form10-ksba.htm Page 1 of 97

10KSB/A 1 form10-ksba.htm FORM 10-KSBA

**Table of Contents** 

# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# AMENDMENT NO. 1 to FORM 10-KSB

(Mark One)

[X] ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 For the fiscal years ended: December 31, 2003, December 31, 2004 and December 31, 2005

| [ ] TRANSITION REPORT PURSUANT TO SECTION | ON 13 OR 15(d) OF THE SECURITIES | S EXCHANGE ACT OF 193 |
|---|----------------------------------|-----------------------|
| For the transitional period from          | to                               |                       |
|   |                                  |                       |
|   |                                  |                       |

# BIOSPECIFICS TECHNOLOGIES CORP.

| (Exact name of registrant as specified in its charter) |  |                     |   |
|--|--|---------------------|---|
| Delaware   | 0-19879  | 11-3054851          |   |
| (State or Other Jurisdiction                           | (Commission File Number)   | (I.R.S. Employer    | _ |
| Of Incorporation)                                      |  | Identification No.) |   |
|  | 35 Wilbur Street Lynbrook, NY 11563 (Address of Principal Executive Office) (Zip Code) |                     |   |
|  | 516.593.7000 (Registrant's telephone number, including area code)                      |                     |   |

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

Securities registered under Section 12(g) of the Exchange Act: Common stock, \$.001 par value

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

Yes \_\_\_ No X

Check if there is no disclosure of delinquent filers in response to Item 405 of Regulation S-B contained in this form, and no disclosure will 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-KSB or any amendment to this Form 10-KSB. []

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

Yes\_\_\_ No X

The issuer's revenues for the year ending December 31, 2005 are \$5,478,239.

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was sold, or the average bid and asked price of such common equity, as of January 18, 2007. (See definition of affiliate in Rule 12b-2 of the Exchange Act.): \$13,139,258.

The number of shares outstanding of the issuer's common stock as of January 18, 2007 is 5,234,549.

form10-ksba.htm Page 2 of 97

form10-ksba.htm Page 3 of 97

#### Table of Contents

# **EXPLANATORY NOTE:**

The accompanying Form 10-KSB reports the annual consolidated financial statements for the years ended December 31, 2005, 2004 and 2003 including a restatement of the one year period ended December 31, 2003, in addition to summary quarterly financial information for the quarterly periods of 2005 and 2004.

i

form10-ksba.htm Page 4 of 97

Table of Contents

# TABLE OF CONTENTS

|  | <u>Page</u> |
|--|-------------|
| PART I   | 2           |
| Item 1. DESCRIPTION OF BUSINESS.   | 2           |
| Item 2. DESCRIPTION OF PROPERTY.   | 29          |
| Item 3. <u>LEGAL PROCEEDINGS.</u>  | 29          |
| Item 4. <u>SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS.</u>                                    | 29          |
| <u>PART II</u>   | 29          |
| Item 5. MARKET FOR COMMON EQUITY, RELATED STOCKHOLDER MATTERS.   | 29          |
| Item 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION                                      | 32          |
| Item 7. <u>FINANCIAL STATEMENTS.</u>   | 46          |
| Item 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.          | 46          |
| Item 8A. CONTROLS AND PROCEDURES.  | 47          |
| PART III   | 49          |
| Item 9. DIRECTORS AND EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) |             |
| OF THE EXCHANGE ACT.   | 49          |
| Item 10. EXECUTIVE COMPENSATION.   | 53          |
| Item 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER        |             |
| MATTERS.   | 54          |
| Item 12. <u>CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.</u>  | 56          |
| Item 13. <u>EXHIBITS.</u>  | 56          |
| Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.   | 58          |
|  |             |

ii

form10-ksba.htm Page 5 of 97

#### Table of Contents

#### **Introductory Comments - Terminology**

Throughout this annual report on Form 10-KSB (this "Report"), the terms "BioSpecifics," "Company," "we," "our," and "us" refer to BioSpecifics Technologies Corp. and its subsidiaries, Advance Biofactures Corporation ("ABC-NY"), Advance Biofactures of Curacao, N.V. ("ABC-Curacao"), which was sold in 2006, and BioSpecifics Pharma GmbH, which was liquidated in 2005. We also owned two dormant companies, BioSpecifics N.V. and Biota N.V., which were liquidated in January 2007.

#### **Introductory Comments - Forward-Looking Statements**

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

http://www.sec.gov/Archives/edgar/data/875622/000095012007000467/form10-ksba.htm

form10-ksba.htm Page 6 of 97

Table of Contents

#### PART I

## Item 1. DESCRIPTION OF BUSINESS.

#### Overview

We are a biopharmaceutical company that has manufactured the active pharmaceutical ingredient ("API" or "API Enzyme") used in a Food and Drug Administration ("FDA") licensed collagenase ointment that has been marketed for over 30 years. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. ("Auxilium") for injectable collagenase (which Auxilium has named "AA4500") for clinical indications in Dupuytren's disease, Peyronies's disease and frozen shoulder (*adhesive capsulitis*), and Auxilium has an option to acquire additional indications that we may pursue, including cellulite and lipomas. As a result of our research and development efforts we have also developed an injectable collagenase for treatment of various diseases or indications. Injectable collagenase has completed a pivotal clinical trial for the treatment of Dupuytren's disease. A Phase III clinical trial has been initiated and is currently on clinical hold. During its earnings conference call on February 15, 2007, Auxilium reported that it expects to resume the Phase III clinical trial in the fourth quarter of 2007.

#### **Marketed Product**

Prior to the sale of our collagenase topical business to DFB Biotech, Inc. and its affiliates ("DFB") in March 2006, BioSpecifics had been in the business of manufacturing the API for a topical collagenase prescription product. This topical collagenase product is a FDA approved biologic product indicated for debridement of chronic dermal ulcers and severely burned areas. Abbott Laboratories, Inc. and its subsidiaries ("Abbott"), under the terms of an exclusive licensing agreement (the "Abbott Agreement"), compounded the API into a topical collagenase ointment utilizing the API Enzyme manufactured by us. Effective January 1, 2004, the Ross Products Division of Abbott assumed United States ("U.S.") marketing responsibility for the topical collagenase product from Smith & Nephew ("S&N"). The topical collagenase is sold primarily to long-term care centers. In 2005, 2004 and 2003 we derived substantially all of our product revenues from the sale of our API Enzyme, and all royalty revenues, from Abbott.

Because sales of this topical collagenase had declined significantly since the peak year of 1999, we decided to sell the collagenase topical business and focus on the clinical indications related to our injectable collagenase business. As part of the sales agreement, DFB assumed ownership and operation of our wholly-owned subsidiary, ABC-Curacao, where the API is manufactured, along with certain other assets, including our FDA manufacturing license and the Abbott Agreement.

# **Development of Injectable Collagenase for Multiple Indications**

We are developing an injectable collagenase for multiple indications. The most advanced indications are for the treatment of Dupuytren's disease, Peyronie's disease and frozen shoulder. In June 2004, we entered into a development and licensing agreement with Auxilium, which was amended on May 6, 2005 (the "Auxilium Agreement"). Under the Auxilium Agreement, we have granted Auxilium an exclusive worldwide license to develop products containing our injectable collagenase for the treatment of Dupuytren's disease and Peyronie's disease and the option to develop and license the technology for use in additional indications other than dermal formulations labeled for topical administration. In December of 2005, Auxilium exercised its option to include the clinical indication of frozen shoulder. The Auxilium Agreement and other licensing agreements are discussed more fully in this Item 1, under the section titled "Licensing and Marketing Agreements."

## **Background on Collagenase**

form10-ksba.htm Page 7 of 97

#### Table of Contents

Collagenase is the only protease that can hydrolyze the triple helical region of collagen under physiological conditions. The specific substrate collagen comprises approximately one-third of the total protein in mammalian organisms and it is the main constituent of skin, tendon, and cartilage, as well as the organic component of teeth and bone. The body relies on endogenous collagenase production to remove dead tissue and collagenase production is an essential biological mechanism, which regulates matrix remodeling and the normal turnover of tissue. The *Clostridial* collagenase produced by us has a broad specificity towards all types of collagen and is acknowledged as much more efficient than mammalian collagenases. *Clostridial* collagenase cleaves the collagen molecule at multiple sites along the triple helix whereas the mammalian collagenase is only able to cleave the molecule at a single site along the triple helix. Because collagenase does not damage the cell membrane, it is widely used for cell dispersion for tissue disassociation and cell culture. Since the main component of scar tissue is collagen, collagenase has been used in a variety of clinical investigations to remove scar tissue without surgery. Histological and biochemical studies have shown that the tissue responsible for the deformities associated with Dupuytren's disease and Peyronie's disease is primarily composed of collagen. The contracture associated with Dupuytren's disease is an example of a disease that results from excessive collagen formation. Surgical removal of scar tissue has the potential to result in complications including increased scar formation. Due to the highly specific nature of the enzyme, we consider its use to be more desirable than the application of general proteolytic enzymes for the removal of unwanted tissue. Treatment with injectable collagenase for removal of excessive scar tissue represents a first in class non-invasive approach to this unmet medical need. New uses involving the therapeutic application of exoge

We have developed a proprietary process to produce a purified collagenase product, which is fully characterized and has shown stability for years.

## Collagenase for Treatment of Dupuytren's Disease

Dupuytren's disease is a deforming condition of the hand in which one or more fingers contract toward the palm, often resulting in physical disability. The onset of Dupuytren's disease is characterized by the formation of nodules in the palm that are composed primarily of collagen. As the disease progresses, the collagen nodules begin to form a cord causing the patient's finger(s) to contract, making it impossible to open the hand fully. Patients often complain about inability to wash their hands, wear gloves, or grasp some objects. Dupuytren's disease has a genetic basis and it is most prevalent in individuals of northern European ancestry. Well-known individuals with Dupuytren's disease include President Ronald Reagan and Prime Minister Margaret Thatcher.

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

Hand surgeons note that the Dupuytren's disease surgery is tedious, lengthy and poorly reimbursed in the U.S. In a conference on February 8, 2007, Auxilium stated that the average cost of Dupuytren's disease surgery is \$5,000 in the U.S. and \$3,500 in Europe. Auxilium has reported that U.S. based hand surgeons would recommend the use of collagenase injection on 76% of the patients who were candidates for surgery. This figure confirms an earlier survey of U.S. hand surgeons conducted by us, which found that they would recommend the use of collagenase injection on 80% of patients considered eligible for Dupuytren's disease surgery.

Phase II Trials

form10-ksba.htm Page 8 of 97

#### Table of Contents

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

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

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

Eighteen out of the twenty-three patients (78%) who received the high number of units returned to normal extension (0°-5°) at one month post-treatment as compared to ten out of twenty-two (45%) in the mid number of units group, and nine out of eighteen (50%) in the low number of units group. There was no response to placebo in any patient. For PIP joints, five out of seven (71%) patients who received the high number of units of collagenase returned to normal extension at the one month post-treatment as compared to four out of seven (57%) patients in the mid number of units group, two out of four (50%) in the low number of units group and zero out of seven (0%) in the placebo group. For MP joints, thirteen out of sixteen (81%) patients who received the high number of units group of collagenase returned to normal extension at the one month post-treatment as compared to six out of fifteen (43%) patients in the mid number of units group, seven out of fourteen (50%) in the low number of units group and zero out of ten (0%) in the placebo group.

None of the serious adverse events that occurred were attributed by the investigators to the study drug.

Pivotal Trial

In its press release dated February 20, 2007, Auxilium reported the following information concerning the first pivotal trial study design and key findings:

This was a randomized, double-blind, placebo-controlled phase III clinical trial. After finishing this pivotal efficacy study, patients from both AA4500 and placebo groups were permitted to receive additional AA4500 injections for either unsuccessfully treated joints or additional untreated joints during an open-label, extended treatment period. This open-label phase provided further support for the long-term safety and efficacy of AA4500 injections in the treatment of Dupuytren's contracture.

form10-ksba.htm Page 9 of 97

#### Table of Contents

In the double-blind study, 35 patients with Dupuytren's contracture and fixed-extension deformity of at least 20 degrees in a single finger were enrolled and randomly assigned in a 2:1 ratio to receive either AA4500 treatment or placebo, with the goal of reaching therapeutic success. Therapeutic success was defined as reducing the contracture of the affected joint to within five degrees of normal, essentially allowing the hand to be flat when placed on a table. AA4500 achieved a 91 percent success rate for the primary endpoint of reduced contracture to within five degrees of normal in treated joints, both PIP and MP joints, after up to three injections, compared to a 0% response rate in the placebo group (p<0.001). When stratified by joint type, 100 percent of PIP joints and 86 percent of MP joints achieved therapeutic success. The mean number of injections per joint was 1.4. The results observed after a single injection of AA4500 showed that 70% of subjects achieved therapeutic success; no patients responded to placebo (p<0.001). When stratified by joint type, 67 percent of PIP joints and 71 percent of MP joints achieved therapeutic success after a single injection.

These results were consistent with those from a Phase II study published in The Journal of Hand Surgery (2002:27A:788-798).

A total of 19 patients enrolled in the open-label extension phase of the study and received up to five injections of AA4500. This treatment period was a continuation of the protocol in the double-blind study. These results demonstrated 88 percent of MP joints and 68 percent of PIP joints achieved therapeutic success after receiving an average of 1.4 injections of AA4500.

Safety data in both studies showed that the most commonly reported adverse events were pain and swelling (edema) of the hand at the injection site, and post-injection temporary swelling of a modest nature in the lymph node area of the armpit. Adverse events were mild to moderate in nature and resolved without treatment within 30 days. There were no serious adverse events reported which were judged by the investigator to be related to treatment with AA4500.

## Development Status

On November 20, 2006, Auxilium announced that they had initiated a Phase III clinical trial for Dupuytren's disease. Auxilium issued a press release dated December 6, 2006 and announced that it had temporarily suspended the dosing of patients in its ongoing Phase III trial for AA4500 for the treatment of Dupuytren's contracture in response to a visual appearance failure of the lyophilized material in some vials of AA4500 for use in the clinical trial. Auxilium said that they were conducting an investigation to determine the cause of this failure and they believe that it is likely related to the higher than expected moisture content within the vial. Based on tests conducted, Auxilium has excluded container closure as a cause and believes that the issue is related to the lyophilization process and/or equipment. The issue was identified as part of routine ongoing stability testing. During its earnings conference call on February 15, 2007, Auxilium reported that it expects to resume the Phase III clinical trial in the fourth quarter of 2007.

# Collagenase for Treatment of Peyronie's Disease

Peyronie's disease affects the penis and it is characterized by the presence of a collagen plaque on the shaft of the penis, which can distort an erection and make intercourse difficult or impossible in advanced cases. The plaque is not elastic and it does not stretch during erection. In some mild cases, the plaque can resolve spontaneously without medical intervention. The most common plaque forms on the top of the penis causing the penis to arc upward. In severe cases, the penis can be bent at a 90-degree angle during erection. Significant psychological distress has been noted in patients with Peyronie's disease who are sexually active. Frequent patient complaints include increased pain, painful erections, palpable plaque, penile deformity, and erectile dysfunction. Patients with Peyronie's disease have been reported to have an increased likelihood of having Dupuytren's disease, frozen shoulder, plantar fibromatosis, knuckle pads, hypertension and diabetes. Peyronie's disease typically affects males in the range of 40-70 years. The cause of Peyronie's disease is unknown, although some investigators have proposed that it may be due to trauma or an autoimmune component. A number of researchers have suggested that the incidence of Peyronie's disease has increased due to the use of erectile dysfunction drugs.

form10-ksba.htm Page 10 of 97

#### Table of Contents

Surgery is the only proven treatment for Peyronie's disease and the results are variable. Surgery often results in shortening of the penis. Auxilium has reported that 33% of Peyronie's disease patients who undergo surgery are subsequently dissatisfied with the results and they frequently require a penile implant.

Patients with Peyronie's disease strongly desire therapeutic alternatives to surgery. Auxilium has reported that 90% of urologists would use collagenase injection to delay or avoid surgery and this finding is consistent with a survey of urologists performed for us.

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

An independent investigator carried out a positive Phase I clinical trial in which he treated approximately 180 patients in an open-label trial.

In addition, two positive open label clinical trials have been conducted by an independent investigator at Tidewater Urology in Norfolk, Virginia, which is the largest center for treatment of Peyronie's disease in the world.

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

Both studies were open label and up to 12 months in duration. They were conducted to evaluate the efficacy and tolerability of AA4500 in the treatment of Peyronie's disease. Clinical success was defined as change from baseline in deviation angle of at least 25 percent.

In Study A (n=25) [25 patients], 3 injections of AA4500, each administered on a separate day, were given over 7-10 days. Patients received a second series of 3 injections 12 weeks later. Patients were evaluated at three, six, and nine months post-last injection. The mean baseline deviation angle was 52.8 degrees. At months three and six, 58 percent and 53 percent of patients (respectively) achieved clinical success with respect to deviation angle.

The best results were achieved with a three-treatment series of three injections each in Study B (n=10) [10 patients]. In Study B, patients received three injections of AA4500 administered one per day, separated by at least one day each, over a one week timeframe. Patients received two additional series of 3 injections, each spaced 6 weeks apart. The mean baseline deviation angle was 50.2 degrees. At 9 month follow up (post-first injections), 25 percent or greater reduction in deviation angle was achieved in 8/9 patients who completed the study (89 percent, 1 patient had 24 percent reduction in deviation angle). Based on the investigator's global assessment, 67 percent of subjects were very much improved or much improved after treatment with AA4500.

The most common adverse events reported in both studies were local administration site reactions that were mid or moderate in severity, non-serious, and resolved in time without medical attention.

## Development Status

Auxilium reported on its earnings conference call on February 15, 2007 that they will initiate a Phase IIb trial for Peyronie's disease in the fourth quarter of 2007.

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

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

Results of a Phase II randomized double-blind, placebo controlled, dose response study were presented at the annual meeting of the American Academy of Orthopaedic Surgeons (AAOS) in March 2006. Based on Auxilium's prior review of the data contained in the oral presentation, they elected to exercise their option to develop and commercialize this additional indication for collagenase injection in December 2005.

form10-ksba.htm Page 11 of 97

#### Table of Contents

#### Other Clinical Indications For Collagenase

## Lipomas

Lipomas are benign fatty tumors that occur as bulges under the skin. An open label clinical trial has been completed for treatment of lipomas utilizing a single injection of collagenase. Based on observations made during pre-clinical studies that a collagenase injection decreased the size of fat pads in animals, a Phase I open label clinical trial was conducted. Favorable initial results from this study for treatment of lipomas were presented at a meeting of the American Society of Plastic Surgeons. We are currently planning the next steps for development of this clinical indication.

## Cellulite

Cellulite is a condition characterized by dimpling of the skin and a mattress phenomenon typically affecting the thighs and buttocks. It is due to irregular and discontinuous subcutaneous connective tissue. An open label study has been completed to assess whether injectable collagenase can restore the cellulite-affected areas to a more cosmetically acceptable appearance. An abstract describing the promising results of this study was published in *Plastic and Reconstructive Surgery* on September 15, 2006 (see A. Dagum and M. Badalamente. "Collagenase Injection in the Treatment of Cellulite." *Plastic and Reconstructive Surgery* 118.4 Sept. 2006: 53). We are currently planning the next steps for development of this clinical indication.

#### Scarred Tendon

Traumatic injuries to the hand may result in an inability to return to normal function due to scar formation between flexor tendon and surrounding tissues. Scarring frequently results in the formation of adhesions, which complicates the ability of the tendon to glide further impairing finger movement. Surgical repairs of the flexor tendon are notably difficult because of the post-traumatic accumulation of scar tissue, as such it is considered to be one of the most difficult issues in orthopaedic surgery. An open label clinical investigation is currently being conducted to determine if collagenase injection can be of help to patients with scarred flexor tendons.

#### **Total Patient Exposure**

Clinical investigations with our collagenase injection have been conducted in the treatment of herniated disc disease, keloids and hypertrophic scars, as an adjunct to vitrectomy, Peyronie's disease, Dupuytren's disease, glaucoma, frozen shoulder, lipoma, flexor tendon adhesions and cellulite. Over 1300 patients have been treated in these studies and the data suggest a very acceptable safety profile for the product.

#### LICENSING AND MARKETING AGREEMENTS

## Topical Collagenase Agreement

Prior to March 2006, we were a party to the Abbott Agreement, an exclusive license agreement with Knoll Pharmaceutical Company, a subsidiary of Abbott, for the production of the API for topical collagenase. In March 2006 we sold our topical collagenase business to DFB, including all rights to the exclusive license agreement and we were released of any obligations thereunder.

In addition, DFB acquired all of the issued and outstanding shares of ABC-Curacao, pursuant to an asset purchase agreement between us, DFB and ABC-NY (the "Asset Purchase Agreement"). ABC-Curacao manufactured the API Enzyme, which in its final formulation was marketed by Abbott.

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

form10-ksba.htm Page 12 of 97

#### Table of Contents

As consideration for the purchased assets we received \$8 million in cash, DFB's assumption of certain liabilities, and the right to receive earn out payments in the future based on sales of certain products. In connection with the closing of the Asset Purchase Agreement, we agreed to provide certain technical assistance and certain transition services to DFB in consideration of fees and costs totaling over \$1.4 million. At the closing, DFB paid to us a partial payment of \$400,000 in respect of the technical assistance to be provided by us. The consulting obligations generally expire during March 2011.

On January 8, 2007, we entered into an Amendment to the Asset Purchase Agreement with ABC-NY and DFB (the "Amendment") in order to clarify the intent of the parties with respect to certain provisions of the Asset Purchase Agreement and the parties are discussing further clarifications to address certain concerns raised by Auxilium.

## Auxilium Agreement

In June 2004, we entered into the Auxilium Agreement, which was amended in May 2005. Under the Auxilium Agreement, we granted to Auxilium exclusive worldwide rights to develop, market and sell certain products containing our injectable collagenase. Auxilium's licensed rights concern the development of products, other than dermal formulations labeled for topical administration, and currently its licensed rights cover the indications of Dupuytren's and Peyronie's diseases and frozen shoulder, for which Auxilium exercised its option in December 2005. Auxilium may further expand the Auxilium Agreement, at its option, to cover other indications as they are developed by us.

The Auxilium Agreement extends, on a country-by-country and product-by-product basis, for the longer of the patent life, the expiration of any regulatory exclusivity period or 12 years. Auxilium may terminate the Auxilium Agreement upon 90 days prior written notice.

Auxilium is responsible, at its own cost and expense (excluding the third party costs for the development of the lyophilization of the injection formulation, which are shared equally by the parties), for developing the formulation and finished dosage form of products and arranging for the clinical supply of products. As permitted under the Auxilium Agreement, Auxilium has qualified Cobra Biomanufacturing Plc as its primary supplier of clinical products. On September 5, 2006, Auxilium reported that they have leased an existing biological manufacturing facility in Pennsylvania. Auxilium is responsible for all clinical development and regulatory costs for Peyronie's disease, Dupuytren's disease, frozen shoulder and all additional indications for which they exercise their options.

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

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

form10-ksba.htm Page 13 of 97

#### Table of Contents

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

Finally, Auxilium will be obligated to make contingent milestone payments upon the filing of regulatory applications and receipt of regulatory approval. Through December 31, 2005, Auxilium paid us both up-front and milestone payments under the Auxilium Agreement of \$8.5 million. Auxilium could make in excess of \$5 million of additional contingent milestone payments for listed indications under the Auxilium Agreement if all existing conditions are met. Additional milestone obligations will be due if Auxilium exercises an option to develop and license AA4500 for additional medical indications.

In-Licensing and Royalty Agreements

We have entered into several in-licensing and royalty agreements with various investigators, universities and other entities throughout the years.

Dupuytren's Disease

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

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

Our obligation to pay royalties to the Research Foundation with respect to sales by the Company, its affiliates or any sublicensee of any Dupuytren's Licensed Product in any country (including the U.S.) arises only upon the first commercial sale of such Dupuytren's Licensed Product. 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 Food and Drug Administration's Orphan Product Division with respect to the Licensed Product or (iii) June 3, 2016.

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

Peyronie's Disease

In October 1993, we entered into a royalty agreement with Martin K. Gelbard, M.D., pursuant to which we are obligated to pay certain royalties on net sales.

Frozen Shoulder

form10-ksba.htm Page 14 of 97

#### Table of Contents

On November 21, 2006, we also entered into a license agreement (the "Frozen Shoulder License Agreement") with the Research Foundation, pursuant to which the Research Foundation granted to us and our affiliates an exclusive worldwide license, with the right to sublicense to certain third parties, to know-how owned by the Research Foundation related to the development, manufacture, use or sale of (i) the Enzyme and (ii) all pharmaceutical products containing the Enzyme or injectable collagenase, in each case to the extent it pertains to the treatment and prevention of Frozen Shoulder. Additionally, the Research Foundation granted to us an exclusive license to the patent applications in respect of Frozen Shoulder. The license granted to us under the Frozen Shoulder License Agreement is subject to the non-exclusive license (with right to sublicense) granted to the U.S. government by the Research Foundation in connection with the U.S. government's funding of the initial research.

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

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

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

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

Other Indications

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

#### **COMPETITION**

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

#### RESEARCH AND DEVELOPMENT

Cost of Research and Development Activities

Through December 31, 2005, 2004 and 2003, the Company had invested approximately \$686,000, \$1,057,000 and \$935,000, respectively, in research and development activities.

Dupuytren's Disease

form10-ksba.htm Page 15 of 97

#### Table of Contents

Following an end-of-Phase II meeting between the FDA and us, we supplied requisite study drug, initiated and monitored a pivotal clinical trial. Auxilium presented the results of this trial in their press release on February 20, 2007, as stated in this Item 1, under the section titled "Collagenase for Treatment of Dupuytren's Disease."

#### Peyronie's Disease

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

#### Frozen Shoulder

We have supplied requisite study drug, initiated and monitored a Phase II clinical trial using the injectable enzyme in the treatment of frozen shoulder. Three different doses of the enzyme were compared to placebo in this double-blind, randomized trial in 60 patients. The results from this trial suggest that local injection of the enzyme are encouraging and may be effective in patients suffering from frozen shoulder. Additional studies are needed to assess the optimal dose and dosing regimen of injectable collagenase in this indication. In its press release dated December 20, 2005, concurrent with its exercise of its option with respect to frozen shoulder, Auxilium reported: "AA4500 is a very important product candidate for Auxilium, and we believe the addition of a third indication for this development program enhances the commercial potential of AA4500."

#### Additional Clinical Indications

#### Lipomas

As described in this Item 1, under the section titled "Other Clinical Indications for Collagenase," we have supplied requisite study drug, initiated and monitored a positive open label clinical study for treatment of lipomas with injectable collagenase. These results suggest the possibility of chemical liposuction. We are in the process of analyzing the results of the study and evaluating the possibility of conducting a Phase II study for the treatment of lipomas with injectable collagenase.

## Cellulite

As described in this Item 1, under the section titled "Other Clinical Indications for Collagenase," we have referenced the promising open label clinical trial results for treatment of cellulite with injectable collagenase. We are currently analyzing the results of the study and evaluating the possibility of conducting a Phase II study for the treatment of cellulite with injectable collagenase.

# Scarred Tendon

Traumatic injuries to the hand may result in an inability to return to normal function due to scar formation between flexor tendon and surrounding tissues. Scarring frequently results in the formation of adhesions, which complicates the ability of the tendon to glide further impairing finger movement. Surgical repairs of the flexor tendon are notably difficult because of the post-traumatic accumulation of scar tissue, as such it is considered to be one of the most difficult issues in orthopaedic surgery. We have supplied requisite study drug and we monitor an open-label clinical investigation with collagenase for the treatment of scarred tendons in the hand. An open label clinical investigation is currently being conducted by independent investigators to determine if collagenase injection can be of help to patients with scarred flexor tendons. The study is enrolling patients slowly and has not yet been completed.

We continue to selectively review new technologies and products in the areas of wound healing and tissue remodeling for possible acquisition or inlicensing.

## GOVERNMENT REGULATION

form10-ksba.htm Page 16 of 97

#### Table of Contents

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

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

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

Assuming successful completion of the required clinical trial, drug developers submit the results of preclinical studies and clinical trials, together with other detailed information including information on the chemistry, manufacture and control of the product, to the FDA, in the form of a NDA or BLA, requesting approval to market the product for one or more indications. In most cases, the NDA/BLA must be accompanied by a substantial user fee. The FDA reviews an NDA/BLA to determine, among other things, whether a product is safe and effective for its intended use.

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

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

form10-ksba.htm Page 17 of 97

#### Table of Contents

If the FDA approves the NDA or BLA, the drug can be marketed to physicians to prescribe in the U.S. After approval, the drug developer must comply with a number of post-approval requirements, including delivering periodic reports to the FDA (i.e., annual reports), submitting descriptions of any adverse reactions reported, biological product deviation reporting, and complying with drug sampling and distribution requirements. The holder of an approved NDA/BLA is required to provide updated safety and efficacy information and to comply with requirements concerning advertising and promotional labeling. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval. Drug manufacturers and their subcontractors are required to register their facilities and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMP which imposes procedural and documentation requirements relating to manufacturing, quality assurance and quality control. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. The FDA may require post-market testing and surveillance to monitor the product's safety or efficacy, including additional studies to evaluate long-term effects.

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

We use, and will continue to use, third-party manufacturers to produce our products in clinical quantities. Future FDA inspections may identify compliance issues at our facilities or at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product or the failure to comply with requirements may result in restrictions on a product, manufacturer or holder of an approved NDA/BLA, including withdrawal or recall of the product from the market or other voluntary or FDA-initiated action that could delay further marketing. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications. Also, new government requirements may be established that could delay or prevent regulatory approval of our products under development.

#### INTELLECTUAL PROPERTY AND RIGHTS

#### PATENT PROTECTION

#### Patents

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

The scope of the intellectual property rights held by pharmaceutical firms involves complex legal, scientific and factual questions and consequently is generally uncertain. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued. Consequently, we do not know whether any of our current patent applications, or the products or product candidates we develop, acquire or license will result in the issuance of patents or, if any patents are issued, whether they will provide significant proprietary protection or will be challenged, circumvented or invalidated. Because patent applications in the U.S. and some other jurisdictions are sometimes maintained in secrecy until patents issue, and since publication of discoveries in the scientific or patent literature often lags behind actual discoveries, we cannot be certain of the priority of inventions covered by pending patent applications. Moreover, we may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office (the "USPTO"), or a foreign patent office to determine priority of invention, or in opposition proceedings in a foreign patent office, either of which could result in substantial cost to us, even if the eventual outcome is favorable to us. There can be no assurance that the patents, if issued and challenged, in a court of competent jurisdiction would be found valid or enforceable. An adverse outcome could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties or require us to cease using such technology.

form10-ksba.htm Page 18 of 97

#### Table of Contents

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

While we attempt to ensure that our product candidates and the methods we employ to manufacture them do not infringe other parties' patents and proprietary rights, competitors or other parties may assert that we infringe on their proprietary rights. Additionally, because patent prosecution can proceed in secret prior to issuance of a patent, third parties may obtain other patents without our knowledge prior to the issuance of patents relating to our product candidates which they could attempt to assert against us.

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

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

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

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

We licensed to Auxilium our injectable collagenase for the treatment of Dupuytren's and Peyronie's diseases as well as frozen shoulder. In addition to the marketing exclusivity which comes with its orphan drug status as a treatment for Dupuytren's and Peyronie's diseases, the enzyme underlying this product candidate is covered by two use patents in the U.S., one for the treatment of Dupuytren's disease and one for the treatment of Peyronie's disease. The Dupuytren's patent expires in 2014, and the Peyronie's patent expires in 2019. The patent relating to Dupuytren's disease is the subject of a reissue application in the USPTO for, among other things, the purpose of submitting prior art that was not previously submitted during the prosecution of the Dupuytren's patent. As a result, the patent may or may not be reissued by the USPTO, and therefore, may or may not be valid and enforceable. Both patents are limited to the use of the enzyme for the treatment of Dupuytren's and Peyronie's diseases within certain dose ranges. Foreign patents also cover these products in certain countries.

Orphan Drug Designations

form10-ksba.htm Page 19 of 97

#### Table of Contents

The FDA's Office of Orphan Products Development ("OOPD") administers the major provisions of the Orphan Drug Act (the "Act"), an innovative program that provides incentives for sponsors to develop products for rare diseases. The incentives for products that qualify under the Act include seven-year exclusive marketing rights post FDA approval, tax credits for expenses associated with clinical trials including a 20 year tax carry-forward, availability of FDA grants, and advice on design of the clinical development plan.

The orphan drug provisions of the Federal Food, Drug, and Cosmetic Act also provide incentives to drug and biologics suppliers to develop and supply drugs for the treatment of rare diseases, currently defined as diseases that affect fewer than 200,000 individuals in the U.S. or, for a disease that affects more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for such disease or condition will be recovered from its sales in the U.S. Under these provisions, a supplier of a designated orphan product can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for that product for the orphan indication. It would not prevent other drugs from being approved for the same indication.

Two indications, Dupuytren's disease and Peyronie's disease, have received Orphan Drug status from the OOPD.

In the European Union ("E.U."), incentives for suppliers to develop medicinal products for the treatment of rare diseases are provided pursuant to the Orphan Medicinal Products Regulation. Orphan medicinal products are those products designed to diagnose, treat or prevent a condition which occurs so infrequently that the cost of developing and bringing the product to the market would not be recovered by the expected sale of the product. In the E.U., the criterion for designation is a prevalence of the relevant condition in no more than 5 per 10,000 of the population. The incentives include, among others, a reduction in the fees payable in respect of the marketing authorization application, protocol assistance for clinical trials in support of the application, and marketing exclusivity once the authorization is granted.

#### **EMPLOYEES**

Following the sale of the collagenase topical business to DFB in March, 2006, the total number of our employees decreased to six and with the death of Edwin H. Wegman on February 16, 2007, we now have five employees. All of our employees are full time employees.

## CORPORATE INFORMATION

BioSpecifics Technologies Corp. was incorporated in Delaware in 1990. ABC-NY was incorporated in New York in 1957. ABC-Curação was incorporated in Curação, Netherlands Antilles in 1976. Our corporate headquarters are located at 35 Wilbur St. Lynbrook NY 11563. Our telephone number is 516-593-7000. Until March 2006, our manufacturing operations were located in Lynbrook, NY and Brievengat Curação, Netherlands Antilles.

#### 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, as part of our sale of our topical collagenase business to DFB, technical assistance payments and contingent earn out payments from DFB.

form10-ksba.htm Page 20 of 97

#### Table of Contents

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

Under the Auxilium Agreement, in exchange for the right to receive royalties and other rights, we granted to Auxilium the right to develop, manufacture, market and sell worldwide products (other than dermal formulations for topical administration) that contain collagenase for the treatment of Dupuytren's and Peyronie's diseases and frozen shoulder, which Auxilium exercised in December 2005, subject to certain reversionary rights. However, we may not receive any royalty payments from Auxilium because we have no control over Auxilium's decision to pursue commercialization, or its ability to successfully manufacture, market and sell candidate products for the treatment of Dupuytren's and Peyronie's diseases, and frozen shoulder. Subject to certain conditions, we have retained an option to manufacture a portion of the developed product licensed to Auxilium after it has been marketed for several years. We have received in the past, and are entitled to receive in the future, certain milestone payments from Auxilium in respect of its efforts to commercialize such candidate products. However, we have no control over Auxilium's ability to achieve the milestones.

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

On December 6, 2006 Auxilium announced the suspension of its Phase III clinical trial for Dupuytren's disease. This suspension will have an effect on the timing of our receipt of milestone payments and the commencement of royalty payments by Auxilium. During its earnings conference call on February 15, 2007, Auxilium reported that it expects the Phase III clinical trial to resume in the fourth quarter of 2007.

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

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

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

Auxilium has disclosed in its securities filings a number of risk factors to consider when evaluating its business and future prospects. Given our dependence upon revenue from Auxilium, Auxilium's operating success or failure has a significant impact on our potential royalty stream and other payment rights. As such, we refer you to the full text of Auxilium's disclosed risk factors in its securities filings. Auxilium's risk factors that may affect our business include, but are not limited to, the following:

form10-ksba.htm Page 21 of 97

#### Table of Contents

Auxilium's Risks Related to its Financial Results and Need for Additional Financing

- Auxilium has incurred significant losses since their inception and may not achieve profitability in the foreseeable future.
- Because Auxilium has limited operating history, its future results are unpredictable, and therefore, its common stock is a highly speculative investment.
- All of Auxilium's revenues to date have been generated from the sale or out-licensing of their product called Testim, and, if these revenues do not grow, and they cannot commercialize new products, they will not become profitable.
- If Auxilium is unable to meet its needs for additional funding in the future, it may be required to limit, scale back or cease its operations.
- Auxilium's revenues, operating results and cash flows may fluctuate in future periods and they may fail to meet investor expectations, which
  may cause the price of Auxilium's common stock to decline.

Auxilium's Risks Related to Development of its Product Candidates

- Auxilium may not be able to develop product candidates into viable commercial products, which would impair its ability to grow and could cause a decline in the price of its stock.
- If clinical trials for Auxilium's product candidates are delayed for any reasons including the inability to enroll patients or the unavailability of clinical material, it would be unable to commercialize its product candidates on a timely basis, which would materially harm Auxilium's business.
- Adverse events, or lack of efficacy in Auxilium's clinical trials, may force it to stop development of its product candidates or prevent regulatory approval of its product candidates, which could materially harm Auxilium's business.
- Auxilium's failure to successfully in-license or acquire additional technologies, product candidates or approved products would impair its ability to grow.
- If Auxilium engages in any acquisition, it will incur a variety of costs, and it may never realize the anticipated benefits of the acquisition.

Auxilium's Risks Related to Regulatory Approval of its Product Candidates

- Auxilium is subject to numerous complex regulatory requirements and failure to comply with these regulations, or the cost of compliance with these regulations, may harm its business.
- If Auxilium's product candidates are not demonstrated to be sufficiently safe and effective, they will not receive regulatory approval and Auxilium will be unable to commercialize them.
- Auxilium's corporate compliance program cannot guarantee that it is in compliance with all potentially applicable regulations.
- Auxilium will incur increased costs as a result of recently enacted and proposed changes in laws and regulations.

Auxilium's Risks Related to Commercialization

- If medical doctors do not prescribe Auxilium's products or the medical profession does not accept Auxilium's products, Auxilium's ability to
  grow its revenues will be limited.
- If testosterone replacement therapies are perceived to create, or do in fact create, health risks, Auxilium's sales of Testim may decrease and its operations may be harmed.
- If other pharmaceutical companies develop generic versions of any products that compete with Auxilium's commercialized products or any of Auxilium's products, its business may be adversely affected.
- If third-party payers do not reimburse customers for Testim or any of Auxilium's product candidates that are approved for marketing, they might not be used or purchased, and Auxilium's revenues and profits will not grow.

form10-ksba.htm Page 22 of 97

• International commercialization of Testim and Auxilium's product candidates faces significant obstacles.

form10-ksba.htm Page 23 of 97

#### Table of Contents

- Healthcare reform measures, including but not limited to any changes in the Act, could adversely affect Auxilium's business.
- Auxilium could be negatively impacted by future interpretation or implementation of federal and state fraud and abuse laws, including anti-kickback laws, false claims laws and federal and state anti-referral laws.
- If product liability lawsuits are brought against Auxilium, it may incur substantial liabilities.
- Auxilium may be exposed to liability claims associated with the use of hazardous materials and chemicals.
- Auxilium's products may be subject to recall.

Auxilium's Risks Related to its Dependence on Third-Party Manufacturers and Service Providers

- Since Auxilium relies on third-party manufacturers and suppliers, Auxilium may be unable to control the availability or cost of manufacturing its products, which could adversely affect its results of operations.
- Auxilium relies on a single source supplier and a limited number of suppliers for two of the primary ingredients for Testim and the loss of any of
  these suppliers could prevent Auxilium from selling Testim, which would materially harm Auxilium's business.
- Due to Auxilium's reliance on contract research organizations or other third parties to assist it in conducting clinical trials, Auxilium is unable to directly control all aspects of its clinical trials.
- Auxilium's third-party manufacturers are subject to regulatory oversight, which may delay or disrupt its development and commercialization
  efforts.
- A high percentage of Auxilium's product shipments are only to a limited number of customers; if any of these customers refuse to distribute Testim on commercially favorable terms, or at all, Auxilium's business will be adversely affected.
- If Auxilium is unable to grow its sales, marketing or distribution capabilities or enter into agreements with third parties to perform some of these functions, Auxilium will not be able to grow its business.

#### Auxilium's Risks Related to Intellectual Property

- If Auxilium breaches any of the agreements under which it licenses commercialization rights to products or technology from others, Auxilium could lose license rights that are critical to its business.
- Auxilium has only limited patent protection for Testim and its product candidates, and Auxilium may not be able to obtain, maintain and protect
  proprietary rights necessary for the development and commercialization of Testim or its product candidates.
- Auxilium may have to engage in costly litigation to enforce or protect its proprietary technology or to defend challenges to its proprietary technology by its competitors, which may harm Auxilium's business, results of operations, financial condition and cash flow.
- Auxilium's ability to market its products may be impaired by the intellectual property rights of third parties.
- Auxilium may not be able to obtain or maintain orphan drug exclusivity for its product candidates, and its competitors may obtain orphan drug
  exclusivity prior to Auxilium, which could significantly harm Auxilium's business.
- If Testim or Auxilium's future products or product candidates infringe the intellectual property of Auxilium's competitors or other third parties, Auxilium may be required to pay license fees or cease these activities and pay damages, which could significantly harm its business.

## Auxilium's Risks Related to Employees and Growth

- If Auxilium is not able to retain its current management team or attract and retain qualified scientific, technical and business personnel,
   Auxilium's business will suffer.
- Changes in the expensing of stock-based compensation will result in unfavorable accounting charges and may require Auxilium to change its
  compensation practices. Any change in Auxilium's compensation practices may adversely affect its ability to attract and retain qualified

form10-ksba.htm Page 24 of 97

scientific, technical and business personnel.

• Auxilium's operations may be impaired unless it can successfully manage its growth.

form10-ksba.htm Page 25 of 97

#### Table of Contents

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

## Risks Related to Limited Supply of Clinical Materials

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

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

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

Although we currently have our own clinical material, which may be sufficient to conduct clinical trials contemplated for cellulite and lipoma, if this clinical material is damaged or otherwise becomes unusable, then we may have insufficient clinical material to conduct other clinical trials. Although Auxilium has agreed to provide us with additional clinical material, there is no guaranty that Auxilium will do so in a timely manner, if at all. Consequently, the lack of availability of clinical material may limit our ability to obtain the option, milestone and contingent royalty payments under the Auxilium Agreement.

## Risks Related to our Agreements with Auxilium and DFB

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

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

#### Risks Related to our Limited Financial and Employee Resources

Our limited financial and employee resources following our sale of the topical collagenase business to DFB limit our ability to develop other indications or products.

Following the sale of our topical business to DFB, we retained only six employees (and with the death of Edwin H. Wegman, we now have only five employees) and the sources of revenue described above. Because we have limited internal research capabilities, we are dependent upon independent investigators, pharmaceutical and biotechnology companies and other researchers to conduct clinical trials, sell or license products or technologies to us.

form10-ksba.htm Page 26 of 97

#### Table of Contents

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

#### Our revenues are difficult to forecast.

Forecasting our revenues is complicated by the difficult task of predicting the level of success that Auxilium and DFB will have in meeting milestones, manufacturing, marketing and selling products or candidate products for which we would receive milestone, earn out or royalty payments.

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

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

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

We believe that our existing cash resources and interest on these funds will be sufficient to meet our anticipated operating requirements until at least the third quarter of 2008. Our future funding requirements will depend on many factors, including:

- DFB's ability to meet its payment obligations and to manufacture and commercialize topical collagenase products for which we would receive earn out payments;
- · Auxilium's ability to manufacture and commercialize injectable product for which we would receive milestone and royalty payments;
- the scope, rate of progress, cost and results of our clinical trials on remaining Additional Indications including lipomas and cellulite, and whether Auxilium exercises its option to acquire rights to them;
- the ability of the estate of our former chairman ("Chairman") and chief executive officer ("CEO") to repay his personal loans owed to the Company;
- · 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.

form10-ksba.htm Page 27 of 97

#### Table of Contents

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, and the fact that we are not current in our SEC filings, 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, which are in the process of being clarified.

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. We are in the process of clarifying the terms of certain of these agreements relating to Peyronie's disease and other indications.

Risks Related to the Recent Death of our Former Chairman and CEO and the Age and Qualifications of the Members of Our Board of Directors

The recent death of our founder, Chairman and CEO on February 16, 2007 may limit our future growth and will cause us to continue to incur significant expenses for outside consulting services. His death may affect our ability to collect the personal debt owed to us by his estate and may thus create a financial hardship for us. His death may also affect the control of the Company.

As a result of the illness and recent death of our founder, former Chairman and CEO, we have and will continue to incur significant expenses for outside consulting services to assist in business planning and execution of transactions. As of December 31, 2006 our former Chairman and CEO owed to us an aggregate amount of \$1,016,595. We entered into an amended and restated promissory note for this amount with our former Chairman and CEO, which is secured by a pledge of 100% of the shares of The S.J. Wegman Company. His death has resulted in the immediate obligation of his estate to repay the loan. However, it is uncertain whether his estate will be able to repay the loan and, if so, on what terms. His death has also resulted in the dissolution of The S.J. Wegman Company, which triggered a default under the pledge agreement, giving our board of directors (the "Board" or "Board of Directors") the right to vote the pledged shares. However, it is unclear as a practical matter whether the Company will be able to foreclose on the pledge. Our inability to collect this debt may create a financial hardship for us. Given his beneficial ownership and/or control of a significant portion of the Company's stock, the death of our former Chairman and CEO may affect the control of the Company and the ability of the Company to obtain majority stockholder consent for certain actions. Thus, the death of our Chairman and CEO may adversely affect our stock price.

Because of the age of some of our independent Board members, we may have to find replacements shortly, and due to our financial condition and Securities and Exchange Commission ("SEC") compliance history this may be difficult, which could impact our ability to be re-listed on the NASDAQ Stock Market ("NASDAQ") or another securities exchange. None of the independent Board members, who are also the members of the Audit Committee is a financial expert, as required by NASDAQ.

The three independent members of our Board, who are also members of our audit committee (the "Audit Committee"), are sixty-six, sixty-six and eighty-six years old, respectively, as of December 31, 2006. Upon the retirement, incapacity or death of one or more of our independent Board members, we would have to find replacements in a short period of time. We were delisted from NASDAQ in March 2004 for, among other reasons, the failure to have a majority of independent directors. Although the independent directors satisfy the NASDAQ requirements for independence, none is a financial expert. As of the date hereof, we are not current in our SEC filings. In light of our financial condition and SEC compliance history, it may be difficult to find any replacements. If we fail to find replacements in a timely manner, or fail to recruit a financial expert for the Audit Committee, it could negatively impact our ability to become re-listed due to the Marketplace Rules of NASDAQ and our stock price.

Risks Related to Regulatory Requirements

form10-ksba.htm Page 28 of 97

#### Table of Contents

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

Conducting clinical trials, and the testing, development and manufacturing and distribution of any product candidates are subject to regulation by numerous governmental authorities in the U.S. and other jurisdictions, if we desire to export the resulting products to such other jurisdictions. These regulations govern or affect the testing, manufacture, safety, labeling, storage, record-keeping, approval, distribution, advertising and promotion of any product candidates, as well as safe working conditions. Noncompliance with any applicable regulatory requirements can result in suspension or termination of any ongoing clinical trials of a product candidate or refusal of the government to approve product candidate for commercialization, criminal prosecution and fines, recall or seizure of products, total or partial suspension of production, prohibitions or limitations on the commercial sale of products or refusal to allow the entering into of federal and state supply contracts. The FDA and comparable governmental authorities have the authority to suspend or terminate any ongoing clinical trials of a product candidate or withdraw product approvals that have been previously granted. Currently, there is a substantial amount of congressional and administrative review of the FDA and the regulatory approval process for drug candidates in the U.S. As a result, there may be significant changes made to the regulatory approval process in the U.S. In addition, the regulatory requirements relating to the development, manufacturing, testing, promotion, marketing and distribution of products candidates may change in the U.S. Such changes may increase our costs and adversely affect our operations.

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

- · restrictions on our products or manufacturing processes;
- warning letters;
- withdrawal of a product candidate from the market;
- voluntary or mandatory recall of a product candidate;
- · fines against us;
- suspension or withdrawal of regulatory approvals for a product candidate;
- refusal to permit the import or export of our products;
- refusal to approve pending applications or supplements to approved applications that we submit;
- denial of permission to file an application or supplement in a jurisdiction;
- · product seizure; and
- injunctions or the imposition of civil or criminal penalties against us.

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

form10-ksba.htm Page 29 of 97

#### Table of Contents

We are a relatively 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 either only recently been adopted or are currently proposals subject to change. We cannot assure you that we are or will be in compliance 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 re-list our securities on NASDAQ or another securities exchange or market. Although we are not required to issue an evaluation of our internal control over financial reporting under Section 404 of SOX until December 31, 2007 at the earliest, preparations for the issuance of this report will result in increased costs to us. If we are not able to issue an evaluation of our internal control over financial reporting as required or we or our independent registered public accounting firm determine that our internal control over financial reporting is not effective, this shortcoming could have an adverse effect on our business and financial results and the price of our common stock could be negatively affected. The new rules could make it more difficult or more costly for us to obtain certain types of insurance, including director and officer liability insurance, and we may be forced to accept reduced policy limits and coverage or incur substantially higher costs to obtain the same or similar coverage. The impact of these events could also make it more difficult for us to attract and retain qualified persons to serve on our board of directors, our board committees and as executive officers. We cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs to comply with these rules and re

We have, and will continue to incur, significant costs to bring the company current in its SEC filings and to re-list our stock on NASDAQ or another securities exchange or market. In addition, there can be no assurance that we will be successful in re-listing.

We are not current in our SEC filings and we have incurred, and will continue to incur, significant costs to become current and to re-list our stock on NASDAQ or another securities exchange. There are no assurances that we will be successful in bringing the company current or re-listing our stock on NASDAQ or another securities exchange or market. Continued failure to comply with SEC filing requirements could expose us to SEC enforcement action and makes it difficult to comply with the requirements relating to the solicitation of proxies from our stockholders.

## Risks Related to Growth and Employees

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

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

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

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

The process of conducting clinical trials and developing product candidates involves a high degree of risk and may take several years. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

form10-ksba.htm Page 30 of 97

#### Table of Contents

clinical trials may show product candidates to be ineffective or not as effective as anticipated or to have harmful side effects or any unforeseen
result:

- product candidates may fail to receive regulatory approvals required to bring the products to market;
- manufacturing costs, the inability to scale up to produce supplies for clinical trials or other factors may make our product candidates uneconomical; and
- the proprietary rights of others and their competing products and technologies may prevent product candidates from being effectively commercialized or to obtain exclusivity.

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

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

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

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

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

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

Because of the specialized nature of our business, the termination of relationships with key management, consulting and scientific personnel or the inability to recruit and retain additional personnel could prevent us from developing our technologies, conducting clinical trials and obtaining financing.

The competition for qualified personnel in the biotechnology field is intense, and we rely heavily on our ability to attract and contract with qualified independent scientific and medical investigators, 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.

form10-ksba.htm Page 31 of 97

#### Table of Contents

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

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

## Risks Related to Intellectual Property Rights

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

We are a party to a number of license agreements by which we have acquired rights to use the intellectual property of third parties that are necessary for us to operate our business. If any of the parties terminate their agreements, whether by their terms or due to a breach by us, our right to use their intellectual property may negatively affect our licenses to Auxilium or DFB and, in turn, their obligation to make option, milestone, contingent royalty or other payments to us.

We may have to engage in costly litigation to enforce our contractual rights or to enforce, or protect, our proprietary technology, or to defend challenges to our proprietary technology by our competitors, which may harm our business, results of operations, financial condition and cash flow.

In connection with the sale of our topical collagenase business to DFB, Auxilium has raised certain concerns regarding certain provisions of the Asset Purchase Agreement. We believe that these concerns have been or will be adequately addressed in amendments to the Asset Purchase Agreement entered into between us, ABC-NY and DFB, discussed above in the section titled "Licensing and Marketing Agreements—Topical Collagenase Agreement," although we cannot be certain that Auxilium will agree.

In connection with the execution of our license agreements with the Research Foundation, Auxilium has raised certain concerns that the parties are discussing.

If we are unable to resolve our current or future issues with Auxilium or DFB then we could be sued by either or both parties. This litigation could be costly and materially adversely affect our business.

In addition, the pharmaceutical field is characterized by a large number of patent filings involving complex legal and factual questions, and, therefore, we cannot predict with certainty whether our patents will be enforceable. Competitors may have filed applications for or have been issued patents and may obtain additional patents and proprietary rights related to products or processes that compete with or are similar to our collagenase enzyme. We may not be aware of all of the patents potentially adverse to our interests that may have been issued to others. Litigation may be necessary to protect our proprietary rights, and we cannot be certain that we will have the required resources to pursue litigation or otherwise to protect our proprietary rights. If patent laws or the interpretation of patent laws change, our competitors may be able to develop and commercialize our discoveries.

Under the agreements executed with Auxilium and DFB, we are obligated to maintain and defend in all relevant jurisdictions, any patents or other intellectual property to which we granted a license to those parties. The cost of maintaining and defending such intellectual property could require significant capital, consume a substantial portion of our resources, and adversely affect our ability to continue to operate.

form10-ksba.htm Page 32 of 97

#### Table of Contents

Competitors may infringe our patents or successfully avoid them through design innovation. To prevent infringement or unauthorized use, we may need to file infringement lawsuits, which are expensive and time-consuming.

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

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

Third parties could bring legal actions against us, our licensees, licensors or collaborators claiming damages and seeking to enjoin clinical testing, manufacturing and marketing of the affected product or products. A third party might request a court to rule that the patents we in-licensed or licensed to others, or those we may in-license in the future, are invalid or unenforceable. In such a case, even if the validity or enforceability of those patents were upheld, a court might hold that the third party's actions do not infringe the patent we in-license or license to others thereby, in effect, limiting the scope of our patent rights and those of our licensees, licensors or collaborators. We are obligated by our agreements with Auxilium and DFB to indemnify them against any claims for infringement based on the use of our technology. If we become involved in any litigation, it could consume a substantial portion of our resources, regardless of the outcome of the litigation. If Auxilium or DFB becomes involved in such litigation, it could also consume a substantial portion of their resources, regardless of the outcome of the litigation, thereby jeopardizing their ability to commercialize candidate products and/or their ability to make option, milestone or royalty payments to us. If any of these actions are successful, in addition to any potential liability for damages, we could be required to obtain a license to permit ourselves, our licensees, licensors or our collaborators to conduct clinical trials, manufacture or market the affected product, in which case we may be required to pay substantial royalties or grant cross-licenses to our patents. However, there can be no assurance that any such license will be available on acceptable terms or at all. Ultimately, we, our licensees, licensors or collaborators could be prevented from commercializing a product, or forced to cease some aspect of their or our business, as a result of patent infringement claims, which could harm our business or right to receive option,

#### Our Dupuytren's patent may not be reissued.

Our U.S. patent covering Dupuytren's disease has been submitted to the USPTO for reissuance. If the attempt to achieve reissuance is not successful, the patent could be invalidated and we would need to rely on orphan drug status for market protection if the patent is invalidated.

#### Risks Related to Stock Price

Our stock price is likely to be volatile, and the market price of our common stock may drop below the current price.

Our stock price has, at times, been volatile. We were delisted from NASDAQ in March 2004 and the OTC Bulletin Board in May 2004 and, currently, our stock is quoted on the Pink Sheets and is thinly traded.

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

- listing of our stock on a securities exchange or market;
- our failure to be current in our SEC filings;
- 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;

form10-ksba.htm Page 33 of 97

#### Table of Contents

- developments or disputes concerning patents or other proprietary rights;
- litigation involving us or our general industry, or both;
- future sales of our common stock by the estate of our former Chairman and CEO or others;
- changes in the structure of healthcare payment systems, including developments in price control legislation;
- departure of key personnel;
- announcements of material events by those companies that are our competitors or perceived to be similar to us;
- changes in estimates of our financial results;
- · investors' general perception of us; and
- general economic, industry and market conditions.

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

## Our outstanding stock options could have a possible dilutive effect.

As of December 31, 2005, stock options to purchase 963,887 shares of common stock were outstanding. In addition, as of December 31, 2005 a total of 1,242,263 stock 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. Until the Company becomes current in its SEC filings, however, we will not be able to issue any freely tradable stock upon the exercise of these options. As a result of this, we may choose to extend the exercise period for certain expiring options, which could result in an unfavorable accounting charge.

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

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

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

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

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

form10-ksba.htm Page 34 of 97

#### Table of Contents

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 January 18, 2007, our executive officers, directors and their affiliates, in the aggregate, beneficially own shares representing approximately 51.4% of our common stock, although the death of Edwin H. Wegman, our former Chairman and CEO, may result in a change of control of certain of these shares. Beneficial ownership includes shares over which an individual or entity has investment or voting power and includes shares that could be issued upon the exercise of options within 60 days. As a result, if these stockholders were to choose to act together, they would 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.

## 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.

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

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

# SUBSEQUENT EVENTS

As discussed in this Item 1, under the section titled "Licensing and Marketing Agreements," we sold our topical collagenase business to DFB in March 2006. In order to help effectuate the transaction with DFB, we repurchased all of the outstanding shares of ABC-NY and ABC-Curacao held by minority shareholders in exchange for a combination of approximately \$83,000 in cash and 102,574 shares of our common stock.

In July 2006, we entered into a Settlement Agreement and Specific Release (the "Settlement Agreement"), with Edwin H. Wegman, Thomas L. Wegman, Bio Partners, L.P. ("Bio Partners"), a Delaware limited partnership (whose sole general partner, Bio Management, Inc., a New York corporation, is wholly-owned by Jeffrey K. Vogel), and Jeffrey K. Vogel to settle a dispute regarding certain loan commitment fees purportedly due from us to Bio Partners under a Letter Agreement, dated January 3, 2006, between Bio Partners and us (the "Letter Agreement"), and to provide for the termination of certain loan and investor related documents that were previously filed as material agreements.

In November 2006, we signed license agreements with the Research Foundation with respect to Dupuytren's disease and frozen shoulder, as described in this Item 1 under the section titled "Licensing and Marketing Agreements—Dupuytren's disease and "—Frozen Shoulder."

form10-ksba.htm Page 35 of 97

#### Table of Contents

On February 16, 2007 our Chairman and CEO, Edwin H. Wegman, died. As of December 31, 2006 our former Chairman and CEO owed to us an aggregate amount of \$1,016,595. We entered into an amended and restated promissory note for this amount with our former Chairman and CEO, which is secured by a pledge of 100% of the shares of The S.J. Wegman Company. His death has resulted in the immediate obligation of his estate to repay the loan. However, it is uncertain whether his estate will be able to repay the loan and, if so, on what terms. His death has also resulted in the dissolution of The S.J. Wegman Company, which triggered a default under the pledge agreement, giving our Board the right to vote the pledged shares. However, it is unclear as a practical matter whether the Company will be able to foreclose on the pledge.

In addition to the foregoing subsequent events, there have been a number of additional events that are described in the Form 8-Ks that have been filed by the Company since December 31, 2005 that are listed in Item 13, "Exhibits—Reports on Form 8-K."

#### Item 2. DESCRIPTION OF PROPERTY.

As of December 31, 2005 we leased two facilities, one in Lynbrook, New York and one in Curacao, Netherlands Antilles. The New York facility, also our administrative headquarters, contains approximately 3,500 square feet of office space and 11,500 square feet of laboratory, production, and storage facilities. As part of the agreement with DFB, DFB has agreed to sublease a part of the New York facility for a period of one year, expiring on March 2, 2007 for an all inclusive monthly payment of \$15,500. DFB has extended its sublease of the New York facility until March 2, 2008 but may terminate the lease upon 90 days notice, which notice cannot be given prior to March 3, 2007. DFB will pay a monthly payment of \$16,500 during this extended lease period. We lease this facility from the Wilbur Street Corporation ("WSC"), which, until the death of Edwin H. Wegman, our former Chairman and CEO, was owned by The S.J. Wegman Company, our principal stockholder and an affiliate of Edwin H. Wegman. Edwin H. Wegman was the general partner of The S.J. Wegman Company, a limited partnership. Upon his death on February 16, 2007, The S.J. Wegman Company was legally dissolved. However, his death had no effect on the legal existence of WSC. The shares of WSC will be distributed to the partners of The S.J. Wegman Company in accordance with the provisions of the partnership agreement. At the present time, we do not know who will own or control the shares of WSC.

We also leased a building in Brievengat, Curacao, Netherlands Antilles from an unrelated company, wholly-owned by the Insular Territory of Curacao. The lease for the Curacao facility was transferred to DFB as part of the sale of the topical product. This building was our principal manufacturing facility, and is licensed by the FDA to produce the topical product.

#### Item 3. LEGAL PROCEEDINGS.

None.

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

In November 2005 we mailed to our stockholders, a proxy for the 2004 annual meeting. It was determined that, because we were not current in our filings and could not provide our stockholders with current financial information, the proxy was invalid. Although the stockholders were unable to re-elect Edwin H. Wegman to the Board, under our by-laws, he retained his seat on the Board until his death on February 16, 2007.

# PART II

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

**Market Information** 

form10-ksba.htm Page 36 of 97

#### Table of Contents

On March 22, 2004 the NASDAQ Listings Qualifications Panel (the "Panel") informed us in writing of its determination to delist our common stock from the NASDAQ Capital Market effective with the open of business on March 24, 2004. The NASDAQ notice stated that the Panel's determination was based on our failure to satisfy the \$2.5 million shareholders' equity requirement as of December 31, 2003. Our common stock was immediately eligible for quotation on the OTC Bulletin Board effective with the open of business on March 24, 2004. The OTC Bulletin Board symbol assigned to us is BSTC. No application was required to be filed for inclusion on the OTC Bulletin Board. Our common stock traded on The NASDAQ Small Cap Market tier of NASDAQ under the symbol BSTCC until March 23, 2004. On March 24, 2004, our common stock began trading on the OTC Bulletin Board under the symbol BSTC. Effective May 21, 2004, our stock was moved from the OTC Bulletin Board to the Pink Sheets due to our failure to file our financial reports on a timely basis with the SEC. Our common stock currently trades under the stock symbol BSTC:PK. The filing of this Report represents the initial step by us to become current in our filings.

The table below sets forth the high and low closing sale prices for our common stock for the period January 1, 2003 through December 31, 2005, as reported by NASDAQ, the OTCBB or as quoted in the Over-The-Counter Pink Sheets, as applicable:

| QUARTERS ENDED 2005 | <u>HIGH</u> | <u>LOW</u> |
|---------------------|-------------|------------|
| December 31, 2005   | \$1.65      | \$0.80     |
| September 30, 2005  | \$2.00      | \$1.01     |
| June 30, 2005       | \$1.37      | \$1.00     |
| March 31, 2005      | \$1.60      | \$1.00     |
|                     |             |            |
| QUARTERS ENDED 2004 | <u>HIGH</u> | LOW        |
| December 31, 2004   | \$2.15      | \$1.49     |
| September 30, 2004  | \$2.30      | \$1.45     |
| June 30, 2004       | \$2.89      | \$1.50     |
| March 31, 2004      | \$1.94      | \$1.46     |
|                     |             |            |
| QUARTERS ENDED 2003 | <u>HIGH</u> | LOW        |
| December 31, 2003   | \$1.99      | \$1.05     |
| September 30, 2003  | \$2.00      | \$0.79     |
| June 30, 2003       | \$1.59      | \$0.60     |
| March 31, 2003      | \$2.15      | \$1.06     |
|                     |             |            |

# Holders

As of January 18, 2007, to the best of our knowledge, there were approximately 750 beneficial stockholders of our common stock.

## Dividends

It is our current policy to retain earnings to finance the growth and development of our business and not pay dividends. Any payment of cash dividends in the future will depend upon our financial condition, capital requirements and earnings as well as such other factors as the Board may deem relevant.

## Transfer Agent

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

#### Equity Compensation Plan Information.

The following table provides information as of December 31, 2005 with respect to the shares of our common stock that may be issued under our existing equity compensation plans:

form10-ksba.htm Page 37 of 97

Table of Contents

|                                       |   |  | Number of securities remaining  |
|---------------------------------------|---|--|---|
|                                       | Number of securities  |  | available   |
| Plan category                         | to be issued upon<br>exercise of outstanding<br>options, warrants and<br>rights | Weighted-average<br>exercise price of<br>outstanding options,<br>warrants and rights | for future issuance under<br>equity compensation plans<br>(excluding securities reflected<br>in column (a)) |
|                                       | (a)   | (b)  | (c)   |
| Equity compensation plans approved by | 973,887   | 1.36   | 1,242,263   |
| security holders <sup>(1)</sup>       |   |  |   |

<sup>(1)</sup> Please see Note 13, "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

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

Issuance of Unregistered Securities upon Exercise of Stock Option Grants

Three option holders exercised some or all of their stock option grants that were provided under the 1993, 1997 and 2001 Stock Option Plans (including the 2003 amendment to the 2001 Stock Option Plan, which increased the shares from 750,000 to 1,750,000) (the "1993 Plan," the "1997 Plan" and the "2001 Plan," respectively). The individuals were all incorrectly given unrestricted shares of common stock because we never filed an S-8 to register the shares to be issued under the 2001 Plan, and once we ceased to be current in our SEC filings, we could no longer rely on the S-8 that had been filed with respect to the shares to be issued under the 1993 and 1997 Plans. The details of each transaction are as follows:

The 1993 and 1997 Stock Option Plans

In April and May 2004, a former officer of the Company exercised 20,000 and 10,000 options under the 1993 and 1997 Plans, respectively.

2001 Stock Option Plan

In April 2004, a former officer of the Company exercised 20,000 options. In June 2004, the estate of a former director exercised 15,425 options following an extension by the Board of the exercise date and resulting in an expense of \$12,837. In September 2005, a former employee of the Company exercised 12,000 options and an additional 1,875 options in October 2005.

Treasury Shares Issued

We issued 127,419 shares of treasury stock to our employees in January 2006. These securities were incorrectly issued without an appropriate restrictive legend.

In March 2006, in connection with the sale of our topical collagenase business to DFB, we repurchased all of the outstanding shares of ABC-NY and ABC-Curacao held by minority shareholders in exchange for a combination of approximately \$83,000 in cash and 102,574 restricted shares of our treasury stock.

Stock Issued in Lieu of Services

During June 2005, the Company issued to an officer 14,819 shares with a total fair market value at the date of issuance of \$15,560, in lieu of cash compensation owed by the Company for services rendered from May 2004 through March 2005. These securities were incorrectly issued without an appropriate restrictive legend.

form10-ksba.htm Page 38 of 97

#### Table of Contents

From 2003 through 2006, the Company issued a total of 56,388 restricted shares to an individual who performed personal services for the Company's former Chairman and CEO for a total fair market value of \$81,657. In March and June 2003, 15,000 shares were issued at a total fair market value of \$16,800 at the dates of issuance. In April, June and December in 2004, 18,888 shares were issued at a total fair market value of \$40,957 at the dates of issuance. In June and November in 2005, this same individual received 15,000 shares at a total fair market value of \$16,125 at the dates of issuance. In May 2006, this individual received 7,500 shares at a total fair market value of \$7,875 at the date of issuance.

#### Item 6. MANAGEMENT'S DISCUSSION AND ANALYSIS OR PLAN OF OPERATION

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

## **Prior Period Adjustments**

In preparation for our 2005 audit and the subsequent review of our 2003 consolidated financial statements by management and our audit committee (the "Audit Committee"), the Company has made the determination that it is necessary to restate our consolidated financial statements for the year ended December 31, 2003 to accrue for additional rent expense due on our U.S. facility, for payroll taxes, penalties and interest attributable to our Curacao facility, interest due on loans due to a former director of the Company and to a partner of The S.J. Wegman Company, an adjustment in notes receivable due from our former Chairman and CEO due to the incorrect allocation between interest and principal and a reclassification to correct prepaid insurance and prepaid payroll. Whereas the Company does not consider the effect to our net loss material, the individual components of each adjustment disclosed above may be considered material to their individual line items within our consolidated financial statements.

Based upon an audit of the adjustments for the year ended 2003 by our current independent registered public accounting firm, Bloom & Co. LLP ("Bloom & Co."), we believe the restated 2003 consolidated financial statements incorporating the required prior period adjustments fairly present our consolidated financial position as of December 31, 2003. The restated 2003 consolidated financial statements are included in this Report in the Notes to Consolidated Financial Statements under Note 2., "Restatement of Financial Statements."

In Item 8A, "Controls and Procedures," we discuss the issues that created the prior period adjustments and the procedures that management, working with the Audit Committee of the Board of Directors (the "Board" or "Board of Directors"), has put into place to reduce the likelihood of such reoccurrences.

## **Change in Fiscal Year**

In March 2003, we changed our fiscal year end from January 31 to December 31. Our first fiscal year using this new basis is the twelve month period ending December 31, 2003. In this report we compare the twelve months ended December 31, 2003 ("calendar year 2003") to the twelve months ended January 31, 2003 ("fiscal year 2003").

# **Selected Financial Data**

form10-ksba.htm Page 39 of 97

## **Table of Contents**

The following selected consolidated financial data for each of the four years in the periods ended December 31, 2005, 2004 and restated 2003 and January 31, 2003 were derived from the audited consolidated financial statements and includes all audited prior period adjustments for the year ended December 31, 2003. The selected consolidated financial data set forth below should be read in conjunction with the consolidated financial statements and the notes thereto, in this Item 6, "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the other financial information appearing elsewhere in this Report.

|  |    | Twelve n    | nont | hs ended Dece | embo | er 31.      |    | Twelve onths ended anuary 31, |
|--|----|-------------|------|---------------|------|-------------|----|-------------------------------|
|  | _  | - 11,021,02 |      |               |      | Restated    |    |                               |
|  |    | 2005        |      | 2004          |      | 2003        |    | 2003                          |
| Revenues:  |    |             |      |               |      |             |    |                               |
| Net sales  | \$ | 3,137,978   | \$   | 1,664,779     | \$   | 1,555,625   | \$ | 1,938,706                     |
| Licensing fees   |    | 1,266,641   |      | 387,045       |      | -           |    | -                             |
| Royalties  |    | 1,073,620   |      | 784,933       |      | 1,683,915   |    | 2,140,534                     |
|  |    | 5,478,239   |      | 2,836,757     |      | 3,239,540   |    | 4,079,240                     |
| Costs and expenses:  |    |             |      |               |      |             |    |                               |
| Cost of sales  |    | 3,622,775   |      | 3,052,492     |      | 2,837,986   |    | 3,205,235                     |
| Research and development   |    | 686,464     |      | 1,057,009     |      | 935,443     |    | 1,069,045                     |
| General and administrative   |    | 2,289,160   |      | 2,094,424     |      | 2,632,399   |    | 3,045,319                     |
|  |    | 6,598,399   |      | 6,203,925     |      | 6,405,828   |    | 7,319,599                     |
| Operating loss   |    | (1,120,160) |      | (3,367,168)   |      | (3,166,288) |    | (3,240,359)                   |
| Other income (expense):  |    |             |      |               |      |             |    |                               |
| Investment income  |    | 2,406       |      | 196           |      | 109,635     |    | 23,462                        |
| Interest expense   |    | (177,764)   |      | (369,778)     |      | (213,677)   |    | (46,556)                      |
| Other expense  |    | (2,519)     |      |               |      |             |    | -                             |
|  |    | (177,877)   |      | (369,582)     |      | (104,042)   |    | (23,094)                      |
| Loss before benefit (expense) for income tax                       |    | (1,298,037) |      | (3,736,750)   |      | (3,270,330) |    | (3,263,453)                   |
| Income tax benefit (expense)                                       |    | (6,118)     | _    |               | _    | (13,000)    | _  | 260,464                       |
| Loss before minority interest                                      |    | (1,304,155) |      | (3,736,750)   |      | (3,283,330) |    | (3,002,989)                   |
| Minority interest in loss of consolidated subsidiaries             | _  | 7,409       | _    | 78,009        |      | 83,787      |    | 78,220                        |
| Net loss   | \$ | (1,296,746) | \$   | (3,658,741)   | \$   | (3,199,543) | \$ | (2,924,769)                   |
| Basic and diluted net loss per share                               | \$ | (0.26)      | \$   | (0.75)        | \$   | (0.68)      | \$ | (0.64)                        |
| Shares used in computation of basic and diluted net loss per share | _  | 4,989,538   | _    | 4,903,773     |      | 4,734,867   |    | 4,564,336                     |

Overview

33

form10-ksba.htm Page 40 of 97

#### Table of Contents

We are a biopharmaceutical company that has manufactured the active pharmaceutical ingredient ("API" or "API Enzyme") used in a Food and Drug Administration ("FDA") licensed collagenase ointment that has been marketed for over 30 years. We have a development and license agreement with Auxilium Pharmaceuticals, Inc. ("Auxilium") for injectable collagenase (which Auxilium has named "AA4500") for clinical indications in Dupuytren's disease, Peyronies's disease and frozen shoulder (*adhesive capsulitis*), and Auxilium has an option to acquire additional indications that we may pursue, including cellulite and lipomas (the "Auxilium Agreement"). As a result of our research and development efforts we have also developed an injectable collagenase for treatment of various diseases or indications. Injectable collagenase has completed a pivotal clinical trial for the treatment of Dupuytren's disease. A Phase III clinical trial has been initiated and is currently on clinical hold. During its earnings conference call on February 15, 2007, Auxilium reported that it expects the Phase III clinical trial to resume in the fourth quarter of 2007.

In March 2006, we sold the collagenase topical business to DFB Biotech and its affiliates ("DFB") to refocus our efforts on the clinical indications related to our collagenase injection business. Sales of this topical collagenase had declined significantly since the peak year of 1999. Under the terms of this agreement, DFB assumed ownership and operation of our wholly-owned subsidiary, ABC-Curacao, where the API is manufactured, along with certain other assets, including our FDA manufacturing license.

Prior to the sale of our collagenase topical business in March 2006, we had been in the business of manufacturing the API for a topical collagenase prescription product. This topical collagenase product is a FDA approved biologic product indicated for debridement of chronic dermal ulcers and severely burned areas. Under the terms of our agreement with Abbott Laboratories, Inc. and its subsidiaries ("Abbott"), Abbott compounded the API into a topical collagenase ointment utilizing the API Enzyme manufactured by us. On January 1, 2004, the Ross Products Division of Abbott assumed U.S. marketing responsibility for the topical collagenase product from Abbott's former third party marketer, Smith & Nephew, Inc. ("S&N"). The topical collagenase is sold primarily to long-term care centers. In 2005, 2004 and 2003 we derived substantially all of our product revenues from the sale of our API Enzyme, and all royalty revenues, from Abbott.

#### Outlook

We foresee the potential to generate income from limited sources in the next several years. Under the terms of our agreement with DFB, we are scheduled to receive certain contractual anniversary payments and, if DFB exceeds a certain sales target, we would be entitled to an earn out on sales. Under the terms of our agreement with Auxilium, we may receive milestone payments upon their achieving certain regulatory progress and if Auxilium elects to pursue additional indications for injectable collagenase ("Additional Indications"). In addition, as a result of our transaction with DFB in the first quarter of 2006, our costs have been significantly reduced due mainly to the reduction in our workforce. Based on our current business model, we expect to have adequate cash reserves until the third quarter of 2008. In the longer term, a significant portion of our revenues are tied directly to the success of Auxilium in commercializing AA4500.

## Significant Risks

In recent history we have had operating losses and may not achieve sustained profitability. As of December 31, 2005, we had an accumulated deficit of \$4,877,590.

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

Critical Accounting Policies, Estimates and Assumptions

form10-ksba.htm Page 41 of 97

#### Table of Contents

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

**Revenue Recognition.** We recognize revenues from product sales when there is persuasive evidence that an arrangement exists, title passes, the price is fixed and determinable, and payment is reasonably assured. We currently recognize revenues resulting from the licensing 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 fees, and milestones related to the achievement of particular stages in product development and royalties. As a result, significant contract interpretation is sometimes required to determine the appropriate accounting, including whether the deliverables specified in a multiple-element arrangement should be treated as separate units of accounting for revenue recognition purposes, and if so, how the aggregate contract value should be allocated among the deliverable elements and when to recognize revenue for each element.

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

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

*Inventory and Warranty Provisions.* Our inventories are stated at the lower of cost or realizable market value. In assessing the ultimate realization of inventories, we are required to make judgments as to future demand requirements and compare that with the current inventory levels.

We warrant to Abbott that our product will comply with applicable regulatory requirements and when delivered will not be adulterated or misbranded within any federal law of the U.S. As we have had minimal claims, we do not set up a reserve until we are notified by Abbott that the product is defective and information is provided to us documenting that the failure was due to our API Enzyme.

Stock Based Compensation. As permitted by SFAS No.123 "Accounting for Stock-Based Compensation," ("SFAS 123"), we elected to continue to apply the provisions of Accounting Principles Board ("APB") Opinion No. 25, "Accounting for Stock Issued to Employees," ("ABP Opinion 25") and related interpretations in accounting for our employee stock option plans. We are generally not required under APB Opinion 25 and related interpretations to recognize compensation expense in connection with our employee stock option plans. To comply with SFAS 123, we presented in the Notes to Consolidated Financial Statements, the pro forma effect on our net loss and loss per share as if we had applied the fair value recognition provisions of SFAS 123, as amended, to options granted to employees under our stock-based employer compensation plans.

form10-ksba.htm Page 42 of 97

#### Table of Contents

In December 2004, the Financial Accounting Standard Board ("FASB") issued SFAS No. 123R "Share Based Payment" ("SFAS 123R"). This statement is a revision to SFAS 123, supersedes ABP Opinion 25 and amends FASB Statement No. 95, "Statement of Cash Flows." This statement requires a public entity to expense the cost of employee services received in exchange for an award of equity instruments. This statement also provides guidance on valuing and expensing these awards, as well as disclosure requirements of these equity arrangements. This statement is effective for the first interim or annual reporting period that begins after December 15, 2005. Effective January 1, 2006, we have adopted the requirements of SFAS 123R, utilizing the 'prospective' method.

#### RESULTS OF OPERATIONS

## RESTATED CALENDAR YEAR ENDED DECEMBER 31, 2003 COMPARED WITH FISCAL YEAR ENDED JANUARY 31, 2003

Product Revenues, net

For the calendar year ended December 31, 2003 we sold API Enzyme produced from our Curacao facility to an international customer and to our U.S. customer, Abbott, after the completion of the renovation of our Curacao facility. Pursuant to an exclusive licensing agreement, Abbott compounds the API Enzyme into the topical collagenase product, which is used to debride dermal ulcers and severely burned areas. For the fiscal year ended January 31, 2003, we derived most of our revenues from sales to Abbott of inventory that had been stockpiled prior to the renovation.

Product revenues include the sales of the API Enzyme recognized at the time it is shipped to customers, including Abbott. Product revenues also include fees we charge Abbott for testing topical collagenase. We had a limited amount of revenue from the sale of collagenase for laboratory use.

Net product revenues were \$1,555,625 and \$1,938,706 for the calendar year 2003 and fiscal year 2003, respectively, which was a decrease in calendar year 2003 of \$383,081 or 19.8% from fiscal 2003. This decrease was the result of our inability to supply our main customer, Abbott, with our product.

Licensing Revenues

No licensing revenue was received in calendar year 2003 or fiscal year 2003.

Royalties

We received all of our royalty revenues from the sale of the topical collagenase product made by Abbott. Royalties are recognized in the quarter in which Abbott delivers the product.

Total royalty revenues recognized under our agreement with Abbott were \$1,683,915 and \$2,140,534 for the calendar year 2003 and fiscal year 2003, respectively, representing a decrease in calendar 2003 of \$456,619 or 21.3%. This decrease in royalties for the calendar year 2003 was due primarily to the lack of sufficient enzyme available to manufacture the product. As previously described, Abbott's inventory, which it has supplied to a third party marketer for distribution and on which we earn royalties, was depleted by the end of July 2003, and only replenished in November 2003. There was no distribution of the product during the three months August through October 2003. Therefore, no royalties were earned during that period.

Cost of Sales

Cost of sales were \$2,837,986 and \$3,205,235 during calendar year 2003 and fiscal year 2003, respectively, which was a decrease in calendar 2003 of \$367,249 or 11.5%. This decrease in calendar year 2003 was primarily attributable to our inability to manufacture sufficient product during the renovation of our Curacao facility. We had a negative gross profit margin in both calendar year 2003 and fiscal year 2003 due to increased costs caused by the delays in manufacturing and personnel issues associated with the renovation.

Research and Development Activities

form10-ksba.htm Page 43 of 97

#### Table of Contents

Research and development expenses were \$935,443 and \$1,069,045 during calendar year 2003 and fiscal year 2003, respectively, which was a decrease in calendar year 2003 of \$133,602 or 12.5%. The decrease in research and development expenses was primarily due to our efforts to reduce certain development activities to conserve our cash resources.

General and Administrative Expenses

General and administrative expenses were \$2,632,399 and \$3,045,319 during calendar year 2003 and fiscal year 2003, respectively, which was a decrease in calendar 2003 of \$412,920, or 13.6%. The decrease in calendar year 2003 as compared to fiscal year 2003 was primarily due to our production and regulatory personnel spending a significant portion of their time preparing for the FDA inspection of the Curacao facility during fiscal 2003. These costs were allocated to general and administrative expenses in fiscal 2003.

Other expense, net

Other expense, net was \$104,042 and \$23,094 during calendar year 2003 and fiscal year 2003, respectively, which was an increase in other expense, net of \$80,948 or 350.5%. The increase is due to interest expense on the 12% senior secured convertible note borrowed in June 2003 (the "2003 Convertible Note") and the March 2003 promissory note from an individual lender, and amortization of the 2003 Convertible Note's discount. These expenses were partially offset by interest income received on a related party loan from our former Chairman and CEO. The interest and discount amortization on these debt instruments approximated \$180,000 during calendar 2003. Interest expense in both periods also includes interest on the two-year, 6.5% non-amortizing loan from Korpodeko, a Curacao development corporation established to develop industry on the island of Curacao ("Korpodeko"). In September 2003, Korpodeko agreed to modify the terms of the loan, by permitting us to repay 20%, or \$91,000 of the loan principal in 2003, and pay the remaining principal, or \$364,000 in November 2004. In return, the Company agreed to an interest rate increase from 6.5% to 7.5% from November 2003 to the new maturity in November 2004. In December 2003, we repaid \$91,000 of the loan principal.

Income Taxes

The expense for income taxes was \$13,000 in calendar year 2003. The income tax benefit in fiscal year 2003 was \$260,464. The net benefit in fiscal 2003 relates to tax refunds of approximately \$425,000 due to available carrybacks. We recorded no income tax benefit for calendar 2003 because of uncertainties with respect to the timing of future utilization of net operating loss benefit. Also, the difference between the U.S. federal statutory tax rate of 35% and the effective tax rate in fiscal 2003 is due to the tax effect of foreign sourced losses for which no benefit can be taken. Since 1976, our Curacao subsidiary has had a 2% profit tax rate granted to it by the Curacao government.

## YEAR ENDED DECEMBER 31, 2004 COMPARED WITH RESTATED YEAR ENDED DECEMBER 31, 2003

Product Revenues, net

For the years ended 2004 and 2003, we derived most of our product revenues from one customer in the U.S., Abbott, who, pursuant to an exclusive licensing agreement, compounds the API Enzyme into the topical collagenase product, which is used to debride dermal ulcers and severely burned areas. In 2004, we also made limited sales of the product to an international customer.

Product revenues include the sales of the API Enzyme recognized at the time it is shipped to customers, primarily Abbott. Product revenues also include fees we charge Abbott for testing topical collagenase. Additionally, we had a limited amount of revenue from the sale of collagenase for laboratory use.

Net product revenues were \$1,664,779 and \$1,555,625 for the calendar years 2004 and 2003, respectively, which was an increase in calendar year 2004 of \$109,154, or 7.0%, from calendar year 2003. The slight increase in product revenues was primarily due to additional sales of product to Abbott.

Licensing Revenues

form10-ksba.htm Page 44 of 97

## Table of Contents

We received \$5.0 million in licensing fees and milestone payments in 2004 under terms of the Auxilium Agreement. We did not receive any such fees in 2003. As mentioned in the section entitled "Critical Accounting Policies Estimates and Assumptions" and under the section entitled "Revenue Recognition," \$387,045 of the cash payments received was recognized as licensing revenue in 2004. Under current accounting guidance, nonrefundable upfront license fees for product candidates where we are providing continuing services related to product development, are deferred and recognized as revenue over the development period. The remaining balance will be recognized over the respective development periods or when we determine that we have no ongoing performance obligations.

#### Royalties

We received all of our royalty revenues from the sale of the topical collagenase product from Abbott. Royalties are recognized in the quarter in which Abbott delivers the product.

Total royalty revenues recognized under our agreement with Abbott were \$784,933 and \$1,683,915 for calendar year 2004 and 2003, respectively, which was a decrease of \$898,982 or 53.4% as compared to calendar year 2003. Sales by Abbott during calendar year 2004 were less than calendar year 2003 levels mainly due to Abbott taking over the marketing responsibilities from S&N effective January 1, 2004 and their inability to quickly ramp up sales. In addition, royalty revenue continued to be negatively impacted in 2004, because we did not achieve our 2003 enzyme manufacturing and inventory level goals. We also experienced difficulties in meeting our production objectives in 2004.

## Cost of Sales

Cost of sales was \$3,052,492 and \$2,837,986, during calendar years 2004 and 2003, respectively, which was an increase in calendar year 2004 of \$214,506 or 7.6%. The increase was primarily due to using the sales price of the enzyme to calculate its cost of sales, as the cost to make the enzyme was greater than its sales price. This resulted, in part, from the manufacturing difficulties experienced in both calendar years 2004 and 2003 in addition to Abbott's taking over, from S&N, the responsibility for marketing the product. We had a negative gross profit margin in both calendar years 2004 and 2003 due to delays in manufacturing and personnel issues associated with the renovation of our Curacao facility.

## Research and Development Activities

Research and development expenses were \$1,057,009 and \$935,443 during calendar years 2004 and 2003, respectively, which was an increase in calendar year 2004 of \$121,566 or 13.0%. The increase in R&D was primarily due to additional personnel and laboratory costs associated with our ongoing injectable collagenase program.

## General and Administrative Expenses

General and administrative expenses were \$2,094,424 and \$2,632,399 during calendar years 2004 and 2003, respectively, which was a decrease in calendar 2004 of \$537,975, or 20.4%. The decrease is primarily due to the classification in calendar year 2003 of the personnel expenses incurred at our Curacao facility as general and administrative expense until we received a letter notification from the FDA approving our supplement to our biologics license to manufacture topical collagenase. in July 2003. The decrease was partially offset by an increase in loan discount realized on the Bio Partners LP, a private investor group ("Bio Partners") note.

Other expense, net

form10-ksba.htm Page 45 of 97

#### Table of Contents

Other expense, net was \$369,582 and \$104,042 during calendar years 2004 and 2003, respectively, which was an increase in other expense, net of \$265,540 or 255.2%. The increase is due to interest expense on the 2003 Convertible Note borrowed in June 2003 and the March 2003 promissory note from an individual lender, and amortization of the 2003 Convertible Note's discount. The interest and discount amortization on these debt instruments approximated \$319,000 during calendar year 2004 and \$180,000 during calendar year 2003. In calendar year 2003, other expense, net was partially offset by interest income received on a related party loan from our former Chairman and CEO. Interest expense in both periods also includes interest on the two-year, 6.5% non-amortizing loan from Korpodeko. In September 2003, Korpodeko agreed to modify the terms of the loan, by permitting us to repay 20%, or \$91,000 of the loan principal in 2003, and pay the remaining principal, or \$364,000 in November 2004. In return, the Company agreed to an interest rate increase from 6.5% to 7.5% from November 2003 to the new maturity in November 2004. In December 2003, we repaid \$91,000 of the loan principal. In November 2004, we repaid \$182,000 and Korpodeko agreed to extend the term of the loan, at no additional cost, for an additional twelve months for the remaining balance.

#### Income Taxes

The expense for income taxes was \$0 and \$13,000 during calendar years 2004 and 2003, respectively. We recorded no income tax benefit for calendar years 2004 and 2003 because of uncertainties with respect to the timing of future utilization of net operating loss benefit. Since 1976, our Curacao subsidiary has had a 2% profit tax rate granted to it by the Curacao government.

## YEAR ENDED DECEMBER 31, 2005 COMPARED WITH YEAR ENDED DECEMBER 31, 2004

## Product Revenues, net

For the calendar years ended 2005 and 2004, we derived most of our product revenues, from one customer in the U.S., Abbott, who, pursuant to an exclusive licensing agreement, compounds the API Enzyme into the topical collagenase product, which is used to debride dermal ulcers and severely burned areas. In calendar year 2005, we also made limited sales of the product to two international customers.

Product revenues include the sales of the API Enzyme recognized at the time it is shipped to customers, primarily Abbott, and we had a small amount of revenue from the sale of collagenase for laboratory use. Product revenues also include fees we charge Abbott for testing topical collagenase. Net product revenues were \$3,137,978 and \$1,664,779 for the calendar years 2005 and 2004, respectively, which was an increase in calendar year 2005 of \$1,473,199, or 88.5% from calendar year 2004. This increase in net product revenues in calendar year 2005 was primarily due to an increase in successful manufacturing campaigns that resulted in our ability to supply our main customer, Abbott, with product.

Product revenues for each of the three month periods ended March, June, September and December in 2005 were \$1,319,177, \$1,551,554, \$82,649 and \$184,598, respectively. Lower sales in the third and fourth quarter were primarily attributable to our inability to manufacture the product during the prior year. Product revenues for each of the three month periods ended March, June, September and December in 2004 were \$602,158, \$43,498, \$481,196 and \$537,927, respectively. Fluctuations in quarterly revenues from 2005 as compared to 2004 were primarily due to the inability to manufacture the product, manufacturing delays related to equipment failures and personnel issues that impacted our ability to supply our main customer, Abbott with product during 2004.

## Licensing Revenues

For calendar year 2005, we received a total of \$3.5 million in milestone payments of which \$3.0 million was paid in the second quarter and \$0.5 million in the fourth quarter under the terms of the Auxilium Agreement. For calendar year 2004, we received a total of \$5.0 million in licensing fees and milestone payments of which \$2.5 million in licensing fees was paid in the second quarter and \$2.5 million in milestone payments was paid in the third quarter under the terms of the Auxilium Agreement.

We recognized as licensing revenue \$1,266,641 and \$387,045 of the cash payments received in calendar years 2005 and 2004, respectively. This increase of \$879,596 or 227.3% was primarily due to the recognition of revenues over the full year as opposed to over half of the year and the additional milestone payments under the Auxilium Agreement.

form10-ksba.htm Page 46 of 97

## Table of Contents

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

## Royalties

We received all of our royalty revenues from the sale of the topical collagenase product from Abbott. Royalties are recognized in the quarter in which Abbott delivers the product.

Total royalty revenues recognized under our agreement with Abbott were \$1,073,620 in calendar year 2005 as compared to \$784,933 for calendar year 2004 resulting in an increase in calendar year 2005 of \$288,687 or 36.8% as compared to calendar year 2004. This increase was primarily due to the increase in reported sales by Abbott of the topical collagenase product during calendar year 2005 as compared to the calendar year 2004 levels.

Royalty revenues for each of the three month periods ended March, June, September and December in 2005 were \$283,743, \$268,996, \$274,640 and \$246,241, respectively. Royalty revenues for each of the three month periods ended March, June, September and December in 2004 were \$94,366, \$130,070, \$257,963 and \$302,534, respectively. Quarterly royalty revenue variances are primarily attributable to the amount of reported sales to us by Abbott of the topical collagenase product.

## Cost of Sales

Cost of sales from the manufacturing of our topical collagenase product was \$3,622,775 and \$3,052,492, for the calendar years 2005 and 2004, respectively, an increase in calendar year 2005 of \$570,283 or 18.7%. The increase was primarily due to increases in labor related expenses including severance payments, plant operating costs and material costs.

Cost of sales for each of the three month periods ended March, June, September and December in 2005 were \$1,563,785, \$1,512,364, \$80,232 and \$466,394, respectively. In 2005, quarterly cost of sales variances resulted primarily from the amount of product sold to our main customer Abbott, as well as our ability to manufacture sufficient quantities of product. Cost of sales for each of the three month periods ended March, June, September and December in 2004 were \$676,133, \$555,173, \$621,351 and \$1,199,835, respectively. During the second quarter of 2004, approximately \$400,000 was attributable to unplanned downtime, which resulted in excess production costs being expensed for the period. In the fourth quarter in 2004 we expensed approximately \$600,000 in excess inventory costs over market.

## Research and Development Activities

Research and development expenses were \$686,464 and \$1,057,009 respectively, for the calendar years 2005 and 2004, a decrease in calendar year 2005 of \$370,545 or 35.1%. The decrease in research and development expenses was primarily due to decreases related to personnel costs, outside consulting and depreciation, which were partially offset by increases in research study costs.

Research and development expenses for the three month periods ended March, June, September and December in 2005 were \$196,129, \$191,718, \$177,407 and \$121,210, respectively. Research and development expenses for the three month periods ended March, June, September and December in 2004 were \$235,099, \$263,342, \$270,969 and \$287,599, respectively. Quarterly variances in 2005 as compared to 2004 were mainly due to our continued efforts to reduce certain development activities to conserve our cash resources.

# General and Administrative Expenses

General and administrative expenses were \$2,289,160 and \$2,094,424 for the calendar years 2005 and 2004, respectively, which was an increase in calendar 2005 of \$194,736 or 9.3%. The increase in general and administrative expenses is primarily due to increases related to personnel costs and facility expenses, which were partially offset by lower general expenses.

form10-ksba.htm Page 47 of 97

#### Table of Contents

General and administrative expenses for the three month periods ended March, June, September and December in 2005 were \$470,761, \$499,139, \$525,894 and \$793,366, respectively. General and administrative expenses for the three month periods ended March, June, September and December in 2004 were \$379,480, \$594,677, \$470,931 and \$649,366, respectively. Quarterly variances in 2005 and 2004 were mainly due to the timing of consulting services received.

Other expense, net

Other expense, net, was \$177,877 and \$369,582 for the calendar years 2005 and 2004, respectively, which was a decrease in other expense, net, of \$191,705 or 51.9%. Interest expense and amortization for calendar year 2005 decreased from calendar year 2004 as a result of the repayment in June 2005 of the 2003 Convertible Note, which had been outstanding during calendar 2005 for six months (first and second quarters) as compared to twelve months (four quarters) of interest expense and amortization in calendar year 2004. In March 2005, we repaid a \$100,000 promissory note, bearing interest at 8%, to a individual lender and the balance of a loan from Korpodeko. The initial interest rate of 6.5% was modified in consideration for an extension in the repayment terms, providing us the right to repay \$364,000 in November 2004. In November 2004 we repaid \$182,000 and Korpodeko agreed to extend the term of the loan, at no additional cost, for an additional twelve months for the remaining balance. We repaid the remaining outstanding balance of \$182,000 in June 2005.

Income Taxes

The expense for income taxes was \$6,118 and \$0 during calendar years 2005 and 2004, respectively. We recorded no income tax benefit for calendar years 2005 and 2004 because of uncertainties with respect to the timing of future utilization of net operating loss benefit. Since 1976, our Curacao subsidiary has had a 2% profit tax rate granted to it by the Curacao government.

## **QUARTERLY FINANCIAL INFORMATION (Unaudited)**

The following tables contain the 2005 and 2004 unaudited consolidated balance sheet as of March 31, June 30 and September 30 and the consolidated statement of operations for the three month periods ended March 31, June 30, September and December 31 of 2005 and 2004. Management believes that the following information reflects all normal recurring adjustments necessary for a fair presentation of the information for the periods presented. Unaudited quarterly results are as follows:

41

form10-ksba.htm Page 48 of 97

Table of Contents

# BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES Quarterly Consolidated Balance Sheet

|   | March 31,<br>2005 | June 30,<br>2005 | September 30,<br>2005 |  |
|---|-------------------|------------------|-----------------------|--|
|   | (Unaudited)       | (Unaudited)      | (Unaudited)           |  |
| Assets  |                   |                  |                       |  |
| Current assets:   | Φ 005 (10         | A 1.505.115      | d 1 002 021           |  |
| Cash and cash equivalents   | \$ 825,619        | \$ 1,507,117     | \$ 1,003,921          |  |
| Accounts receivable, net  | 431,270           | 1,089,218        | 385,445               |  |
| Inventories, net  | 1,413,296         | 906,279          | 1,932,541             |  |
| Prepaid expenses and other current assets   | 166,712           | 136,849          | 160,889               |  |
| Total current assets  | 2,836,897         | 3,639,463        | 3,482,796             |  |
| Other assets - loan costs   | 32,284            | -                | -                     |  |
| Property, plant and equipment, net  | 3,252,543         | 3,090,187        | 2,937,041             |  |
| Total assets  | 6,121,724         | 6,729,650        | 6,419,837             |  |
| Liabilities and Stockholders' Equity  |                   |                  |                       |  |
| Current liabilities:  |                   |                  |                       |  |
| Accounts payable and accrued expenses   | 2,274,880         | 2,088,446        | 2,190,890             |  |
| Deferred revenue  | 985,755           | 1,528,893        | 1,583,205             |  |
| Deferred employee stock bonus plan  | -                 | -                | -                     |  |
| Notes payable to related parties  | 67,839            | 67,839           | 67,839                |  |
| Short-term debt - Korpodeko   | 182,000           | -                | -                     |  |
| Total current liabilities   | 3,510,474         | 3,685,178        | 3,841,934             |  |
| Deferred revenue - license fees   | 3,437,011         | 5,550,055        | 5,151,926             |  |
| Minority interest in subsidiaries   | 10,049            | 7,498            | 4,484                 |  |
| Deferred compensation   | 22,210            | 22,210           | 22,210                |  |
| Senior secured convertible 12% note, net of discount                              | 1,575,000         | -                | -                     |  |
| 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;                     |                   |                  |                       |  |
| 5,249,528 shares issued at March 31, 2005, 5,316,341 shares issued at             | 5 222             | 5 241            | 5.255                 |  |
| June 30, 2005 and 5,355,216 shares issued at September 30, 2005                   | 5,333             | 5,341            | 5,355                 |  |
| Additional paid-in capital  | 4,250,509         | 4,202,973        | 4,216,721             |  |
| Retained earnings Treasury stock, 361,380 shares at cost as of March 31, 2005 and | (4,053,598)       | (4,186,715)      | (4,265,903            |  |
| 346,561 shares at cost as of June 30, 2005 and September 30, 2005                 | (1,911,237)       | (1,832,863)      | (1,832,863            |  |
| Notes receivable from former Chairman and CEO and other related party             | (724,027)         | (724,027)        | (724,027              |  |
| Total stockholders' equity  |                   |                  |                       |  |
|   | (2,433,020)       | (2,535,291)      | (2,600,717            |  |
| Total liabilities and stockholders' equity  | \$ 6,121,724      | \$ 6,729,650     | \$ 6,419,837          |  |

form10-ksba.htm Page 49 of 97

Table of Contents

# BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES Quarterly Consolidated Statements of Operations

|  | Quarterly Period Ended |            |          |            |               |            |      |            |
|--|------------------------|------------|----------|------------|---------------|------------|------|------------|
|  | March 31,              |            | June 30, |            | September 30, |            | De   | cember 31, |
|  |                        | 2005       |          | 2005       |               | 2005       | 2005 |            |
|  | J)                     | Unaudited) | (1       | Unaudited) | (U            | Inaudited) | J)   | Jnaudited) |
| Revenues:  |                        |            |          |            |               |            |      |            |
| Net sales  | \$                     | 1,319,177  | \$       | 1,551,554  | \$            | 82,649     | \$   | 184,598    |
| Licensing fees   |                        | 235,189    |          | 343,817    |               | 343,817    |      | 343,818    |
| Royalties  |                        | 283,743    |          | 268,996    |               | 274,640    |      | 246,241    |
|  |                        | 1,838,109  |          | 2,164,367  |               | 701,106    |      | 774,657    |
| Costs and expenses:  |                        |            |          |            |               |            |      |            |
| Cost of sales  |                        | 1,563,785  |          | 1,512,364  |               | 80,232     |      | 466,394    |
| Research and development                                       |                        | 196,129    |          | 191,718    |               | 177,407    |      | 121,210    |
| General and administrative                                     |                        | 470,761    |          | 499,139    |               | 525,894    |      | 793,366    |
|  |                        | 2,230,675  |          | 2,203,221  |               | 783,533    |      | 1,380,970  |
| Operating loss   |                        | (392,566)  |          | (38,854)   |               | (82,427)   |      | (606,313)  |
| Other income (expense):  |                        |            |          |            |               |            |      |            |
| Investment income  |                        | 1,711      |          | 323        |               | 232        |      | 140        |
| Interest expense   |                        | (77,195)   |          | (97,137)   |               | (7)        |      | (3,425)    |
| Other expense  |                        |            |          |            |               |            |      | (2,519)    |
|  |                        | (75,484)   |          | (96,814)   |               | 225        |      | (5,804)    |
| Loss before expense for income taxes                           |                        | (468,050)  |          | (135,668)  |               | (82,202)   |      | (612,117)  |
| Income tax benefit (expense)                                   |                        |            |          | _          |               | _          |      | (6,118)    |
| Loss before minority interest                                  |                        | (468,050)  |          | (135,668)  |               | (82,202)   |      | (618,235)  |
| Minority interest in loss (gain) of consolidated subsidiaries  |                        | (4,704)    |          | 2,551      |               | 3,014      |      | 6,548      |
| Net loss   | \$                     | (472,754)  | \$       | (133,117)  | \$            | (79,188)   | \$   | (611,687)  |
| Basic and diluted net loss per share                           | \$                     | (0.10)     | \$       | (0.03)     | \$            | (0.02)     | \$   | (0.12)     |
| Shares used in computation of basic and diluted loss per share |                        | 4,972,461  |          | 4,974,684  |               | 4,981,983  |      | 5,029,025  |

form10-ksba.htm Page 50 of 97

Table of Contents

# BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES Quarterly Consolidated Balance Sheet

|  | March 31,<br>2004 | June 30,<br>2004     | September 30,<br>2004 |  |
|--|-------------------|----------------------|-----------------------|--|
|  | (Unaudited)       | (Unaudited)          | (Unaudited)           |  |
| Assets   |                   |                      |                       |  |
| Current assets:  |                   |                      |                       |  |
| Cash and cash equivalents  | \$ 558,749        | \$ 1,749,715         | \$ 2,981,379          |  |
| Marketable securities  | 3,026             | 3,026                | 3,026                 |  |
| Accounts receivable, net   | 18,087            | 9,262                | 42,141                |  |
| Inventories, net   | 1,248,645         | 1,737,798            | 2,160,773             |  |
| Prepaid expenses and other current assets  | 73,390            | 70,830               | 116,035               |  |
| Total current assets   | 1,901,897         | 3,570,631            | 5,303,354             |  |
| Other assets - loan costs  | 257,809           | 481,017              | 187,673               |  |
| Property, plant and equipment, net   | 3,704,461         | 3,571,698            | 3,509,686             |  |
| Total assets   | 5,864,167         | 7,623,346            | 9,000,713             |  |
| Liabilities and Stockholders' Equity   |                   |                      |                       |  |
| Current liabilities: Accounts payable and accrued expenses   | 2,900,600         | 2 524 196            | 2.050.961             |  |
| Deferred revenue   | 45,000            | 3,534,186<br>412,296 | 2,950,861<br>862,359  |  |
| Notes payable to related parties   | 20,953            | 65,963               | 65,963                |  |
| Short-term debt - Korpodeko  | 364,000           | 364,000              | 364,000               |  |
| Short-term debt - promissory note  | 100,000           | 100,000              | 100,000               |  |
| Total current liabilities  | 3,430,553         | 4,476,445            | 4,343,183             |  |
| Deferred revenue - license fees  |                   | 2,014,244            | 3,952,389             |  |
| Minority interest in subsidiaries  | 72,197            | 69,563               | 51,001                |  |
| Deferred compensation  | 22,210            | 22,210               | 22,210                |  |
| Senior secured convertible 12% note, net of discount   | 1,413,578         | 1,445,863            | 1,478,148             |  |
| 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; 5,249,528 shares issued at March 31, 2004, 5,316,341 shares issued |                   |                      |                       |  |
| at June 30, 2004 and 5,326,341 shares issued at September 30, 2004   | 5,250             | 5,316                | 5,326                 |  |
| Additional paid-in capital   | 4,165,027         | 4,190,427            | 4,190,427             |  |
| Retained earnings  | (597,196)         | (1,953,270)          | (2,394,519)           |  |
| Treasury stock, 361,380 shares at cost as of March 31, 2004,   |                   |                      |                       |  |
| June 30, 2004 and September 30, 2004   | (1,911,237)       | (1,911,237)          | (1,911,237)           |  |
| Notes receivable from former Chairman and CEO and other related party  | (736,215)         | (736,215)            | (736,215)             |  |
| Total stockholders' equity   | 925,629           | (404,979)            | (846,218)             |  |
| Total liabilities and stockholders' equity   | \$ 5,864,167      | \$ 7,623,346         | \$ 9,000,713          |  |

form10-ksba.htm Page 51 of 97

Table of Contents

# BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES Quarterly Consolidated Statements of Operations

|  | Three Months Ended |           |          |             |               |            |    |             |
|--|--------------------|-----------|----------|-------------|---------------|------------|----|-------------|
|  | March 31,          |           | June 30, |             | September 30, |            | De | cember 31,  |
|  |                    | 2004      | _        | 2004        |               | 2004       |    | 2004        |
|  | (U                 | naudited) |          | (Unaudited) | J)            | Unaudited) | (1 | Unaudited)  |
| Revenues:  |                    |           |          |             |               |            |    |             |
| Net sales  | \$                 | 602,158   | \$       | 43,498      | \$            | 481,196    | \$ | 537,927     |
| Licensing fees   |                    | -         |          | 73,460      |               | 156,792    |    | 156,793     |
| Royalties  |                    | 94,366    | _        | 130,070     |               | 257,963    |    | 302,534     |
|  |                    | 696,524   |          | 247,028     |               | 895,951    |    | 997,254     |
| Costs and expenses:  |                    |           |          |             |               |            |    |             |
| Cost of sales  |                    | 676,133   |          | 555,173     |               | 621,351    |    | 1,199,835   |
| Research and development                                       |                    | 235,099   |          | 263,342     |               | 270,969    |    | 287,599     |
| General and administrative                                     |                    | 379,480   |          | 594,677     |               | 470,931    |    | 649,336     |
|  |                    | 1,290,712 |          | 1,413,192   |               | 1,363,251  |    | 2,136,770   |
| Operating loss   |                    | (594,188) |          | (1,166,164) |               | (467,300)  |    | (1,139,516) |
| Other income (expense):  |                    |           |          |             |               |            |    |             |
| Investment income  |                    | 13        |          | 1           |               | 8          |    | 174         |
| Interest expense   |                    | (92,075)  |          | (92,545)    |               | (92,519)   |    | (92,639)    |
|  |                    | (92,062)  |          | (92,544)    |               | (92,511)   |    | (92,465)    |
| Loss before expense for income taxes                           |                    | (686,250) |          | (1,258,708) |               | (559,811)  |    | (1,231,981) |
| Income tax benefit (expense)                                   |                    | -         |          | -           |               |            | _  | -           |
| Loss before minority interest                                  |                    | (686,250) |          | (1,258,708) |               | (559,811)  |    | (1,231,981) |
| Minority interest in loss of consolidated subsidiaries         |                    | 11,157    |          | 2,634       |               | 18,562     |    | 45,656      |
| Net loss   | \$                 | (675,093) | \$       | 1,256,074   | \$            | (541,249)  | \$ | (1,186,325) |
| Basic and diluted net loss per share                           | \$                 | (0.14)    | \$       | (0.26)      | \$            | (0.11)     | \$ | (0.24)      |
| Shares used in computation of basic and diluted loss per share |                    | 4,888,148 | _        | 4,880,915   |               | 4,909,032  |    | 4,936,995   |

## **Liquidity and Capital Resources**

To date, we have financed our operations primarily through product sales, debt instruments and licensing revenues and royalties under agreements with third parties. At December 31, 2005, 2004 and 2003 we had cash and cash equivalents in the aggregate of \$539,380, \$1,345,800 and 268,998, respectively.

Net cash provided from operating activities in calendar year 2005 was \$1,092,223 as compared to net cash provided from operating activities in calendar year 2004 of \$1,190,059. In 2005, as compared to 2004, the changes in net cash provided from operating activities was primarily attributable to our product sales and increased revenues from royalties, which was partially offset by lower licensing fees paid under the Auxilium Agreement and an increase in spending for manufacturing our product and personnel costs. In 2004, the changes in cash provided by operating activities as compared to 2003, \$1,547,848 net cash used in operating activities was primarily related to the cash payment received under the Auxilium Agreement.

form10-ksba.htm Page 52 of 97

#### Table of Contents

Net cash used in investing activities in 2005 was \$112,279 compared to \$182,458 in 2004 and net cash provided by investing activities of \$377,904 in 2003. In 2005 and 2004, the net cash used for investing activities was primarily attributable to capital expenditures. The net cash provided by investing activities in 2003 was primarily the result of payments we received from our former Chairman and CEO on outstanding loan balances. The capital expenditures in 2005 and 2004 were primarily related to ongoing annual capital requirements.

Net cash used in financing activities in 2005 was \$1,786,365 compared to net cash provided by financing activities of \$69,201 and \$1,397,031 in 2004 and 2003, respectively. The \$1,786,365 net cash used in financing activities in 2005 was primarily due to the repayment of \$1,575,000 on the 2003 Convertible Note with Bio Partners, which matured in June 2005. In addition, the Company repaid the remaining balances of \$182,000 on the Korpodeko loan and \$100,000 from an individual lender, which was partially offset by the 2003 Convertible Note deferred loan costs. Net cash provided by financing activities in 2004 primarily related to deferred loan costs associated with the 2003 Convertible Note, proceeds from the exercise of stock options and an increase in short-term debt borrowings, which was partially offset by a payment to reduce the Korpodeko loan. In 2003, net cash provided by financing activities primarily related to the proceeds received from the 2003 Convertible Note and a loan from an individual investor, which was partially offset by deferred loans costs associated with the 2003 Convertible Note and a payment made on the Korpodeko loan.

As previously mentioned, under the terms of the Auxilium Agreement we received in June 2004 and August 2004, payments totaling \$5.0 million. In June 2005, we received an additional \$3.0 million as a one-year anniversary payment. In August 2005, we presented Auxilium with clinical trial data for the clinical indication frozen shoulder under the terms of the Auxilium Agreement. In December 2005, Auxilium elected to exercise its option to develop this indication and paid us \$0.5 million as required under terms of the agreement, which was recorded as deferred revenue.

In June 2003, we entered into a financing transaction with Bio Partners, pursuant to which the Company sold to Bio Partners in a private placement (i) the \$1,575,000 2003 Convertible Note, issued at face value, and (ii) 295,312 shares of Company common stock, issued at par value, or \$.001 per share. The 2003 Convertible Note matured in June 2005 and bore interest at a rate of 12% per annum. Interest-only payments under the 2003 Convertible Note were payable monthly in arrears and the entire principal amount was repaid at maturity. None of the 2003 Convertible Note was converted into the Company's common stock. The loan discount of approximately \$281,000 and loan costs of approximately \$258,000 on the 2003 Convertible Note were amortized over the life of the 2003 Convertible Note.

In November 2001, ABC-Curacao borrowed a non-amortizing loan of \$455,000 at 6.5% interest due in November 2003 from Korpodeko. In September 2003, Korpodeko agreed to modify the terms of the loan. In return, we agreed to an interest rate increase from 6.5% to 7.5% from November 2003 to the new maturity in November 2004. In December 2003, we repaid \$91,000 of this loan principal. We repaid half of the remaining balance of \$182,000 in November 2004. At that time, Korpodeko agreed to extend the payment, with no additional consideration, of the balance for up to an additional twelve months. In June 2005, we repaid the remaining outstanding balance of \$182,000.

#### Item 7. FINANCIAL STATEMENTS.

For the discussion of Item 7, "Financial Statements" please see the Consolidated Financial Statements, beginning on page F-1 of this Report.

## Item 8. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

Our Audit Committee engaged Bloom & Co. on January 6, 2005 as our Independent Registered Public Accounting Firm to audit our financial statements after BDO Seidman, LLP ("BDO") was dismissed on January 6, 2005 as our Independent Registered Public Accounting Firm.

BDO's report dated March 22, 2004, (except for note 15, as to which the date is June 3, 2004) on our consolidated balance sheet as of December 31, 2003, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years then ended, did not contain an adverse opinion or disclaimer of opinion, or qualification or modification as to uncertainty, audit scope, or accounting principles.

form10-ksba.htm Page 53 of 97

#### Table of Contents

In connection with the audit of our consolidated financial statements as of December 31, 2003, there were no disagreements with BDO on any matters of accounting principles or practices, financial statement disclosure, or auditing scope and procedures which, if not resolved to the satisfaction of BDO would have caused BDO to make reference to the matter in their report. BDO furnished us with a letter addressed to the Commission stating that they agree with the above statements. A copy of that letter, dated January 11, 2005 was filed as Exhibit 16.1 to our Form 8-K filed with the Commission on January 13, 2005.

During the years ended December 31, 2005 and December 31, 2004, neither we nor anyone on our behalf consulted with Bloom & Co. regarding either the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on our consolidated financial statements, nor has Bloom & Co. provided to us a written report or oral advice regarding such principles or audit opinion or any matter that was the subject of a disagreement or reportable events set forth in Item 304(a)(iv) and (v), respectively, of Regulation S-K with our former accountant.

#### Item 8A. CONTROLS AND PROCEDURES.

Our principal executive officer and principal financial officer evaluated the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act")) as of the end of the period covered by this report. Based on this evaluation, our principal executive officer and principal financial officer have concluded that (i) our controls and procedures are not effective to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act, as amended, is accumulated and communicated to our management, including our principal executive officer and principal financial officer, to allow timely decisions regarding required disclosure, and (ii) our controls and procedures are not effective in providing reasonable assurance that the information required to be disclosed in this Report has been recorded, processed, summarized and reported as of the end of the period covered by this Report.

In light of the material weaknesses described below, we performed additional analyses and other procedures to ensure that our consolidated financial statements included in this Report were prepared in accordance with GAAP. These measures included, among other things, expansion of our year-end closing procedures, and dedication of additional external consultants to scrutinize account analyses and reconciliations at a detailed level. As a result of these and other expanded procedures, we concluded that the consolidated financial statements included in this Report present fairly, in all material respects, our financial position, results of operations and cash flows for the periods presented in conformity with GAAP.

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 existing policies or procedures may deteriorate. Further, because of changes in conditions, effectiveness of internal controls over financial reporting may vary over time.

A material weakness is a control deficiency, or combination of control deficiencies (within the meaning of Public Company Accounting Oversight Board Auditing Standard No. 2), that results in there being more than a remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected on a timely basis by employees in the normal course of their assigned functions. Management has identified the following material weaknesses in our internal control over financial reporting as of December 31, 2005:

• We did not maintain an effective control environment and specifically, elements of our finance organization were not structured with appropriate resources to ensure the consistent execution of their responsibility to provide independent and pro-active leadership in the areas of monitoring of controls, disclosure reviews and financial reporting. In 2005, we put in place new accounting software to address these issues.

form10-ksba.htm Page 54 of 97

#### Table of Contents

• We lacked appropriate internal controls over our cash disbursement system. As a result, duplicate payments were made to certain vendors and may have been made to others. We believe that the total amount of duplicate payments was less than \$10,000. We are pursuing those vendors who received duplicate payments and who have not yet made refunds. Our new accounting software referred to above should minimize the likelihood of this problem from occurring in the future.

- We advanced our former Chairman and CEO \$6,000, which could be considered a loan, in contravention of SEC rules and regulations, which
  was subsequently repaid approximately two weeks later.
- In order to minimize the risk of loss, the Audit Committee mandated in 2006 that non-recurring payments over \$10,000 require Board approval and that all checks in excess of \$10,000 require two signatures. We implemented the dual signature requirement until the termination of our CFO. After the termination of our CFO, such amounts require approval by one member of our Audit Committee.
- We did not maintain effective control of our capital structure, resulting in the issuance of 56,388 shares of our common stock by management, without Board approval, to an outside consultant who provided personal services to our former Chairman and CEO in addition to providing services to the Company. In addition, the value of these services were not recorded as compensation to our former Chairman and CEO for tax purposes in prior years. In 2006, we recorded \$73,882 in additional compensation to our former Chairman and CEO. In addition, management, without proper Board approval, extended the exercise period of 148,800 incentive stock options to January 2006, April 2007 and July 2007 for three former employees beyond that allowed by the various stock option plans that were approved by stockholders resulting in an expense of \$59,326. The Audit Committee subsequently implemented controls in order to prevent the recurrence of such actions without the prior approval of the Compensation Committee.
- Based on the advice of former legal counsel the Company issued 127,419 freely tradable securities to its employees from treasury stock. We have since been advised by our current legal counsel that such issuances are not permitted and we have since discontinued such practice.
- In June 2005 our former Chief Financial Officer ("CFO") was issued by the Company and improperly sold, based on the advice of former legal counsel, 14,819 shares at a fair market value of \$13,485 with an issuance value of \$15,560. In July 2006 the former CFO sold 10,000 shares at a fair market value of approximately \$9,600 with an issuance value of \$15,000. In December 2006, our insider trading policy was revised to require the approval of our current legal counsel prior to executing any such transactions.
- We did not maintain effective controls over the financial reporting process due to an insufficient number of personnel with an appropriate level of accounting knowledge, experience and training in the application of GAAP commensurate with its financial reporting requirements and the complexity of the our operations and transactions. Additionally, we did not maintain effective controls to ensure there is adequate monitoring and oversight of the work performed by accounting and financial reporting personnel to ensure the accuracy and completeness of the consolidated financial statements in accordance with GAAP. As a result, we had to re-create our financial records for 2005 by reviewing the original source documents and we re-entered all transactions into our new accounting system.

form10-ksba.htm Page 55 of 97

#### Table of Contents

• We did not maintain effective controls to ensure there is adequate analysis, documentation, reconciliation, and review of accounting records and supporting data. Specifically, we did not utilize a network computer system for our accounting department, which was not adequately backed up. As a result of the failure to both back up the system, and the failure of the stand alone PC, we may not have adequate financial records to support our financial statements prior to the year ended December 31, 2004.

- We did not maintain adequate records concerning various corporate matters.
- We made the determination that it is necessary to restate our consolidated financial statements for the year ended December 31, 2003 to accrue for additional rent expense due on our U.S. facility, for payroll taxes, penalties and interest attributable to our Curacao facility, interest due on loans due to a former director of the Company and to a partner of The S.J. Wegman Company, an adjustment in notes receivable due from our former Chairman and CEO due to the incorrect allocation between interest and principal and a reclassification to correct prepaid insurance and prepaid payroll. Whereas we do not consider the effect to our net loss material, the individual components of each adjustment disclosed above may be considered material to their individual line items within our consolidated financial statements. We filed a report on Form 8-K with the SEC regarding the 2003 restatement on January 25, 2007, as amended on February 7, 2007.
- We did not adequately monitor the business expenses of our officers who were also our directors at the time. The independent Board members have mandated that such expenses be reviewed and approved by our CFO. Following the termination of our CFO, such expenses require approval by one member of our Audit Committee. We believe these amounts are less than \$100,000 per year in the aggregate.
- The Company has not filed either its federal or state corporate tax returns since the calendar year 2002 but has paid the estimated tax due New York state. However, due to the existence of net operating loss and tax credit carry forwards, the Company believes that no tax is due for those years. The Company plans to file these returns and to pay any associated fines therewith.

There have been changes in our internal control over financial reporting identified in connection with the evaluation that occurred during the fourth fiscal quarter of 2005 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting. Specifically we have made the following changes

• In response to the identified material weaknesses, our management, with oversight from our Audit Committee, has dedicated additional resources and engaged external consultants to support management in its efforts to improve our control environment. We have replaced both internal staff and external consultants with experienced external consultants. As we have only five employees as of fiscal year end 2005, we will be utilizing external consultants unless and until the business model allows for full time accounting staff to support the CFO. Following the termination of our CFO, the Company has relied more heavily on such external consultants. These ongoing efforts are focused on implementing process changes to strengthen our internal control and monitoring activities.

Notwithstanding the above mentioned weaknesses, we believe that the consolidated financial statements included in this Report fairly present our consolidated financial position as of, and the consolidated results of operations for the years ended December 31, 2005, 2004 and 2003.

## **PART III**

Item 9. DIRECTORS AND EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS; COMPLIANCE WITH SECTION 16(a) OF THE EXCHANGE ACT.

form10-ksba.htm Page 56 of 97

#### Table of Contents

## **Directors and Executive Officers**

The Board is divided into three classes, each of which serves for a term of three years, with only one class of directors being elected in each year. The term of office of the first class of directors, presently consisting of Thomas L. Wegman and Dr. Paul A. Gitman was scheduled to expire at the Annual Meeting for the year 2005; the term of office of the second class of directors, presently consisting of Henry Morgan and Michael Schamroth is scheduled to expire on the date of the Annual Meeting for the year 2006; and the third class of directors, consisting of Edwin H. Wegman was scheduled to expire on the date of the Annual Meeting for the year 2004. Because of the death of Edwin H. Wegman on February 16, 2007 the third class of directors is vacant. Because we had not filed all required financial statements with the SEC, we were advised by current legal counsel not to hold a vote of the stockholders for any class of directors until after our filings become current. With respect to each class of directors, each director shall hold office for the term for which elected and until his or her successor shall be elected and shall qualify and be subject to such director's earlier death, resignation or removal.

Our directors have the positions and principal occupations set forth in the table below.

| Name                   | Age on 12/31/06 | Position with the Company and                                       | Director | Term    |
|------------------------|-----------------|---|----------|---------|
|                        |                 | Principal Occupation  | Since    | Expires |
| Edwin H. Wegman (2)    | 87              | Chairman of Board and CEO   | 1990     | 2005    |
| Thomas L. Wegman       | 52              | Director, President and Secretary                                   | 1994     | 2006    |
| Dr. Paul A. Gitman (1) | 66              | Director, Medical Director and Vice President for Clinical Care and | 1990     | 2006    |
|                        |                 | Resource Management of Long Island Jewish Medical Center            |          |         |
| Henry Morgan (1)       | 86              | Director, partner of law firm of Morgan Melhuish Abrutyn            | 1990     | 2007    |
| Michael Schamroth (1)  | 66              | Director, self-employed   | 2004     | 2007    |

<sup>(1)</sup> Member of Audit Committee and Compensation Committee

## **Committees and Board Meetings**

During the fiscal year that ended December 31, 2005, the Board met four times. All incumbent directors attended at least 75% of Board meetings.

Audit Committee. The Board has an Audit Committee consisting of Dr. Paul A. Gitman, Henry Morgan and Michael Schamroth. The function of the Audit Committee is to select our independent registered public accounting firm, review with the independent accountants the results of their audits, review with the independent accountants and management, our financial reporting and operating controls and the scope of audits, review our budgets and make recommendations concerning our financial reporting, accounting practices and policies and financial, accounting and operating controls and safeguards and review matters relating to the relationship between us and our auditors, including the engagement fee for the independent registered public accounting firm. The Audit Committee met once during the year ended December 31, 2005.

Stock Option Committee. The stock option committee (the "Stock Option Committee") consisted of Dr. Paul A. Gitman and Henry Morgan. The function of the Stock Option Committee was to administer both our 1997 stock option plan (the "1997 Plan"), and our 2001 stock option plan (the "2001 Plan"). The Stock Option Committee did not meet during the year 2005, but acted by unanimous written consent once during the year ended December 31, 2005. At a meeting on December 4, 2006, the Board decided to convert the Stock Option Committee into a Compensation Committee and to appoint Michael Schamroth as the third member.

Executive Committee. The executive committee (the "Executive Committee") consisted of Edwin H. Wegman and Thomas L. Wegman. The function of the Executive Committee was, except for certain matters reserved to the full Board, to exercise all of the powers of the Board in the management of our business during intervals between Board meetings, if necessary. The Executive Committee did not meet during the year ended December 31, 2005. At its meeting on December 4, 2006, the Board decided to abolish the Executive Committee.

<sup>(2)</sup> Upon his death on February 16, 2007, Edwin H. Wegman ceased to be a director of the Company.

form10-ksba.htm Page 57 of 97

#### Table of Contents

At the Board meeting of December 16, 2005, the Board approved the formation in principal of both a compensation committee and a nominating committee, but these committees were never formed. At its meeting on December 4, 2006, the Board decided to convert the Stock Option Committee into a Compensation Committee, as noted above, and to abolish the nominating committee.

## Audit Committee and Audit Committee Financial Expert

Our Board has determined that it does not have a member of its Audit Committee that qualifies as an "audit committee financial expert" as defined in Item 401(e) of Regulation S-B, and is "independent" as the term is used in Item 7(d)(3)(iv) of Schedule 14A under the Exchange Act.

We believe that retaining an independent director who would qualify as an "audit committee financial expert" would be overly costly and burdensome and is not warranted in our current circumstances.

## **Director Compensation**

We had no specific policy for compensating directors for fiscal years 2005, 2004 or 2003 nor was any cash compensation earned by any outside director during these periods. The non-independent members of the Board on September 6, 2006 approved a compensation plan for the independent directors which provides a set fee for each board meeting attended in person or telephonically. It also provides an annual retainer paid in arrears and a grant of options for the independent Board members.

#### Family Relationships

Edwin H. Wegman, our former Chairman and CEO, was the father of Thomas L. Wegman, who is our President.

## Code of Business Conduct and Ethics

The Board adopted an Amended and Restated Code of Business Conduct and Ethics ("Code of Ethics") at its Board meeting on December 4, 2006 that will apply to, among other persons, members of our Board, our officers, including our President (being our principal executive officer upon the death of Edwin H. Wegman, our former Chairman and CEO) and our CFO (being our principal financial and accounting officer), contractors, consultants and advisors. As adopted, our Code of Ethics sets forth written standards that are designed to deter wrongdoing and to promote:

- 1. honest and ethical conduct, including the ethical handling of actual or apparent conflicts of interest between personal and professional relationships;
- 2. full, fair, accurate, timely, and understandable disclosure in reports and documents that we file with, or submit to, the SEC and in other public communications made by us;
- 3. compliance with applicable governmental laws, rules and regulations;
- 4. the prompt internal reporting of violations of the Code of Ethics to an appropriate person or persons identified in the Code of Ethics; and
- 5. accountability for adherence to the Code of Ethics.

A copy of our Code of Ethics, as amended and restated is filed as an exhibit to this Report.

## Compliance with Section 16(a) of the Exchange Act

form10-ksba.htm Page 58 of 97

## **Table of Contents**

Section 16(a) of the Exchange Act requires our executive officers, directors and persons who beneficially own more than ten percent of the common stock to file reports of ownership and changes in ownership with the SEC. These reporting persons also are required to furnish us with copies of all Section 16 (a) forms they file. Our executive officers and directors and their affiliates did not make any Section 16(a) reports, as required under the Exchange Act for the fiscal years ending December 31, 2005, 2004 or 2003. However, as of the date of this filing, we believe that our executive officers, directors and persons who beneficially own more than ten percent of our common stock are current in their Section 16 filings.

form10-ksba.htm Page 59 of 97

Table of Contents

## Item 10. EXECUTIVE COMPENSATION.

#### SUMMARY COMPENSATION TABLE

|                               |      |                       |        | ]                           | LONG TERM CO        | MPENSATIO                 | N            |                           |
|-------------------------------|------|-----------------------|--------|-----------------------------|---------------------|---------------------------|--------------|---------------------------|
|                               |      | ANNUAL (              | COMPEN | SATION                      | AWARDS              |                           | PAYOUTS      | S                         |
|                               |      |                       |        | Other<br>Annual             | Restricted<br>Stock | Securities<br>Under-Lying |              | All other<br>Compensation |
| Name And                      |      | Salary <sup>(2)</sup> | Bonus  | Compensation <sup>(3)</sup> | Award(s)            | Options/                  | LTIP         | (1)                       |
| Principal Position            | Year | (\$)                  | (\$)   | (\$)                        | (\$)                | SARs (#)                  | Payouts (\$) | (\$)                      |
| Edwin H. Wegman,              | 2005 | 408,466               | -      | 2,350                       |                     |                           | -            | - 16,125                  |
| Chairman & CEO <sup>(6)</sup> | 2004 | 403,685               | -      | 2,350                       | -                   |                           | -            | - 40,957                  |
|                               | 2003 | 297,402               | -      | 3,100                       |                     |                           | -            | - 16,800                  |
| Thomas L. Wegman,             | 2005 | 203,224               | -      | 6,850                       | 22,500              | )                         |              |                           |
| President <sup>(4)</sup>      | 2004 | 199,182               | -      | 6,850                       |                     |                           |              |                           |
|                               | 2003 | 193,147               | -      | 6,850                       |                     |                           |              |                           |
| Lawrence Dobroff,             | 2005 | 125,560               | -      | -                           | 15,000              | 17,054                    | ļ            |                           |
| CFO <sup>(5)</sup>            | 2004 | 60,000                | -      | -                           |                     | 958                       | 3            |                           |

<sup>(1)</sup> Other compensation for 2005, 2004 and 2003 was for the value at the time of issuance of restricted stock issued to an individual who provided personal services for Edwin H. Wegman.

## **Bonuses and Deferred Compensation**

The Board approved a stock bonus in 2005, which was distributed in 2006, of 15,000 shares to Thomas L. Wegman and of 10,000 shares to Lawrence Dobroff. In December 2004, Lawrence Dobroff was promoted to Chief Financial Officer and on a monthly basis will receive a stock grant based upon a set dollar limit of \$1,667. This promotion in 2004 resulted in 17,054 shares being granted at various dates in 2005 and 958 shares in 2004. In December 2006, the Board authorized the discontinuation of the CFO's stock option grants on a monthly basis, effective as of January 1, 2007.

# Option Grants, Option Exercises and Fiscal Year-End Values

The following tables set forth certain information concerning the grant of stock options and the number and value of securities underlying exercisable and unexercisable stock options for the fiscal years ended December 31, 2005, 2004 and 2003 by the executive officers listed in the Summary Compensation Table above. None of these named persons has exercised any stock options.

<sup>(2)</sup> Lawrence Dobroff received in June 2005 14,819 shares of stock in lieu of cash compensation owed him between May 2004 and March 2005, the value of which at the date of issuance was \$15,560.

<sup>(3)</sup> Other annual compensation for 2005, 2004 and 2003 was for the value of vehicles owned or leased by the Company.

<sup>(4)</sup> Thomas L Wegman was elected President October of 2005. Prior to that time he served as an executive vice-president.

<sup>(5)</sup> Lawrence Dobroff commenced employment with the Company in May 2004.

<sup>(6)</sup> Upon his death on February 16, 2007, Edwin H. Wegman ceased to be the Chairman & CEO of the Company.

form10-ksba.htm Page 60 of 97

**Table of Contents** 

## Options/SAR Grants in Last Fiscal Year

# **Individual Grants**

| Nama              | Very/Date of Court         | Number of<br>Securities<br>Underlying<br>Options/<br>SARs | % of Total Options/ SARS Granted to Employee(s) in Fiscal | Exercise<br>on Base<br>Price | Expiration |
|-------------------|----------------------------|---|---|------------------------------|------------|
| Name              | Year/Date of Grant<br>2005 | Granted (#)   | Year  | (\$/Sh)                      | Date       |
| Edwin H. Wegman   | 2003                       | _   | _   | _                            | _          |
| Edwin II. Weginan | 2003                       |   |   |                              |            |
|                   | 2005                       |   | _   | _                            | _          |
| Thomas L. Wegman  | 2004                       | _   |   |                              |            |
| Thomas E. Wegman  | 2003                       | _   |   |                              |            |
|                   | 1/62005                    | 1272  | 3.4%  | \$1.45                       | 1/5/2015   |
|                   | 2/4/2005                   | 1149  | 3.1%  | \$1.60                       | 2/3/2015   |
|                   | 3/4/2005                   | 1149  | 3.1%  | \$1.60                       | 3/3/2015   |
|                   | 4/6/2005                   | 1543  | 4.2%  | \$1.20                       | 4/5/2015   |
|                   | 5/6/2005                   | 1543  | 4.2%  | \$1.20                       | 5/5/2015   |
|                   | 6/6/2005                   | 1754  | 4.7%  | \$1.05                       | 6/5/2015   |
| Lawrence Dobroff  | 7/6/2005                   | 1701  | 4.6%  | \$1.08                       | 7/5/2015   |
|                   | 8/5/2005                   | 921   | 2.5%  | \$2.00                       | 8/4/2015   |
|                   | 9/6/2005                   | 1082  | 2.9%  | \$1.70                       | 9/5/2015   |
|                   | 10/6/2005                  | 1476  | 4.0%  | \$1.25                       | 10/5/2015  |
|                   | 11/4/2005                  | 2315  | 6.2%  | \$0.80                       | 11/3/2015  |
|                   | 12/6/2005                  | 1149  | 3.1%  | \$1.60                       | 12/5/2015  |
|                   | 2004                       | 958   | 4.6%  | \$2.05                       | 12/5/2014  |

## Aggregate Option/SAR Exercises in Last Fiscal Year and FY-End Option/SAR Values

|                  |      |                    |                     |                              | Value of             |
|------------------|------|--------------------|---------------------|------------------------------|----------------------|
|                  |      |                    |                     | <b>Number of Securities</b>  | Unexercised In-the-  |
|                  |      |                    |                     | <b>Underlying Unexercise</b> | d Money              |
|                  |      |                    |                     | Options/SARs At Fisca        | l Options/SARs At    |
|                  |      |                    |                     | Year End (#)                 | Fiscal Year End (\$) |
|                  |      | Shares Acquired on |                     | Exercisable/                 | Exercisable/         |
| Name             | Year | Exercise (#)       | Value Realized (\$) | Unexercisable                | Unexercisable (\$)*  |
|                  | 2005 | _                  | _                   | _                            | _                    |
| Edwin H. Wegman  | 2004 | _                  | _                   | _                            | _                    |
|                  | 2003 | _                  | _                   | _                            | _                    |
|                  | 2005 | _                  | _                   | _                            | _                    |
| Thomas L. Wegman | 2004 | _                  | _                   | _                            | _                    |
|                  | 2003 | _                  | _                   | _                            | _                    |
| Lawrence Dobroff | 2005 | _                  | _                   | 17,054/0                     | 46/0                 |
| Lawrence Doblott | 2004 | _                  | _                   | 958/0                        | _                    |

Employment Contracts and Termination of Employment and Change-in-Control Arrangements

None.

# Item 11. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The following table sets forth certain information with respect to the beneficial ownership of our common stock as of January 18, 2007 by:

form10-ksba.htm Page 61 of 97

form10-ksba.htm Page 62 of 97

#### Table of Contents

- each security holder known by us to be the beneficial owner of more than 5% of our outstanding common stock;
- each current director;
- each of our named executive officers listed in the table under the caption "Executive Compensation" and
- all current directors and executive officers as a group.

Unless otherwise specified, the address of each of the persons set forth below is in care of BioSpecifics Technologies Corp., 35 Wilbur Street, Lynbrook, NY 11563.

| Name and Address of Beneficial Owner (1)      | Amount and<br>Nature of<br>Beneficial<br>Ownership | Percent of<br>Common Stock |
|---|--|----------------------------|
| Edwin H. Wegman <sup>(2)</sup>                | 2,187,442  | 36.5%                      |
| Thomas L. Wegman <sup>(3)</sup>               | 368,244  | 6.1%                       |
| Lawrence Dobroff (4)                          | 77,425   | 1.3%                       |
| Paul Gitman (5)                               | 150,175  | 2.5%                       |
| Henry Morgan (6)                              | 117,703  | 2.0%                       |
| Michael Schamroth (7)                         | 175,550  | 3.0%                       |
| Jeffrey K. Vogel (8)                          | 444,952  | 7.4%                       |
| All current directors and officers as a group | 3,076,539  | 51.4%                      |

(1) Beneficial ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Each of the beneficial owners listed above has direct ownership of and sole voting power and investment power with respect to the shares of our common stock.

A total of 5,996,374 shares of our common stock is considered to be outstanding pursuant to Rule 13d-3(d)(1) under the Securities Exchange Act of 1934. For each beneficial owner above, any options which become exercisable within 60 days have been included.

- (2) Includes 1,843,327 shares of common stock owned by The S.J. Wegman Company, a partnership of which Edwin H. Wegman was the sole general partner. The S.J. Wegman Company was legally dissolved upon Edwin H. Wegman's death on February 16, 2007 and the shares will be distributed in accordance with the partnership agreement. At the present time, we do not know what this distribution will be. These shares are, however, subject to a pledge agreement, under which the dissolution of The S.J. Wegman Company constitutes an event of default, giving the Board the right to vote the pledged shares. Includes 139,000 options to purchase shares of common stock that are currently exercisable. With respect to these options, the estate of Edwin H. Wegman has six months from the date of his death to exercise the options or they will expire. Edwin H. Wegman was the father of Thomas L. Wegman.
- (3) Includes 7,300 shares of common stock held by Thomas L. Wegman's wife and child. Includes 318,300 options which are currently exercisable. Excludes 100,000 options which are contingent and are currently not exercisable. Thomas L. Wegman is the son of Edwin H. Wegman.
- (4) Includes 77,425 options to purchase shares of common stock that are currently exercisable.
- (5) Includes 7,500 shares of common stock held by Dr. Gitman's wife. Includes 94,175 options to purchase shares of common stock that are currently exercisable.
- (6) Includes 94,175 options to purchase shares of common stock that are currently exercisable.

form10-ksba.htm Page 63 of 97

#### **Table of Contents**

(7) Includes 136,800 shares owned by M. Schamroth & Sons and options to purchase 38,750 shares of common stock that are currently exercisable. Mr. Schamroth has disclaimed any ownership interest in the 136,800 shares owned by M. Schamroth & Sons.

(8) Includes 149,640 shares of common stock held directly by Jeffrey K. Vogel, the sole shareholder and President of Bio Management, which is the sole general partner of Bio Partners, and 295,312 shares of common stock held by Bio Partners. The foregoing information is based solely on Jeffrey K. Vogel's Section 13 filings with the SEC without independent verification.

## Item 12. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS.

Until the death of Edwin H. Wegman, our former Chairman and CEO, The S.J. Wegman Company owned WSC, which has leased to us a building serving as a manufacturing facility and headquarters in Lynbrook, New York for over 30 years. The building also serves as our administrative headquarters. Edwin H. Wegman was the President of WSC and the sole general partner of The S.J. Wegman Company, a limited partnership. Upon his death on February 16, 2007, The S.J. Wegman Company was legally dissolved. However, his death had no effect on the legal existence of WSC. The shares of WSC will be distributed to the partners of The S.J. Wegman Company in accordance with the provisions of the partnership agreement. At the present time, we do not know who will own or control the shares of WSC.

In January 1998, WSC and we entered into a triple net lease agreement that provided for an annual rent starting at \$125,000, which was to increase annually by the amount of annual increase in the consumer price index for the greater New York metropolitan region. The lease term was 7 years, expiring January 31, 2005. Without Board approval, the lease was renewed (a related party transaction) in July 2005 for an additional 5 years, expiring on June 30, 2010. The extension of the lease may thus not be valid. The annual rent, effective February 2006, is \$150,000 (\$10 per square foot) per annum.

In January 2007 we entered into amended and restated demand promissory notes with Edwin H. Wegman and WSC reflecting the prior outstanding principal amounts of the loans and compounded interest (collectively, the "Notes"). Upon the death of Edwin H. Wegman on February 16, 2007, his note became the obligation of his estate. As of December 31, 2006, the aggregate principal amounts, including compounded interest, owed to us by Edwin H. Wegman and WSC were \$1,016,595 and \$304,390, respectively. Under the Notes, the respective principal amounts remaining unpaid at any time shall each bear interest at the rate of nine percent (9%) per annum compounded annually. The loans are secured by a pledge of 100% of the shares owned by The S.J. Wegman Company. Notwithstanding the dissolution of The S.J. Wegman Company upon the death of Edwin H. Wegman, the Notes continue to be secured by The S.J. Wegman Company pledge.

During March 2005, the former Chairman and CEO received an advance, which under SEC rules could be considered a loan in the amount of \$6,000, which was subsequently repaid within two weeks. No interest was accrued on this.

We had notes payable to Sherman Vogel, a former director and an affiliate of ours and Myron Wegman, a limited partner of The S.J. Wegman Company, an affiliate, amounting to \$24,894 at December 31, 2005. The notes, which bear interest at 9% per annum, are payable on demand. These notes were repaid in December 2006.

During April 2004, we received a \$45,000 non-interest bearing loan from the wife of the former Chairman and CEO. The loan was repaid in December 2006.

## Item 13. EXHIBITS.

| Exhibit Number | Description  |
|----------------|--|
| 3.1            | Registrant's Certificate of Incorporation, as amended*   |
| 3.2            | Registrant's Amended and Restated By-laws*   |
| 10.1           | Copy of Promissory Note, dated January 1, 2007, executed by Edwin H. Wegman in favor of the Company*           |
| 10.2           | Copy of Promissory Note, dated January 1, 2007, executed by Wilbur Street Corporation in favor of the Company* |
| 10.3           | Copy of Pledge Agreement, dated January 1, 2007, executed by The S.J. Wegman Company in favor of the Company*  |

56

form10-ksba.htm Page 64 of 97

## Table of Contents

| 10.4  | Copy of Lease, dated January 30, 1998, between the Company and the Wilbur Street Corporation (incorporated by reference to Exhibit 10.14 of the Registrant's Form 10-KSB filed with the Commission on May 7, 1998)                   |
|-------|--|
| 10.5  | Copy of Extension and Modification Agreement, dated July 1, 2005, between the Company and the Wilbur Street Corporation*   |
| 10.6  | Development and License Agreement between the Company and Auxilium Pharmaceuticals, Inc. dated June 3, 2004 (incorporated by reference to Exhibit 24 of the Registrant's Form 10-KSB filed with the Commission on November 22, 2004) |
| 10.7  | Amendment No. 1 to the Development and License Agreement between the Company and Auxilium Pharmaceuticals, Inc. dated May 5, 2005*   |
| 10.8  | 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)                                  |
| 10.9  | Amendment to Asset Agreement between the Company, ABC-NY and DFB dated January 8, 2007 (incorporated by reference to Exhibit 10.1 of the Registrant's Form 8-K filed with the Commission on January 12, 2007)                        |
| 10.10 | 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)        |
| 10.11 | 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)    |
| 10.12 | License Agreement dated October 1, 1993 between the Company and Martin K. Gelbard, M.D.*   |
| 10.13 | Form of 1993 Stock Option Plan of Registrant (incorporated by reference as Exhibit 10.2 of the Registrant's Form S-8 filed with the Commission on July 27, 1995)   |
| 10.14 | 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)   |
| 10.15 | Form of 2001 Stock Option Plan of Registrant (incorporated by reference as Exhibit 10.15 of the Registrant's Form 10-KSB filed with the Commission on May 17, 2001)  |
| 10.16 | Amendment to 2001 Stock Option Plan of Registrant (incorporated by reference to the Registrant's Form 14A filed with the Commission on November 12, 2003)  |
| 10.17 | Warrant to purchase common stock of the Company dated March 12, 2003 between the Company and David Geller*   |
| 10.18 | Rights Agreement dated as of May 14, 2002 (incorporated by reference as Exhibit 1 to the Registrant's Form 8-A filed with the Commission on May 30, 2002)  |
| 10.19 | Amendment No.1 to Rights Agreement, dated June 19, 2003*   |
| 14.1  | Amended and Restated Code of Business Conduct and Ethics*  |
| 16.1  | Letter from BDO Seidman, LLP dated January 11, 2005 (incorporated by reference as Exhibit 16.1 of the Registrant's Form 8-K filed with the Commission on January 13, 2005)   |
| 21.1  | Subsidiaries of the Registrant*  |
| 23.1  | Consent of Bloom & Co. LLP*  |
| 31.1  | Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*  |
| 31.2  | Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002*  |
| 32.1  | Certification of Principal Executive and Financial Officers pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*   |

<sup>\*</sup> filed herewith

# (B) REPORTS ON FORM 8-K:

April 1, 2003

May 20, 2003

June 20, 2003

57

form10-ksba.htm Page 65 of 97

#### Table of Contents

August 1, 2003

August 4, 2003

March 24, 2004

June 10, 2004 (two filings)

December 13, 2004

January 13, 2005

October 19, 2005

March 9, 2006

July 28, 2006

September 12, 2006

September 19, 2006

November 28, 2006

December 8, 2006

January 12, 2007

January 24, 2007

January 25, 2007

February 7, 2007

February 26, 2007

## Item 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

During January 2005, the Audit Committee appointed and the Board subsequently ratified Bloom & Co. as its principal independent registered accountants for calendar year 2004. During May 2005 Bloom & Co. was reappointed for calendar year 2005. For the year 2003, our principal accounting firm was BDO.

## Audit Fees

The aggregate audit fees billed for professional services rendered by our principal accountants for the audit of our annual consolidated financial statements included this Report and review of our quarterly consolidated financial statements included in our Reports on Form 10-QSB were \$78,000, \$86,500 and \$131,200 for the calendar years ended December 31, 2005, December 31, 2004 and December 31, 2003, respectively.

#### Audit Related Fees

For the calendar years ended December 31, 2005, December 31, 2004 and December 31, 2003 there were no aggregate fees billed for assurance and related services by Bloom & Co. and BDO respectively, relating to the performance of the audit of our consolidated financial statements, which are not reported under the caption "Audit Fees" above.

## Tax Fees

The aggregate fees billed for professional services rendered by our principal accountants for tax compliance, tax advice and tax planning were \$0, \$0 and \$26,000 in fiscal years ended December 31, 2005, December 31, 2004 and December 31, 2003, respectively. These services included, preparation of our corporate income tax returns, tax planning advice related to our tax returns and tax advice relating to contemplated corporate transactions.

# All Other Fees

We have not incurred any fees for services rendered by our principal accounting firm, other than the fees described above.

## Pre-Approval Policies and Procedures

None.

form10-ksba.htm Page 66 of 97

Table of Contents

# BIOSPECIFICS TECHNOLOGIES CORP.

# INDEX TO CONSOLIDATED FINANCIAL STATEMENTS FOR THE YEARS ENDED DECEMBER 31, 2005, 2004 AND 2003

|  | <u>Page</u> |
|--|-------------|
| Report of Independent Registered Public Accounting Firm  | F-2         |
| Consolidated Balance Sheets  | F-3         |
| Consolidated Statements of Operations  | F-4         |
| Consolidated Statements of Cash Flows  | F-5         |
| Consolidated Statements of Stockholders' Equity  | F-6         |
| Notes to Consolidated Financial Statements (including the Restatement of the 2003 Consolidated Financial Statements) | F-8         |
|  |             |
| F-1  |             |

form10-ksba.htm Page 67 of 97

Table of Contents

BLOOM & CO., L.L.P. 50 CLINTON STREET HEMPSTEAD NEW YORK 11550 CERTIFIED PUBLIC ACCOUNTANTS

FREDERICK PAUKER, CPA SIROUSSE TABRIZTCHI, Ph.D. MEMBER OF

TEL: 516 - 486 - 5900

FAX: 516 - 486 - 5476

AMERICAN INSTITUTE OF CPA CERTIFIED PUBLIC ACCOUNTANTS

## REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Shareholders BioSpecifics Technologies Corp. Lynbrook, NY

We have audited the accompanying consolidated balance sheets of BioSpecifics Technologies Corp. as of December 31, 2005 and 2004, and the related consolidated statements of operations, stockholders' equity, and cash flows for the years then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We also audited the adjustments described in Note 2 that were applied to restate the 2003 financial statements. In our opinion, such adjustments are appropriate and have been properly applied. The Financial Statements of BioSpecifics Technologies Corp. as of December 31, 2003 were audited by other auditors whose report dated March 22, 2004, expressed an unqualified opinion on those statements.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of BioSpecifics Technologies Corp. as of December 31, 2005 and 2004, and the consolidated results of its operations and its cash flows for the years then ended in conformity with U.S. generally accepted accounting principles.

/s/ Bloom & Co., LLP

Certified Public Accountants Hempstead. New York February 27, 2007

F-2

form10-ksba.htm Page 68 of 97

**Table of Contents** 

# BioSpecifics Technologies Corp. and Subsidiaries Consolidated Balance Sheets

|  | Years ended December 31, |                |               |  |  |
|--|--------------------------|----------------|---------------|--|--|
|  | 2005                     | 2004           | Restated 2003 |  |  |
| Assets   |                          |                |               |  |  |
| Current assets:  |                          |                |               |  |  |
| Cash and cash equivalents  | \$ 539,380               | 0 \$ 1,345,800 | \$ 268,998    |  |  |
| Marketable securities  |                          | - 3,026        | 3,026         |  |  |
| Accounts receivable, net   | 445,14                   | 1 160,777      | 306,786       |  |  |
| Inventories, net   | 2,616,710                | 5 2,005,263    | 880,452       |  |  |
| Prepaid expenses and other current assets  | 129,23                   | 4 109,041      | 108,540       |  |  |
| Total current assets   | 3,730,47                 | 3,623,907      | 1,567,802     |  |  |
| Other assets - loan costs  |                          | - 54,817       | 193,707       |  |  |
| Construction in Progress   | 59,10                    | -              | -             |  |  |
| Property, plant and equipment, net   | 2,795,35                 | 3,395,391      | 3,845,103     |  |  |
| Total assets   | 6,584,932                |                | 5,606,612     |  |  |
| Liabilities and Stockholders' Equity   |                          |                |               |  |  |
| Current liabilities:   |                          |                |               |  |  |
| Accounts payable and accrued expenses  | 2,638,832                | 2,494,168      | 2,048,812     |  |  |
| Deferred revenue   | 2,137,51                 | 7 985,755      | 45,000        |  |  |
| Deferred employee stock bonus plan   | 168,90                   | -              | -             |  |  |
| Notes payable to related parties   | 69,89                    | 4 67,839       | 20,953        |  |  |
| Short-term debt - Korpodeko  |                          | - 182,000      | 364,000       |  |  |
| Short-term debt - promissory note  |                          | - 100,000      | 100,000       |  |  |
| Total current liabilities  | 5,015,14.                | 3,829,762      | 2,578,765     |  |  |
| Deferred revenue - license fees  | 4,753,79                 | 7 3,672,200    | -             |  |  |
| Minority interest in subsidiaries  | (2,064                   | 4) 5,345       | 83,354        |  |  |
| Deferred Compensation  | 22,210                   | 22,210         | -             |  |  |
| Senior secured convertible 12% note, net of discount                                   |                          | 1,504,863      | 1,364,591     |  |  |
| 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;                          |                          |                |               |  |  |
| 5,362,716, 5,333,841 and 5,249,528 shares issued and outstanding                       |                          |                |               |  |  |
| at December 31, 2005, 2004 and 2003 respectively                                       | 5,363                    | 5,334          | 5,250         |  |  |
| Additional paid-in capital   | 4,224,964                | 4,250,509      | 4,144,207     |  |  |
| Retained earnings  | (4,877,59)               | 0) (3,580,844) | 77,897        |  |  |
| Treasury stock, 346,561 shares at cost as of December 31, 2005 and                     |                          |                |               |  |  |
| 361,380 shares at cost as of December 31, 2004 and 2003                                | (1,832,864               | 4) (1,911,237) | (1,911,237)   |  |  |
| Notes receivable from former Chairman and CEO and other related party                  | (724,02                  | 7) (724,027)   | (736,215)     |  |  |
| Total stockholders' equity   | (3,204,154               | 4) (1,960,265) | 1,579,902     |  |  |
| Total liabilities and stockholders' equity   | \$ 6,584,932             | 2 \$ 7,074,115 | \$ 5,606,612  |  |  |

See accompanying notes to consolidated financial statements

F-3

form10-ksba.htm Page 69 of 97

Table of Contents

# BioSpecifics Technologies Corp. and Subsidiaries Consolidated Statements of Operations

Twelve months ended December 31, Restated 2005 2004 2003 **Revenues:** 3,137,978 1,555,625 Net sales \$ 1,664,779 1,266,641 387,045 Licensing fees Royalties 1,073,620 784,933 1,683,915 5,478,239 2,836,757 3,239,540 Costs and expenses: Cost of sales 3,622,775 3,052,492 2,837,986 Research and development 686,464 1,057,009 935,443 General and administrative 2,289,160 2,094,424 2,632,399 6,598,399 6,203,925 6,405,828 **Operating loss** (1,120,160)(3,367,168)(3,166,288)Other income (expense): Investment income 2,406 196 109,635 (177,764)(369,778)Interest expense (213,677)Other expense (2,519)(177,877)(369,582)(104,042)Loss before benefit (expense) for income tax (1,298,037)(3,736,750)(3,270,330)Income tax benefit (expense) (13,000)(6,118)(1,304,155)(3,736,750)(3,283,330)Loss before minority interest (1,304,155)(3,736,750)(3,283,330)Minority interest in loss of consolidated subsidiaries 7,409 78,009 83,787 Net loss (1,296,746)(3,658,741)(3,199,543)Basic and diluted net loss per share (0.26)(0.75)(0.68)4,989,538 Shares used in computation of basic and diluted net loss per share 4,903,773 4,734,867

See accompanying notes to consolidated financial statements

form10-ksba.htm Page 70 of 97

**Table of Contents** 

# BioSpecifics Technologies Corp. and Subsidiaries Consolidated Statements of Cash Flows

|  | Twelve months ended December 31, |         |             |               |
|--|----------------------------------|---------|-------------|---------------|
|  |                                  |         |             | Restated      |
| Cash flows from operating activities:                                    | 200                              | 5       | 2004        | 2003          |
| Net loss   | \$ (1,2                          | 96,746) | (3,658,741) | \$ (3,199,543 |
| Adjustments to reconcile net loss to net cash provided                   |                                  |         |             |               |
| by operating activities:   |                                  |         |             |               |
| Depreciation and amortization  | 6                                | 53,209  | 644,359     | 699,129       |
| Options and warrants issued for services                                 |                                  | -       | _           | 14,000        |
| Issuance of stock for services   |                                  | 16,125  | 40,960      | 15,000        |
| Issuance of treasury stock as employee bonus                             |                                  | 22,969  | -           |               |
| Amortization of loan discount  |                                  | 70,137  | 140,272     | 70,137        |
| Deferred compensation  |                                  | -       | 22,210      |               |
| Minority interest in loss of subsidiaries                                |                                  | (7,409) | (78,009)    | (83,787       |
| Changes in operating assets and liabilities:                             |                                  | , ,     | , , ,       |               |
| Accounts receivable  | (2)                              | 84,364) | 146,009     | 562,024       |
| Marketable securities  | `                                | 3,026   | -           | ĺ.            |
| Inventories  | (6                               | 11,453) | (1,124,811) | (231,572      |
| Prepaid expenses and other current assets                                |                                  | 20,194) | (501)       | (74,392       |
| Accounts payable and accrued expenses                                    |                                  | 44,644  | 445,356     | 264,156       |
| Deferred revenue   |                                  | 33,359  | 4,612,955   | 20.,100       |
| Deferred employee stock bonus plan                                       |                                  | 68,900  | -           |               |
| Income taxes   | •                                | _       | _           | 417,000       |
| Net cash provided by (used in) operating activities                      | 1,0                              | 92,223  | 1,190,059   | (1,547,848    |
| Cash flows from investing activities:                                    |                                  |         |             |               |
| Net (increase) decrease of notes receivable from former Chairman and CEO |                                  |         | 12,189      | 394,093       |
| Expenditures for property, plant and equipment                           | (1                               | 12 270) | (194,647)   | (16,189       |
|  |                                  | 12,279) |             |               |
| Net cash provided by (used in) investing activities                      | (1                               | 12,279) | (182,458)   | 377,904       |
| Cash flows from financing activities:                                    |                                  | 2.055   | 1.007       | C 440         |
| Interest accrued on notes payable to related parties                     |                                  | 2,055   | 1,886       | 6,443         |
| Increase in short-term debt  | (2                               | -       | 45,000      | 100,000       |
| Decrease in short-term debt  |                                  | 82,000) | (182,000)   | (91,000       |
| Increase (decrease) in senior secured convertible debt                   |                                  | 75,000) | -           | 1,575,000     |
| Proceeds from issuance of common stock                                   |                                  | 13,763  | 65,425      | 295           |
| Deferred loan costs, net   |                                  | 54,817  | 138,890     | (193,707      |
| Net cash provided by (used in) financing activities                      | (1,7)                            | 86,365) | 69,201      | 1,397,031     |
| Effect of exchange rates on cash and equivalents                         |                                  | -       | -           | (8,988        |
| Increase (decrease) in cash and cash equivalents                         | (8)                              | 06,420) | 1,076,802   | 218,099       |
| Cash and cash equivalents at beginning of year                           | 1,3                              | 45,800  | 268,998     | 50,899        |
| Cash and cash equivalents at end of year                                 | 5.                               | 39,380  | 1,345,800   | 268,998       |
| Supplemental disclosures of cash flow information:                       |                                  |         |             |               |
| Cash paid during the year for:   |                                  |         |             |               |
| Interest   | \$                               | - \$    | 211,568     | \$ 157,599    |
|  |                                  |         |             |               |

See accompanying notes to consolidated financial statements

form10-ksba.htm Page 71 of 97

## Table of Contents

# **BioSpecifics Technologies Corp. and Subsidiaries Consolidated Statements of Stockholders' Equity**

|                                       | Shares    |    | Amount |    | Additional<br>Paid in Capital |    | Retained<br>Earnings |  |
|---------------------------------------|-----------|----|--------|----|-------------------------------|----|----------------------|--|
| Balances - December 31, 2002          | 4,939,216 | \$ | 4,939  | \$ | 3,834,677                     | \$ | 3,277,440            |  |
| Foreign currency translation          | -         |    | -      |    | -                             |    | -                    |  |
| Consultant option grants              | 15,000    |    | 15     |    | 14,985                        |    | -                    |  |
| Bio Partners loan/discount            | 295,312   |    | 296    |    | 280,545                       |    | -                    |  |
| Issuance of warrants, options         | -         |    | -      |    | 14,000                        |    | -                    |  |
| Proceeds from former Chairman and CEO | -         |    | -      |    | -                             |    | -                    |  |
| Net loss                              |           |    | -      |    | -                             |    | (3,199,543)          |  |
| Balances - Restated December 31, 2003 | 5,249,528 | \$ | 5,250  | \$ | 4,144,207                     | \$ | 77,897               |  |
| Shares for services                   | 18,888    |    | 19     |    | 40,941                        |    | -                    |  |
| Exercise of options                   | 65,425    |    | 65     |    | 65,360                        |    | -                    |  |
| Proceeds from former Chairman and CEO | -         |    | -      |    | -                             |    | -                    |  |
| Net loss                              | -         |    | -      |    | -                             |    | (3,658,741)          |  |
| Balances - December 31, 2004          | 5,333,841 | \$ | 5,334  | \$ | 4,250,508                     | \$ | (3,580,844)          |  |
| Shares for services                   | 15,000    |    | 15     |    | 16,110                        |    | -                    |  |
| Exercise of options                   | 13,875    |    | 14     |    | 13,749                        |    | -                    |  |
| Proceeds from former Chairman and CEO | -         |    | -      |    | -                             |    | -                    |  |
| Issue of treasury shares              | -         |    | -      |    | (55,404)                      |    | -                    |  |
| Net loss                              | -         |    | -      |    | -                             |    | (1,296,746)          |  |
| Balances - December 31, 2005          | 5,362,716 | \$ | 5,363  | \$ | 4,224,963                     | \$ | (4,877,590)          |  |

|                                       | Treasury<br>Stock | Due from<br>Chairman | Currency<br>Translation | Shareholder<br>Equity<br>Total | Comprehensive<br>Income (loss) |
|---------------------------------------|-------------------|----------------------|-------------------------|--------------------------------|--------------------------------|
| Balances - December 31, 2002          | (1,911,237)       | (1,130,308)          | 8,988                   | 4,084,498                      |                                |
| Foreign currency translation          |                   |                      | (8,988)                 | (8,988)                        | (8,988)                        |
| Consultant option grants              |                   |                      |                         | 15,000                         |                                |
| Bio Partners loan/discount            |                   |                      |                         | 280,841                        |                                |
| Issuance of warrants, options         |                   |                      |                         | 14,000                         |                                |
| Proceeds from former Chairman and CEO |                   | 394,093              |                         | 394,094                        |                                |
| Net loss                              |                   |                      |                         | (3,199,543)                    | (3,199,543)                    |
| Balances - Restated December 31, 2003 | (1,911,237)       | <b>\$</b> (736,215)  | \$ -                    | \$ 1,579,902                   | \$ (3,208,531)                 |
| Shares for services                   | -                 | -                    | -                       | 40,960                         | -                              |
| Exercise of options                   | -                 | -                    | -                       | 65,425                         | -                              |
| Proceeds from former Chairman and CEO | -                 | 12,188               | -                       | 12,189                         | -                              |
| Net loss                              | -                 | -                    | -                       | (3,658,741)                    | (3,658,741)                    |
| Balances - December 31, 2004          | (1,911,237)       | <b>\$</b> (724,027)  | \$ -                    | \$ (1,960,265)                 | \$ (6,867,272)                 |
| Shares for services                   | -                 | -                    | -                       | 16,125                         | -                              |
| Exercise of options                   | -                 | -                    | -                       | 13,763                         | -                              |
| Proceeds from former Chairman and CEO | -                 | -                    | -                       |                                | -                              |
| Issue of treasury shares              | 78,373            | -                    | -                       | 22,969                         | -                              |
| Net loss                              | -                 | -                    | -                       | (1,296,746)                    | (1,296,746)                    |
| Balances - December 31, 2005          | (1,832,864)       | \$ (724,027)         | \$ -                    | \$ (3,204,154)                 | \$ (8,164,018)                 |

form10-ksba.htm Page 72 of 97

Table of Contents

See accompanying notes to consolidated financial statements

F-7

form10-ksba.htm Page 73 of 97

Table of Contents

#### BIOSPECIFICS TECHNOLOGIES CORP. AND SUBSIDIARIES

Notes to Consolidated Financial Statements December 31, 2005, 2004 and Restated 2003

## 1. ORGANIZATION AND DESCRIPTION OF BUSINESS

We are a biopharmaceutical company that has manufactured the active pharmaceutical ingredient, which is referred to as "API or "API Enzyme" in this Report, used in an FDA licensed collagenase ointment that has been marketed for over 30 years. We have a development and license agreement with Auxilium for injectable collagenase (which Auxilium has named "AA4500") for clinical indications in Dupuytren's disease, Peyronies's disease and frozen shoulder (*adhesive capsulitis*), and Auxilium has an option to acquire additional indications that we may pursue, including cellulite and lipomas. As a result of our research and development efforts we have also developed an injectable collagenase for treatment of various diseases or indications. Injectable collagenase has completed a pivotal clinical trial for the treatment of Dupuytren's disease. A Phase III clinical trial has been initiated and is currently on clinical hold. During its earnings conference call on February 15, 2007, Auxilium reported that it expects the Phase III clinical trial to resume in the fourth quarter of 2007.

# 2. RESTATEMENT OF CONSOLIDATED FINANCIAL STATEMENTS

During the preparation of our consolidated financial statements for the year ended December 31, 2005, management revised the accounting and certain related account balances previously reported in the 2003 Form 10-KSB filing. These restatements reflect changes to the Company's previously reported financial results for the year ended December 31, 2003. These restatements had no effect on our cash position for any of these periods.

The consolidated financial statements for the twelve months ended December 31, 2003 have been restated as follows:

form10-ksba.htm Page 74 of 97

**Table of Contents** 

# **BioSpecifics Technologies Corp. and Subsidiaries Restated Consolidated Balance Sheets**

Twelve Months Ended December 31, 2003

|   |    |                        | Dec | cember 31, 2003         |    |               |
|---|----|------------------------|-----|-------------------------|----|---------------|
|   |    | Previously<br>Reported | A   | djustment               |    | As Restated   |
| Assets  |    | reporteu               |     |                         |    | 110 110000000 |
| Current assets:   |    |                        |     |                         |    |               |
| Cash and cash equivalents   | \$ | 268,998                | \$  | _                       | \$ | 268,998       |
| Marketable securities   | *  | 3,026                  | •   | _                       | •  | 3,026         |
| Accounts receivable, net  |    | 306,786                |     | _                       |    | 306,786       |
| Inventories, net  |    | 880,452                |     | -                       |    | 880,452       |
| Prepaid expenses and other current assets                             |    | 47,151                 |     | 61,389 (1)              |    | 108,540       |
| Total current assets  |    | 1,506,413              |     | 61,389                  | _  | 1,567,802     |
| Other assets - loan costs   |    | 203,457                |     | (9,750) <sup>(2)</sup>  |    | 193,707       |
| Property, plant and equipment, net                                    |    | 3,845,102              |     | 1 (3)                   |    | 3,845,103     |
| Total assets  | \$ | 5,554,972              | \$  | 51,640                  | \$ | 5,606,612     |
| Liabilities and Stockholders' Equity                                  |    |                        |     |                         |    |               |
| Current liabilities:  |    |                        |     |                         |    |               |
| Accounts payable and accrued expenses                                 | \$ | 1,806,850              | \$  | 241,963 (4)             | \$ | 2,048,813     |
| Notes payable to related parties                                      |    | 15,010                 |     | 5,943 (5)               |    | 20,953        |
| Deferred revenue  |    | 45,000                 |     | -                       |    | 45,000        |
| Short-term debt - Korpodeko   |    | 364,000                |     | -                       |    | 364,000       |
| Short-term debt - promissory note                                     |    | 100,000                |     | -                       |    | 100,000       |
| Total current liabilities   |    | 2,330,860              |     | 247,906                 |    | 2,578,766     |
| Minority interest in subsidiaries                                     |    | 89,728                 |     | (6,374) (6)             |    | 83,354        |
| Senior secured convertible 12% note, net of discount                  |    | 1,364,591              |     | -                       |    | 1,364,591     |
| 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; 5,249,528 shares issued as of December 31, 2003 5,249     |    |                        |     | 1 (7)                   |    | 5,250         |
| Additional paid-in capital  |    | 4,144,207              |     | -                       |    | 4,144,207     |
| Retained earnings   |    | 180,949                |     | $(103,052)^{(8)}$       |    | 77,897        |
| Accumulated other comprehensive income                                |    | -                      |     | -                       |    | -             |
| Treasury stock, 361,380 shares at cost                                |    | (1,911,237)            |     | -                       |    | (1,911,237)   |
| Notes receivable from former Chairman and CEO and other related party |    | (649,375)              |     | (86,841) <sup>(9)</sup> | _  | (736,215)     |
| Total stockholders' equity  |    | 1,769,793              |     | (189,891)               |    | 1,579,901     |
| Total liabilities and stockholders' equity                            | \$ | 5,554,972              | \$  | 51,640                  | \$ | 5,606,612     |

# See accompanying notes to consolidated financial statements

F-9

<sup>(1)</sup> Correction to prepaid insurance of \$31,079 and prepaid payroll of \$30,310 previously expensed.

<sup>(2)</sup> Correction to Bio Partners, a private investor group, loan amortization of \$9,750.

form10-ksba.htm Page 75 of 97

## **Table of Contents**

- (3) Rounding correction of property, plant and equipment, net.
- (4) Increase in rent accrual for Lynbrook, NY facility of \$206,963 for 2003 and prior periods and payroll tax liability for our Curacao employees of \$35,000 resulting in total additional expense of \$241,963.
- (5) Increase in interest expense owed to a related party and a former director of \$5,943.
- (6) Change due to restated financial statements based on ownership percentage held by minority shareholders.
- (7) Correction of rounding error for outstanding shares.
- (8) Correction to retained earnings based on restatement and prior period adjustments affecting the consolidated statement of operations.
- (9) Correction of related party loan payment received from former Chairman and CEO, misapplied to principal instead of interest due.

F-10

form10-ksba.htm Page 76 of 97

Table of Contents

# **BioSpecifics Technologies Corp. and Subsidiaries Restated Consolidated Statements of Operations**

Twelve Months ended December 31, 2003

|  | As Previously<br>Reported |    | Adjustment |     |    | As Restated |
|--|---------------------------|----|------------|-----|----|-------------|
| Revenues:  |                           |    |            |     |    |             |
| Net sales  | \$<br>1,555,625           | \$ | -          |     | \$ | 1,555,625   |
| Royalties  | 1,683,915                 |    |            |     |    | 1,683,915   |
|  | 3,239,540                 |    | -          |     |    | 3,239,540   |
| Costs and expenses:  |                           |    |            |     |    |             |
| Cost of sales  | 2,843,921                 |    | (5,935)    |     |    | 2,837,986   |
| General and administrative   | 2,615,007                 |    | 17,392     |     |    | 2,632,399   |
| Research and development   | <br>884,685               |    | 50,758     | (3) |    | 935,443     |
|  | 6,343,613                 |    | 62,215     |     |    | 6,405,828   |
| Operating loss   | (3,104,073)               |    | (62,215)   |     |    | (3,166,288) |
| Other income (expense):  |                           |    |            |     |    |             |
| Investment Income  | 22,794                    |    | 86,841     | (4) |    | 109,635     |
| Interest expense   | (207,734)                 |    | (5,943)    | (5) |    | (213,677)   |
|  | (184,940)                 |    | 80,898     |     |    | (104,042)   |
| Loss before benefit (expense) for income tax                       | (3,289,013)               |    | 18,683     |     |    | (3,270,330) |
| Income tax expense   | <br>(13,000)              |    |            |     |    | (13,000)    |
| Loss before minority interest                                      | (3,302,013)               |    | 18,683     |     |    | (3,283,330) |
| Minority interest in earnings of consolidated subsidiaries         | 77,413                    |    | 6,374      | (6) |    | 83,787      |
| Net loss   | \$<br>(3,224,600)         | \$ | 25,057     |     | \$ | (3,199,543) |
| Basic and diluted net loss per share                               | \$<br>(0.68)              | \$ | 0.00       |     | \$ | (0.68)      |
| Shares used in computation of basic and diluted net loss per share | 4,734,867                 |    | NA         |     |    | 4,734,867   |

# See accompanying notes to consolidated financial statements

<sup>(1)</sup>Cost of sales decrease is related to a reduction in insurance expense of \$19,007 and payroll costs of \$30,310 partially offset by increases in payroll tax expense of \$35,000 for our Curacao employees and rent expense of \$8,382 resulting in a total reduction of \$5,935.

<sup>(2)</sup> General and administrative expense increases include \$19,714 related to rent expense and \$9,750 related to loan amortization costs with a private investor group, Bio Partners, partially offset by reductions of \$12,072 in insurance expenses resulting in a total increase of \$17,392.

<sup>(3)</sup> Research and development expense increases include \$50,758 related to rent expense.

<sup>(4)</sup> Investment income increased by \$86,841due to a reclassification of interest associated with the related party loan repayment by the former Chairman and CEO.

<sup>(5)</sup> Interest expense increased by \$5,943 due to a correction to a related party loan to the former Chairman and CEO.

<sup>(6)</sup> Change due to restated financial statements based on ownership percentage held by minority shareholders.

form10-ksba.htm Page 77 of 97

**Table of Contents** 

# **BioSpecifics Technologies Corp. and Subsidiaries Restated Consolidated Statements of Cash Flows**

Twelve months ended

December 31, 2003

|  | December 31, 2003 |                        |       |                         |    |             |  |  |  |
|--|-------------------|------------------------|-------|-------------------------|----|-------------|--|--|--|
|  |                   | Previously<br>Reported | Adjus | stment                  | _  | As Restated |  |  |  |
| Cash flows from operating activities:                        |                   |                        |       |                         |    | _           |  |  |  |
| Net loss   | \$                | (3,224,600)            | \$    | 25,057 (1)              | \$ | (3,199,543) |  |  |  |
| Adjustments to reconcile net loss to net cash provided       |                   |                        |       |                         |    |             |  |  |  |
| by operating activities:                                     |                   |                        |       |                         |    |             |  |  |  |
| Depreciation and amortization                                |                   | 699,129                |       | -                       |    | 699,129     |  |  |  |
| Options and warrants issued for services                     |                   | 14,000                 |       | -                       |    | 14,000      |  |  |  |
| Issuance of stock for services                               |                   | 15,000                 |       | -                       |    | 15,000      |  |  |  |
| Amortization of loan discount                                |                   | 70,137                 |       | -                       |    | 70,137      |  |  |  |
| Minority interest in loss of subsidiaries                    |                   | (77,413)               |       | $(6,374)^{(2)}$         |    | (83,787)    |  |  |  |
| Deferred taxes   |                   | -                      |       | -                       |    | -           |  |  |  |
| Changes in operating assets and liabilities:                 |                   |                        |       |                         |    |             |  |  |  |
| Accounts receivable  |                   | 562,024                |       | -                       |    | 562,024     |  |  |  |
| Inventories  |                   | (231,572)              |       | -                       |    | (231,572)   |  |  |  |
| Prepaid expenses and other current assets                    |                   | (13,003)               |       | $(61,389)^{(3)}$        |    | (74,392)    |  |  |  |
| Accounts payable and accrued expenses                        |                   | 150,302                |       | 113,854 (4)             |    | 264,156     |  |  |  |
| Income taxes   |                   | 417,000                |       |                         |    | 417,000     |  |  |  |
| Net cash provided (used) by operating activities             |                   | (1,618,996)            |       | 71,148                  |    | (1,547,848) |  |  |  |
| Cash flows from investing activities:                        |                   |                        |       |                         |    |             |  |  |  |
| Net paydown of notes receivable from former Chairman and CEO |                   | 480,934                |       | (86,841) <sup>(5)</sup> |    | 394,093     |  |  |  |
| Expenditures for property, plant and equipment               |                   | (16,189)               |       |                         |    | (16,189)    |  |  |  |
| Net cash provided (used) by investing activities             |                   | 464,745                |       | (86,841)                |    | 377,904     |  |  |  |
| Cash flows from financing activities:                        |                   |                        |       |                         |    |             |  |  |  |
| Interest accrued on notes payable to related parties         |                   | 500                    |       | 5,943 (6)               |    | 6,443       |  |  |  |
| Increase in short-term debt                                  |                   | 100,000                |       | -                       |    | 100,000     |  |  |  |
| Decrease in short-term debt                                  |                   | (91,000)               |       | -                       |    | (91,000)    |  |  |  |
| Proceeds from senior secured convertible debt                |                   | 1,575,000              |       | -                       |    | 1,575,000   |  |  |  |
| Proceeds from issuance of common stock                       |                   | 295                    |       | -                       |    | 295         |  |  |  |
| Deferred loan costs, net                                     |                   | (203,457)              |       | 9,750 (7)               |    | (193,707)   |  |  |  |
| Net cash provided by financing activities                    |                   | 1,381,338              |       | 15,693                  |    | 1,397,031   |  |  |  |
| Effect of exchange rates on cash and equivalents             |                   | (8,988)                |       | -                       |    | (8,988)     |  |  |  |
| Increase in cash and cash equivalents                        |                   | 218,099                |       | _                       |    | 218,099     |  |  |  |
| Cash and cash equivalents at beginning of year               |                   | 50,899                 |       | <u>-</u>                |    | 50,899      |  |  |  |
| Cash and cash equivalents at end of year                     | \$                | 268,998                | \$    |                         | \$ | 268,998     |  |  |  |
| Supplemental disclosures of cash flow information:           |                   |                        |       |                         |    |             |  |  |  |
| Cash paid during the year for:                               |                   |                        |       |                         |    |             |  |  |  |
| Interest   | \$                | 157,599                | \$    | <u>-</u>                | \$ | 157,599     |  |  |  |
| Income taxes   |                   | _                      |       | _                       |    | _           |  |  |  |
|  |                   |                        |       |                         |    |             |  |  |  |

See accompanying notes to consolidated financial statements

form10-ksba.htm Page 78 of 97

F-12

form10-ksba.htm Page 79 of 97

## **Table of Contents**

- (1)Net loss decreased due to changes reflected in the restated consolidated statement of operations above.
- (2) Minority interest in loss of subsidiaries change due to restated financial statements based on ownership percentage held by minority shareholders.
- (3) Prepaid expenses and other current assets change due to prepaid insurance of \$31,079 and prepaid payroll of \$30,310.
- (4) Accounts payable and accrued expenses change due to Wilbur Street rent accrual increase of \$78,854 and payroll tax liability accrual of \$35,000 for our Curacao employees.
- (5) Net paydown of notes receivable from former Chairman and CEO change due to the improper treatment of prior period payments.
- (6) Interest accrued on notes payable to a related party and a former director.
- (7) Deferred loan costs, net change due to a decrease in loan amortization of \$9,750 of Bio Partners, a private investor group.

F-13

form10-ksba.htm Page 80 of 97

#### Table of Contents

## 3. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

# **Principles of Consolidation**

The consolidated financial statements include the accounts of the Company and its majority-owned subsidiaries, Advance Biofactures Corp., ("ABC-NY"), Advance Biofactures of Curacao N.V. ("ABC-Curacao"), BioSpecifics of Curacao N.V., Biota and its wholly-owned subsidiary, BioSpecifics Pharma GmbH ("Bio Pharma") of Germany, which was liquidated during December 2005. All significant intercompany transactions and balances have been eliminated in consolidation.

#### **Management Estimates**

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

## Cash and Cash Equivalents

For purposes of the statement of cash flows, the Company considers all temporary investments and time deposits with original maturities of three months or less to be cash equivalents.

#### **Marketable Securities**

Marketable securities principally consist of investments in common and preferred stocks. These investments are classified as trading securities and are adjusted to market value at the end of each accounting period. Unrealized holding gains and losses on trading securities are included in investment and other income in the accompanying consolidated statements of operations.

#### **Inventories**

Inventories are stated at the lower of cost or market, with costs approximating the first-in, first-out method. When the inventory carrying value exceeds the market estimated value, reserves are recorded for the difference between the cost and the estimated market value. These reserves are determined based on management's estimates. Inventories consist of finished goods, work-in-process and raw materials.

## Warranty Provisions

We warrant to Abbott that our product will comply with applicable regulatory requirements and when delivered will not be adulterated or misbranded within any federal law of the U.S. As we have had minimal claims, we do not set up a reserve until we are notified by Abbott that the product is defective and information is provided to us documenting that the failure was due to our API Enzyme. Product warranty liabilities are as follows:

|  | 1 weive month period |           |    |          |      |          |  |  |  |  |
|--|----------------------|-----------|----|----------|------|----------|--|--|--|--|
|  | 2003                 |           |    | 2004     | 2005 |          |  |  |  |  |
| Beginning balance product warranty liability | \$                   | 318,342   | \$ | 178,342  | \$   | 165,824  |  |  |  |  |
| Change in liability                          |                      | (140,000) |    | (12,518) |      | (67,965) |  |  |  |  |
| Ending balance of product warranty liability | \$                   | 178,342   | \$ | 165,824  | \$   | 97,859   |  |  |  |  |

# **Revenue Recognition**

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

form10-ksba.htm Page 81 of 97

#### Table of Contents

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

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

#### **Product Sales**

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

Net sales include the sales of the API Enzyme that are recognized at the time the product is shipped to customers. Net sales also include fees the Company charges Abbott for testing topical collagenase products manufactured by Abbott. Net sales from testing are recognized when invoiced. The Company also earns royalties on topical collagenase sales in the U.S. pursuant to its licensing agreement with Abbott. Royalties are recognized during the period in which the product is delivered to distributors in the U.S., as reported to the Company by Abbott.

# Royalty Revenue

Royalties are based on the licensees' net sales of products that utilize our technology and are recognized as earned in accordance with the contract terms when royalties from licensees can be reliably measured, and collectibility is reasonably assured, such as upon the receipt of a royalty statement from our licensees. We have historically recognized royalty revenue in the quarter in which the sale was made by our licensees.

## License Fees

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

## Upfront License Fees

We generally recognize revenue from upfront 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 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

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.

form10-ksba.htm Page 82 of 97

#### Table of Contents

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

## **Allowance for Doubtful Accounts**

Our policy is to write off bad debts as uncollectible when it is determined that they cannot be collected. We have not set up a reserve because almost all of over receivables are from one customer, Abbott.

## **Research and Development Expenses**

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

# **Clinical Trial Expenses**

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

# Stock Based Compensation.

The Company has three stock-based employee compensation plans in effect which are described more fully in Note 13. We account for our plans under the recognition and measurement principles of Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees," (APB Opinion No. 25) and related Interpretations. Accordingly, we recognize no compensation expense in our consolidated statements of operations with respect to options awarded to our employees with exercise prices greater than or equal to the fair value of the underlying common stock at the date of grant. However, we recognize compensation expense in our consolidated statements of operations with respect to the modification of certain employee stock option awards. In 2005 and 2004, we recognized approximately \$60,000 and \$13,000, respectively, in stock-based compensation expense related to modification of certain employee stock option awards, compared to none in 2003. The tables below illustrate the effect on net loss and net loss per share if we had applied the fair value recognition provisions of Financial Accounting Standards Board ("FASB") Statement No. 123, "Accounting for Stock-Based Compensation" ("SFAS 123"), as amended by FASB Statement No. 148, "Accounting for Stock-Based Compensation - Transition and Disclosure," ("SFAS 128") to our stock-based employee compensation plans.

form10-ksba.htm Page 83 of 97

#### Table of Contents

| Year Ended  | December 31,<br>2005 |             | <br>December 31,<br>2004 | <br>Restated<br>December 31,<br>2003 |
|---|----------------------|-------------|--------------------------|--------------------------------------|
| Net loss as reported  Deduct: Total stock-based employee compensation expenses determined under fair value based method for | \$                   | (1,296,746) | \$<br>(3,658,741)        | \$<br>(3,199,543)                    |
| all awards, net effect of minority interest   |                      | (105,587)   | (236,573)                | (221,361)                            |
| Pro forma net loss<br>Basic and diluted net loss per share:   | \$                   | (1,402,333) | \$<br>(3,895,314)        | \$<br>(3,420,904)                    |
| As reported   |                      |             |                          |                                      |
| Basic and diluted   | \$                   | (0.26)      | \$<br>(0.75)             | \$<br>(0.68)                         |
| Pro forma   |                      |             |                          |                                      |
| Basic and diluted   | \$                   | (0.28)      | \$<br>(0.79)             | \$<br>(0.72)                         |

The fair value for each option granted was estimated at the date of grant using the Black-Scholes option-pricing model, one of the allowable valuation methods under SFAS 123, as amended by SFAS 148 with the following assumptions:

| Year Ended                       | <u>December 31, 2005</u> | <u>December 31, 2004</u> | <u>December 31, 2003</u> |
|----------------------------------|--------------------------|--------------------------|--------------------------|
| Average risk free interest rates | 6.00%                    | 4.51%                    | 4.75%                    |
| Average expected life (in years) | 5.00                     | 5.00                     | 5.00                     |
| Volatility                       | 87%                      | 82%                      | 82%                      |

The weighted-average fair value of the options granted during the calendar years 2005, 2004 and 2003 were estimated to be \$1.43, \$1.55 and \$0.95, respectively, for options granted at market value.

We account for stock options granted to non-employees at fair value using the Black-Scholes option-pricing model in accordance with EITF Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services." Stock options granted to non-employees 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 over the service period in which the non-employee provides services to the Company. We recognized stock-based compensation expense related to stock options issued to non-employees of approximately \$0, \$77,000 and \$14,000 for the calendar years ended December 31, 2005, 2004 and 2003, respectively.

## Property, Plant and Equipment

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

# Impairment of Long-Lived Assets

The Company evaluates the net realizable value of its property and equipment and other assets in accordance with Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS 144"), relying on a number of factors including operating results, business plans, economic projections and anticipated future cash flows. SFAS 144 requires recognition of impairment of long-lived assets in the event the net book value of such assets exceed the estimated future undiscounted cash flows attributable to such assets or the business to which such intangible assets relate. The Company recorded no impairment charges for the years ended December 31, 2005, 2004 and 2003.

form10-ksba.htm Page 84 of 97

#### Table of Contents

#### Fair Value of Financial Instruments

The carrying amounts reported in the balance sheet for cash, accounts payable, and accrued expenses approximate fair value based on the short-term maturity of these instruments.

#### **Concentration of Credit Risk**

The Company's financial instruments that are exposed to concentrations of credit risk consist primarily of cash and cash equivalents and trade accounts receivable. The Company places its cash and cash equivalents with high quality credit institutions. At times, such investments may be in excess of the FDIC or SIPC insurance limit. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risks. Financial instruments, which potentially subject the Company to concentrations of credit risk, consist principally of trade accounts receivable, as the Company does not require collateral or other securities to support customer receivables (see Note 10 below).

## **Income Taxes**

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

# **Cumulative Translation Adjustment**

The assets and liabilities of ABC-Curacao are denominated in U.S. dollars. ABC-Curacao conducts local transactions in local currency, which is translated using average exchange rates for the period. The local currency in Curacao is pegged to the U.S. dollar. Therefore, gains and losses resulting from translation are minimal and are included in stockholders' equity as a foreign currency translation.

#### **Recent Accounting Pronouncements**

FIN No. 46 "Consolidation of Variable Interest Entities" was effective immediately upon its issuance during fiscal 2003 for all enterprises with interests in variable interest entities created after January 31, 2003. In December 2003, FASB issued FIN No. 46 (R) that changes the effective dates for the recording of interests in variable interest entities created before February 1, 2003 beginning with the first interim reporting period ending after March 15, 2004. If an entity is determined to be a variable interest entity, it must be consolidated by the enterprise that absorbs the majority of the entity's expected losses if they occur, or receives a majority of the entity's expected residual returns if they occur, or both. Where it is reasonably possible that the enterprise will consolidate or disclose information about a variable interest entity, the enterprise must disclose the nature, purpose, size and activity of the variable interest entity and the enterprise's maximum exposure to loss as a result of its involvement with the variable interest entity in all financial statements issued after January 31, 2003. A determination has been made that although the lessor of our operating facility is a variable interest entity, the Company is not the primary beneficiary. Under FIN 46 the lessor will not be consolidated in the Company's consolidated balance sheet. The adoption of this interpretation in 2004 did not have an effect on the Company's financial statements.

In November 2004, the FASB issued SFAS No. 151, Inventory Costs-An Amendment of ARB No. 43, Chapter 4 ("SFAS No. 151"), SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing ("ARB No. 151"), SFAS No. 151 amends the guidance in ARB No. 43, Chapter 4, Inventory Pricing ("ARB No. 43") to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material (spoilage). Among other provisions, the new rule requires that items, such as idle facility expense, excessive spoilage, double freight, and re-handling costs, be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal" as stated in ARB No. 43. Additionally, SFAS No. 151 requires the allocation of fixed production overheads in the costs of conversion be based on the normal capacity of the production facilities. SFAS No. 151 is effective for fiscal years beginning after June 15, 2005, and is required to be adopted by the Company in the first quarter of fiscal 2006, beginning on January 1, 2006. The Company has determined that the adoption of SFAS No. 151 will have no effect on its consolidated results of operations and financial condition.

form10-ksba.htm Page 85 of 97

#### **Table of Contents**

In December 2004, the FASB issued SFAS No. 123 (revised 2004), "Share-Based Payment" (SFAS 123R), which replaces SFAS 123, "Accounting for Stock-Based Compensation," and supersedes APB Opinion No. 25, "Accounting for Stock Issued to Employees." SFAS 123R requires all share-based payments to employees, including grants of employee stock options and restricted stock, to be recognized in the financial statements based on their fair values, beginning with the first interim or annual period after December 15, 2005. The pro forma disclosures previously permitted under SFAS 123, will no longer be an alternative to financial statement recognition. We were required to adopt SFAS 123R on January 1, 2006. Under SFAS 123R, we must determine the appropriate fair value model to be used for valuing share-based payments, the amortization method for compensation cost and the transition method to be used at date of adoption. The transition methods include prospective and retroactive adoption options. Under the retroactive options, prior periods may be restated either as of the beginning of the year of adoption or for all periods presented. The prospective method requires that compensation expense be recorded for all unvested stock options and restricted stock at the beginning of the first quarter of adoption of SFAS 123R, while the retroactive methods would record compensation expense for all unvested stock options and restricted stock beginning with the first period restated. The adoption of SFAS 123R will have a material impact on our consolidated results of operations. We will adopt SFAS 123R using the prospective method and the Black-Scholes valuation model to calculate stock-based compensation expense. Based on this approach, we expect that total stock-based compensation expense for 2006 will be in the range of approximately \$700,000 to \$900,000. However, our estimate of future stock-based compensation expense is affected by our stock price, the number of stock-based awards our Board granted in 2006, as well as a number of complex and subjective valuation assumptions and the related tax effect. These valuation assumptions include, but are not limited to, the volatility of our stock price and employee stock option exercises. Actual results may differ materially from our estimates as a result of these factors, and we disclaim any obligation to update or revise this or any other forward-looking statements in this Report.

In March 2005, the FASB issued FASB Interpretation No. 47, Accounting for Conditional Asset Retirement Obligations - an interpretation of FASB Statement No. 143 (FIN 47), which requires companies to recognize a liability for the fair value of a legal obligation to perform asset retirement activities that are conditional on a future event if the amount can be reasonably estimated. We adopted the provisions of FIN 47 on December 31, 2005. No conditional asset retirement obligations were recognized and, accordingly, the adoption of FIN 47 had no effect on our financial statements.

In June 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections - a replacement of APB Opinion No. 20 and FASB Statement No. 3" (SFAS No. 154), which replaces APB Opinion No. 20, Accounting Changes and SFAS No. 3, Reporting Accounting Changes in Interim Financial Statements, and changes the requirements for the accounting for and reporting of a change in accounting principle. SFAS No. 154 applies to all voluntary changes in accounting principle, and also applies to changes required by an accounting pronouncement in the unusual instance that the pronouncement does not include specific transition provisions. SFAS No. 154 will be effective for accounting changes and corrections of errors made by us in fiscal years beginning after December 15, 2005. SFAS No. 154 does not change the transition provisions of any existing accounting pronouncements, including those that are in a transition phase as of the effective date of SFAS No. 154. We do not believe the adoption of SFAS No. 154 will have a material impact on our financial statements.

In July 2006, FASB issued Interpretation No. 48, "Accounting for Uncertainty in Income Taxes," which is effective for fiscal years beginning after December 15, 2006. The Interpretation prescribes a recognition threshold and measurement attribute for the financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. The Interpretation also provides guidance on derecognition, classification, interest and penalties, accounting for interim periods, disclosure, and transition. We will adopt the Interpretation on January 1, 2007. We are in the process of determining the impact of the Interpretation on our financial position and results of operations.

# 4. NET LOSS PER SHARE

form10-ksba.htm Page 86 of 97

#### Table of Contents

In accordance with FASB Statement No. 128, "Earnings Per Share," basic net loss per share amount is computed using the weighted-average number of shares of common stock outstanding during the periods presented, while diluted net loss per share is computed using the sum of the weighted-average number of common and common equivalent shares outstanding. Common equivalent shares used in the computation of diluted earnings per share result from the assumed exercise of stock options and restricted stock, using the treasury stock method. For all periods presented, we incurred a net loss, and as such, we did not include the effect of outstanding stock options and outstanding restricted stock, or in the diluted net loss per share calculations, as their effect would be anti-dilutive.

|                  | 1       | December 31, |           |  |  |  |  |  |
|------------------|---------|--------------|-----------|--|--|--|--|--|
| (In thousands)   | 2005    | 2004         | 2003      |  |  |  |  |  |
| Stock options    | 963,887 | 1,055,440    | 1,350,625 |  |  |  |  |  |
| Convertible Note |         | 456,750      | 456,750   |  |  |  |  |  |
| Warrants         | 10,000  | 10,000       | 10,000    |  |  |  |  |  |
| Total            | 973,887 | 1,522,190    | 1,817,375 |  |  |  |  |  |

Furthermore, for the calendar years ended December 31, 2004 and 2003, the Company also had 456,750 shares that would have been issued assuming \$1,141,875 aggregate principal amount of the 2003 Convertible Note was converted into the Company's common stock at a conversion price of \$2.50 per share. The investor made no election to convert the debt into equity and the 2003 Convertible Note was paid off in June 2005. These potentially dilutive securities are excluded in the calculation for calendar 2004 and 2003, since their effect would be anti-dilutive due to the net loss incurred in both years. In March 2003, the Company granted to an individual lender in consideration of a loan, warrants to purchase up to 10,000 common shares of the Company at \$1.18 per share, until March 11, 2008. We repaid the total outstanding balance in March 2005.

# 5. MARKETABLE SECURITIES

Marketable securities at December 31, 2004 and 2003 consist of common and preferred stock, with a cost basis of \$245,713 unrealized holding losses of \$242,687, and fair market value of \$3,026. Fair values are based upon quoted market prices.

We sold all marketable securities during 2005 realizing a loss of \$2,519 for the year ended December 31, 2005.

# 6. INVENTORIES, NET

Inventories, net consist of:

|                     | December 31, |           |    |           |    |         |  |  |
|---------------------|--------------|-----------|----|-----------|----|---------|--|--|
|                     |              | 2005      |    | 2004      |    | 2003    |  |  |
| Raw materials       | \$           | 84,087    | \$ | 109,671   | \$ | 65,166  |  |  |
| Work-in-process     |              | 2,532,629 |    | 2,028,732 |    | 815,286 |  |  |
| Reserved for recall |              |           |    | (133,140) |    |         |  |  |
|                     | \$           | 2,616,716 | \$ | 2,005,263 | \$ | 880,452 |  |  |

# 7. PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment consist of:

| December 31, |             |  |   |   |  |  |
|--------------|-------------|--|---|---|--|--|
| 2005         |             | 2004   |   |   | 2003   |  |
| \$           | 2,478,966   | \$   | 2,530,068   | \$  | 2,379,796  |  |
|              | 173,339     |  | 381,588   |   | 371,917  |  |
|              | 4,139,235   |  | 4,114,595   |   | 4,079,120  |  |
|              | 6,791,540   |  | 7,026,251   |   | 6,830,833  |  |
|              | (3,996,185) |  | (3,630,860)   |   | (2,985,730)  |  |
| \$           | 2,795,355   | \$   | 3,395,391   | \$  | 3,845,103  |  |
|              | \$          | \$ 2,478,966<br>173,339<br>4,139,235<br>6,791,540<br>(3,996,185) | 2005<br>\$ 2,478,966 \$<br>173,339<br>4,139,235<br>6,791,540<br>(3,996,185) | 2005     2004       \$ 2,478,966     \$ 2,530,068       173,339     381,588       4,139,235     4,114,595       6,791,540     7,026,251       (3,996,185)     (3,630,860) | 2005     2004       \$ 2,478,966     \$ 2,530,068     \$ 173,339       \$ 4,139,235     \$ 4,114,595       \$ 6,791,540     \$ 7,026,251       \$ (3,996,185)     \$ (3,630,860) |  |

form10-ksba.htm Page 88 of 97

## **Table of Contents**

Depreciation and amortization expense amounted to \$653,209, \$644,359 and \$699,129 for calendar years 2005, 2004 and 2003, respectively.

# 8. ACCOUNTS PAYABLE AND ACCRUED LIABILITIES

Accounts payable and accrued liabilities consist of the following:

|   |    | December 31, |    |           |    |           |  |  |  |  |
|---|----|--------------|----|-----------|----|-----------|--|--|--|--|
|   |    | 2005         |    | 2004      |    | 2003      |  |  |  |  |
| Trade accounts payable and accrued expenses | \$ | 1,898,002    | \$ | 1,184,401 | \$ | 1,191,471 |  |  |  |  |
| Accrued legal and other professional fees   |    | 124,984      |    | 940,545   |    | 542,036   |  |  |  |  |
| Accrued payroll and related costs           |    | 615,846      |    | 369,221   |    | 315,305   |  |  |  |  |
|   | \$ | 2,638,832    | \$ | 2,494,168 | \$ | 2,048,812 |  |  |  |  |

# 9. INCOME TAXES

The expense for income taxes consist of the following:

| Year ended       | December 31, |       |    |     |    |        |  |  |  |
|------------------|--------------|-------|----|-----|----|--------|--|--|--|
|                  |              | 2005  | 2  | 004 |    | 2003   |  |  |  |
| <u>Current:</u>  |              |       |    |     |    |        |  |  |  |
| Federal          | \$           |       | \$ |     | \$ | 13,000 |  |  |  |
| State            |              | 6,118 |    |     |    |        |  |  |  |
|                  | \$           | 6,118 | \$ |     | \$ | 13,000 |  |  |  |
| <u>Deferred:</u> |              |       |    |     |    |        |  |  |  |
| Federal          |              |       |    |     |    |        |  |  |  |
| State            |              |       |    |     |    |        |  |  |  |
|                  |              |       |    |     |    |        |  |  |  |
| Total            | \$           | 6,118 | \$ |     | \$ | 13,000 |  |  |  |

The effective income tax rate of the Company differs from the federal statutory tax rate of 35% in calendar years 2005, 2004 and 2003 as a result of the effect of the following items:

| Year ended                                     | December 31, |           |    |             |    |           |  |  |  |
|--|--------------|-----------|----|-------------|----|-----------|--|--|--|
|  |              | 2005      |    | 2004        |    | 2003      |  |  |  |
| Computed tax benefit at statutory rate         | \$           | 453,861   | \$ | 1,307,863   | \$ | 1,031,677 |  |  |  |
| Tax effect of foreign sourced income (loss)    |              | (150,495) |    | 163,923     |    | (397,422) |  |  |  |
| State income taxes, net of federal tax benefit |              | (3,971)   |    |             |    |           |  |  |  |
| Non-deductible expenses                        |              | (9,191)   |    | (13,909)    |    | (4,116)   |  |  |  |
| Orphan drug and other tax credits              |              | 554,498   |    | 99,038      |    | 25,394    |  |  |  |
| Increase in valuation allowance                |              | (844,702) |    | (1,556,914) |    | (642,533) |  |  |  |
|  | \$           |           | \$ |             | \$ | (13,000)  |  |  |  |

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

|                                 | December 31, |           |      |           |      |           |
|---------------------------------|--------------|-----------|------|-----------|------|-----------|
|                                 | 2005         |           | 2004 |           | 2003 |           |
| Tax Credit carryforward         | \$           | 2,119,864 | \$   | 1,158,125 | \$   | 1,059,087 |
| Inventory                       |              | 37,007    |      | 87,452    |      | 34,226    |
| Accrued expenses                |              | 68,727    |      | 68,726    |      | 61,918    |
| Depreciation and amortization   |              | 17,170    |      | 58,383    |      | 49,351    |
| Capital loss carryforward       |              | 68,178    |      | 68,178    |      | 66,412    |
| Net operating loss carryforward |              | 2,320,640 |      | 2,252,554 |      | 870,465   |

form10-ksba.htm Page 89 of 97

| Net deferred tax assets before valuation allowance<br>Valuation allowance |      | 4,631,586<br>(4,631,586) | 3,693,418<br>(3,693,418) | 2,141,458<br>(2,141,458) |
|---|------|--------------------------|--------------------------|--------------------------|
| Net deferred tax asset  |      | \$<br>                   | \$<br>- \$               |                          |
|   | F-21 |                          |                          |                          |

form10-ksba.htm Page 90 of 97

#### Table of Contents

SFAS No. 109 requires a valuation allowance against deferred tax assets if, based on the weight of available evidence, it is more likely than not that some or all of the deferred tax assets may not be realized. The Company increased the valuation allowance by \$844,702, \$1,556,914 and \$642,533 during the years ended December 31, 2005, 2004 and 2003, respectively. The net deferred tax asset has been fully reserved due to the uncertainty of the Company's ability to generate taxable income under the more likely than not criteria of FAS 109.

The Company had domestic losses before taxes of \$1,537,343 for the year ended December 31, 2005 and domestic losses before taxes of \$3,794,437 and \$1,787,960 for the years ended December 31, 2004 and 2003, respectively. The Company had foreign income before taxes of \$233,188 for the year ended December 31, 2005 and foreign income before taxes of \$135,697 for the year ended December 31, 2004. For the year ended December 31, 2003 the Company had foreign losses before taxes of \$1,482,370. The Company has permanently reinvested the accumulated earnings of its foreign subsidiaries, mostly in the form of plant, property and equipment, and therefore will not repatriate the net balance of such earnings (approximately \$1.3 million as of December 31, 2005) to the U.S.

In November 2000, the Curacao government extended a 2% profit tax rate to ABC-Curacao for an additional 15 years. The statutory rate is 30%.

At December 31, 2005, 2004 and 2003, the Company had net operating loss carryforwards of approximately \$5.8 million, \$5.1 million and \$2.1 million for Federal income tax purposes, respectively. At December 31, 2005, 2004 and 2003, the Company had net operating loss carryforwards of approximately \$7.8 million, \$7.0 million and \$4.1 million for State income tax purposes, respectively. These will expire at various dates from 2022 through 2025. As of December 31, 2005, the Company has approximately \$2.1 million in tax credits, which expire at various dates from 2018 through 2025.

#### 10. CREDIT FACILITIES

In November 2001, ABC-Curacao borrowed a non-amortizing loan of \$455,000 at 6.5% interest due in November 2003 from Korpodeko. In September 2003, Korpodeko agreed to modify the terms of the loan. In return, we agreed to an interest rate increase from 6.5% to 7.5% from November 2003 to the new maturity in November 2004. We repaid \$91,000 of the loan in December 2003. In November 2004 we repaid \$182,000 and Korpodeko agreed to extend the payment, with no additional consideration, of the balance for up to an additional twelve months. We repaid the remaining outstanding balance in full in June 2005.

In March 2003, the Company borrowed \$100,000 from an individual lender, evidenced by a one-year promissory note, bearing interest of 8% per annum, which was due March 11, 2004. In March 2004, the holder of the note extended the note for one year at which time the loan was repaid in full. The Company granted to the lender warrants to purchase up to 10,000 common shares of the Company at \$1.18 per share, until March 11, 2008.

On June 19, 2003, the Company entered into a financing transaction with Bio Partners, pursuant to which the Company sold to Bio Partners in a private placement (i) the \$1.575 million 2003 Convertible Note issued at face value, and (ii) 295,312 shares of Company common stock, issued at par value, or \$.001 per share. The net proceeds to the Company were approximately \$890,000, after the payment of expenses and repayment of \$500,000 previously advanced to the Company by a principal of Bio Partners.

form10-ksba.htm Page 91 of 97

#### Table of Contents

The 2003 Convertible Note matured on June 19, 2005 and bore interest at a rate of 12% per annum. Interest-only payments under the 2003 Convertible Note were payable monthly in arrears and the entire principal amount was payable at maturity. We repaid the loan in full on the maturity date. At the time the agreement was made, up to \$1,141,875 aggregate principal amount of the 2003 Convertible Note was convertible into the Company's common stock at any time, at a conversion price of \$2.50 per share, subject to customary adjustments. None of the 2003 Convertible Note was converted into the Company's common stock. The loan discount of approximately \$281,000 and loan costs of approximately \$258,000 on the 2003 Convertible Note were amortized over two years, the life of the 2003 Convertible Note.

#### 11. MAJOR CUSTOMER AND ROYALTY AND LICENSE AGREEMENTS

The Company derives most of its net sales of the product, and all of its royalty revenues, from one customer in the U.S., Abbott, who, pursuant to an exclusive licensing agreement, compounds the product into topical collagenase, which is used to debride chronic dermal ulcers and severely burned areas.

Abbott accounted for approximately \$3,975,000, \$2,340,000 and \$2,906,000 of our product sales and royalties for the calendar years 2005, 2004 and 2003, respectively. These amounts were approximately 94%, 96% and 90% of our non licensing revenues during calendar years 2005, 2004 and 2003, respectively.

The royalty revenues from Abbott were earned on U.S. sales of topical collagenase. Royalties from Abbott were \$1,073,620, \$784,933 and \$1,683,915 in calendar years 2005, 2004 and 2003, respectively.

In fiscal 1997, the Company entered into an agreement to license topical collagenase for sale in Germany to the German subsidiary of an international pharmaceutical company. The agreement calls for an initial payment on signing and further payments if and when the German health authority grants marketing approval of topical collagenase. Accordingly, deferred revenue at December 31, 2005 is \$45,000 from this agreement. DFB has acquired this liability as part of their purchase of the topical collagenase business.

## 12. FOREIGN OPERATIONS

The Company had a manufacturing facility located in Curacao, Netherlands Antilles through March 6, 2006. The local currency is tied to the U.S. dollar; as a result no material gain or loss is incurred on foreign currency transactions.

# 13. STOCKHOLDERS' EQUITY

## **Stock Option Plans**

In July 1994, the Company's stockholders approved a stock option plan for eligible key employees, directors, independent agents, and consultants who make a significant contribution toward the Company's success and development and to attract and retain qualified employees (the "1993 Plan"), which expired in July 2004. Under the 1993 Plan, qualified incentive stock options and non-qualified stock options may be granted to purchase up to an aggregate of 200,000 shares of the Company's common stock, subject to certain anti-dilution provisions. The exercise price per share of common stock may not be less than 100% (110% for qualified incentive stock options granted to stockholders owning at least 10% of common shares) of the fair market value of the Company's common stock on the date of grant. In general, the options vest and become exercisable in four equal annual installments following the date of grant, although the Board, at its discretion, may provide for different vesting schedules. The options expire ten years (five years for qualified incentive stock options granted to stockholders owning at least 10% of common shares) after such date. In accordance with terms of the 1993 Plan, no option shall be granted ten years after the effective date of the 1993 Plan, or July 2004.

In July 1997, the Company's stockholders approved a stock option plan (the "1997 Plan") with terms identical to the 1993 Plan. The 1997 Plan authorizes the granting of awards of up to an aggregate of 500,000 shares of the Company's common stock, subject to certain anti-dilution provisions. The 1997 Plan expires in July 2007.

form10-ksba.htm Page 92 of 97

#### Table of Contents

In August 2001, the Company's stockholders approved a stock option plan (the "2001 Plan"), with terms similar to the 1997 Plan. The 2001 Plan authorizes the granting of awards of up to an aggregate of 750,000 shares of the Company's common stock, subject to certain anti-dilution provisions. On December 16, 2003, stockholders approved an amendment to the 2001 Plan, which increased the number of shares authorized for grant from 750,000 shares to 1,750,000 shares, an increase of 1,000,000 shares. A total of 1,750,000 shares of common stock are now authorized for issuance under the amended 2001 Plan. The 2001 Plan, as amended expires in August 2011. The Company never filed an S-8 for the 2001 Plan.

As of December 31, 2005 there were a total of 1,242,263 shares available for grant from the 1997 and 2001 Plans.

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

|                                   | December 31, |           |          |           |    |         |           |            |         |
|-----------------------------------|--------------|-----------|----------|-----------|----|---------|-----------|------------|---------|
|                                   | 200          | <u>05</u> |          | 200       | )4 |         | 200       | <u> 13</u> |         |
|                                   |              | W         | eighted  |           | W  | eighted |           | W          | eighted |
|                                   |              | A         | verage   |           | A  | verage  |           | A          | verage  |
|                                   |              | E         | exercise |           | E  | kercise |           | E          | xercise |
|                                   | Shares       |           | Price    | Shares    | 1  | Price   | Shares    |            | Price   |
| Outstanding at beginning of year  | 1,056,358    | \$        | 1.63     | 1,350,625 | \$ | 1.77    | 1,358,325 | \$         | 1.98    |
| Options granted                   | 37,054       |           | 1.44     | 80,958    |    | 1.56    | 50,000    |            | 1.28    |
| Options exercised                 | (13,875)     |           | 1.00     | (65,425)  |    | 1.00    |           |            |         |
| Options canceled or expired       | (115,650)    |           | 2.36     | (309,800) |    | 4.62    | (57,700)  |            | 2.77    |
| Outstanding at end of year        | 963,887      | \$        | 1.63     | 1,056,358 | \$ | 1.63    | 1,350,625 | \$         | 1.77    |
| Options exercisable at year end   | 918,887      | \$        | 1.44     | 920,913   | \$ | 1.67    | 1,250,625 |            | 1.86    |
| Shares available for future grant | 1,242,263    |           |          | 1,226,200 |    |         | 1,006,150 |            |         |

During calendar year 2005, the Company granted 37,054 options to employees. During calendar year 2004, the Company granted 20,958 options to employees, 50,000 options to a consultant and 10,000 options to a director. The options granted in 2005 and 2004 were granted at exercise prices ranging from \$0.80 to \$2.05 per share. In both 2005 and 2004, 20,000 options that were granted vested over 4 years, while the remaining options that were granted vested immediately. In 2003, the Company granted 35,000 options to employees at prices ranging from \$1.20 to \$1.38 that vested over a 4 year period. In 2003, the Company granted 15,000 options to consultants at an exercise price of \$1.23 that vested one year from the date of grant.

The following table summarizes information relating to stock options by exercise price at December 31, 2005:

| <b>Outstanding</b> |               |              | <b>Exercisable</b> |               |               |  |
|--------------------|---------------|--------------|--------------------|---------------|---------------|--|
|                    |               |              | Weighted           |               | Weighted      |  |
| Option             |               | Weighted     | Average            |               | Average       |  |
| Exercise           |               | Average Life | Exercise           |               | Option        |  |
| <b>Price</b>       | <b>Shares</b> | (years)      | <b>Price</b>       | <b>Shares</b> | <b>Price</b>  |  |
| \$0.80-1.49        | 693,604       | 6.08         | \$1.01             | 684,224       | \$1.01        |  |
| 1.50-1.99          | 180,737       | 6.81         | 1.69               | 144,355       | 1.72          |  |
| 2.00-2.99          | 35,671        | 4.60         | 2.65               | 35,583        | 2.65          |  |
| 3.00-3.99          | 27,500        | 2.83         | 3.23               | 27,500        | 3.23          |  |
| 4.00-4.99          | 23,875        | 2.36         | 4.29               | 23,875        | 4.29          |  |
| 5.00-6.05          | <u>2,500</u>  | <u>2.33</u>  | <u>\$5.81</u>      | <u>2,500</u>  | <u>\$5.81</u> |  |
|                    | 963,887       | 5.88         | \$1.45             | 938,038       | \$1.44        |  |

# 14. COMMITMENTS AND CONTINGENCIES

# Lease Agreements

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

form10-ksba.htm Page 93 of 97

#### Table of Contents

Year ending December 31,

| 2006       | \$160,000 |
|------------|-----------|
| 2007       | 154,000   |
| 2008       | 154,000   |
| 2009       | 153,000   |
| 2010       | 75,000    |
| thereafter | -0-       |

The above schedule includes the lease for the Curacao facility for the months of January and February 2006 only, as a result of the transfer of the lease to DFB as part of the sale of the topical collagenase business.

Rent expense under all operating leases amounted to approximately \$240,000 for both calendar years 2005 and 2004 and \$244,000 for 2003. Until the death of Edwin H. Wegman, our former Chairman and CEO, The S.J. Wegman Company was the 100% shareholder of the Wilbur Street Corporation ("WSC"), which owns and leases the Lynbrook, NY facility to ABC-NY. Edwin H. Wegman was the general partner of The S.J. Wegman Company, a limited partnership. Upon his death on February 16, 2007, The S.J. Wegman Company was legally dissolved. However, his death had no effect on the legal existence of WSC. The shares of WSC will be distributed to the partners of The S.J. Wegman Company in accordance with the provisions of the partnership agreement. At the present time, we do not know who will own or control the shares of WSC.

In January 1998, WSC and the Company entered into a triple net lease agreement that provides for an annual rent starting at \$125,000, which can increase annually by the amount of the annual increase in the consumer price index for the greater New York metropolitan region. The lease term was 7 years and expired on January 31, 2005. The Company paid and accrued approximately \$204,000, \$199,000 and \$214,000 representing rent, real estate taxes and insurance to WSC in 2005, 2004 and 2003, respectively. Without Board approval, the lease was renewed (a related party transaction) in July 2005 for an additional 5 years, expiring on June 30, 2010. The extension of the lease may thus not be valid. The annual base rent, exclusive of taxes and related insurance, will be \$150,000 (\$10 per square foot) per annum commencing in February 2006. Our rent can increase annually by the amount of the annual increase in the consumer price index for the greater New York metropolitan region.

ABC-Curacao leases a building in Brievengat, Curacao, Netherlands Antilles from an unrelated company wholly-owned by the Insular Territory of Curacao. The lease term, which originally commenced on January 1, 1977, is automatically renewed upon the same terms every five years, unless either party gives three months notice prior to the expiration of the five-year period. The lessor is entitled to revalue the rent for each successive five-year period. The lease has been renewed through March 1, 2011 and was assumed by DFB effective March 6, 2006. Rent expense, exclusive of charges for guard service amounted to approximately \$30,000 in calendar years 2005, 2004 and 2003.

# **Potential Product Liability**

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

# **Employment Agreement**

We have no employment agreements with any employees. The Company had an employment agreement with the managing director of our German subsidiary, BioSpecifics Pharma GmbH, which was cancelable upon one year's written notice. The agreement provided for an annual salary of \$195,000, and a severance payment if we terminated the agreement without cause. The managing director resigned from the Company in January 2004 and as a director on April 30, 2004. We believe that we have no liability to him for severance pay.

form10-ksba.htm Page 94 of 97

Table of Contents

#### **FDA Observation**

Following an inspection by the FDA in 1999, the Company was informed that its license to manufacture the API Enzyme and topical collagenase would be revoked unless the Company could immediately provide satisfactory assurance of its compliance with the applicable cGMP regulations (the "1999 FDA Letter"). The Company submitted such a plan to the FDA later in 1999.

On July 28, 2003 the Company received a letter notification from the FDA approving our supplement to our biologics license to manufacture topical collagenase. Regardless of this FDA approval, the 1999 FDA Letter will remain in effect until the Company demonstrates compliance with the applicable federal standards and regulations discussed above. During the quarter ended June 30, 2004, the FDA completed an inspection of the Company's Lynbrook facility. In May 2004, the FDA inspected the facility of Abbott, the Company's subcontractor. No action was taken by the FDA in regards to either of these inspections. In January 2005 the FDA completed an inspection of our Curacao facility. We have responded to various observations made by the FDA as a result of this inspection. The FDA letter was still in effect when BioSpecifics sold the topical collagenase business to DFB in March of 2006.

As a result of the sale of the Curacao facility to DFB, the FDA has transferred all rights under our license related to the manufacturing of topical collagenase to DFB. We were only required to report any adverse events for the topical collagenase product that occurred prior to the date of sale.

## 15. RELATED PARTY TRANSACTIONS

The S.J. Wegman Company owns WSC, which has leased to ABC-NY a building serving as a manufacturing facility and headquarters in Lynbrook, New York for over 30 years. The building also serves as the Company's administrative headquarters. Edwin H. Wegman, the Company's former Chairman and CEO, was the President of WSC and the sole general partner of The S.J. Wegman Company, a limited partnership. Upon his death on February 16, 2007, The S.J. Wegman Company was legally dissolved. However, his death had no effect on the legal existence of WSC. The shares of WSC will be distributed to the partners of The S.J. Wegman Company in accordance with the provisions of the partnership agreement. At the present time, we do not know who will own or control the shares of WSC. These shares are subject to a pledge agreement, under which the dissolution of The S.J. Wegman Company constitutes an event of default, giving the Board the right to vote the pledged shares.

In January 1998, WSC and the Company entered into a triple net lease agreement that provides for an annual rent starting at \$125,000, which was to increase annually by the amount of annual increase in the consumer price index for the greater New York metropolitan region. The lease term was 7 years and expired on January 31, 2005. Without Board approval, the lease was renewed (a related party transaction) in July 2005 for an additional 5 years, expiring on June 30, 2010. The extension of the lease may thus not be valid. The annual rent, effective February 2006, is \$150,000 (\$10 per square foot) per annum.

The Company has an outstanding loan to the Company's former Chairman and CEO. The loan, whose principal balance at December 31, 2005, 2004 and 2003 was \$625,774 and is a demand promissory note, bears interest at 9% per annum. The Company also has two loans with WSC, an affiliate of our former Chairman and CEO. One loan is in the amount of \$82,606 and bears interest at 9% per annum; the other is for advances to WSC in the amount of \$15,647 and bears no interest. For financial statement purposes, all these loans, which aggregate \$724,027 of principal, are classified as components of stockholders' equity in the balance sheet and appear as "Notes due from former Chairman and CEO and other related party." During calendar years 2005 and 2004, the former Chairman and CEO repaid net principal of \$0 and \$12,189, respectively, on these loans. There is no assurance that the Company will be able to collect on these notes. Interest income accrued for these loans, but not recognized for financial statement purposes, aggregated approximately \$107,000, \$99,000 and \$37,000 for the calendar years 2005, 2004 and 2003, respectively.

In January 2007 we entered into amended and restated demand promissory notes with Edwin H. Wegman and WSC reflecting the prior outstanding principal amounts of the loans and compounded interest (collectively, the "Notes").

form10-ksba.htm Page 95 of 97

#### Table of Contents

Upon the death of Edwin H. Wegman on February 16, 2007, his note became the obligation of his estate. As of December 31, 2006, the aggregate principal amounts, including compounded interest, owed to us by Edwin H. Wegman and WSC were \$1,016,595 and \$304,390, respectively. Under the Notes, the respective principal amounts remaining unpaid at any time shall each bear interest at the rate of nine percent (9%) per annum compounded annually. The loans are secured by a pledge of 100% of the shares owned by The S.J. Wegman Company. Notwithstanding the dissolution of The S.J. Wegman Company upon the death of Edwin H. Wegman, the Notes continue to be secured by The S.J. Wegman Company pledge.

During March of 2005, the former Chairman and CEO received an advance, which could be considered a loan, in the amount of \$6,000, which was subsequently repaid within two weeks. No interest was accrued.

ABC-NY had notes payable to a former director of the Company and to a partner of the S.J. Wegman Company, an affiliate, amounting to \$24,894 at December 31, 2005. The notes, which bore interest at nine percent (9%) per annum, were payable on demand. The loan was subsequently repaid in December 2006.

During April 2004, we received a \$45,000 loan from the wife of the former Chairman and CEO. The loan was subsequently repaid in December 2006.

## 16. 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 2005, 2004 or 2003.

# 17. SUBSEQUENT EVENTS

In March 2006, we sold our topical collagenase business to DFB. In order to help effectuate the transaction with DFB, we repurchased all of the outstanding shares of ABC-NY and ABC-Curacao held by minority shareholders in exchange for a combination of approximately \$83,000 in cash and 102,574 restricted shares of our treasury stock.

In July 2006, we entered into a settlement agreement and specific release with Edwin H. Wegman, Thomas L. Wegman, Bio Partners, (whose sole general partner, Bio Management, Inc., a New York corporation, is wholly-owned by Jeffrey K. Vogel), and Jeffrey K. Vogel to settle a dispute regarding certain loan commitment fees purportedly due from us to Bio Partners under a letter agreement, dated January 3, 2006, between Bio Partners and us and to provide for the termination of certain loan and investor related documents that were previously filed as material agreements.

In November 2006, we signed license agreements with respect to Dupuytren's disease (the "Dupuytren's Disease License Agreement") and frozen shoulder (the "Frozen Shoulder License Agreement"). In the Dupuytren's Disease License Agreement the Research Foundation granted to us and our affiliates an exclusive worldwide license, with the right to sublicense to certain third parties, to know-how owned by the Research Foundation related to the development, manufacture, use or sale of (i) the collagenase enzyme obtained by a fermentation and purification process (the "Enzyme"), and (ii) all pharmaceutical products containing the Enzyme or injectable collagenase, in each case to the extent it pertains to the treatment and prevention of Dupuytren's disease.

In the Frozen Shoulder License Agreement 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 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.

form10-ksba.htm Page 96 of 97

## Table of Contents

On February 16, 2007 our Chairman and CEO, Edwin H. Wegman, died. As of December 31, 2006 our former Chairman and CEO owed to us an aggregate amount of \$1,016,595. We entered into an amended and restated promissory note for this amount with our former Chairman and CEO, which is secured by a pledge of 100% of the shares of The S.J. Wegman Company. His death has resulted in the immediate obligation of his estate to repay the loan. However, it is uncertain whether his estate will be able to repay the loan and, if so, on what terms. His death has also resulted in the dissolution of The S.J. Wegman Company, which triggered a default under the pledge agreement, giving our Board the right to vote the pledged shares. However, it is unclear as a practical matter whether the Company will be able to foreclose on the pledge.

In addition to the foregoing subsequent events, there have been a number of additional events that are described in the Form 8-Ks that have been filed by the Company since December 31, 2005 that are listed in Item 13, "Exhibits—Reports on Form 8-K."

form10-ksba.htm Page 97 of 97

## **SIGNATURES**

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

Date: August 28, 2007

# BIOSPECIFICS TECHNOLOGIES CORP.

By: /s/ Thomas L. Wegman

Thomas L. Wegman 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    | President (Principal Executive Officer and Principal Financial Officer) |
| Name: Thomas L. Wegman  |   |
| /s/ Thomas L. Wegman    |   |
| Name: Thomas L. Wegman  | Director  |
| /s/ Henry Morgan        |   |
| Name: Henry Morgan      | Director  |
| /s/ Michael Schamroth   |   |
| Name: Michael Schamroth | Director  |
| /s/ Paul Gitman         |   |
| Name: Paul Gitman       | Director  |