license agreement with Auxilium, we have clarified the rights and responsibilities of the joint development of XIAFLEX. We resolved what had been an on-going dispute with Auxilium concerning the appropriate amount of creditable third

party development expenses related to the lyophilization of the injection formulation and certain patent expenses for research and development costs that are reimbursable under the Auxilium Agreement. We agreed to reimburse Auxilium by offsetting future royalties payable for the amount invoiced us for third party development costs related to the development of the lyophilization of the injection formulation. Any 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 or decrease 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 expenses which are creditable against future royalty revenues.

As of December 31, 2011 our net reimbursable third party development and certain patent costs accrual is zero.

Research and Development Expenses

Research and development expenses include, but are not limited to, internal costs, such as salaries and benefits, costs of materials, lab expense, facility costs and overhead. Research and development (“R&D”) expenses also consist of third party costs, such as medical professional fees, product costs used in clinical trials, consulting fees and costs associated with clinical study arrangements. We may fund R&D at medical research institutions under agreements that are generally cancelable. All of these costs are charged to R&D as incurred, which may be measured by percentage of completion, contract milestones, patient enrollment, or the passage of time.

Table of Content

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.

Income Taxes

Deferred tax assets and liabilities are recognized based on the expected future tax consequences, using current tax rates, of temporary differences between the financial statement carrying amounts and the income tax basis of assets and liabilities. A valuation allowance is applied against any net deferred tax asset if, based on the weighted available evidence, it is more likely than not that some or all of the deferred tax assets will not be realized.

We use the asset and liability method of accounting for income taxes, as set forth in Accounting Standards Codification 740-10-25-2. Under this method, deferred income taxes, when required, are provided on the basis of the difference between the financial reporting and income tax basis of assets and liabilities at the statutory rates enacted for future periods. In accordance with Accounting Standards Codification 740-10-45-25, Income Statement Classification of Interest and Penalties, we classify interest associated with income taxes under interest expense and tax penalties under other.

Stock Based Compensation

The Company has two stock-based compensation plans in effect which are described more fully in Note 9. Accounting Standards Codification 718, Compensation - Stock Compensation ("ASC 718") requires the recognition of compensation expense, using a fair-value based method, for costs related to all 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 ASC 718, we estimate the fair value of our employee stock awards at the date of grant using the Black-Scholes option-pricing model, which requires the use of certain subjective assumptions. The most significant of these assumptions are our estimates of the expected volatility of the market price of our stock and the expected term of an award. When establishing an estimate of the expected term of an award, we consider the vesting period for the award, our recent historical experience of employee stock option exercises (including forfeitures) and the expected volatility. When there is uncertainty in the factors used to determine the expected term of an award, we use the simplified method. 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 company did not grant stock options during the 2011 and 2010 periods.

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

Table of Content

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

	December 31,		
	2011	2010	2009
Research and development	$ 96,849	$ 109,385	$ 108,465
General and administrative	420,518	1,792,396	1,381,618
Total stock-based compensation expense	$ 517,367	$ 1,901,781	$ 1,490,083

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 Accounting Standards Codification 505-50, Equity Based Payments to Non-Employees (“ASC 505-50”). 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-employee consultants for the years ended December 31, 2011, 2010 and 2009 was zero, $685,096 and zero, 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.

Patent Costs

We amortize intangible assets with definite lives on a straight-line basis over their estimated useful lives, ranging from 2 to 8 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, 2011, the Company’s capitalized costs related to certain patents paid by Auxilium on behalf of the Company and are reimbursable to Auxilium under the Auxilium Agreement. These patent costs are creditable against future royalty revenues. At December 31, net patent costs consisted of:

	2011	2010	2009
Patents, net	$ 190,416	$ 173,443	$ 223,458

The amortization expense for patents was $50,685, $36,041 and $33,983, for the years ended December 31, 2011, 2010 and 2009. The net patent amortization expense for 2010 was $18,339 due to a reduction of reimbursable patents fees under the Auxilium Agreement from prior periods. The estimated aggregate amortization expense for each of the next five years is as follows:

2012	$52,000
2013	46,000
2014	36,000
2015	13,000
2016	13,000

Table of Content

Income Taxes

In accordance with Accounting Standards Codification 740-10-45-25, Income Statement Classification of Interest and Penalties ("ASC 740-10-45-25") we classify interest associated with income taxes under interest expense and tax penalties under other.

Qualifying Therapeutic Discovery Project Program

In November 2010, we were notified that we had been awarded a total cash grant of approximately $426,000 under the Qualifying Therapeutic Discovery Project program administered under section 48D of the Internal Revenue Code, of which approximately $102,000 relates to qualifying expenses we had previously incurred during the 2009 fiscal year which was received during the fourth quarter of fiscal 2010. The remainder of the grant of approximately $324,000 was received in February 2011 based on qualifying expenses that we incurred during the 2010 fiscal year. In the 2010 period, we recognized the full $426,000 of the grant since we had already incurred all of the qualifying expenses. Since this program is non-recurring, we elected to classify this revenue as other income in the Consolidated Statement of Operations.

Future Impact of Recently Issued Accounting Standards

In May 2011, the Financial Accounting Standards Board ("FASB") issued a new standard on fair value measurement and disclosure requirements. The new standard changes fair value measurement principles and disclosure requirements including measuring the fair value of financial instruments that are managed within a portfolio, the application of applying premiums and discounts in a fair value measurement, and additional disclosure about fair value measurements. The new standard is effective for interim and annual periods beginning after December 15, 2011. We do not expect a material impact with the adoption of this new standard.

In June 2011, the FASB issued a new standard on the presentation of comprehensive income. The new standard eliminated the current option to report other comprehensive income and its components in the statement of changes in equity. Under the new standard, companies can elect to present items of net income and other comprehensive income in one continuous statement or in two separate, but consecutive statements. The new standard is effective at the beginning of fiscal years beginning after December 15, 2011, and we will comply with this requirement in the first quarter 2012.

In September 2011, the FASB issued a new standard to simplify how an entity tests goodwill for impairment. The new standard allows companies an option to first assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining if it is necessary to perform the two-step quantitative goodwill impairment test. Under the new standard, a company is no longer required to calculate the fair value of a reporting unit unless the company determines, based on the qualitative assessment, that it is more likely than not that its fair value is less than its carrying amount. The new standard is effective for annual and interim goodwill impairment tests performed for fiscal years beginning after December 15, 2011. We do not expect a material impact with the adoption of this new standard.

3. FAIR VALUE MEASUREMENTS

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

As of December 31, 2011, the Company held certain investments that are required to be measured at fair value on a recurring basis. The following tables present the Company's fair value hierarchy for these financial assets as of December 31, 2011, 2010 and 2009:

December 31, 2011	Fair Value	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 3,196,831	$ 3,196,831	-	-
Certificates of Deposit	5,000,000	5,000,000	-	-

Table of Content

December 31, 2010	Fair Value	Level 1	Level 2	Level 3
Cash and cash equivalents	$ 2,470,852	$ 2,470,852	-	-
Certificates of Deposit	5,360,970	5,360,970	-	-
December 31, 2009				
Cash and cash equivalents	$ 3,950,389	$ 3,950,389	-	-
Certificates of Deposit	4,548,541	4,548,541	-	-

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.

	2011	2010	2009
Net income (loss) for diluted computation	$ 6,601,626	$ (1,508,540)	$ (1,956,543)
Weighted average shares:			
Basic	6,340,648	6,261,214	6,065,939
Effect of dilutive securities:			
Stock options	611,738	-	-
Diluted	6,952,386	6,261,214	6,065,939
Net income (loss) Per Share:			
Basic	$ 1.04	$ (0.24)	$ (0.32)
Diluted	$ 0.95	$ (0.24)	$ (0.32)

For the years ended December 31, 2010 and 2009, 912,001 and 923,900 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 net loss.

5. INVENTORIES, NET

None.

6. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment from continuing operations consist of:

	December 31,		
	2011	2010	2009
Machinery and equipment	$ 562,610	$ 562,610	$ 562,610
Furniture and fixtures	91,928	91,928	91,928
Leasehold improvements	1,185,059	1,185,059	1,185,059
	1,839,597	1,839,597	1,839,597
Less accumulated depreciation and amortization	(1,839,597)	(1,839,597)	(1,838,987)
	$ -	$ -	$ 610

Table of Content

Total depreciation expense amounted to zero, $610 and $1,687 for calendar years 2011, 2010 and 2009, respectively.

7. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following:

	December 31,		
	2011	2010	2009
Trade accounts payable and accrued expenses	$ 407,954	$ 674,917	$ 378,872
Accrued legal and other professional fees	50,000	77,442	70,935
Accrued payroll and related costs	144,048	140,725	134,702
	$ 601,002	$ 893,084	$ 584,509

8. INCOME TAXES

The provision for income taxes consists of the following:

Year ended December 31,

	2011	2010	2009
Current taxes:			
Federal	$-	$-	$(198,239)
State	3,525	1,351	1,784
Total current taxes	3,525	1,351	(196,455)
Deferred taxes:			
Federal	(122,593)	-	-
State	(1,219,190)	-	-
Total deferred taxes	(1,341,783)		
Total provision for income taxes	$(1,338,258)	$1,351	$(196,455)

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,

	2011	2010	2009
Statutory rate	34.0 %	34.0 %	34.0 %
State income taxes, net of federal income tax benefit	7.1 %	5.0 %	5.0 %
Stock-based compensation	4.0 %	(42.8 %)	(23.9 %)
Other, net	(5.9 %)	21.4 %	10.7 %
Increase (decrease) in valuation allowance	(64.6 %)	(17.6 %)	(25.8 %)
Effective tax rate (benefit)	(25.4 %)	-	3.2 %

The effective rate reconciliation includes the permanent differences and changes in valuation allowance for windfalls, stock-based compensation, and net operating loss.

F-15

Table of Content

Year ended December 31,

	2011	2010	2009
Tax credit carry forward	$1,027,633	$1,027,633	$1,039,390
Deferred revenues	293,297	466,981	741,714
Other	17,252	-	54,846
Options	1,687,780	1,757,303	406,517
Net operating loss carry forward	21,992	350,617	556,504
Net deferred tax assets before valuation allowance	3,047,955	3,602,534	2,798,971
Valuation allowance	-	(3,602,534)	(2,798,971)
Net deferred tax asset	$3,047,955	$ -	$ -

In assessing the realization of deferred tax assets, we consider whether it is more likely than not that some portion or all of the deferred tax assets will not be realized. The ultimate realization of deferred tax assets is dependent upon the generation of future taxable income during the periods in which the temporary differences representing net future deductible amounts become deductible. Based on our current and anticipated future taxable income, we have released the valuation allowance for all or our deferred tax assets.

At December 31, 2010, we had a full valuation allowance of $3.6 million against our tax assets. In 2011, 2010 and 2009, we had $0.7 million, $2.0 million and $1.9 million of unutilized tax deductible expenses from the exercise of non-qualified and disqualified disposition of incentive stock options, respectively. Based on the results of our operations over the last two years, the growth in the market for XIAFLEX, and the trend in actual and anticipated royalty income, we have determined that is was more likely than not that the benefit of our deferred tax assets will be realized. Consequently, we have eliminated the valuation allowance of $3.6 million and increased our deferred tax assets by $0.3 million to reflect the application of our state statutory rates of 7.1% to temporary differences.

Under the ASC 718-25-09, we recognized the tax effect of $4.6 million in disqualifying disposition of options and the exercise of nonqualified options in our financial statements for the year ended December 31, 2011. The exercise of nonqualified options and disposition of disqualified options lowered our taxes payable by $1.9 million, reduced our tax assets related to non-qualified options by $0.2 million and increased additional paid in capital and provision for income tax benefits by $1.7 million and $30,239, respectively. Additionally, we utilized tax assets from our federal and state net operating loss carryforwards of $0.3 million and deferred licensing revenue of $0.2 million to reduce our taxes payable. Because our state net operating losses exceeded our federal net operating losses we set up a valuation allowance of $0.2 million against our tax asset for our state net operating loss carryforwards.

In the 2010 period we had a tax expense of $1,351. The income tax expense for 2010 was the result of minimum New York State taxes.

As of December 31, 2011, the Company believes that there are no significant uncertain tax positions, and no amounts have been recorded for interest and penalties. The Company does not anticipate any events that would require it to record a liability related to any uncertain tax position.

9. STOCKHOLDERS’ EQUITY

Stock Option Plans

In July 1997, the Company's stockholders approved a stock option plan (the “1997 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 which expired in July 2007. Under the 1997 Plan, qualified incentive stock options and non-qualified stock options may be granted to purchase up to an aggregate of 500,000 shares of the Company's common stock, subject to certain anti-dilution provisions. The exercise price per share of common stock may not be less than 100% (110% for qualified incentive stock options granted to stockholders owning at least 10% of common shares) of the fair market value of the Company's common stock on the date of grant. In general, the options vest and become exercisable in four equal annual installments following the date of grant, although the Company’s board of directors, 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. The Company filed with the Securities and Exchange Commission a Registration Statement on Form S-8 for the 1997 Plan on September 26, 1997 to register these securities. 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, and there are no shares available for grant remaining under the 1997 Plan. As of December 31, 2011 there were 9,000 options outstanding under the 1997 Plan.

Table of Content

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. On June 17, 2009, our stockholders approved an amendment to the 2001 Plan to extend the term of the 2001 Plan from April 6, 2011 to April 23, 2019 and to authorize an additional 300,000 shares of our common stock for issuance under the 2001 Plan. A total of 2,050,000 shares of common stock are now authorized for issuance under the amended 2001 Plan. The Company filed with the Securities and Exchange Commission a Registration Statement on Form S-8 for the 2001 Plan on October 5, 2007 and on July 15, 2009 as amended to register these securities. As of December 31, 2011 options to purchase 1,261,425 shares of common stock were outstanding under the 1997 Plan and 2001 Plan, and a total of 269,098 shares available for grant remaining under the 2001 Plan.

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

	Shares	Weighted Average Exercise Price
Outstanding at December 31, 2010	1,346,425	$ 7.81
2011		
Options granted	-	-
Options exercised	(85,000)	0.97
Options canceled or expired	--	--
Outstanding at end of year	1,261,425	8.27
Options exercisable at year end	1,163,925	7.16
Shares available for future grant	269,098	--

The Company did not grant any stock options during 2011.

The following table summarizes information relating to stock options by exercise price at December 31, 2011:

Option Exercise Price	Outstanding Shares	Weighted Average Life (years)	Weighted Average Exercise Price	Exercisable Shares	Weighted Average Option Price
$ 0.83-2.00	576,925	3.76	$ 1.01	576,925	$ 1.01
4.00-6.00	257,000	5.42	4.69	257,000	4.69
13.00-14.00	125,000	6.38	13.51	117,500	13.53
17.00-18.99	70,000	6.93	17.69	50,000	17.48
19.00-21.00	112,500	6.75	20.57	62,500	20.23
26.00-28.00	45,000	7.69	26.43	45,000	26.43
29.00-31.00	75,000	7.88	29.53	55,000	29.64
	1,261,425	5.18	$ 8.27	1,163,925	$ 7.16

Table of Content

We did not grant any stock options during 2011. The weighted-average grant-date fair value for options granted during 2009 was $24.43 per share. During the 2011, 2010 and 2009, $82,450, $673,375 and $380,029 were received from stock options exercised by employees, respectively. The aggregate intrinsic value of options outstanding and exercisable as of December 31, 2011 was approximately $11.0 million. Aggregate intrinsic value represents the total pre-tax intrinsic value, based on the closing price of our common stock of $16.62 on December 30, 2011, which would have been received by the option holders had all option holders exercised their options as of that date. Total unrecognized compensation cost related to non-vested stock options outstanding as of December 31, 2011 was approximately $0.2 million which we expect to recognize over a weighted-average period of 1.5 years.

10. COMMITMENTS AND CONTINGENCIES

Lease Agreements

Our corporate headquarters are currently located at 35 Wilbur St., Lynbrook, NY 11563. As previously reported, our previous lease for our headquarters terminated on June 30, 2010. Our subsidiary, ABC-NY (together with the Company, the “Tenant”) and Wilbur St. Corp. (the “Landlord”) were parties to a lease agreement initially dated as of January 30, 1998 and modified as of June 24, 2009 (the “Lease Agreement”), pursuant to which the Landlord leased to the Tenant the premises located at 35 Wilbur Street, Lynbrook, NY 11563 (the “Premises”) until June 30, 2010 and for a monthly rental price of $11,250 plus utilities and real estate taxes. Following the expiration of the Lease Agreement, the Tenant continued to lease the Premises from the Landlord on a month-to-month basis. We notified the Landlord of our termination of the Lease Agreement effective March 31, 2011, but continue to hold over in the Premises.

On April 14, 2011, the Landlord entered into an agreement to sell the Premises to an unrelated third party named 35 Wilbur Street Associates, LLC. In October 2011, this agreement was terminated, and the sale did not occur. We are currently evaluating our options with respect to remaining in or leaving the Premises. Until that evaluation is complete, we will continue to hold over in the Premises on a month-to-month basis.

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

Rent expense under all operating leases amounted to approximately $135,000, $136,250 and $136,250 for calendar year 2011, 2010 and 2009.

11. RELATED PARTY TRANSACTIONS

As described above in Note 10, the Tenant and the Landlord were parties to the Lease Agreement. Following the expiration of the Lease Agreement, the Tenant continued to lease the Premises from the Landlord on a month-to-month basis. We notified the Landlord of our termination of the Lease Agreement effective March 31, 2011, but continue to hold over in the Premises.

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 2011, 2010 or 2009.

13. SUBSEQUENT EVENTS

In a February 23, 2012 press release, Auxilium announced that it had entered into a Collaboration Agreement with Actelion pursuant to which Actelion has the right to develop and commercialize XIAFLEX for the treatment of Dupuytren's contracture and Peyronie's disease in Canada, Australia, Brazil and Mexico. According to the release, XIAFLEX for the treatment of Dupuytren's contracture has been accepted for review by Health Canada and regulatory action is expected in the second half of 2012. Additionally, Actelion expects to file for approval of XIAFLEX for the treatment of Dupuytren's contracture in Australia, Brazil and Mexico over the next 12 months. Under the terms of the agreement with Actelion, Auxilium is to receive a $10 million upfront payment from Actelion, as well as up to $16 million in potential regulatory, pricing, and reimbursement milestone payments and $42.5 million in potential sales milestone payments. Under the terms of the Auxilium Agreement, we will receive a certain percentage from Auxilium in connection with the upfront payment by Actelion, and a specified percentage of any additional milestones received by Auxilium. We will also receive from Auxilium royalties from net sales and payments on costs of goods sold in Canada, Australia, Brazil and Mexico, which will be a specified percentage of what Auxilium is entitled to receive from Actelion without regard to any offset that Actelion may have with respect to Auxilium.

Table of Content

We have evaluated subsequent events for recognition or disclosure through the time of filing these consolidated financial statements on Form 10-K with the U.S. Securities and Exchange Commission on March 12, 2012.

14. SELECTED QUARTERLY DATA (Unaudited)

The following table sets forth certain unaudited quarterly data for each of the four quarters in the years ended December 31, 2011 and 2010. The data has been derived from the Company's unaudited consolidated financial statements that, in management's opinion, include all adjustments (consisting of normal recurring adjustments) necessary for a fair presentation of such information when read in conjunction with the Consolidated Financial Statements and Notes thereto. The results of operations for any quarter are not necessarily indicative of the results of operations for any future period.

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year ended December 31, 2011				
Net revenues	$ 1,856,915	$ 5,008,824	$ 1,921,395	$ 2,608,592
Operating profit (loss)	135,323	3,320,009	452,100	1,284,335
Net income (loss)	3,691,123	2,569,341	268,836	71,326
Basic earnings per share (1)	$ 0.59	$ 0.40	$ 0.04	$ 0.01
Diluted earnings per share (1)	$ 0.51	$ 0.36	$ 0.04	$ 0.01

	First Quarter	Second Quarter	Third Quarter	Fourth Quarter
Year ended December 31, 2010				
Net revenues	$ 2,659,032	$ 854,807	$ 1,004,097	$ 1,143,413
Operating profit (loss)	(271,963)	(936,157)	(501,784)	(323,128)
Net income (loss)	(254,180)	(910,232)	(484,297)	140,169
Basic earnings per share (1)	$ (0.04)	$ (0.15)	$ (0.08)	$ 0.02
Diluted earnings per share (1)	$ (0.04)	$ (0.15)	$ (0.08)	$ 0.02

Table of Content

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)
4.1	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)
4.2	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)
4.3	Amendment No. 2 to Rights Agreement, dated as of February 3, 2011 (incorporated by reference to Exhibit 4.1 to the Registrant's Current Report on Form 8-K filed with the Securities and Exchange Commission on February 4, 2011)
10.1	Lease Modification Agreement dated June 22, 2009 between ABC-NY, the Company and Wilbur St. Corp. (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed with the Commission on June 29, 2009)
10.2	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)
10.3	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)
10.4	Amendment to Asset Purchase 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)
10.5	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)
10.6	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)
10.7	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)
10.8	Amended and Restated 2001 Stock Option Plan of Registrant (incorporated by reference to Appendix D of the Registrant's Schedule14A filed with the Commission on April 30, 2009)
10.9	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)
10.10	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)
10.11	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)

10.12	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)

Table of Content

10.13	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)
10.14	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)
10.15	Change of Control Agreement, dated October 1, 2008 between the Company and Dr. Matthew Geller (incorporated by reference to Exhibit 10.23 of the Registrant's Form 10-K filed with the Commission on March 31, 2009)
10.16	Second Amended and Restated Development and License Agreement, dated as of August 31, 2011, by and between BioSpecifics Technologies Corp. and Auxilium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed with the SEC on September 1, 2011)
10.17	Settlement Agreement, dated as of August 31, 2011, by and between BioSpecifics Technologies Corp. and Auxilium Pharmaceuticals, Inc. (incorporated by reference to Exhibit 10.2 of the Registrant's Form 8-K filed with the SEC on September 1, 2011)
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

Table of Content

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 12, 2012

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 12, 2012	President, Director, and Principal Executive, Financial and Accounting Officer
/s/ Dr. Matthew Geller Name: Dr. Matthew Geller Date: March 12, 2012	Director
/s/ Dr. Paul Gitman Name: Dr. Paul Gitman Date: March 12, 2012	Director
/s/ George Gould Name: George Gould Date: March 12, 2012	Director
/s/ Henry G. Morgan Name: Henry G. Morgan Date: March 12, 2012	Director
/s/ Michael Schamroth Name: Michael Schamroth Date: March 12, 2012	Director

/s/ Dr. Mark Wegman
Name: Dr. Mark Wegman
Date March 12, 2012

Director

/s/ Toby Wegman
Name: Toby Wegman
Date: March 12, 2012

Director