P.E 9/30/06

AR/S

0-51383

FEB 09, 2007

PROCESSED

FEB 16 2007

THOMSON
FINANCIAL

ACCENTIA
BIOPHARMACEUTICALS

2006 ANNUAL REPORT

To Our Shareholders:

We are pleased to present our fiscal 2006 annual report and share the clinical and commercial developments achieved by Accentia during the fiscal year. We reached significant clinical milestones in the development of SinuNase™ and BiovaxID™ during the year and also accomplished the commercial launch of MD Turbo™ and regulatory approval of AutovaxID™. We remain focused on the development and commercialization of late-stage, targeted therapeutic clinical products in the areas of respiratory disease and, through our majority-owned publicly-traded subsidiary, Biovest International Inc., oncology.

> > > Looking Back on Fiscal 2006

Product Development Programs:

Significant progress was made during the year in the development of SinuNase and BiovaxID, our two primary product candidates, both of which are currently in Phase 3 clinical trials. With respect to SinuNase, a potential prescription intranasal amphotericin B formulation in development to treat chronic sinusitis was granted Fast-Track Status from the product from the U.S. Food and Drug Administration (FDA) in June 2006. As a result, we moved forward and recently commenced the first of two confirmatory 16-week Phase 3 clinical trials. If SinuNase is approved by the FDA, Accentia will have the first product available for the estimated 31 million Americans that suffer from chronic sinusitis. Additionally, in August we signed an amendment to our license agreement with the Mayo Foundation for Medical Research and Education (Mayo Clinic) that granted Accentia an exclusive worldwide license to all non-prescription, over-the-counter products based on amphotericin B that are intended to treat symptoms associated with chronic sinusitis. We intend to explore all commercial opportunities through our agreement with Mayo and look forward to reporting SinuNase developments in 2007.

Through our majority-owned subsidiary, Biovest International, significant advancements were made this year in the development of BiovaxID, a personalized biologic therapeutic vaccine in development for follicular non-Hodgkin's lymphoma. Biovest was granted Fast-Track Status from the FDA and Orphan Medicinal Product Designation by the European Medicines Agency in October 2006. In 2006 Biovest received regulatory approval to open up to 30 new clinical sites in Russia and the Ukraine which is expected to

dramatically increase the number of patients being enrolled for treatment with BiovaxID during the next 12 to 18 months. BiovaxID also received further clinical recognition this year through an independent study that demonstrated a highly significant clinical benefit from the use of a BiovaxID formulation in relapsed non-Hodgkins lymphoma patients. We are targeting patient enrollment to be complete in 2008 and look forward to updating you on BiovaxID developments as we move forward.

Commercial Launch

This year, we also announced the commercial launch of MD Turbo and FDA approval of AutovaxID, and we look forward to the commercialization of both products in 2007. In the third quarter, we received inventory of MD Turbo and initiated the U.S. commercial launch in June. The device is now available at pharmacies to patients by prescription, and is the first and only commercial product available to provide breath-activated delivery and dose-counting capabilities for traditional asthma inhalers. We also successfully established MD Turbo as a covered prescription benefit in managed care plans covering approximately 150 million people and as a covered benefit with plan sponsors under Medicare Part D. Through our internal sales force at Accentia Pharmaceuticals and the co-promotion agreement with Exaeris, Inc., we are aggressively marketing MD Turbo and anticipate that the product will gain significant exposure in 2007.

In the fourth quarter of fiscal 2006, Biovest received clearance from the FDA for the commercial sale of AutovaxID, the first and only device to automate the production of complex biologics including BiovaxID. Commercial sales of the AutovaxID commenced in the 4th quarter of 2006. Biovest is in the process of creating a new 24,000 sq. ft. AutovaxID manufacturing facility in St. Louis, Missouri to meet the anticipated demand for these instruments. We feel that AutovaxID has the potential to replace conventional cell-growth chambers that require up to ten times as much laboratory space, as well as additional labor and increased expenses. The instrument is expected to be a significant enabling technology for the emerging field of personalized medicine by allowing companies to process personalized therapeutics in far less costly facilities while still maintaining sterility and strict segregation of patient-specific materials. We look forward to accelerating the AutovaxID production program and anticipate reporting expanding sales in fiscal year 2007.

> > > Business Strategy Moving Forward

Since our inception, our goal has been to acquire, develop, and commercialize innovative late-stage biopharmaceutical and medical device products that offer the potential for superior efficacy and safety and that address significant unmet medical needs. Both SinuNase and BiovaxID are good examples of our product strategy. As we move forward, we will remain focused on identifying, acquiring, developing and commercializing additional late-stage clinical products. In particular, we will seek products that are based on already approved drugs for new indications, and/or new formulations pursuant to issued patents, in order to create additional clinically and economically valuable products. These kinds of opportunities often can access the less costly and less time-consuming 505(b)(2) regulatory pathway, which allows sponsors to reference prior publications and approvals of the active pharmaceutical ingredient, albeit in different formulations. By focusing on these kinds of product opportunities, Accentia believes that it can expand its product offerings with less risk, less expense, and less time than required for new chemical entities, which must use a lengthier and more rigorous regulatory pathway. On this front, we intend to pursue the acquisition of these kinds of additional products that could increase the value of our development pipeline and complement our existing products and product candidates. This may consist of product or technology acquisitions, in-licensing, or company acquisitions. Although our primary emphasis in acquiring new products will be in the respiratory and oncology therapeutic areas, including supportive care, we will consider products in other therapeutic areas that meet our stringent criteria.

We would like to note the extraordinary efforts throughout fiscal 2006 of our management team and employees. They continue to build value for Accentia, and we appreciate their dedication to the company. We also thank you, our shareholders, for your ongoing commitment and support. We are pleased to have you as a part of the Accentia family.

Sincerely,

Francis E. O'Donnell, Jr., M.D.
Chairman and Chief Executive Officer

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

FORM 10-K

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

For the fiscal year ended September 30, 2006

OR

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

For the transition period from _____ to _____ .

Commission File Number 000-51383

ACCENTIA BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Florida	**04-3639490**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
324 South Hyde Park Ave., Suite 350 Tampa, Florida	**33606**
(Address of principal executive offices)	***(Zip Code)***

(813) 864-2554
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

None

Securities registered pursuant to Section 12(g) of the Act:

Common Stock, par value $0.001 per share
(Title of class)

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer. See *definition of* "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐ Accelerated filer ☐ Non-Accelerated filer ☒

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.): Yes ☐ No ☒

As of March 31, 2006, the aggregate market value of the voting stock held by non-affiliates of the registrant, computed by reference to the last sale price of such stock as of such date on the Nasdaq Global Market, formerly known as, Nasdaq National Market, was approximately $31,218,033.

As of December 1, 2006, there were 31,717,467 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's *definitive Proxy Statement* for the 2007 Annual Meeting of Stockholders, which will be filed with the Securities and Exchange Commission pursuant to Regulation 14A not later than 120 days after the end of the fiscal year covered by this Form 10-K, are incorporated by reference in Part III of this Form 10-K.

Forward-Looking Statements

Statements in this annual report on Form 10-K that are not strictly historical in nature are forward-looking statements. These statements include, but are not limited to, statements about: the timing of the commencement, enrollment, and completion of our clinical trials for our product candidates; the progress or success of our product development programs; the status of regulatory approvals for our product candidates; the timing of product launches; our ability to protect our intellectual property and operate our business without infringing upon the intellectual property rights of others; and our estimates for future performance, anticipated operating losses, future revenues, capital requirements, and our needs for additional financing. In some cases, you can identify forward-looking statements by terms such as "anticipates," "believes," "could," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "will," "would," "goal," and similar expressions intended to identify forward-looking statements. These statements are only predictions based on current information and expectations and involve a number of risks and uncertainties. The underlying information and expectations are likely to change over time. Actual events or results may differ materially from those projected in the forward-looking statements due to various factors, including, but not limited to, those set forth under the caption "Risk Factors" in "ITEM 1A. RISK FACTORS" and elsewhere in this annual report on Form 10-K. Except as required by law, we undertake no obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

PART I

ITEM 1. BUSINESS

In this annual report on Form 10-K, unless the context indicates otherwise, references to "Accentia," "the Company," "our company," "we," "us," and similar references refer to Accentia Biopharmaceuticals, Inc. and its subsidiaries. All references to years in this Form 10-K, unless otherwise noted, refer to our fiscal years, which end on September 30. For example, a reference to "2006" or "fiscal 2006" means the 12-month period ended September 30, 2006.

Overview

We are a biopharmaceutical company focused on the development and commercialization of late-stage, targeted therapeutic clinical products in the areas of respiratory disease and, through our majority-owned publicly-traded subsidiary, Biovest International Inc., oncology. We have two products with fast-track status in Phase 3 clinical trials. Our first such product candidate, SinuNase™, is being developed as a treatment for chronic rhinosinusitis (CRS), also commonly referred to as chronic sinusitis, which is a chronic inflammatory condition of the paranasal sinuses that results in nasal congestion, facial pain and pressure, nasal discharge, and headaches. SinuNase is an amphotericin B suspension that is self-administered into a patient's nasal cavity for the treatment of CRS. If approved by the FDA, we expect that SinuNase would be the first pharmaceutical product indicated for the treatment of chronic sinusitis. We submitted an Investigational New Drug Application, or IND, with the FDA for SinuNase in April 2005 and we have recently commenced the first of two Phase 3 clinical trials for SinuNase for patients who have recurrent CRS.

Our second product candidate, BiovaxID™, under development by our subsidiary, Biovest International Inc., a publicly held company in which we currently hold approximately 78% of the outstanding capital stock ("Biovest") is a patient-specific anti-cancer vaccine focusing on the treatment of follicular non-Hodgkins lymphoma, or follicular NHL. Follicular NHL is a cancer of the lymphatic system that results when the body's follicle center cells, which are a type of white blood cell, become abnormal and eventually spread throughout the body growing and dividing in an uncontrolled fashion. BiovaxID is a customized anti-cancer vaccine that is derived from a patient's own cancer cells and is designed to utilize the power of the patient's immune system to recognize and destroy cancerous lymphoma cells while sparing normal cells. We produce this vaccine by extracting the patient's tumor cells and then replicating and purifying the unique antigen that is present only on the surface of the patient's own tumor cells. Biovest is currently conducting a pivotal Phase 3 clinical trial for BiovaxID in patients with the indolent, or low-grade, form of B-cell follicular NHL.

We are a vertically-integrated commercial enterprise with demonstrated competencies in the identification, development, regulatory approval, pricing, reimbursement, managed care contracting, manufacturing, and sales and marketing of biopharmaceuticals and medical devices. We currently market respiratory products through our Accentia Pharmaceuticals division, which has a dedicated specialty sales force. Our pharmaceutical product consulting business provides a broad range of services, including product candidate selection, outcomes research on the economic profiles of pharmaceuticals and biologics, pricing and market assessment on these products, reimbursement strategies and various services designed to expedite clinical trials to companies and institutions in the pharmaceutical, biotechnology, and medical markets as well as for our internal use. Our instrument business manufactures equipment used in the production of cells and other biologics based on the hollow-fiber production method and includes our newly introduced automated instrument, AutovaxID.

We were incorporated in Florida in 2002. Our principal executive offices are located at 324 South Hyde Park Avenue, Suite 350, Tampa, Florida 33606. Our telephone number at that address is (813) 864-2554. Our Internet website address is www.accentia.net, and all of our filings with the Securities and Exchange Commission are available free of charge on our website. Any information that is included on or linked to our Internet site is not a part of this annual report on Form 10-K.

Our Business Strategy

Our goal is to acquire, develop, and commercialize innovative late-stage biopharmaceutical products that offer the potential for superior efficacy and safety as compared to competitive products and that address significant unmet medical needs. To achieve this goal, the key elements of our strategy include:

- *Completing clinical development and obtaining regulatory approval for SinuNase and BiovaxID.* We intend to complete our Phase 3 clinical trials for SinuNase and BiovaxID and to aggressively pursue regulatory approvals for both products.
- *Identifying and acquiring additional late-stage clinical products and technologies.* We intend to pursue the acquisition of additional late-stage products that could increase the value of our development pipeline and complement our existing products and product candidates. This may consist of product acquisition, in-licensing, or company acquisitions. We intend to screen product opportunities and focus on products for which substantial clinical evidence of safety and efficacy has already been demonstrated. We also intend to screen potential product opportunities based on their regulatory pathways, pharmacoeconomic profiles and their payor reimbursement prospects. Although our primary emphasis in acquiring new products will be in the respiratory and oncology therapeutic areas, we will consider products in other therapeutic areas if they satisfy our screening criteria.
- *Leveraging our broad range of internal capabilities to support our ongoing development and commercialization efforts.* We believe that our broad range of in-house service capabilities provides a strong platform on which to develop new biopharmaceutical products. We plan to leverage our specialty pharmaceutical business, pharmaceutical product consulting business and biologics production capabilities to pursue, attract, screen, and develop new therapies to increase the size of our development pipeline and commercialize our products.
- *Pursuing strategic relationships on a selective basis for product development or distribution.* We may from time to time consider entering into strategic relationships with third-parties in order to facilitate the development of new products and to market and distribute our approved products. Such strategic relationships could be in the form of licensing, distribution arrangements, or joint ventures. In some cases, the acquisition of new products could be effected through the acquisition or licensing of individual products or technologies or the acquisition of an entire business.

We evaluate on a continuing basis, and as appropriate, adjust, our business strategy as discussed above in light of market conditions and other relevant factors such as available financing, opportunities for strategic relationships, and changes impacting our current and future products and product candidates.

SinuNase

We are developing a product for the treatment of chronic rhinosinusitis or CRS based on an intranasal formulation of amphotericin B, and we intend to market and sell this product under the name SinuNase. Rhinosinusitis is an inflammatory condition of the paranasal sinuses, which are air cavities within the facial bones that are lined by mucus. Rhinosinusitis occurs when the mucus membrane in the nose and the paranasal sinuses become inflamed and swell, thereby blocking the nasal passage or limiting drainage from the sinuses into the nose and throat and causing pressure and pain in the sinuses. Rhinosinusitis results in a variety of symptoms, including nasal congestion, facial pain and pressure, nasal discharge, and headaches. Rhinosinusitis is generally categorized into two types: acute rhinosinusitis, which is a temporary short-term condition commonly associated with colds and other viral infections, and chronic rhinosinusitis, which is an ongoing condition that lasts for three or more months but often continues for years. The FDA has advised us, and we concur, that chronic sinusitis or CS should be considered to be the indication for SinuNase rather than CRS, although there is a growing belief in the medical community that the terms are interchangeable.

SinuNase is an intranasal antifungal suspension formulated for the treatment of CRS. SinuNase's active ingredient is amphotericin B, which is an antifungal medication currently used as an intravenous formulation to treat a wide variety of systemic fungal infections. As a result of research and studies performed at Mayo Clinic in Rochester, Minnesota, it has been discovered that a hypersensitivity to airborne molds plays a significant role in CRS and that the condition can be substantially relieved using an intranasal application of low-dose antifungals. Mayo Foundation for Medical Education and Research ("MAYO") has been issued a U.S. patent relating to this treatment method and has filed a European counterpart patent

application for the therapy. Our rights to SinuNase are based on a license agreement with MAYO which gives us the exclusive worldwide right to commercialize MAYO's patented CRS treatment method using the antifungal amphotericin B. Although Mayo Foundation's clinical trials on its CRS therapy were based on the use of amphotericin B, MAYO's patents and patent applications with respect to the therapy broadly apply to the topical application of any antifungals for the treatment of CRS. In December 2005, we entered into an option agreement with MAYO giving us the exclusive right until December 2006 (which has since been extended to December 2007), without obligation, to seek to negotiate a license for all antifungals in addition to Amphotericin B. In the event that we are not successful in negotiating such additional licenses, MAYO is not precluded from licensing to third-parties, including potential competitors, the use of antifungals other than amphotericin B for the treatment of CRS. If MAYO grants such a license to a third-party, and if the use of such other antifungal is shown to have an efficacy and safety profile that equals or exceeds that of amphotericin B for treatment of CRS, we may not be able to commercialize or generate revenue from SinuNase and our business, financial condition, and results of operations could be adversely affected.

Market Opportunity

Rhinosinusitis is one of the most commonly reported chronic diseases in the U.S., affecting an estimated 14% of the population. Approximately 31 million Americans suffer from rhinosinusitis every year, and an estimated 90% of all rhinosinusitis cases are chronic. According to the March 1999 Journal of Allergy and Clinical Immunology, overall health care expenditures attributable to rhinosinusitis were estimated to be $5.8 billion in direct costs during 1996. A primary diagnosis of acute bacterial rhinosinusitis or chronic rhinosinusitis accounted for 58.7% of all expenditures, or $3.5 billion, for 1996. CRS also results in indirect costs for Americans, such as greater than 70 million lost activity days and reduced social and physical functioning. As set forth in the December 2004 Journal of Allergy and Clinical Immunology, at least 30 million courses of antibiotics are prescribed each year for CRS, and it is one of the leading forms of chronic disease. The U.S. Department of Health and Human Services estimated that, during a 12-month period ending in 2000, CRS accounted for 9.2 million primary care office visits, 1.1 million surgical specialty office visits, 951,000 medical specialty office visits, 1.3 million outpatient department hospital visits, and 693,000 emergency department visits. The U.S. Department of Health & Human Services also estimates that approximately 500,000 people resorted to sinus surgery in 1996.

Causes and Treatment of CRS

Currently, there is no FDA-approved therapy for CRS. The lack of an effective treatment for CRS has historically been due to an inability of the medical community to identify the underlying cause of the condition. Due to lack of knowledge regarding the cause of CRS, most treatment methods for CRS have focused only on the symptoms of the disease.

As a result of studies begun by Mayo Clinic, researchers have discovered that airborne fungi play a major role in triggering CRS. Like pollen, fungi are present in the air in every region of the world, and Mayo Clinic's studies have demonstrated that fungi are normally present in the mucus of the nasal passages and the sinuses of most everyone, including those without CRS. Mayo Clinic's research has also shown that, in patients with CRS, the production of certain key mediators that mediate the inflammation in CRS result from an abnormal immune system response to certain airborne fungi. In CRS patients, the presence of this normally innocuous fungi in the mucus triggers an immune response that results in the activation of esonophils, which are immune cells that are predominantly involved in the body's defense against parasites and foreign organisms. In the mucus, the activation of esonophils triggers an immune defense response and leads to a release of highly destructive and toxic defensive proteins. One such protein is eosinophilic major basic protein, or MBP, which is a substance that attacks fungi but also severely damages the nasal and sinus membrane tissue. Over time, this damage typically leads to inflammation, modification, and blockage of the nasal and sinus drainage passages, as well as polyps and small growths in the nasal passage and the sinuses. Because the damaged tissue is vulnerable to invasion by bacteria and viruses, this damage can also lead to secondary infections.

Prior to the research done at Mayo Clinic, the presence of fungi in the nasal mucus of CRS patients was theorized but largely undetected due to the unavailability of effective and accurate methods to detect the presence of the fungi. A study published by Mayo Clinic in 2002 described a new technique for detecting the fungi in mucus, and using this technique, researchers found that 96% of patients with CRS had fungi in their mucus. These results were confirmed in a European study that was published in 2003 in Laryngoscope by the American Laryngological, Rhinological and Otological Society, which reported that the presence of fungal organisms in both healthy and CRS patients was demonstrated by positive fungal cultures in 91% of individuals in each group. A study by the University of Mainz in Germany published in 2004 in the American Journal of Rhinology reported that fungal DNA was detected in 100% of mucus samples from CRS patients.

Historically, the treatment of CRS has largely focused on the use of antibiotics, intranasal or orally administered corticosteroids, and sinus surgery. While antibiotics are useful in treating the acute exacerbations that result from the bacterial invasion of the damaged paranasal tissue of CRS patients, no antibiotic has proven effective in eradicating the underlying cause of CRS. Intranasal and orally administered corticosteroids, which are potent anti-inflammatory hormones, have been

used to reduce the inflammation and immune response that play a role in CRS, but oral corticosteroids can cause serious side effects and must be avoided or cautiously used with patients that have certain conditions, such as gastrointestinal ulcers, renal disease, hypertension, diabetes, osteoporosis, thyroid disorders, and intestinal disease. Surgery is frequently used in CRS patients to improve the drainage of their sinuses based on the assumption that the disease can be reversed by identifying and correcting the obstruction associated with the condition, but while such surgery usually offers temporary relief of symptoms, studies have shown that it is typically not curative.

Clinical Studies on Amphotericin B Therapy

In several published studies, an intranasal administration of amphotericin B has been shown to reduce paranasal inflammation in CRS patients by suppressing the population of fungi in the nasal cavity and mucus, thereby reducing or preventing the immune system response that causes CRS. The following is an overview of the studies that were referenced in our IND as submitted to the FDA:

Study	Nature of Study	Number of Patients	Results
2002 Mayo Clinic Study	• Open label study • Twice daily intranasal application of 20 millimeters of amphotericin B in each nstril • Formulation: 100 micrograms of amphotericin B per milliliter of solution	51	• 75% demonstrated improvement in sinus symptoms. • 35% demonstrated elimination of signs of paranasal inflammation (endoscopic evaluation). • 39% showed improvement of at least one disease stage (endoscopic evaluation)
2002 Geneva University Study	• Open label study • Four weeks of twice daily of 20 millimeters of amphotericin B in each nostril • Formulation: 100 micrograms of amphotericin B per milliliter suspension	74	• 48% of patients with stage I or II nasal polyposis had complete disappearance of nasal polyposis.
2004 Mayo Clinic Study	• Double blind, randomized placebo controlled study • Twice daily intranasal applications of a 20 milliliter solution with a concentration of 250 micrograms of amphotericin B per milliliter	24	• Statistically significant reduction in mucosal inflammation and reduction in inflammatory markers.

2002 Mayo Clinic Study. In this prospective open label clinical trial conducted at Mayo Clinic and published in 2002 in the Journal of Allergy and Clinical Immunology, 51 patients were given a twice daily intranasal application of an amphotericin B solution in each nostril in the amount of 20 milliliters per application per nostril. Generally, in an open label trial, both the researchers and participants know the drug and dosage that the participant is taking. The concentration of the administered solution was 100 micrograms of amphotericin B per milliliter of solution. The study reported that the therapy resulted in symptom improvement and a reduction in nasal obstruction and discharge, as assessed by endoscopic evaluation and/or CT scan. In this study, patients received the intranasal amphotericin B solution for 3 to 17 months (at an average of 11.3 months), and following a three-month or longer treatment course, improvement in nasal obstruction and nasal discharge symptoms was demonstrated in 38 of 51 of patients, or 75%, as demonstrated by a patient questionnaire. Endoscopic evaluation found 18 of 51 patients, or 35%, to be free from signs of paranasal inflammation at the conclusion of the trial, and an additional 20 patients, or 39%, had improvement of at least one disease stage. CT scans were available for 13 patients and demonstrated significant reduction in nasal mucosal thickening and occlusion of the paranasal sinuses.

2002 Geneva University Study. In this prospective open label study conducted by Geneva University in Switzerland and published in 2002 in the Journal of Laryngology & Otology, 74 patients were administered four weeks of twice daily intranasal application of an amphotericin B suspension. The dosage regimen and amphotericin B concentration used in this study were the same as in the open label Mayo Clinic study. The endpoint of the study was a determination of whether there was complete disappearance of nasal polyposis after endoscopic examination. Of the 74 patients in the study, prior to treatment, 13 had stage I, 48 had stage II, and 13 had stage III of nasal polyposis. Following four weeks of treatment with

amphotericin B, the number of patients with stage I, II, and III of the disease was 5, 21, and 13, respectively. This represented a complete disappearance of nasal polyposis in 48% of the combined number of patients with stages I or II of the disease, although none of the patients with stage III of the disease experienced a complete disappearance. Partial disappearance of nasal polyposis or other improvements in condition were not a part of the reported outcomes in this study.

2004 Mayo Clinic Study. In this double blind study of 24 patients conducted at Mayo Clinic and published in the January 2004 Journal of Allergy and Clinical Immunology, amphotericin B was shown to be effective in decreasing mucosal thickening associated with CRS. Generally, in a double blind trial, neither the subjects of the study nor the researchers know the drug, dosage, or other critical aspects of the study in order to guard against bias and the effects of the placebo. In this study, the patients were given twice daily intranasal applications of a 20 milliliter solution with a concentration of 250 micrograms of amphotericin B per milliliter. The primary outcome measure, which was a reduction in mucosal thickening measured by CT scan, was statistically significant at six months with an approximate 9% reduction in mucosal thickening in patients treated with amphotericin B versus a slight worsening of mucosal thickening in placebo-treated patients. Endoscopic evaluation of the patients demonstrated statistically significant improvement at three and six months. Eosinophil-derived neurotoxin and other markers of inflammation were decreased in the mucus of patients treated with the amphotericin B.

Development Status

We submitted an IND with the FDA for SinuNase in April 2005, and the IND was accepted by the FDA in May 2005. In April 2006, the FDA granted our SinuNase trial Fast Track status. In calendar year 2006, we commenced the first of two Phase 3 clinical trials for SinuNase. Each of these trials is expected to enroll enough patients to allow 300 patients to be randomized 1:1 between treatment arm and placebo control arm. Our primary endpoint for these studies is patient reported outcomes measuring the resolution of cardinal symptoms associated with severe post-surgical CRS and secondary endpoints including nasal endoscopy and CT scan of the sinuses.

We anticipate that the SinuNase NDA will be filed as a 505(b) (2) application, which is a type of NDA that will enable us to rely in part on the FDA's previous findings of safety and efficacy for an oral suspension of amphotericin B and on previously published clinical studies of intranasal amphotericin B for CRS.

Our initial IND for SinuNase is for an amphotericin B suspension that is self-administered by squirting the antifungal suspension from a plastic applicator through each nostril in order to bathe the nasal cavity. We expect to subsequently file a supplement to the IND to add a second product consisting of an encochleated version of the amphotericin B. Encochleation is a proprietary process in which a phospholipid, a phosphorous-containing fatty acid, is used as an excipient, an inert additive used as a drug delivery vehicle, to extend the shelf-life of the product in an aqueous, or water-based, medium. We anticipate that the encochleated version of SinuNase, if successfully developed and approved, will be administered with a pump spray and will be indicated for maintenance treatments in patients whose CRS is less severe. The encochleated version of the product is being developed by us under a license agreement with BioDelivery Sciences International, Inc., or BDSI, under which we have been granted exclusive worldwide rights to BDSI's encochleation technology for amphotericin B used in CRS and asthma treatments.

Even though SinuNase is not approved by the FDA for treatment of CRS, based on available research and scientific articles, a number of physicians currently prescribe a compounded formulation of amphotericin B solution to treat CRS. Our representatives educate physicians about Mayo Clinic's research and studies relating to the causes and potential treatment methods for CRS, and the availability of compounding services. These compounded formulations are custom-produced solutions made by pharmacists for individual patients and their needs because commercially available dosage forms are not available. While we are not permitted to market SinuNase unless and until the therapy is approved by the FDA, we currently sublicense our rights to the compounded variant of the therapy to compounding pharmacies in exchange for a royalty. However, if SinuNase is approved by the FDA, these sublicenses will terminate, and compounding pharmacies will be unable to compound copies of the approved solution without individual medical need for a compounded variation, such as substitution of an inactive ingredient to which a patient is allergic.

Proprietary Rights

Our rights to SinuNase are based on a license agreement with MAYO. Our license agreement with MAYO gives us the exclusive worldwide right to commercialize MAYO's patented CRS treatment method using the antifungal amphotericin B. Although MAYO's clinical trials on its CRS therapy were based on the use of amphotericin B, MAYO's patents and patent applications with respect to the therapy broadly apply to the topical application of any antifungals for the treatment of CRS. In December 2005, we entered into an Option Agreement with MAYO giving us the exclusive right until December 2006 (which has since been extended to December 2007), without obligation, to seek to negotiate a license for all antifungals in addition to amphotericin B. In the event that we are not successful in negotiating such additional licenses, MAYO is not precluded from licensing to third-parties, including potential competitors, the use of antifungals other than amphotericin B for

the treatment of CRS. If MAYO grants such a license to a third-party, and if the use of such other antifungal is shown to have an efficacy and safety profile that equals or exceeds that of amphotericin B for this application, we may not be able to commercialize or generate revenue from SinuNase and our business, financial condition, and results of operations could be adversely affected.

We hold an exclusive license to market and sell products made from amphotericin B based on MAYO's patented treatment method for CRS. Although amphotericin B has not been approved by the FDA for the treatment of CRS, a number of physicians currently prescribe a compounded formulation of amphotericin B solution for their CRS patients. These formulations are prepared by compounding pharmacies that are in the business of preparing custom-made solutions using FDA-approved active ingredients. While we have sublicensed our rights to the compounded variant of the product to compounding pharmacies, we are aware that other compounding pharmacies may be preparing similar compounded formulations in violation of one or more claims of our licensed patents. Because these patent violations may be sporadic and dispersed, we may not be able to easily identify the violations. In addition, because the patents that we license from MAYO relate to a method of treating CRS, if other amphotericin B solutions become commercially available for other indications, we may not be able to prevent physicians from prescribing such other solutions for CRS on an off-label basis. Such actions could hinder our ability to generate enough revenue to justify development costs and to achieve or maintain profitability.

Sales, Marketing, and Manufacturing

If the FDA approves SinuNase for the initial indication of recurrence of CRS after sinus surgery, we anticipate that we may market and sell the product through our own sales force directly to otolaryngologists (ear, nose, and throat surgeons) who are treating CRS patients and potentially through third-party sales and marketing relationships. There are approximately 10,500 ear, nose, and throat specialists in the U.S., and we currently market other products to these specialists. Additionally, we may seek to establish marketing relationships with third-parties. We anticipate that the labeling for SinuNase will be indicated specifically for "chronic sinusitis," which is a more widely used name for the condition than "chronic rhinosinusitis."

We anticipate that the initial SinuNase suspension will be self-administered by patients, who will use a single-dose, packet of ingredients to be mixed by the patient with sterile water and then administered by the patient into the nasal cavity through each nostril. We have selected the third-party contract manufacturer to produce the product for our clinical trials.

BiovaxID

BiovaxID is an injectable patient-specific vaccine that we are developing to treat the follicular form of non-Hodgkin's lymphoma, or NHL. We acquired our rights for BiovaxID through a cooperative research and development agreement (CRADA) with National Cancer Institute (NCI). BiovaxID is a customized immunotherapy that is derived from a patient's own cancer cells and is designed to utilize the power of each patient's immune system to recognize and destroy cancerous lymphoma cells while sparing normal cells. BiovaxID is currently undergoing a pivotal Phase 3 clinical trial with patients diagnosed with the indolent follicular form of B-cell NHL. BiovaxID is being developed by Biovest, our publicly held, majority-owned subsidiary.

The Human Immune System

The immune system is the body's natural defense mechanism for recognizing and combating viruses, bacteria, cancer cells, and other disease-causing organisms. The primary disease fighting functions of the immune system is carried out by white blood cells. In response to the presence of disease, white blood cells can mediate two types of immune responses, referred to as innate immunity and adaptive immunity. Innate immunity refers to a broad, first line of immune defense that occurs as a part of an individual's natural biological makeup. Adaptive immunity, on the other hand, is specifically generated by a person's immune system throughout the person's lifetime as he or she is exposed to particular pathogens, which are agents such as bacteria or other microorganisms that cause disease. In contrast to the broad but unspecific response of innate immunity, the adaptive immune response generates a highly specific, long-lasting, and powerful protection from repeated infection by the same pathogen. This adaptive immune response facilitates the use of preventative vaccines that protect against viral and bacterial infections such as measles, polio, diphtheria, and tetanus.

Adaptive immunity is mediated by a subset of white blood cells called lymphocytes, which are divided into two types: B-cells and T-cells. In the bloodstream, B-cells and T-cells recognize molecules known as antigens, which are proteins or other substances that are capable of triggering a response in the immune system. Antigens include toxins, bacteria, foreign blood cells, and the cells of transplanted organs. When a B-cell recognizes a specific antigen, it secretes proteins, known as antibodies, which in turn bind to a target containing that antigen and tag it for destruction by other white blood cells. When a T-cell recognizes an antigen, it either promotes the activation of other white blood cells or initiates destruction of the target cells directly. A person's B-cells and T-cells can collectively recognize a wide variety of antigens, but each individual B-cell

or T-cell will recognize only one specific antigen. Consequently, in each person's bloodstream, only a relatively few lymphocytes will recognize the same antigen.

In the case of cancer, cancer cells produce molecules known as tumor-associated antigens, which may or may not be present in normal cells but may be over-produced in cancer cells. T-cells and B-cells have receptors on their surfaces that enable them to recognize the tumor associated antigens. While cancer cells may naturally trigger a T-cell-based immune response during the initial appearance of the disease, the immune system response may not be sufficiently robust to eradicate the cancer. The human body has developed numerous immune suppression mechanisms to prevent the immune system from destroying the body's normal tissues, and because all cancer cells are originally normal tissue cells, they are often able to aberrantly exploit these mechanisms to suppress the body's immune response, which would normally destroy them. Even with an activated immune system, the number and size of tumors can overwhelm the immune system.

In the case of cancer and other diseases, immunotherapies are designed to utilize a person's immune system in an attempt to combat the disease. There are two forms of immunotherapy used to treat diseases: passive and active. Passive immunotherapy is exemplified by the intravenous infusion into a patient of antibodies specific to the particular antigen, and while passive immunotherapies have shown clinical benefits in some cancers, they require repeated infusions and can cause the destruction of normal cells in addition to cancer cells. An active immunotherapy, on the other hand, generates an adaptive immune response by introducing an antigen into a patient, often in combination with other components that can enhance an immune response to the antigen. Although active immunotherapeutics have been successful in preventing many infectious diseases, their ability to combat cancers of various types has been limited by a variety of factors, including the inability of tumor antigens to elicit an effective immune response, difficulty in identifying suitable target tumor antigens, inability to manufacture tumor antigens in sufficiently pure form, and inability to manufacture sufficient quantities of tumor antigens. Nevertheless, there are many active immunotherapeutics for cancer in the late stages of clinical trials, and some are demonstrating encouraging results.

There are two features of B-cell follicular NHL that make it a particularly attractive form of cancer for treatment with an active immunotherapeutic approach. First, the malignant B-cell lymphocytes in follicular NHL have a unique, identifiable tumor-specific antigen domain that is expressed on the surface of each and every cancerous B-cell in a particular patient and not expressed on any other cells. This is in contrast to other solid cancer tumors, such as prostate, pancreatic, or lung carcinomas, which have a heterogeneous expression of different kinds of antigens on their cell surfaces and for which identification and inclusion of all tumor-specific antigens is very challenging. Second, in cases of relapse after conventional treatment, the malignant B-cells in follicular NHL represent the original cancerous clone. Consequently, the cancer cells that survive treatment of NHL seem to always represent tumor cells with the same antigen idiotype as the original tumor. An idiotype consists of the characteristics of an antigen that make it unique. In follicular NHL patients, the idiotype antigen protein expressed on the tumor cell's surface is not functioning as an antigen because of its failure to elicit a sufficient immune response to the presence of the tumor cells, and the goal of our BiovaxID active immunotherapy is to trigger the body's immune system to recognize such protein as an antigen by introducing a purified version of the idiotype antigen, modified by conjugation to a foreign carrier protein, into the patient's system in conjunction with an immune system stimulant, as described more specifically below.

Non-Hodgkin's Lymphoma

NHL is a cancer of the lymphatic system, which is a part of the immune system and serves as the body's primary blood filtering and disease fighting tissue. In NHL, specific cells in the lymphatic system become abnormal and multiply in an uncontrolled manner, outliving their normal programmed lifespan, and spreading through the body. NHL can occur in both B-cells and T-cells.

NHL is the sixth most common cancer and the sixth leading cause of death among cancers in the U.S. Approximately 85% of diagnosed cases of NHL are in the form of B-cell NHL, while 15% are T-cell NHL. There are approximately 55,000 new cases of NHL diagnosed each year in the U.S. with a comparable number estimated in Europe, and an estimated 12,500 of the U.S. cases each year are a type of B-cell NHL known as indolent follicular NHL. Our IND and Phase 3 clinical trial for BiovaxID are for indolent follicular NHL.

NHL is usually classified for clinical purposes as being either "indolent" or "aggressive," depending on how quickly the cancer cells are likely to grow and spread. The indolent, or slow-growing, form of NHL has a very slow growth rate and may need little or no treatment for months or possibly years. Aggressive, or fast-growing, NHL tends to grow and spread quickly and cause severe symptoms. Indolent and aggressive NHL each constitute approximately half of all newly diagnosed B-cell NHL, and roughly half of the indolent B-cell NHL is follicular NHL. Follicular NHL is a form of NHL that is derived from a type of cell known as a follicle center cell. Despite the slow progression of indolent B-cell NHL, the disease is almost invariably fatal. According to the American Cancer Society, the median survival time from diagnosis for patients with

indolent B-cell NHL having stage III or IV follicular B-cell NHL is between seven and ten years. Unlike indolent B-cell NHL, approximately 30-60% of aggressive B-cell NHL cases are cured by standard chemotherapy.

Chemotherapy is widely used as a first line of treatment for NHL. Although chemotherapy can substantially reduce the tumor mass and in most cases achieve a clinical remission, the remissions are generally short-lived. Indolent B-cell NHL patients generally relapse within a few months or years of initial treatment, and the cancer usually becomes increasingly resistant to further chemotherapy treatments. Eventually, the patient's response to therapy is so brief and weak that further chemotherapy would offer no clinical benefit.

A number of passive immunotherapies, such as Rituxan, Bexxar, and other monoclonal antibodies, are approved by the FDA for the treatment of indolent B-cell follicular lymphoma. These therapies have been used as primary treatment and also as part of combination treatment including chemotherapy. A monoclonal antibody is a type of antibody produced in large quantity that is specific to an antigen that is expressed by tumor cells but may also be expressed by at least some normal cells. These NHL antibody therapies target an antigen that all B-cell lymphocytes, both normal and cancerous, have on their surface. As such, the effects of therapy include a temporary reduction in normal B-cell lymphocytes, which can predispose patients to the risk of infection. Generally, these therapies alone have failed to provide unlimited remissions for most patients, and their cost and side-effects are often significant. Moreover, as passively administered antibodies, they do not elicit a sustained immune response to tumor cells. Nevertheless, some recent studies suggest that sustained remissions might be possible with the use of these passive immunotherapies at or near the time of initial diagnosis, either alone or in combination with chemotherapy, and we do not believe that the use of passive and active immunotherapeutics are necessarily mutually exclusive. Rituxan is used in approximately 85% of all new cases of NHL per year, and U.S. sales of Rituxan exceeded $1.8 billion in 2005.

Development of Patient-Specific Vaccine for NHL

During the late 1980s, physicians at Stanford University began development of an active immunotherapy for the treatment of indolent B-cell NHL, and the work was thereafter continued by Dr. Larry Kwak and his colleagues at the NCI. In 1996, the NCI began a Phase 1 clinical trial and selected our Biovest subsidiary to produce the vaccine for the trial. In 2001, Biovest entered into CRADA, with the NCI under which we jointly conducted the Phase 3 clinical trial pursuant to the Investigational New Drug application, or IND, which had been filed by the NCI in 1994. In April 2004, sponsorship of the IND was formally transferred from the NCI to us and in November 2006 the CRADA terminated.

Studies have shown that treatment with an active immunotherapy should allow a patient's own immune system to produce both B-cells and T-cells that recognize numerous portions of the tumor antigen and generate clinically significant immune responses. These studies have been published in the October 22, 1992 issue of *The New England Journal of Medicine*, the May 1, 1997 issue of *Blood*, and the October 1999 issue of *Nature Medicine*. With respect to follicular NHL and other cancers, tumor cells remaining in the patient after completion of surgery, radiation, and chemotherapy are the cause of tumor relapse. These residual tumor cells cannot be detected by imaging, but their destruction may be feasible by active immunotherapy. With a patient-specific active vaccine, patients receive their own tumor idiotype, as the vaccine is customized for the tumor target of the individual patient. Repeated vaccination with such a tumor vaccine provides the patient's immune system with an additional opportunity to be effectively activated by the tumor cell itself.

Our research has focused on the indolent form of follicular NHL, which accounts for about 90% of newly diagnosed cases of follicular NHL. In about 40-70% of the indolent cases, there is transformation of the indolent form to a more aggressive lymphoma, such as large-cell follicular NHL. This transformation is typically an early event in the course of the disease, usually occurring before the sixth year after diagnosis, and it is mainly observed in patients with known adverse prognostic factors. It is the goal of BiovaxID to intervene in the transformation process by treating newly diagnosed patients in their first clinical remission with the hope of inducing indefinitely prolonged remission and thereby eliminating the possibility of transformation to a more aggressive form of the disease.

BiovaxID Treatment and Production Process

BiovaxID is designed to utilize the power of each patient's immune system and cause it to recognize and destroy cancerous lymphoma B-cells while sparing normal B-cells. Typically, all of a patient's cancerous B-cells are replicate clones of a single malignant B-cell, and, accordingly, all of a patient's cancerous B-cells express the same surface antigen idiotype which is absent from non-cancerous cells. BiovaxID is designed to use the patient's own antigen idiotype from the patient's tumor cells to direct the patient's immune system to mount a targeted immune response against the tumor cells. In general, the therapy seeks to accomplish this result through the extraction of tumor cells from the patient, the culturing and growing of a cell culture that secrets idiotype proteins found in the patient's tumor cells, the production and enhancement of a purified version of the cancer idiotype antigen, and the injection of the resulting vaccine into the patient. By introducing a highly-concentrated purified version of the cancer antigen into the patient's system, the vaccine is designed to trigger the immune

system to mount a more robust response to the specific antigen, in contrast to the comparatively weak and insufficient pre-vaccination response. Because the antigen is specific to the cancerous B-cells and not found on normal B-cells, the immune response should target the cancerous B-cells for destruction and not cause harm to the normal cells.

The BiovaxID production and treatment process begins when a sample of the patient's tumor is extracted by a biopsy performed by the treating physician at the time of diagnosis, and the sample is shipped refrigerated to our manufacturing facility in Worcester, Massachusetts. At our manufacturing facility, we identify the antigen idiotype that is expressed on the surface of the patient's tumor cells through laboratory analysis. The patient's tumor cells are then fused with an exclusively licensed laboratory cell line from Stanford University to create a hybridoma. A hybridoma is a hybrid cell resulting from the fusion of a patient tumor cell and a murine/human heterohybridoma myeloma cell, which is an antibody-secreting cell created from a fused mouse and human cell. The purpose of creating a hybridoma is to create a cell that secretes antibody proteins bearing the same idiotype or antigen as the patient's tumor cells. The hybridoma cell can be used to produce the vaccine because the tumor-specific antigen expressed on the surface of the patient's tumor cells is itself an antibody.

After the creation of the hybridoma, we determine which hybridoma cells display the same antigen idiotype as the patient's tumor cells, and those cells are selected to produce the vaccine. The selected hybridoma cells are then seeded into our hollow fiber bioreactors, where they are cultured and where they secrete an antibody bearing the same idiotype antigen as the patient's tumor cells. The secreted antigens are then collected from the cells growing on the hollow fibers. After a sufficient amount of antigen is collected for the production of an appropriate amount of the vaccine, the patient's antigen idiotype is purified using an affinity chromatography column. Affinity chromatography is a technique used to separate and purify a biological molecule from a mixture by passing the mixture through a column containing a substance to which the biological molecule binds.

The resulting purified idiotype antigen is then conjugated, or joined together, with keyhole limpet hemocyanin, or KLH, to create the vaccine. KLH is a foreign carrier protein that is used to improve the immunogenicity, or ability to evoke an immune response, of the tumor-specific antigen. The vaccine is then frozen and shipped to the treating physician. At the treating physician's office, the vaccine is thawed and injected into the patient as an antigen.

We expect that the initial vaccination will typically commence six months after the patient enters clinical remission following chemotherapy. The vaccine is administered in conjunction with GM-CSF, a natural immune system growth factor that is administered with an antigen to stimulate the immune system and increase the response to the antigen. The patient is administered five monthly injections of the vaccine in the amount of ½ milligram of vaccine per injection, with the injections being given over a six-month period of time in which the fifth month is skipped. Through this process, the patient-specific antigens are used to stimulate the patient's immune system into targeting and destroying B-cells bearing the same antigen idiotype.

To our knowledge, BiovaxID is the only NHL vaccine currently in development under an IND that is produced through a hybridoma process. The hybridoma process is different from the recombinant processes being used by other companies that are currently developing an active idiotype immunotherapeutic for NHL. In the recombinant process, the patient's own tumor cells are not fused with lymphocytes, but instead the vaccine is produced by introducing genetic material bearing certain portions (known as the variable light and variable heavy chains) of the tumor-derived idiotype protein into mammalian or insect cells. Whereas the hybridoma method will produce high-fidelity copies of the antigen that, through clonal reproduction, exactly replicates the original gene sequences of the tumor specific idiotype of the parent tumor cell, the recombinant method gives rise to protein products that have combinations of gene sequences different from those of the patient's tumor.

We use a method known as "hollow-fiber perfusion" to produce the cell cultures used in the manufacture of BiovaxID. Hollow-fiber perfusion, as compared to other cell culture methods, seeks to grow cells to higher densities more closely approaching the density of cells naturally occurring in body tissue. The hollow-fiber perfusion method involves using hair-like plastic fibers with hollow centers which are intended to simulate human capillaries. Thousands of these fibers are inserted in a cartridge, which we refer to as a bioreactor. The cells are grown on the outside of the hollow fibers while nutrient media used to support cell growth is delivered through the hollow centers of the fibers. The fiber walls have small pores, allowing nutrients to pass from the hollow center to the cells. The fibers act as filters and yield concentrated secreted products. Because the cells are immobilized in the bioreactor, the concentrated product can be harvested during the ongoing cell growth process. We believe that hollow-fiber technology permits the harvests of cell culture products with generally higher purities than stirred-tank fermentation, a common alternative cell culture method, thereby reducing the cost of purification as compared to stirred tank fermentation. Additionally, the technology associated with the hollow-fiber process generally minimizes the amount of costly nutrient media required for cell growth as opposed to other cell culturing techniques.

We believe that our vaccine's anti-tumor effect could exceed that of non-targeted traditional therapy, such as chemotherapy, as our therapy arises from the immune system's defense cells' innate ability to selectively target tumor antigen while not attacking the normal healthy B-cells. The immune response triggered by our vaccine against the cancerous tissue is a natural disease-fighting mechanism without causing the side-effects associated with chemotherapy and radiation used to traditionally treat NHL. We also believe that our vaccine's effectiveness could exceed that of passive immunotherapies, such as Rituxan, Bexar, and other monoclonal antibodies. Unlike BiovaxID, these therapies do not target the unique antigen idiotype that is found on the surface of the patient's tumor cells. Instead, they target an antigen that is common to all B-cells, known as the CD-20 antigen, which results in the undesirable destruction of normal B-cells.

Manufacture of BiovaxID

We manufacture BiovaxID at Biovest's own manufacturing facility in Worcester, Massachusetts. If we receive FDA approval of the vaccine, we may continue to manufacture the vaccine at our existing facility in Worcester, although we will likely need to develop additional facilities or utilize third-party contract manufacturers to fully support commercial production for the U.S. markets. To penetrate markets outside of the U.S., we may enter into agreements such as collaborations with well-established companies that have the capabilities to produce the product, licenses, joint ventures or other arrangements to produce and/or market the product in such countries. To facilitate commercial production of the vaccine, we are developing proprietary manufacturing equipment, for which we have filed "AutovaxID™" as a trademark. AutovaxID integrates and automates various stages of vaccine production. We believe that the AutovaxID system will reduce the space and staff currently required for production of the vaccine. We are also planning to commercially manufacture and sell AutovaxID instruments.

Because we use KLH in the BiovaxID manufacturing process, we have entered into a supply agreement with BioSyn Arzneimittel GmbH, or BioSyn, to supply us with KLH. Under this agreement, BioSyn is obligated to use commercially reasonable efforts to fulfill all of our orders of KLH, subject to certain annual minimum orders by us. However, BioSyn does not have a specific obligation to supply us with the amounts of KLH currently being supplied and necessary for our current clinical trial purposes or for commercialization. The supply agreement specifies a purchase price for the KLH and also provides for a one-time licensing fee payable by us in installments. The agreement expires in December 2007 but will automatically renew for unlimited successive terms of five years each unless we provide notice of termination to BioSyn at least six months before the expiration of any term. The agreement can be terminated prior to expiration by either party upon the winding-up or receivership of the other party or upon a default that remains uncured for 60 days. Also, the agreement can be terminated by BioSyn if we cease to develop BiovaxID.

Development Status

In April 2004, the NCI formally transferred sponsorship of the IND for BiovaxID to our Biovest subsidiary, which gives Biovest the right to communicate and negotiate with the FDA relating to the approval of BiovaxID and to conduct the clinical trials for the vaccine. BiovaxID is in a pivotal Phase 3 clinical trial which was started in January 2000 by the NCI. In November 2006, we terminated our CRADA with the NCI to continue the Phase 3 clinical trial of BiovaxID with a new principal investigator, primary clinical trial site, and Data Monitoring Committee outside of the NCI, as further described in the section titled "Proprietary Rights to BiovaxID" below. As of September 30, 2006, there were 17 clinical sites and 216 patients enrolled in the clinical trial.

The following summarizes the results and status of our ongoing, recently completed, and currently planned clinical trials for BiovaxID as of September 30, 2006:

Trial / Indication	Clinical Phase	Study Design	No. of Patients Treated with BiovaxID or Control	Median Time-to-Disease Progression	Status
Trial No. BV301 Indolent follicular B-cell NHL patients in first complete remission following chemotherapy; 5 immunizations over 24 weeks	Phase 3	Randomized, double blind with KLH-treated control group	375 planned	Treatment phase in progress	Enrolling patients to treatment phase; 216 have been enrolled (164 of which had been randomized to receive BiovaxID or control)
Trial No. T93-0164 Indolent follicular B-cell NHL patients in first complete remission following chemotherapy; 5 immunizations over 24 weeks	Phase 2	Open label, single arm	20	Follow-up period exceeded 9 years as of September 2006: 45% of patients were disease free at that time and 95% of patients were alive at that time	Treatment phase completed; patients in long-term follow-up

The objective of our Phase 3 clinical study is to measure the efficacy of the active idiotype vaccination in regard to prolongation of the period of disease-free survival when compared to treatment with a control vaccine consisting solely of KLH in patients with B-cell indolent follicular NHL. The patients being treated under this protocol have been diagnosed with previously untreated Stage 2 with bulky adenopathy or 3-4 follicular NHL, Grades I-IIIa, which are the indolent slowly progressing forms of the disease that historically have been incurable. PACE chemotherapy (prednisone, doxorubicin, cytoxan and etoposide) is administered until patients achieve their best response, which is a minimum of six cycles over six to eight months. Those patients achieving a complete remission are then randomized to receive vaccination with either BiovaxID or the KLH control in a 2:1 ratio, respectively. Of the 375 patients who will be in a complete remission (CR/CRu) after chermotherapy in the BV301 study, 250 patients are scheduled to be randomly selected, or randomized, for the BiovaxID treatment arm, and 125 are scheduled to be randomized to the control arm, KLH-KLH. Of the 250 patients who are scheduled to be randomized to the BiovaxID treatment arm, we estimate that approximately one third have completed the series of vaccinations and are in the follow-up phase of the trial. The patients being treated with BiovaxID have received or are receiving a series of five subcutaneous injections of the therapeutic vaccine administered over a six-month period. Each vaccination is accompanied by a series of four injections of GM-CSF. After a six-month waiting period while the patient's immune system reconstitutes, the patient initiates the vaccination series. The primary endpoint is a comparison between treatment groups of the median duration of disease-free survival measured from the time of randomization to the point of confirmed relapse. Data from the trial are reviewed periodically (at least annually) by an independent safety data monitoring board, and at the June 2006 meeting of this board, no safety concerns regarding the trial were identified. We are seeking to complete enrollment for our Phase 3 clinical trial by the fourth quarter of 2008. To complete enrollment in that timeframe, we will need to continue our efforts to significantly increase the rate at which we are currently enrolling patients. To accomplish our desired rate of enrollment, we have already activated various clinical sites in Russia and will initiate sites in Ukraine as well. The first patients were enrolled from those countries in November 2006. Furthermore, the Rituxan-based regimen, CHOP-R may be added to the current protocol as an additional choice of induction chemotherapy next to PACE by the end of 2006. This might allow the addition of U.S. sites and increase in the overall patient accrual. The implementation of CHOP-R would increase the desired overall randomization number of 375 to 540. Following the completion of enrollment, we will continue to monitor the participating patients and analyze resulting data. At such time that an interim analysis of the data confirms a statistically significant difference between the active and control groups in relation to our clinical endpoint, the data will be assembled for submission of a Biologics License Application requesting the FDA's approval for commercialization of BiovaxID. The time it takes to reach the clinical endpoint following the completion of enrollment, which may take several years, will depend on a variety of factors, including the relative efficacy of the vaccine, the magnitude of the impact of the vaccine on time-to-tumor progression, drop-out rates of clinical trial patients, and the median follow-up time subsequent to administration of vaccine or control.

The objective of the NCI's Phase 2 clinical investigation was to study the ability of an idiotype vaccine to elicit tumor-specific T-cell immunity in follicular B-cell NHL patients, as measured by the ability of the patient's T-cells to specifically destroy their own tumor cells *in vitro* and to exert anti-tumor effects as measured by the elimination of cells from the peripheral blood of a uniform group of patients. In this study conducted by the NCI, 20 patients who had achieved complete remission following chemotherapy received a series of five BiovaxID and GM-CSF injections over a six-month period. Of the 20 patients, 11 had a molecular marker in their lymphoma cells considered a hallmark of follicular NHL. As assessed by clearance of this marker from their blood, eight of these 11 patients (73%) totally cleared all residual tumor cells post vaccination (molecular remission). The molecular remission was sustained for as long as the patients were followed, for a median follow-up of 18 months, with a range of eight to 32 months. In the Phase 2 study, 75% of the patients treated with BiovaxID developed antibodies to their individual tumor cells and 95% developed T-cell immune responses specific for the patient's NHL idiotype. At an interim study assessment, 18 of 20 patients remained in continuous complete remission for a median 42 months, with a range of 28 to 52 months. After long-term follow-up at nine years post vaccination, as reported by the NCI in 2005 to the American Society of Hematology, 19 of 20 patients remained alive, and 9 of 20 patients remained in complete continuous remission.

In October 2006, we were granted orphan drug *designation* for BiovaxID by the EMEA (European Medicines Agency). This designation is intended to promote the development of products that may offer therapeutic benefits for diseases affecting less than five in 10,000 people in the European Union (EU). The Commission of the European Union entered BiovaxID into the European Community's Drug Register for Rare Diseases. Orphan drug designation provides opportunities for free protocol assistance, fee reductions for access to the centralized community procedures before and after marketing authorization, and 10 years of market exclusivity following drug approval. The EMEA represents 25 EU countries, including France, Germany, Belgium, Italy, Spain, and the United Kingdom. We had previously applied to the FDA for orphan drug designation for the use of BiovaxID for the treatment of certain forms of follicular B-cell NHL, but the FDA has determined that BiovaxID is ineligible for orphan drug designation in the absence of further information and clarification. We have no plans to further pursue this designation with the FDA at this time.

In May 2006, we were granted fast-track designation for BiovaxID by the FDA. Fast-Track is a formal mechanism to interact with the FDA using approaches that are available to all applicants for marketing applications. The benefits of Fast-Track include scheduled meetings to seek FDA input into development plans, the option of submitting a NDA in sections rather than all components simultaneously, and the option of requesting evaluation of studies using surrogate endpoints. The Fast-Track designation is intended for the combination of a product and a claim that addresses an unmet medical need, but is independent of Priority Review and Accelerated Approval. An applicant may use any or all of the components of Fast-Track without the formal designation. Fast-Track designation does not necessarily lead to a Priority Review or Accelerated Approval.

Proprietary Rights to BiovaxID

Our proprietary position in the BiovaxID vaccine and production process is based on a combination of patent protection, trade secret protection and our ongoing innovation. Although the composition of matter of the BiovaxID vaccine is not patentable, we have filed a PCT patent application relating to the type of cell media that is used to grow cell cultures in the production of our vaccine. In addition, we have filed a PCT patent application relating to certain features of an integrated production and purification system that we are developing to produce and purify the vaccine in an automated closed system. Our proprietary production system will use fully enclosed and disposable components for each patient's vaccine. We believe that, without the availability of an automated production and purification system, the methods used to produce a patient-specific immunotherapy are time-consuming and labor-intensive, resulting in a very expensive process that would be difficult to scale up. An application has also been filed for the registration of the trademark BiovaxID.

On August 30, *2001, our Biovest* subsidiary entered into the CRADA with the NCI under which we began the process of assuming control over the ongoing Phase 3 clinical trial being conducted pursuant to NCI's protocol. On April 29, 2004, the IND for BiovaxID was formally transferred from the NCI to our Biovest subsidiary, making us, rather than the NCI, the sponsor and responsible party. Following the transfer of the IND to us, the trial related functions that continued to be performed at the NCI were largely limited to pathology laboratory services, the operation and maintenance of the small primary trial site and administrative trial oversight through the NCI Data Safety and Monitoring Board (DSMB). On September 25, 2006, our Biovest subsidiary provided written notice to the NCI in accordance with the terms of the CRADA to terminate the CRADA at the end of the sixty day notice period. Under the terms of the CRADA, we are obligated to continue to provide vaccine to the NCI at no charge for purposes of the NCI's studies that are within the scope of the CRADA. We believe that our trial site at MD Anderson Cancer Center, Houston, Texas, which is presently the most active trial site, will become the new primary trial site. We have identified two highly qualified pathology laboratories, including the University of Turino, Italy, one of which will be selected to provide the on-going pathology laboratory services. A new Data Monitoring Committee has replaced the functions previously performed by the DSMB. We do not believe that the

termination of the CRADA or the pending transfer of certain trial related functions will adversely impact the treatment of existing patients, the enrollment of new patients, or the overall time line of the trial.

In September 2004, we entered into an agreement with Stanford University giving us worldwide rights to use two proprietary hybridoma cell lines that are used in the production of BiovaxID. These are the same cell lines that have been used by researchers at Stanford and the NCI to perform their studies of the hybridoma idiotype vaccine in NHL. This agreement gives us exclusive rights to these cell lines through 2019 in the fields of B-cell and T-cell cancers, and it gives us non-exclusive rights in such fields of use at all times after 2019.

The agreement also gives us the right to sublicense or transfer the licensed biological materials to collaborators in the licensed fields. Under our agreement with Stanford, we paid Stanford an up-front license fee of $15,000 and are obligated to pay a yearly maintenance fee of $10,000 per year thereafter. The agreement also provides that we will pay Stanford $100,000 within one year following FDA approval of BiovaxID or five years following the agreement date (whichever occurs first), and following approval we will pay Stanford a running royalty of the higher of $50.00 per patient or 0.05% of the amount received by us for each BiovaxID patient treated using this cell line. This running royalty will be creditable against the yearly maintenance fee. Our agreement with Stanford obligates us to diligently develop, manufacture, market, and sell BiovaxID and to provide progress reports to Stanford regarding these activities. We can terminate this agreement at any time upon 30 days prior written notice, and Stanford can terminate the agreement upon a breach of the agreement by us that remains uncured for 30 days after written notice of the breach from Stanford.

Sales and Marketing

If BiovaxID moves closer to potential regulatory approval, we currently plan to seek to identify a suitable strategic partner for purposes of collaborating in the marketing and distribution of BiovaxID in the U.S. Alternatively, if we obtain regulatory approval for BiovaxID prior to forming such a strategic relationship, we plan to build a small, highly-focused sales and marketing force to market BiovaxID to oncologists. We believe that a relatively small but highly trained sales force can serve the oncology market in North America due to the limited number of oncologists. There are approximately 8,400 medical oncologists in the U.S. To penetrate oncology markets outside the U.S., we may establish collaborations with companies already positioned in the oncology field to assist in the commercialization of BiovaxID.

On February 27, 2004, we entered into a Biologics Distribution Agreement with McKesson Corporation, a large pharmaceutical distributor that gives McKesson Corporation exclusive distribution rights for all of our biologic products, which include BiovaxID, antigens, monoclonal antibodies, and cell cultures.

Previously, we had agreed to provide commercialization services relating to BiovaxID under an exclusive agreement with Biovest. On October 31, 2006, the Commercialization Agreement was superseded by a Licensing Agreement under which we earn a 19.5% royalty on all sales of BiovaxID.

Specialty Pharmaceutical Products

We have a specialty pharmaceutical business, Accentia Pharmaceuticals, through which we currently sell our Respi-TANN®, MD Turbo™ products and CRSFungal Profile™ test through our dedicated sales force. At September 30, 2006, we had approximately 48 salespeople. Our specialty pharmaceutical business, previously named TEAMM Pharmaceuticals, Inc., has been renamed, Accentia Pharmaceuticals.

Respi~TANN is a unique family of antitussive and other ingredients, including a decongestant for temporary relief of cough and nasal congestion accompanying respiratory tract conditions associated with the common cold, influenza, sinusitis, and bronchitis. MD Turbo is a breath-actuated inhaler device that is designed to work in conjunction with most metered-dose inhalers. Metered-dose inhalers, or MDIs, are small hand-held devices that are used to deliver inhaled drugs by housing the aerosol canisters containing such drugs and triggering the release of the drugs from the canisters. MDIs are the most commonly prescribed type of inhalation device for patients with asthma and chronic obstructive pulmonary disease. CRSFungal Profile is a proprietary diagnostic test for determining the level of major basic protein, or MBP, in a patient's mucus. MBP is an esonophils-derived protein that we believe can be used to diagnose CRS by measuring the concentration of it in a patient's mucus.

In addition to our currently marketed products, we have two products, AllerNase™ and Emezine®, currently being developed for us by third-parties. AllerNase is a novel formulated suspension of an intranasal topical steroid indicated for the treatment of allergic and non-allergic rhinitis. Emezine is a product for control of nausea and vomiting, consisting of a formulation of prochlorperazine maleate that is placed between the upper lip and gum for transbuccal absorption, which is absorption into the bloodstream through the cheek.

We anticipate that our specialty pharmaceutical business may strategically support our commercialization efforts related to SinuNase especially among specialists such as otolarnygologists (ENTs) and allergists, assuming FDA approval. This business may further facilitate our ability to acquire additional products and/or product candidates and potentially establish strategic relationships.

Pharmaceutical Product Consulting Services

Through our subsidiary, Analytica International, Inc. (Analytica), we provide a broad range of consulting services to companies and institutions in the pharmaceutical, biotechnology, and medical markets, including some of the world's largest pharmaceutical companies. We provide these services to clients throughout the world, and we also utilize these services for our own product development efforts in order to, among other things, evaluate and analyze the market and potential pricing of our product candidates. Our development and commercialization services include outcomes research on the economic profiles of pharmaceuticals and biologics, pricing and market assessment on these products, and various services designed to expedite clinical trials. We also use these services to evaluate the payor reimbursement prospects of our products and to develop reimbursement strategies.

We provide our commercialization and development services through a team of employees who are based in offices in New York and Germany. This team includes research professionals at the Master's and Doctoral level in the fields of medicine, epidemiology, biochemistry, statistics, engineering, public health, pharmacy, health economics, and business administration.

Instrument Production

We manufacture instruments to produce biologic products such as mammalian cells, proteins, monoclonal antibodies, and other cell culture products. Our instruments are based on the hollow-fiber method of biologic production. In November 2006, we announced the introduction of our new automated instrument, named AutovaxID™, which is designed to reduce the cost and space-dependent requirements of manual biologics production. In addition to selling our instruments, including the AutovaxID, to biopharmaceutical and biotechnology companies, medical schools, universities, research facilities, hospitals, and public and private laboratories, we use our instruments to manufacture our BiovaxID vaccine. Additionally, we produce biologic materials for third-parties on a contract basis using our instruments. This business is conducted through Biovest, our majority owned subsidiary, which is also the developer and manufacturer of our BiovaxID vaccine.

Sales and Marketing

Our sales force currently consists of approximately 48 full-time employees for the marketing and sale of our current specialty pharmaceutical products. We expect that we will continue to use our sales force to market and sell Respi~TANN, CRS Fungal Profile, and MD Turbo and if approved, SinuNase, AllerNase, and Emezine. Alternatively, we may elect to enter into third-party sales relationships. If we obtain regulatory approval for BiovaxID, we plan to build at Biovest a small, highly-focused sales and marketing force or enter into third-party sales and marketing relationships to market the product to the oncology market, although we may also establish marketing relationships with third-parties to penetrate this market, particularly in foreign countries. We are evaluating our business strategy with regard to our specialty pharmaceutical business, including its staffing requirements and the availability of co-promotion marketing opportunities.

Competition

The pharmaceutical industry is highly competitive and includes a number of established large and mid-sized pharmaceutical companies, as well as smaller emerging companies, whose activities are directly focused on our target markets and areas of expertise. If approved, our product candidates will compete with a large number of products that could include over-the-counter treatments, prescription drugs, and prescription drugs that are prescribed off-label. In addition, new developments, including the development of other drug technologies and methods of preventing the incidence of disease, occur in the pharmaceutical industry at a rapid pace. These developments may render our product candidates or technologies obsolete or noncompetitive.

If approved, each of our product candidates will compete for a share of the existing market with numerous products that have become standard treatments recommended or prescribed by physicians. For example, we believe the primary competition for our product candidates are:

- For SinuNase, we are not aware of any third-party that is marketing or developing a comparable product to treat CRS with amphotericin B, although it is possible that other antifungals may be formulated for CRS. In addition, our CRS therapy will compete with alternative treatments for CRS, including surgery, antibiotics, and corticosteroids.

- For BiovaxID, we are aware of several companies focusing on the development of active immunotherapies for NHL, including Genitope Corporation, Antigenics, Inc., and Favrille, Inc. None of these companies uses the hybridoma method to produce a patient-specific vaccine, and of these companies, only Genitope and Favrille have a product candidate in Phase 3 clinical trials. Several companies, such as Biogen Idec, and Immunomedics, Inc., are involved in the development of passive immunotherapies for NHL. These passive immunotherapies include Rituxan, a monoclonal antibody, and Zevalin and Bexxar, which are passive radioimmunotherapy products.
- For AllerNase, we will compete with the other intransal corticosteroids currently marketed including Flonase®, Nasonex®, Rhinocort Aqua®, Nasacort AQ®, and Nasarel®
- For MD Turbo, we will compete with 3M Corporation's Maxair™ product, which is a breath-actuated inhaler device usable with only one medication, as well as with standard MDIs that are not breath-actuated, including MDIs manufactured by generic albuterol manufacturers such as Dey, IVAX, Zenith, and GlaxoSmithKline. We believe that the Maxair™ breath-actuated MDI represented about 2% of MDI sales in 2003 in the U.S. We will also compete with MDI spacers and holding chambers such as Opti-Chamber, Inspirease, and Aerochamber.
- For Emezine, we are not aware of any other transbuccal administered formulation of prochlorperazine maleate that is approved for marketing in the U.S., although we will compete with other prochlorperazine products being marketed and sold in the U.S. by GlaxoSmithKline and other generic manufacturers.
- For Respi~TANN we compete with a wide variety of branded and generic prescription cough, cold, and allergy medications, such as Tussionex. Our Respi~TANN product competes in the antitussive combination market, in which Allegra-D and Zyrtec D are the largest competitors with about 58% and 28% of the market, respectively.

We expect to compete on, among other things, the safety and efficacy of our products and more desirable treatment regimens, combined with the effectiveness of our experienced management team. Competing successfully will depend on our continued ability to attract and retain skilled and experienced personnel, to identify and secure the rights to and develop pharmaceutical products and compounds and to exploit these products and compounds commercially before others are able to develop competitive products.

Government Regulation

Government authorities in the United States at the federal, state, and local levels and foreign countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing, and import and export of pharmaceutical products, biologics, and medical devices. All of our products in development will require regulatory approval by government agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials 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, safety, labeling, storage, and record-keeping related to such products and their marketing. The process of obtaining these approvals and the subsequent process of maintaining substantial compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. In addition, statutes, rules, regulations, and policies may change and new legislation or regulations may be issued that could delay such approvals.

Pharmaceutical Product Regulation

In the United States, the U.S. Food and Drug Administration, or FDA, regulates drugs and well-characterized biologics under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implementing regulations that are adopted under the FDCA. In the case of biologics, the FDA regulates such products under the Public Health Service Act. If we fail to comply with the applicable requirements under these laws and regulations at any time during the product development process, approval process, or after approval, we may become subject to administrative or judicial sanctions. These sanctions could include the FDA's refusal to approve pending applications, withdrawals of approvals, clinical holds, warning letters, product recalls, product seizures, total or partial suspension of our operations, injunctions, fines, civil penalties or criminal prosecution. Any agency enforcement action could have a material adverse effect on us. The FDA also administers certain controls over the export of drugs and biologics from the U.S.

Under the United States regulatory scheme, the development process for new pharmaceutical products can be divided into three distinct phases:

- *Preclinical Phase.* The preclinical Phase 1nvolves the discovery, characterization, product formulation and animal testing necessary to prepare an Investigational New Drug application, or IND, for submission to the FDA. The IND must be accepted by the FDA before the drug can be tested in humans.
- *Clinical Phase.* The clinical phase of development follows a successful IND submission and involves the activities necessary to demonstrate the safety, tolerability, efficacy, and dosage of the substance in humans, as well as the ability to produce the substance in accordance with the FDA's current Good Manufacturing Processes (cGMP) requirements. Data from these activities are compiled in a New Drug Application, or NDA, or for biologic products a Biologics License Application, or BLA, for submission to the FDA requesting approval to market the drug.
- *Post-Approval Phase.* The post-approval phase follows FDA approval of the NDA or BLA, and involves the production and continued analytical and clinical monitoring of the product. The post- approval phase may also involve the development and regulatory approval of product modifications and line extensions, including improved dosage forms, of the approved product, as well as for generic versions of the approved drug, as the product approaches expiration of patent or other exclusivity protection.

Each of these three phases is discussed further below.

Preclinical Phase. The development of a new pharmaceutical agent begins with the discovery or synthesis of a new molecule or well-characterized biologic. These agents are screened for pharmacological activity using various animal and tissue models, with the goal of selecting a lead agent for further development. Additional studies are conducted to confirm pharmacological activity, to generate safety data, and to evaluate prototype dosage forms for appropriate release and activity characteristics. Once the pharmaceutically active molecule is fully characterized, an initial purity profile of the agent is established. During this and subsequent stages of development, the agent is analyzed to confirm the integrity and quality of material produced. In addition, development and optimization of the initial dosage forms to be used in clinical trials are completed, together with analytical models to determine product stability and degradation. A bulk supply of the active ingredient to support the necessary dosing in initial clinical trials must be secured. Upon successful completion of preclinical safety and efficacy studies in animals, an IND submission is prepared and provided to the FDA for review prior to commencement of human clinical trials. The IND consists of the initial chemistry, analytical, formulation, and animal testing data generated during the preclinical phase. In general, the review period for an IND submission is 30 days, after which, if no comments are made by the FDA, the product candidate can be studied in Phase 1 clinical trials.

The process for the development of biologic products, such as our BiovaxID product, parallels the process outlined above. Biologics, in contrast to drugs that are chemically synthesized, are derived from living sources, such as humans, animals, and microorganisms. Most biologics are complex mixtures that are not easily identified or characterized and have activity that is different from the activity of small, organic molecules normally found in drugs. Because of the diversity of the nature of biologic products and their substantial molecular size (usually hundreds of times larger than small, organic molecules associated with drugs), special technology is often required for their production and subsequent analysis. Biologic products, especially proteins, may be produced with living cells. Purity testing of biologics can be complex since living cells may harbor viruses and other agents. The potential presence of these agents, and the requirement to establish degradation profiles and identify impurities associated with production and purification, further require establishing, validating, and conducting specialized tests and analyses. Formulation development in this area is often more complex than for small, organic drug substances. For example, molecules produced using recombinant DNA technology are inherently less stable than their organic counterparts because structural integrity must be maintained through administration and distribution of the product. Accordingly, certain aspects of the development process for biologic products may be more challenging than similar aspects encountered in the development of drugs.

Clinical Phase. Following successful submission of an IND, the sponsor is permitted to conduct clinical trials involving the administration of the investigational product candidate to human subjects under the supervision of qualified investigators in accordance with good clinical practice. Clinical trials are conducted under protocols detailing, among other things, the objectives of the study and the parameters to be used in assessing the safety and the efficacy of the drug. Each protocol must be submitted to the FDA as part of the IND prior to beginning the trial. Each trial must be reviewed, approved and conducted under the auspices of an independent Institutional Review Board, and each trial, with limited exceptions, must include the patient's informed consent. Typically, clinical evaluation involves the following time-consuming and costly three-phase sequential process:

- *Phase 1.* Phase 1 human clinical trials are conducted in a limited number of healthy individuals to determine the drug's safety and tolerability and includes biological analyses to determine the availability

and metabolization of the active ingredient following administration. The total number of subjects and patients included in Phase 1 clinical trials varies, but is generally in the range of 20 to 80 people.

- *Phase 2.* Phase 2 clinical trials involve administering the drug to individuals who suffer from the target disease or condition to determine the drug's potential efficacy and ideal dose. These clinical trials are typically well controlled, closely monitored, and conducted in a relatively small number of patients, usually involving no more than several hundred subjects. These trials require scale up for manufacture of increasingly larger batches of bulk chemical. These batches require validation analysis to confirm the consistent composition of the product.
- *Phase 3.* Phase 3 clinical trials are performed after preliminary evidence suggesting effectiveness of a drug has been obtained and safety (toxicity), tolerability, and an ideal dosing regimen have been established. Phase 3 clinical trials are intended to gather additional information about the effectiveness and safety that is needed to evaluate the overall benefit-risk relationship of the drug and to complete the information needed to provide adequate instructions for the use of the drug, also referred to as the Official Product Information. Phase 3 trials usually include from several hundred to several thousand subjects.

Throughout the clinical phase, samples of the product made in different batches are tested for stability to establish shelf life constraints. In addition, large-scale production protocols and written standard operating procedures for each aspect of commercial manufacture and testing must be developed.

Phase 1, 2, and 3 testing may not be completed successfully within any specified time period, if at all. The FDA closely monitors the progress of each of the three phases of clinical trials that are conducted under an IND 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 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 additional clinical trials be conducted as a condition to product approval. Additionally, new government requirements may be established that could delay or prevent regulatory approval of our products under development. Furthermore, institutional review boards, which are independent entities constituted to protect human subjects in the institutions in which clinical trials are being conducted, have the authority to suspend clinical trials at any time for a variety of reasons, including safety issues.

New Drug Application (NDA) or Biologics License Application (BLA)

After the successful completion of Phase 3 clinical trials, the sponsor of the new drug submits an NDA, or BLA in the case of biologics, to the FDA requesting approval to market the product for one or more indications. An NDA, or BLA, is a comprehensive, multi-volume application that includes, among other things, the results of all preclinical and clinical studies, information about the drug's composition, and the sponsor's plans for producing, packaging, and labeling the drug. Under the Pediatric Research Equity Act of 2003, an application also is required to include an assessment, generally based on clinical study data, on the safety and efficacy of drugs for all relevant pediatric populations before the NDA is submitted. The statute provides for waivers or deferrals in certain situations. We have applied for a pediatric assessment waiver for Emezine but we can make no assurances that such situations apply to our other products. In most cases, the NDA or BLA must be accompanied by a substantial user fee. In return, the FDA assigns a goal of 10 months from acceptance of the application to return of a first "complete response," in which the FDA may approve the product or request additional information.

The submission of the application is no guarantee that the FDA will find it complete and accept it for filing. The FDA reviews all NDAs and BLAs submitted before it accepts them for filing. It may refuse to file the application and request additional information rather than accept the application for filing, in which case, the application must be resubmitted with the supplemental information. After application is deemed filed by the FDA, the FDA reviews an NDA or BLA to determine, among other things, whether a product is safe and effective for its intended use. The FDA has substantial discretion in the approval process and may disagree with an applicant's interpretation of the data submitted in its NDA or BLA. Drugs that successfully complete NDA or BLA review may be marketed in the United States, subject to all conditions imposed by the FDA. Prior to granting approval, the FDA generally conducts an inspection of the facilities, including outsourced facilities, which will be involved in the manufacture, production, packaging, testing and control of the drug product for cGMP compliance. The FDA will not approve the application unless cGMP compliance is satisfactory. If the FDA determines that the marketing 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 marketing application does not satisfy the regulatory criteria for approval and refuse to approve the application by issuing a "not approvable" letter.

The length of the FDA's review ranges from a few months to many years.

Fast-Track Review

The Food and Drug Administration Modernization Act of 1997, or the Modernization Act, establishes a statutory program for the approval of "Fast-Track" products, which are defined under the Modernization Act as new drugs or biologics intended for the treatment of a serious or life-threatening condition that demonstrate the potential to address unmet medical needs for this condition. To determine whether a condition is "serious" for the purposes of Fast-Track designation, the FDA considers several factors including, the condition's impact on survival, day-to-day functioning, and the likelihood that the disease, if left untreated, will progress from a less severe condition to a more serious one. If awarded, the Fast-Track designation applies to the product only for the indication for which the designation was received. Under the Fast-Track program, the sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast-Track product in writing at any time during the clinical development of the product. The act specifies that the FDA must determine if the product qualifies for Fast-Track designation within 60 days of receipt of the sponsor's request.

Fast-Track designation offers a product the benefit of approval based on surrogate endpoints that generally would not be acceptable for approval and also offers possible early or rolling acceptance of the marketing application for review by the agency. However, the time periods to which the FDA has committed in reviewing an application do not begin until the sponsor actually submits the application. The FDA may subject approval of an application for a Fast-Track product to post-approval studies to validate the surrogate endpoint or confirm the effect on the clinical endpoint, and the FDA may also subject such approval to prior review of all promotional materials. In addition, the FDA may withdraw its approval of a Fast-Track product on a number of grounds, including the sponsor's failure to conduct any required post-approval study with due diligence and failure to continue to meet the criteria for designation.

Fast-Track designation should be distinguished from the FDA's other programs for expedited development and review, although products awarded Fast-Track status may also be eligible for these other benefits. Accelerated approval refers to the use of less than well-established surrogate endpoints discussed above. Priority review is a designation of an application after it has been submitted to FDA for approval. The agency sets the target date for agency actions on the applications of products that receive priority designation for six months, where products under standard review receive a ten month target.

The FDA has granted "Fast-Track" review status to both SinuNase and BiovaxID, which means that these products may be eligible for expedited review procedures by the FDA. However, we cannot predict the impact, if any, that Fast-Track designation will actually have on the duration of the regulatory approval process for these product candidates, and the FDA may deny regulatory approval of either or both of these product candidates notwithstanding their Fast-Track designation.

Post-Approval Phase

If the FDA approves the NDA, BLA, or ANDA application, as applicable, the pharmaceutical product becomes available for physicians to prescribe in the United States. After approval, we are still subject to continuing regulation by FDA, including record keeping requirements, submitting periodic reports to the FDA, reporting of any adverse experiences with the product, and complying with drug sampling and distribution requirements. In addition, we are required to maintain and provide updated safety and efficacy information to the FDA. We are also required to comply with requirements concerning advertising and promotional labeling. In that regard, our advertising and promotional materials must be truthful and not misleading. We are also prohibited from promoting any non-FDA approved or "off-label" indications of products. Failure to comply with those requirements could result in significant enforcement action by the FDA, including warning letters, orders to pull the promotional materials, and substantial fines. Also, quality control and manufacturing procedures must continue to conform to cGMP after approval.

Drug and biologics manufacturers and their subcontractors are required to register their facilities and products manufactured annually with FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA to assess compliance with cGMP regulations. Facilities may also be subject to inspections by other federal, foreign, state, or local agencies. In addition, approved biological drug products may be subject to lot-by-lot release testing by the FDA before these products can be commercially distributed. 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. We use, and will continue to use, third-party manufacturers, to produce certain of our products in clinical and commercial quantities, and 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, following FDA approval of a product, 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 marketing application, 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, the FDA may require post-market testing and

surveillance to monitor the product's safety or efficacy, including additional clinical studies, known as Phase 4 trials, to evaluate long-term effects.

Hatch-Waxman Act

Under the Drug Price Competition and Patent Term Restoration Act of 1984, also known as the Hatch-Waxman Act, Congress created an abbreviated FDA review process for generic versions of pioneer (brand name) drug products. In order to preserve the incentives of pioneer drug manufacturers to innovate, the Hatch-Waxman Act also provides for patent term restoration and the award, in certain circumstances, of non-patent marketing exclusivities.

Abbreviated New Drug Applications (ANDAs)

An ANDA is a type of application in which approval is based on a showing of "sameness" to an already approved drug product. ANDAs do not contain full reports of safety and effectiveness, as do NDAs, but rather demonstrate that their proposed products are "the same as" reference products with regard to their conditions of use, active ingredient(s), route of administration, dosage form, strength, and labeling. ANDA applicants are also required to demonstrate the "bioequivalence" of their products to the reference product. Bioequivalence generally means that there is no significant difference in the rate and extent to which the active ingredient(s) in the products becomes available at the site of drug action.

All ANDAs must contain data relating to product formulation, raw material suppliers, stability, manufacturing, packaging, labeling, and quality control, among other information. The timing of final FDA approval of an ANDA depends on a variety of factors, including whether the applicant has challenged any patents claiming the reference product and whether the pioneer manufacturer is entitled to one or more periods of non-patent marketing exclusivity. In certain circumstances, these marketing exclusivities can extend beyond the life of a patent, and block the approval of ANDAs after the date on which the patent expires. If the FDA concludes that all substantive ANDA requirements have been satisfied, but final approval is blocked because of a patent or a non-patent marketing exclusivity, the FDA may issue the applicant a "tentative approval" letter.

505(b)(2) Applications

If a proposed product represents a change from an already approved product, yet does not qualify for submission under an ANDA pursuant to an approved suitability petition, the applicant may be able to submit a type of NDA referred to as a "505(b)(2) application." A 505(b)(2) application is an NDA for which one or more of the investigations relied upon by the applicant for approval was not conducted by or for the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigation was conducted. The FDA has determined that 505(b)(2) applications may be submitted for products that represent changes from approved products in conditions of use, active ingredient(s), route of administration, dosage form, strength, or bioavailability. A 505(b)(2) applicant must provide FDA with any additional clinical data necessary to demonstrate the safety and effectiveness of the product with the proposed change(s). Consequently, although duplication of preclinical and certain clinical studies is avoided through the use a 505(b)(2) application, specific studies may be required. We plan to submit a 505(b)(2) application for SinuNase, and Arius, our development partner for our Emezine product, submitted a 505(b)(2) application for Emezine in April 2005.

Patent Term Restoration

The Hatch-Waxman Act also provides for the restoration of a portion of the patent term lost during product development and FDA review of an application. However, the maximum period of restoration cannot exceed 5 years, or restore the total remaining term of the patent to greater than 14 years from the date of FDA approval of the product. The patent term restoration period is generally one-half the time between the effective date of the IND and the date of submission of the NDA, plus the time between the date of submission of the NDA and the date of FDA approval of the product. Only one patent claiming each approved product is eligible for restoration and the patent holder must apply for restoration within 60 days of approval. The United States Patent and Trademark Office, in consultation with FDA, reviews and approves the application for patent term restoration. In the future, we may consider applying for patent term restoration for some of our currently owned or licensed patents, depending on the expected length of clinical trials and other factors involved in the filing of an NDA.

ANDA and 505(b)(2) Applicant Challenges to Patents and Generic Exclusivity

ANDA and 505(b)(2) applicants are required to list with FDA each patent that claims their approved products and for which claims of patent infringement could reasonably be asserted against unauthorized manufacturers. ANDA and 505(b)(2) applicants must then certify regarding each of the patents listed with the FDA for the product(s) it references. An applicant can certify that there is no listed patent, that the listed patent has expired, that the application may be approved upon the date

of expiration of the listed patent, or that the patent is invalid or will not be infringed by the marketing of the applicant's product. This last certification is referred to as a "Paragraph IV certification."

If a Paragraph IV certification is filed, the applicant must also provide notice to the NDA holder and patent owner stating that the application has been submitted and providing the factual and legal basis for the applicant's opinion that the patent is invalid or not infringed. The NDA holder or patent owner may sue the ANDA or 505(b)(2) applicant for patent infringement. If the NDA holder or patent owner files suit within 45 days of receiving notice of the application, a one-time 30-month stay of FDA's ability to approve the ANDA or 505(b)(2) application is triggered. FDA may approve the proposed product before the expiration of the 30-month stay if a court finds the patent invalid or not infringed or shortens the period because parties have failed to cooperate in expediting the litigation.

As an incentive to encourage generic drug manufacturers to undertake the expenses associated with Paragraph IV patent litigation, the first ANDA applicant to submit a substantially complete ANDA with a Paragraph IV certification to a listed patent may be eligible for a 180-day period of marketing exclusivity. For ANDAs filed after December 8, 2003 that use a reference product for which no Paragraph IV certification was made in any ANDA before that date, this exclusivity blocks the approval of any later ANDA with a Paragraph IV certification referencing the same product. For these ANDAs, the exclusivity period runs from the date when the generic drug is first commercially marketed.

For other ANDAs, the 180-day exclusivity period blocks the approval of any later ANDA with a Paragraph IV certification referencing at least the same patent, if not the same product, and may be triggered on the date the generic drug is first commercially marketed or the date of a decision of a court holding that the patent that was the subject of the Paragraph IV certification is invalid or not infringed. This decision must be from a court from which no appeal can be or has been taken, other than a petition to the United States Supreme Court.

If multiple generic drug manufacturers submit substantially complete ANDAs with Paragraph IV certifications on the first day that any such ANDAs are submitted, all of these manufacturers will share in a single 180-day exclusivity period. Note also that these periods of 180-day exclusivity may be subject to forfeiture provisions, requiring relinquishment of the exclusivity in some situations, including cases where commercial marketing of the generic drug does not occur within a certain time period.

Non-Patent Marketing Exclusivities

The Hatch-Waxman Act also provides three years of "new use" marketing exclusivity for the approval of NDAs, 505(b)(2) applications, and supplements, where those applications contain the results of new clinical investigations (other than bioavailability studies) essential to the FDA's approval of the applications. Such applications may be submitted for new indications, dosage forms, strengths, or new conditions of use of already approved products. So long as the new clinical investigations are essential to the FDA's approval of the change, this three-year exclusivity prohibits the final approval of ANDAs or 505(b)(2) applications for products with the specific changes associated with those clinical investigations. It does not prohibit the FDA from approving ANDAs or 505(b)(2) applications for other products containing the same active ingredient.

Orphan Drug Designation and Exclusivity

Some jurisdictions, including the United States and the European Union, designate drugs intended for relatively small patient populations as "orphan drugs." The FDA, for example, grants orphan drug designation to drugs intended to treat rare diseases or conditions that affect fewer than 200,000 individuals in the United States or drugs for which there is no reasonable expectation that the cost of developing and making the drugs available in the United States will be recovered. In the United States orphan drug designation must be requested before submitting an application for approval of the product. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to a marketing exclusivity. For seven years, the FDA may not approve any other application, including NDAs or ANDAs, to market the "same drug" for the same indication. The only exception is where the second product is shown to be "clinically superior" to the product with orphan drug exclusivity, as that phrase is defined by the FDA and if there is an inadequate supply.

Manufacturing

Changes to the manufacturing process or site during or following the completion of clinical trials requires sponsors to demonstrate to the FDA that the product under new conditions is comparable to the product that was the subject of earlier clinical testing. This requirement applies to relocations or expansions of manufacturing facilities, such as the recent consolidation of all of the steps in the BiovaxID production process to our Worcester, Massachusetts plant and possible expansion to additional facilities that may be required for successful commercialization of the vaccine. A showing of

comparability requires data demonstrating that the product continues to be safe, pure, and potent and may be based on chemical, physical, and biological assays and, in some cases, other non-clinical data. If we demonstrate comparability, additional clinical safety and/or efficacy trials with the new product may not be needed. If the FDA requires additional clinical safety or efficacy trials to demonstrate comparability, our clinical trials or the FDA approval of BiovaxID may be delayed.

We anticipate that the manufacture of the other products in our development pipeline will be outsourced to experienced cGMP-compliant medical manufacturing companies. In addition, our currently marketed specialty pharmaceutical products are manufactured by third-party contract manufacturers, as identified elsewhere in this annual report on Form 10-K.

Prescription Drug Wrap-Up (DESI II Products)

The Federal Food, Drug, and Cosmetic Act (the Act) of 1938 was the first statute requiring pre-market-approval of drugs by the FDA. These approvals, however, focused exclusively on safety data. In 1962, Congress amended the Act to require that sponsors demonstrate that new drugs are effective, as well as safe, in order to receive FDA approval. This amendment also required the FDA to conduct a retrospective evaluation of the effectiveness of the drug products that the FDA approved between 1938 and 1962 on the basis of safety alone. The agency contracted with the National Academy of Science/National Research Council (NAS/NRC) to make an initial evaluation of the effectiveness of many drug products. The FDA's administrative implementation of the NAS/NRC reports was called the Drug Efficacy Study Implementation (DESI).

Drugs that were not subject to applications approved between 1938 and 1962 were not subject to DESI review. For a period of time, the FDA permitted these drugs to remain on the market without approval. In 1984, however, spurred by serious adverse reactions to one of these products, Congress urged the FDA to expand the new drug requirements to include all marketed unapproved prescription drugs. The FDA created a program, known as the Prescription Drug Wrap-Up, to address these remaining unapproved drugs. Most of these drugs contain active ingredients that were first marketed prior to the 1938 Act. We believe that several of our marketed pharmaceutical products fall within this category.

The FDA asserts that all drugs subject to the Prescription Drug Wrap-Up are on the market illegally and are subject to FDA enforcement discretion because there is an argument that all prescription drugs must be the subject of an approved drug application. There are a couple of narrow exceptions. For example, both the 1938 and 1962 Acts include grandfather provisions exempting certain drugs from the new drug requirements. The 1938 clause exempts drugs that were on market prior to the passage of the 1938 Act and contain the same representations concerning the conditions of use as they did prior to passage of the Act. The 1962 Act exempts, in certain circumstances, drugs that have the same composition and labeling as they had prior to the passage of the 1962 Act. The agency and the courts have interpreted these two exceptions very narrowly. As to drugs marketed over the counter, the FDA exempts through regulation products that are determined to be generally recognized as safe and effective (GRAS/GRASE) and have been used to a material extent and for a material time.

The FDA has adopted a risk-based enforcement policy that prioritizes enforcement of new drug requirements for unapproved drugs that pose a safety threat, lack evidence of effectiveness and prevent patients from pursuing effective therapies, and that are marketed fraudulently. In addition, the FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may also trigger agency enforcement of the new drug requirements. Once the FDA issues an approved NDA for one of the drug products at issue or completes the efficacy review for that drug product, it may require other manufacturers to also file a NDA or an abbreviated NDA (ANDA) for that same drug in order to continue marketing it in the United States. While the FDA generally provides sponsors a one year grace period, the agency is not statutorily required to do so.

Pharmacy Compounding

The FDA does not regulate the practice of pharmacy but does evaluate pharmacies to determine if their compounding practice qualifies them as drug manufacturers for the purpose of food and drug laws. If the FDA considers the actions of a compounding pharmacy to be similar to those of a drug manufacturer, the FDA will take action to stop such pharmacy compounding until a new drug application is approved for the marketing of such drugs.

Medical Device Regulation

New medical devices, such as our MD Turbo product, are also subject to FDA approval and extensive regulation under the FDCA. Under the FDCA, medical devices are classified into one of three classes: Class I, Class II, or Class III. The classification of a device into one of these three classes generally depends on the degree of risk associated with the medical device and the extent of control needed to ensure safety and effectiveness.

Class I devices are those for which safety and effectiveness can be assured by adherence to a set of general controls. These general controls include compliance with the applicable portions of the FDA's Quality System Regulation, which sets forth

good manufacturing practice requirements; facility registration and product reporting of adverse medical events listing; truthful and non-misleading labeling; and promotion of the device only for its cleared or approved intended uses. Class II devices are also subject to these general controls, and any other special controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. Review and clearance by the FDA for these devices is typically accomplished through the so-called 510(k) pre-market notification procedure. When 510(k) clearance is sought, a sponsor must submit a pre-market notification demonstrating that the proposed device is substantially equivalent to a previously approved device. If the FDA agrees that the proposed device is substantially equivalent to the predicate device, then 510(k) clearance to market will be granted. After a device receives 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a major change in its intended use, requires a new 510(k) clearance or could require pre-market approval. Our instruments and disposables used for the production of cell cultures are generally regulated as Class I devices exempt from the 510(k) clearance process.

Clinical trials are almost always required to support a PMA application and are sometimes required for a 510(k) pre-market notification. These trials generally require submission of an application for an investigational device exemption, or IDE. An IDE must be supported by pre-clinical data, such as animal and laboratory testing results, which show that the device is safe to test in humans and that the study protocols are scientifically sound. The IDE must be approved in advance by the FDA for a specified number of patients, unless the product is deemed a non-significant risk device and is eligible for more abbreviated investigational device exemption requirements.

Both before and after a medical device is commercially distributed, manufacturers and marketers of the device have ongoing responsibilities under FDA regulations. The FDA reviews design and manufacturing practices, labeling and record keeping, and manufacturers' required reports of adverse experiences and other information to identify potential problems with marketed medical devices. Device manufacturers are subject to periodic and unannounced inspection by the FDA for compliance with the Quality System Regulation, current good manufacturing practice requirements that govern the methods used in, and the facilities and controls used for, the design, manufacture, packaging, servicing, labeling, storage, installation, and distribution of all finished medical devices intended for human use.

If the FDA finds that a manufacturer has failed to comply or that a medical device is ineffective or poses an unreasonable health risk, it can institute or seek a wide variety of enforcement actions and remedies, ranging from a public warning letter to more severe actions such as:

- fines, injunctions, and civil penalties;
- recall or seizure of products;
- operating restrictions, partial suspension or total shutdown of production;
- refusing requests for 510(k) clearance or PMA approval of new products;
- withdrawing 510(k) clearance or PMA approvals already granted; and
- criminal prosecution.

The FDA also has the authority to require repair, replacement or refund of the cost of any medical device.

The FDA also administers certain controls over the export of medical devices from the U.S., as international sales of medical devices that have not received FDA approval are subject to FDA export requirements. Additionally, each foreign country subjects such medical devices to its own regulatory requirements. In the European Union, a single regulatory approval process has been created, and approval is represented by the CE Mark.

Other Regulation in the United States

Controlled Substances Act. Our Xodol pain product, and one of our Histex products all contain hydrocodone or oxycodone, a narcotic that is a "controlled substance" under the Controlled Substances Act. The federal Controlled Substances Act (CSA), Title II of the Comprehensive Drug Abuse Prevention and Control Act of 1970, is a consolidation of numerous laws regulating the manufacture and distribution of narcotics and other substances, including stimulants, depressants and hallucinogens. The CSA is administered by the Drug Enforcement Administration (DEA), a division of the U.S. Department of Justice, and is intended to prevent the abuse or diversion of controlled substances into illicit channels of commerce.

Any person or firm that manufactures, distributes, dispenses, imports, or exports any controlled substance (or proposes to do so) must register with the DEA. The applicant must register for a specific business activity related to controlled substances, including manufacturing or distributing, and may engage in only the activity or activities for which it is registered. The DEA conducts periodic inspections of registered establishments that handle controlled substances. In addition, a recent law requires DEA review of labeling, promotion, and risk management plans for certain controlled substances as a condition of DEA spending. Failure to comply with relevant DEA regulations, particularly as manifested in the loss or diversion of controlled substances, can result in regulatory action including civil penalties, refusal to renew necessary registrations, or

initiating proceedings to revoke those registrations. In certain circumstances, violations can lead to criminal prosecution. Mikart, which manufactures our pain products, is registered with the DEA to manufacture and distribute controlled substances.

Some of our products also contain pseudoephedrine. The DEA regulates pseudoephedrine, pursuant to the CSA and the Domestic Chemical Diversion Control Act of 1993, as a "listed chemical" because it can be used in the production of illicit drugs. There are two groups of listed chemicals, List I chemicals and List II chemicals; List I chemicals are more strictly regulated. Pseudoephedrine is a List I chemical. Persons or firms who manufacture, distribute, import, or export listed chemicals in amounts above specified threshold levels, or chemical mixtures that contain listed chemicals above specified threshold amounts, must fulfill certain requirements regarding, among other things, registration, recordkeeping, reporting, and security. Pseudoephedrine is subject to tighter controls than most other listed chemicals that are lawfully marketed under the Federal Food, Drug, and Cosmetic Act.

In addition to these federal statutory and regulatory obligations, there may be state and local laws and regulations relevant to the handling of controlled substances or listed chemicals.

Toxic Substances Control Act. The Environmental Protection Agency, or EPA, has promulgated regulations under Section 5 of the Toxic Substances Control Act, or TSCA, which require notification procedures for review of certain so-called Intergeneric microorganisms before they are introduced into commerce. Intergeneric microorganisms are those formed by deliberate combinations of genetic material from organisms classified in different taxonomic genera, which are types of animal or plant groups. The regulations provide exemptions from the reporting requirements for new microorganisms used for research and development when the researcher or institution is in mandatory compliance with the National Institutes of Health Guidelines for Research Involving Recombinant DNA Molecules, or NIH Guidelines. Those researchers voluntarily following the NIH Guidelines can, by documenting their use of the NIH Guidelines, satisfy EPA's requirements for testing in contained structures. The EPA may enforce the TSCA through enforcement actions such as seizing noncompliant substances, seeking injunctive relief, and assessing civil or criminal penalties. We believe that our research and development activities involving intergeneric microorganisms comply with the TSCA, but there can be no assurance that restrictions, fines or penalties will not be imposed on us in the future.

Health Care Coverage and Reimbursement. Commercial success in marketing and selling our products depends, in part, on the availability of adequate coverage and reimbursement from third-party health care payers, such as government and private health insurers and managed care organizations. Third-party payers are increasingly challenging the pricing of medical products and services. Government and private sector initiatives to limit the growth of health care costs, including price regulation, competitive pricing, coverage and payment policies, and managed-care arrangements, are continuing in many countries where we do business, including the U.S. These changes are causing the marketplace to put increased emphasis on the delivery of more cost-effective medical products.

Government programs, including Medicare and Medicaid, private health care insurance, and managed-care plans have attempted to control costs by limiting the amount of reimbursement they will pay for particular procedures or treatments. This has created an increasing level of price sensitivity among customers for our products. Examples of how limits on drug coverage and reimbursement in the United States may cause drug price sensitivity include the growth of managed care, changing Medicare reimbursement methodologies, and drug rebates and price controls. Some third-party payors must also approve coverage for new or innovative devices or therapies before they will reimburse health care providers who use the medical devices or therapies. Even though a new medical product may have been cleared for commercial distribution, we may find limited demand for the product until reimbursement approval has been obtained from governmental and private third-party payors.

Anti-Kickback Laws. In the United States, there are federal and state anti-kickback laws that prohibit the payment or receipt of kickbacks, bribes or other remuneration to induce the purchase, order or recommendation of health care products and services. These laws constrain the sales, marketing and other promotional activities of pharmaceutical companies, such as us, by limiting the kinds of financial arrangements (including sales programs) we may have with prescribers, purchasers, dispensers and users of drugs and biologics. The HHS Office of Inspector General (OIG) has issued Compliance Guidance for pharmaceutical manufacturers which, among other things, identifies manufacturer practices implicating the federal anti-kickback law (42 U.S.C. § 1320a-7b(b)) and describes elements of an effective compliance program. The OIG Compliance Guidance is voluntary, and we have not adopted a formal compliance program modeled after the one described in the OIG guidance. Although none of our practices have been subject to challenge under any anti-kickback laws, due to the breadth of the statutory provisions of some of these laws, it is possible that some of our practices might be challenged under one or more of these laws in the future. Violations of these laws can lead to civil and criminal penalties, including imprisonment, fines and exclusion from participation in federal health care programs. Any such violations could have a material adverse effect on our business, financial condition, results of operations or cash flows.

Health Information Privacy and Security. Individually identifiable health information is subject to an array of federal and state regulation. Federal rules promulgated pursuant to the Health Information Portability and Accountability Act of 1996 ("HIPAA") regulate the use and disclosure of health information by "covered entities" (which includes individual and institutional providers from which we may receive individually identifiable health information). These regulations govern, among other things, the use and disclosure of health information for research purposes, and require the covered entity to obtain the written authorization of the individual before using or disclosing health information for research. Failure of the covered entity to obtain such authorization (absent obtaining a waiver of the authorization requirement from an Institutional Review Board) could subject the covered entity to civil and criminal penalties. As the implementation of this regulation is still in its early phases, we may experience delays and complex negotiations as we deal with each entity's differing interpretation of the regulations and what is required for compliance. Further, HIPAA's criminal provisions are not limited in their applicability to "covered persons," but apply to any "person" that knowingly and in violation of the statute obtains or discloses individually identifiable health information. Also, where our customers or contractors are covered entities, including hospitals, universities, physicians or clinics, we may be required by the HIPAA regulations to enter into "business associate" agreements that subject us to certain privacy and security requirements, including making our books and records available for audit and inspection by HHS and implementing certain health information privacy and security safeguards. In addition, many states have laws that apply to the use and disclosure of health information, and these laws could also affect the manner in which we conduct our research and other aspects of our business. Such state laws are not preempted by the federal privacy law where they afford greater privacy protection to the individual. While activities to assure compliance with health information privacy laws are a routine business practice, we are unable to predict the extent to which our resources may be diverted in the event of an investigation or enforcement action with respect to such laws.

Foreign Regulation

Whether or not we obtain FDA approval for a product, we must obtain approval of a product by the comparable regulatory authorities of foreign countries before we can commence clinical trials or marketing of the product in those countries. The approval process varies from country to country, and the time may be longer or shorter than that required for FDA approval. The requirements governing the conduct of clinical trials, product licensing, pricing, and reimbursement also vary greatly from country to country. Although governed by the applicable country, clinical trials conducted outside of the United States typically are administered under a three-phase sequential process similar to that discussed above for pharmaceutical products. Clinical trials conducted in the European Union must comply with the EU Clinical Trials Directive.

Under European Union regulatory systems, we may submit marketing authorization applications either under a centralized or decentralized procedure for most products. The centralized procedure, which is available for medicines produced by biotechnology or which are highly innovative, provides for the grant of a single marketing authorization that is valid for all European Union member states. Under European Commission Regulation 726/2004, the centralized authorization procedure is required for all biotechnology-derived medicinal products developed through recombinant DNA technology, controlled expression of genes coding for biologically active proteins, and hybridoma and monoclonal antibody methods. It is also required for designated orphan medicinal products and all new active substances indicated for the treatment of AIDS, cancer, neurodegenerative disorder, or diabetes. This authorization is a marketing authorization approval, or MAA. The decentralized procedure provides for mutual recognition of national regulatory authority approval decisions. Under this procedure, the holder of a national marketing authorization granted by one member state may submit an application to the remaining member states. Within 90 days of receiving the applications and assessment report, each member state must decide whether to recognize approval. This procedure is referred to as the mutual recognition procedure, or MRP.

In addition, regulatory approval of prices is required in most countries other than the United States. We face the risk that the prices which result from the regulatory approval process would be insufficient to generate an acceptable return to us or our collaborators.

BiovaxID Manufacturing

We manufacture BiovaxID primarily at Biovest's manufacturing facility in Worcester, Massachusetts operated by its subsidiary, Biovax, Inc. We believe that our facilities are sufficient to produce the vaccine required for the product's clinical trials. We are in the process of conforming to FDA regulations that will enable this consolidation. If we receive FDA approval of the vaccine, we may continue to manufacture the vaccine at our existing facility in Worcester, although we will likely need to develop additional facilities or utilize third-party contract manufacturers to fully support commercial production for the U.S. markets. To penetrate markets outside of the U.S., we may enter into collaborations with well-established companies that have the capabilities to produce the product. To facilitate commercial production of the vaccine, we are developing proprietary manufacturing equipment that integrates and automates various stages of vaccine production. We believe that such equipment will reduce the space and staff currently required for production of the vaccine.

We anticipate that the manufacture of the other products in our development pipeline will be outsourced to experienced cGMP-compliant medical manufacturing companies. In addition, our currently marketed specialty pharmaceutical products are manufactured by third-party contract manufacturers, as identified elsewhere in this annual report on Form 10-K.

Intellectual Property

We are pursuing a number of methods to establish and maintain market exclusivity for our product candidates to the greatest extent possible, including seeking patent protection, the use of statutory market exclusivity provisions, and otherwise protecting our intellectual property.

Our success depends in part on our ability to obtain and maintain proprietary protection for our product candidates, technology, and know-how; to operate without infringing the proprietary rights of others; and to prevent others from infringing our proprietary rights. Our policy is to seek to protect our proprietary position by, among other methods, filing United States and foreign patent applications when possible relating to our proprietary technology, inventions, and improvements that are important to our business. We also rely on trade secrets, know-how, continuing technological innovation, and in-licensing opportunities to develop and maintain our proprietary position.

The following is information regarding our owned and licensed patents and patent applications that we consider material to our business:

- With respect to SinuNase, MAYO holds one issued U.S. patent relating to the treatment of CRS with intranasal antifungals and another U.S. patent relating to the treatment of asthma through muco-administration of antifungals. It also holds one related European Union counterpart patent application for the CRS therapy. Each of these patents expires in October 2018. Each of these issued patents and patent applications are exclusively licensed by us under our license agreement with MAYO.
- With respect to BiovaxID, we have filed a first PCT application relating to the type of cell media used to grow cell cultures in the production of BiovaxID, and we have filed a second PCT application relating to certain features of the integrated production and purification system used to produce and purify the vaccine in an automated closed system.
- With respect to the MD Turbo device, Respirics holds four issued U.S. patents relating to the device, each of which expires in June 2016, and one pending U.S. patent application relating to the device. We have exclusive U.S. distribution rights to the device under our agreement with Respirics.
- With respect to AllerNase, Collegium filed a patent application titled "Temperature Stable Formulations and Methods of Development" (Pub #: US-2005-0153946) on December 14th 2004.

The patent positions of companies like ours are generally uncertain and involve complex legal and factual questions. Our ability to maintain and solidify our proprietary position for our technology will depend on our success in obtaining effective claims and enforcing those claims once granted. We do not know whether any of our patent applications or those patent applications that we license will result in the issuance of any patents. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, invalidated, or circumvented, which could limit our ability to stop competitors from marketing related products or the length of term of patent protection that we may have for our products. In addition, the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar technology. Furthermore, our competitors may independently develop similar technologies or duplicate any technology developed by us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before any of our products can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We rely in some circumstances on trade secrets to protect our technology, particularly with respect to certain aspects of our BiovaxID manufacturing process. However, trade secrets are difficult to protect. We seek to protect our proprietary technology and processes, in part, by confidentiality agreements with our employees, consultants, scientific advisors, and other contractors. These agreements may be breached, and we may not have adequate remedies for any breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our employees, consultants, or contractors use intellectual property owned by others in their work for us, disputes may arise as to the rights in related or resulting know-how and inventions.

We use Accentia™, Accentia Biopharmaceuticals™, and the Accentia Biopharmaceuticals logo as trademarks in the U.S. and other countries, and we are seeking U.S. trademark registrations for Accentia Biopharmaceuticals™ and the Accentia Biopharmaceuticals logo. We are also seeking U.S. trademark registrations for BiovaxID™, Biovest™, SinuNase™, CRSFungal Profile™. Respi~TANN® is a registered trademark of TEAMM Pharmaceuticals, Inc., our wholly owned subsidiary. We use AllerNase™ as trademarks in the U.S. and other countries.

Customers

For the 2006 fiscal year, two of our customers, both wholesale distributors, accounted for more than 10% of our revenue. Revenues from Cardinal Health and McKesson Corporation represented approximately 18.9% and 17.5% of our revenue for the years ended September 30, 2006. For the 2005 and 2004 fiscal years, two of our customers, both wholesale distributors, accounted for more than 10% of our revenue. Revenues from Cardinal Health represented approximately 25.0% and 15.3% of our revenue for the years ended September 30, 2005 and 2004, respectively, and revenues from McKesson Corporation represented approximately 14.6% of our revenue for the year ended September 30, 2004.

Third-Party Reimbursement and Pricing Controls

In the United States and elsewhere, sales of pharmaceutical products depend in significant part on the availability of reimbursement to the consumer from third-party payors, such as government and private insurance plans. Third-party payors are increasingly challenging the prices charged for medical products and services. It will be time-consuming and expensive for us to go through the process of seeking reimbursement from Medicare and private payors. Our products may not be considered cost effective, and coverage and reimbursement may not be available or sufficient to allow us to sell our products on a competitive and profitable basis. The passage of the Medicare Prescription Drug and Modernization Act of 2003 imposes new requirements for the distribution and pricing of prescription drugs which may affect the marketing of our products.

In many foreign markets, including the countries in the European Union, pricing of pharmaceutical products is subject to governmental control. In the United States, there have been, and we expect that there will continue to be, a number of federal and state proposals to implement similar governmental pricing control. While we cannot predict whether such legislative or regulatory proposals will be adopted, the adoption of such proposals could have a material adverse effect on our business, financial condition and profitability.

Employees

As of September 30, 2006, we had 258 full-time employees (including Biovest). None of our employees is represented by labor unions or covered by collective bargaining agreements. We have not experienced any work stoppages, and we consider our employee relations to be good.

Executive Officers

The following table sets forth our current executive officers and their ages as of September 30, 2006:

Name	Age	Position
Francis E. O'Donnell, Jr., M.D.	56	Chairman of the Board; Chief Executive Officer
Steven R. Arikian, M.D.	49	President and Chief Operating Officer, Biopharmaceutical Products and Services; Director
Alan M. Pearce	57	Chief Financial Officer; Director
Martin G. Baum*	40	President and Chief Operating Officer of Specialty Pharmaceuticals/Director *

Francis E. O'Donnell, Jr., M.D. has served as our Chairman of the Board since the company's founding in March 2002 and has served as our Chief Executive Officer since September 2003. Dr. O'Donnell also served as our President from September 2003 through November 2004. Since 1995, Dr. O'Donnell has served as manager of The Hopkins Capital Group, LLC, a biotechnology business development and investment company. Since May 2002, Dr. O'Donnell has also served as the Chairman of the Board of BioDelivery Sciences International, Inc., a publicly traded drug delivery technology company, and since June 2003, he has served as a director (and as Co Vice-Chairman since 2004) of Biovest International, Inc., our majority owned, publicly held subsidiary. He is co-founder and a director of RetinaPharma Technologies, Inc., a privately held biotechnology company developing novel pharmaceuticals and related products for the prevention, treatment, rescue, and recovery of ophthalmic and other neurodegenerative and neurovascular disease. He is the former Professor and Chairman, Department of Ophthalmology, St. Louis University School of Medicine. Dr. O'Donnell has published over 30 peer-reviewed scientific articles and has been awarded 34 U.S. patents. He is the recipient of the 2000 Jules Stein Award from Retinitis Pigmentosa International and is a Trustee for St. Louis University and The Health Careers Foundation. Dr. O'Donnell is a graduate of the Johns Hopkins School of Medicine, where he received his specialty training at the Wilmer Ophthalmological Institute.

Steven R. Arikian, M.D. began serving as a director in April 2002. Since November 2004, Dr. Arikian has served as President and Chief Operating Officer of Product Development and Market Services. In February 2005, his title was changed to President and Chief Operating Officer, Biopharmaceutical Products and Services. From January 2003 to November 2004, he was President of Pre-Market Services and Operations and from April 2002 to January 2003, he was President of Pre-Market

Services. Since 1997, Dr. Arikian has served as the Chairman, Chief Executive Officer, and founder of our Analytica subsidiary, and September 2004, he has served and the Chairman and Chief Executive Officer of Biovest. Since 2003, Dr. Arikian has served as a director, and since 2004 has served as Chief Executive Officer, President, and Chairman, of Biovest International, Inc., our majority-owned, publicly held subsidiary. Dr. Arikian began providing pharmaceutical clients with Clinical and Outcomes Research services in 1988. He served as President of The Center for Health Outcomes and Economics at Bristol Myers Squibb from May 1995 to July 1997, where he supervised a staff of over 50 professionals responsible for development of global health outcomes research. He has designed and implemented research projects in the United States, Canada, Latin America and Europe. Dr. Arikian holds a faculty appointment at the Columbia University Mailman School of Public Health. He has also held faculty appointments at the University of Toronto and the University of Kentucky. He is widely published in the peer-reviewed literature and has been a frequent speaker at industry and trade group sponsored meetings on topics including Formulary Management, Pharmaceutical Pricing, Multi-National Health Economic Studies, and Pharmacoepidemiology. Dr. Arikian is a graduate of Fordham University with a degree in Biology and is also a graduate of the University of Catania (Italy) Medical School.

Alan M. Pearce has served as a director and our Chief Financial Officer since August 2004. Prior to serving as our Chief Financial Officer, Mr. Pearce served as Senior Vice President, Financial Services for McKesson Corporation, a large publicly traded healthcare company, from April 1999 to March 2004. Mr. Pearce also currently serves on the advisory boards of The Georgia Institute of Technology and Emory University BioEngineering Foundation and The Hopkins Capital Group. He also previously served as a director and a member of the finance committee of XL Insurance Company. From September 2002 to September 2005, Mr. Pearce served as a director of BioDelivery Sciences International, Inc. Mr. Pearce is a graduate of Georgia Tech, where he earned a B.S. degree in Industrial Management, and the University of Texas, where he earned an MBA degree in finance.

---

* On October 27, 2006, Martin G. Baum resigned as President and Chief Operating Officer, Specialty Pharmaceuticals, a division of the Company, and as an employee of the Company and its subsidiaries including Teamm Pharmaceuticals, Inc., as well as and from any Boards of subsidiaries of the Company on which he served The resignations described above were not the result of any disagreement with the Company known to an executive officer of the Company on any matter relating to the Company's operations, policies or practices.

Available Information

We were incorporated in the State of Florida in 2002. Our principal executive offices are located at 324 South Hyde Park Avenue, Suite 350, Tampa, Florida 33606, and our telephone number at that address is (813) 864-2554. We maintain an Internet website at www.accentia.net. However, information found on, or that can be accessed through, our website is not incorporated by reference into this annual report on Form 10-K. We make available free of charge on or through our website our filings with the Securities and Exchange Commission, or SEC, including this annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC. Further, a copy of this annual report is located at the SEC's Public Reference Room at 100 F Street N. E., Washington, D.C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains an Internet website that contains reports, proxy and information statements, and other information regarding our filings at www.sec.gov.

ITEM 1A. RISK FACTORS

Risk Factors

This report contains forward-looking statements (within the meaning of the Private Securities Litigation Reform Act of 1995) that are based on management's current expectations, estimates, forecasts, and projections about the Company and its business. In addition, other written or oral statements which constitute forward-looking statements may be made from time to time by or on behalf of Accentia Biopharmaceuticals, Inc. Any statement in this report that is not a statement of historical fact is a forward-looking statement, and in some cases, words such as "believe," "estimate," "project," "expect," "intend," "may," "anticipate," "plans," "seeks," and similar expressions identify forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause actual outcomes and results to differ materially from the anticipated outcomes or result. These statements are not guarantees of future performance, and undue reliance should not be placed on these statements. Accentia Biopharmaceuticals, Inc. undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise.

Factors that could cause actual results to differ materially from what is expressed or forecasted in our forward-looking statements include, but are not limited to, the following:

Risks Related to Our Business

We are largely dependent on the success of our two most significant product candidates, SinuNase and BiovaxID, and we may not be able to successfully commercialize these therapies.

We have expended and will continue to expend significant time, money, and effort on the development of our two most significant product candidates, SinuNase and BiovaxID. We have incurred significant costs and may never generate significant revenues from commercial sales of these products, if approved. Neither of these products is approved for marketing in any jurisdiction, and they may never be commercialized. Before we can market and sell these products, we will need to demonstrate in clinical trials that these products are safe and effective and will also need to obtain necessary approvals from the U.S. Food and Drug Administration, or FDA, and similar foreign regulatory agencies.

If we fail to successfully commercialize either or both of SinuNase and BiovaxID, we may be unable to generate sufficient revenue to sustain and grow our business, and our business, financial condition, and results of operations will be adversely affected.

If we fail to obtain FDA approval of SinuNase, BiovaxID, or any of our other current or future product candidates, we will be unable to commercialize these products.

Development, testing, manufacturing and marketing of pharmaceutical products are subject to extensive regulation by numerous governmental authorities in the U.S. and other countries. The process of obtaining FDA approval of pharmaceutical products is costly and time consuming. Any new pharmaceutical product must undergo rigorous preclinical and clinical testing and an extensive regulatory approval process mandated by the FDA. Such regulatory review includes the determination of manufacturing capability and product performance.

In addition to seeking approval from the FDA for SinuNase and BiovaxID, we intend to seek the governmental approval required to market our products in England, Germany, France, Italy, Spain, and potentially additional countries. We anticipate commencing the applications required in some or all of these countries following approval by the FDA; however, we may determine to file applications in advance of the FDA approval if we determine such filings to be both time and cost effective. Marketing of our products in these countries, and in most other countries, is not permitted until we have obtained required approvals or exemptions in each individual country.

In addition, patient-specific active immunotherapies such as BiovaxID are complex, and regulatory agencies lack experience with them. To date, the FDA has not approved for marketing a patient-specific active idiotype immunotherapy for any form of cancer. This lack of precedent and experience may lengthen the regulatory review process and impede our ability to obtain timely FDA approval for BiovaxID, if at all. Even if BiovaxID is approved by the FDA, the FDA's lack of precedent and experience with respect to a patient-specific active idiotype vaccine may increase our development costs and otherwise delay or prevent commercialization.

There can be no assurance that the pharmaceutical products currently in development, or those products acquired or in-licensed by us, will be approved by the FDA. In addition, there can be no assurance that all necessary approvals will be granted for future products or that FDA review or actions will not involve delays caused by the FDA's request for additional information or testing that could adversely affect the time to market and sale of the products. For our currently marketed products and our future products, failure to comply with applicable regulatory requirements can, among other things, result in the suspension of regulatory approval, as well as possible civil and criminal sanctions.

Any delay in any approval or any failure to obtain approval of a product could delay or impair our ability to commercialize that product and to generate revenue as well as increase costs for that product.

Before we can seek regulatory approval of SinuNase, BiovaxID, or any other product candidates, we may need to successfully complete clinical trials, outcomes of which are uncertain.

Conducting clinical trials is a lengthy, time-consuming, and expensive process, and the results of these trials are inherently uncertain. Completion of necessary clinical trials may take several years or more. Our commencement and rate of completion of clinical trials may be delayed by many factors, including:

- ineffectiveness of our product candidate or perceptions by physicians that the product candidate is not safe or effective for a particular indication;
- inability to manufacture sufficient quantities of the product candidate for use in clinical trials;
- delay or failure in obtaining approval of our clinical trial protocols from the FDA or institutional review boards;

- slower than expected rate of patient recruitment and enrollment;
- inability to adequately follow and monitor patients after treatment;
- difficulty in managing multiple clinical sites;
- unforeseen safety issues;
- government or regulatory delays; and
- clinical trial costs that are greater than we currently anticipate.

Even if we achieve positive interim results in clinical trials, these results do not necessarily predict final results, and positive results in early trials may not be indicative of success in later trials. A number of companies in the pharmaceutical industry have suffered significant setbacks in advanced clinical trials, even after promising results in earlier trials. Negative or inconclusive results or adverse medical events during a clinical trial could cause us to repeat or terminate a clinical trial or require us to conduct additional trials. We do not know whether our existing or any future clinical trials will demonstrate safety and efficacy sufficiently to result in marketable products. Our clinical trials may be suspended at any time for a variety of reasons, including if the FDA or we believe the patients participating in our trials are exposed to unacceptable health risks or if the FDA finds deficiencies in the conduct of these trials.

Failures or perceived failures in our clinical trials will directly delay our product development and regulatory approval process, damage our business prospects, make it difficult for us to establish collaboration and partnership relationships, and negatively affect our reputation and competitive position in the pharmaceutical community.

We have incurred significant costs in our development efforts to date and may never generate significant revenues from commercial sales of our product candidates, if approved.

With respect to our product candidates, we have focused primarily on developing and preparing for the regulatory approval process for SinuNase, the patented therapy for CRS that we license from MAYO and conducting clinical trials and seeking regulatory approval for BiovaxID, a patient-specific vaccine for treating indolent follicular NHL. With respect to SinuNase, we have paid $2.0 million in up-front royalties on this product. To date, we have received only limited revenues in connection with sublicensing fees from pharmacies for using the patented therapy for CRS to compound patient-specific antifungal nasal products. We have generated no revenues to date from the commercial sale of BiovaxID and must conduct significant additional clinical trials before we can seek the regulatory approvals necessary to begin commercial sales of this vaccine. Our net loss for the fiscal years ended September 30, 2006, 2005 and 2004 was $43.4 million and $44.7 million and $23.2 million, respectively As of September 30, 2006, we had an accumulated deficit of $161.6 million. We expect to continue to incur significant operating expenses and capital expenditures as we:

- conduct clinical trials;
- conduct research and development on existing and new product candidates;
- seek regulatory approvals for our product candidates;
- commercialize our product candidates, if approved;
- hire additional clinical, scientific, sales and marketing and management personnel; and
- identify and license additional product candidates.

If product candidates fail in clinical trials or do not gain regulatory approval or gain regulatory approval for more restricted indications than we have anticipated, we may not generate significant revenues from any of our product candidates. In addition, we may continue to experience net losses for the foreseeable future, in which case our accumulated deficit will continue to increase, and we may exhaust our resources and be unable to complete the development of our product candidates. If we are unable to fund the continuing development of our product candidates or if we fail to generate significant revenues from any of our product candidates, you could lose all or part of your investment.

We anticipate that we will need substantial additional funding in the future, and if we are unable to raise capital when needed, we would be forced to delay, reduce, or eliminate our product development programs or commercialization efforts.

Developing biopharmaceutical products, conducting clinical trials, establishing manufacturing capabilities, and marketing developed products is expensive. We anticipate that we will need to raise substantial additional capital in the future in order to complete the commercialization of SinuNase following the submission of the NDA and to fund the development and commercialization of our specialty pharmaceutical product candidates. Furthermore, we anticipate that Biovest will need to raise substantial additional capital in order to continue the clinical trials for BiovaxID. Additional sources of funding have not been established; however, additional financing is currently being sought from a number of sources, including the sale of Biovest equity or debt securities, strategic collaborations, recognized research funding programs, as well as domestic and/or foreign licensing of Biovest's vaccine. Biovest management is currently in the process of exploring various financing alternatives, and has hired investment consultants to assist in these efforts. Based on our

current operating plans, we expect that our existing capital and cash flow from operations, together with borrowing availability under our existing lines of credit, will be sufficient to fund our operations and development activities into the fourth quarter of fiscal 2007 assuming Biovest receives its own funding. We have received a report from our independent registered public accounting firm on our consolidated financial statements for our fiscal years ended September 30, 2006, 2005, 2004, in which our auditors have included explanatory paragraphs indicating that our significant net losses and working capital deficiency cause substantial doubt about our ability to continue as a going concern.

We expect to finance future cash needs through public or private equity offerings, debt financings, or corporate collaboration and licensing arrangements. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional dilution, and debt financing, if available, may involve restrictive covenants. If our Biovest subsidiary raises funds through the issuance of equity securities, our equity interest in Biovest could be substantially diminished. If our Biovest subsidiary raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that are not favorable to us. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available from the foregoing sources, we may consider additional strategic financing options, including sales of assets or business units (such as specialty pharmaceuticals, market services or cell culture equipment) that are non-essential to the ongoing development or future commercialization of SinuNase, or we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or curtail some of our commercialization efforts. We may seek to access the public or private equity markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at this time.

We cannot predict the impact, if any, that "Fast-Track" status will have on the regulatory approval process for SinuNase and BiovaxID.

The FDA has granted "Fast-Track" review status to both SinuNase and BiovaxID, which means that these products may be eligible for expedited review procedures by the FDA. However, we cannot predict the impact, if any, that Fast-Track designation will actually have on the duration of the regulatory approval process for these product candidates, and the FDA may deny regulatory approval of either or both of these product candidates notwithstanding their Fast-Track designation.

Failure to enroll patients in our clinical trials may cause delays in developing SinuNase, BiovaxID, or any other product candidate.

We may encounter delays in development and commercialization, or fail to obtain marketing approval, of SinuNase, BiovaxID, or any other product candidate that we may develop if we are unable to enroll enough patients to complete clinical trials. Our ability to enroll sufficient numbers of patients in our clinical trials depends on many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites, the eligibility criteria for the trial, and competing clinical trials. We have from time to time experienced, and are currently experiencing, slower-than-expected patient enrollment in our BiovaxID clinical trial. To complete enrollment of our Phase 3 clinical trial for BiovaxID in 2008, as anticipated, we will need to continue our efforts to significantly increase the rate at which we are enrolling patients in that trial and to increase the number of clinical trial sites. Also, the Phase 3 clinical trial for our BiovaxID vaccine may experience slower-than-anticipated enrollment due to an increasing tendency of physicians to prescribe Rituxan, a monoclonal antibody, as a first line of treatment for NHL instead of chemotherapy, while our clinical trial protocol for BiovaxID requires a patient to first achieve a six-month remission following chemotherapy treatment. The NCI Data Safety Monitoring Board (DSMB) for BiovaxID has expressed concerns about the rate of enrollment in our BiovaxID clinical trial and has therefore recommended that the trials be discontinued at the NCI site. Accordingly, we have transferred the safety and monitoring oversight function in this trial to a new global Data Monitoring Committee (DMC) and will designate a new principal investigative site. Delays in planned patient enrollment may result in increased costs and harm our ability to complete our clinical trials and obtain regulatory approval.

In light of the perceived change in the standard of care for initial treatment of NHL, we have submitted a Protocol amendment to the FDA to add a CHOP-R treatment arm to the trial. CHOP-R is an alternative chemotherapy regimen that includes Rituxan. We have received the verbal approval of this amendment from FDA, and upon formal approval of the amended Protocol, we will commence accrual of patients to the trial who will receive CHOP-R. While we expect that this alternative chemotherapy will significantly increase patient accrual, we cannot guarantee that the enrollment increase will be sufficient to complete trial enrollment in the desired timeframe.

Our clinical trials for SinuNase and/or BiovaxID may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing for these product candidates or cease our trials.

We are currently engaged in a pivotal Phase 3 clinical trial for BiovaxID, and we have commenced the first of two Phase 3 clinical trials for SinuNase. We do not know whether our existing or future clinical trials will demonstrate safety and efficacy sufficiently to result in marketable products. For example, safety and efficacy results attained in our anticipated

Phase 3 clinical trials for SinuNase may be less positive than the results obtained in Mayo Clinic's previous clinical trials for SinuNase, and we may be unable to establish efficacy or the safety profile required for approval without supporting Phase 1 and 2 studies. Furthermore, we could be required to conduct a Phase 2 study or safety study contemporaneously with, the Phase 3 studies, or could be required to conduct more than two Phase 3 clinical trials for SinuNase if our two initial concurrent trials are not confirmatory. With respect to BiovaxID, safety and efficacy results attained in our pivotal Phase 3 clinical trial for BiovaxID may be less positive than the results obtained in the NCI's Phase 2 clinical trials for BiovaxID. Because our clinical trials for both BiovaxID and SinuNase may produce negative or inconclusive results, we may decide, or regulators may require us, to conduct additional clinical and/or preclinical testing for these product candidates or cease our clinical trials. If this happens, we may not be able to obtain approval for these products or the anticipated time to market for these products may be substantially delayed, and we may also experience significant additional development costs. We may also be required to undertake additional clinical testing if we change or expand the indications for our product candidates.

The clinical trials for SinuNase and BiovaxID have demonstrated that certain side effects may be associated with these treatments, and ongoing or future clinical trials may reveal additional unexpected or unanticipated side effects.

In clinical trials conducted to date by Mayo Clinic, a small number of CRS patients have demonstrated a sensitivity or suspected allergy to amphotericin B that was non-systemic and temporary, but these patients fully recovered quickly after the cessation of treatment with amphotericin B. A relatively small number of patients in the BiovaxID clinical trials have experienced adverse events, none of which were life-threatening, at the time of vaccine or control administration, but it seems likely from the nature of these events that they were either unrelated to the study or were due to the concomitant administration of GM-CSF. Also, skin irritation consisting of redness and induration, or hardening of the tissue, at the site of BiovaxID or control injection has been noted, but this condition has generally lasted only a few days and was limited to skin surrounding the injection site. The NCI Data Safety Monitoring Board (DSMB) for BiovaxID, which historically has reviewed all adverse event reports related to BiovaxID, has not expressed any concerns to date about the safety of the vaccine, although we are transferring the trial to a new DMC following concerns raised by the NCI DSMB regarding administrative matters, including the rate of enrollment in our BiovaxID clinical trial. We cannot guarantee that our current or future trials for BiovaxID and SinuNase will not demonstrate additional adverse side effects that may delay or even preclude regulatory approval. Even if either or both of BiovaxID and SinuNase receive regulatory approval, if we or others identify previously unknown side effects following approval, regulatory approval could be withdrawn and sales of the product could be significantly reduced.

If we do not in the future obtain a license from MAYO for antifungals other than amphotericin B in the treatment of CRS, then MAYO will not be precluded from licensing its patented CRS therapy to third-parties using other antifungals.

Our rights to SinuNase are based on a license agreement with MAYO. Our license agreement with MAYO gives us the exclusive worldwide right to commercialize MAYO's patented CRS treatment method using the antifungal amphotericin B. Although MAYO's clinical trials on its CRS therapy were based on the use of amphotericin B, MAYO's patents and patent applications with respect to the therapy broadly apply to the topical application of any antifungals for the treatment of CRS. In December 2005, we entered into an Option Agreement with MAYO giving us the exclusive right until December 2006 (which has since been extended to December 2007), without obligation, to seek to negotiate a license for all antifungals in addition to amphotericin B. In the event that we are not successful in negotiating such additional licenses, MAYO is not precluded from licensing to third-parties, including potential competitors, the use of antifungals other than amphotericin B for the treatment of CRS. If MAYO grants such a license to a third-party, and if the use of such other antifungal is shown to have an efficacy and safety profile that equals or exceeds that of amphotericin B for this application, we may not be able to commercialize or generate revenue from SinuNase and our business, financial condition, and results of operations could be adversely affected.

Delays in clinical testing could result in increased costs to us and delay our ability to generate revenue.

Significant delays in clinical testing could materially impact our product development costs. We do not know whether planned clinical trials will begin on time, will need to be restructured, or will be completed on schedule, if at all. Clinical trials can be delayed for a variety of reasons, including delays in obtaining regulatory approval to commence and continue a study, delays in reaching agreement on acceptable clinical study terms with prospective sites, delays in obtaining institutional review board approval to conduct a study at a prospective site, and delays in recruiting patients to participate in a study. For example, when the IND for BiovaxID was transferred by the NCI to us, we experienced delays in our clinical trials because the investigative sites for the trials were required to get new approvals from institutional review boards, which are independent bodies that oversee the conduct of research involving human subjects.

The FDA may require that we conduct clinical studies on the safety and efficacy of our drug product candidates for all relevant pediatric populations as part of the approval process. We have applied for a pediatric assessment waiver from FDA for our Emezine product and plan to submit waiver applications for our other products, as applicable, but we can make no assurances that such waivers will be granted. If the FDA requires us to amend our study protocols to address pediatric populations, the approval of our products may be delayed.

In addition, we typically rely on third-party clinical investigators to conduct our clinical trials and other third-party organizations to oversee the operations of such clinical trials and to perform data collection and analysis. As a result, we may face additional delays outside of our control if these parties do not perform their obligations in a timely fashion. Significant delays in testing or regulatory approvals for SinuNase, BiovaxID, or any of our other current or future product candidates, could cause delays in, and could even prevent the commercialization of such product and generation of revenue from that product and could cause our costs to increase.

Inability to obtain regulatory approval for our manufacturing facility or to manufacture on a commercial scale may delay or disrupt our commercialization efforts.

Before we can obtain FDA approval for any new drug, the manufacturing facility for the drug must be inspected and approved by the FDA. Therefore, before we can obtain the FDA approval necessary to allow us to begin commercially manufacturing BiovaxID, we must pass a pre-approval inspection of our BiovaxID manufacturing facility by the FDA. In order to obtain approval, we will need to ensure that all of our processes, methods, and equipment are compliant with the current Good Manufacturing Practices, or cGMP, and perform extensive audits of vendors, contract laboratories, and suppliers. The cGMP requirements govern quality control of the manufacturing process and documentation policies and procedures. We have undertaken steps towards achieving compliance with these regulatory requirements required for commercialization. In complying with cGMP, we will be obligated to expend time, money, and effort in production, record keeping, and quality control to assure that the product meets applicable specifications and other requirements. If we fail to comply with these requirements, we could experience product liability claims from patients receiving our vaccines, we might be subject to possible regulatory action and we may be limited in the jurisdictions in which we are permitted to sell BiovaxID.

We are currently manufacturing BiovaxID for our clinical trials at our facility in Worcester, Massachusetts. Our manufacturing facility in Worcester is currently subject to licensing requirements of the Massachusetts Department of Public Health. Our facility is subject to inspection by the FDA as well as by the Massachusetts Department of Public Health at any time. Failure to obtain and maintain a license from the Massachusetts Department of Public Health or to meet the inspection criteria of the FDA and the Massachusetts Department of Public Health would disrupt our manufacturing processes, increase costs, and would harm our business. If an inspection by the FDA, the Massachusetts Department of Public Health, or foreign regulatory authorities indicates that there are deficiencies, we would be required to take remedial actions or our facility may be closed, and we may be subject to additional enforcement activity.

In order to commercialize BiovaxID, or any other immunotherapies that we may develop, we will need to develop and qualify one or more additional manufacturing facilities. Preparing a facility for commercial manufacturing may involve unanticipated delays, and the costs of complying with state, local, and FDA regulations may be higher than we anticipated. In addition, any material changes we make to the manufacturing process may require approval by the FDA and state or foreign regulatory authorities. Obtaining these approvals is a lengthy, involved process, and we may experience delays. Such delays could increase costs and adversely affect our business. In general, the FDA views cGMP standards as being more rigorously applied as products move forward in development and commercialization. In seeking to comply with these standards, we may encounter problems with, among other things, controlling costs and quality control and assurance. Although we believe that our BiovaxID manufacturing facility in Worcester, Massachusetts is currently cGMP compliant, it may be difficult to maintain compliance with cGMP standards as the development and commercialization of BiovaxID progresses, if it progresses. In addition, although we intend to use the Worcester facility for purposes of commercial-scale manufacturing of BiovaxID, the demands and increasingly rigorous cGMP standards that will be applicable to that facility may require us to construct a new and different facility or seek a third-party contract manufacturer for the therapy, which could also cause increased costs.

We have been denied orphan drug exclusivity for BiovaxID, and our competitors may obtain orphan drug exclusivity.

We have applied for orphan drug designation for the use of BiovaxID for the treatment of certain forms of follicular B-cell NHL. Under the Orphan Drug Act, the FDA may grant orphan drug designation to drugs intended to treat a "rare disease or condition," which generally is a disease or condition that affects fewer than 200,000 individuals in the United States. Orphan drug designation must be requested before submitting a Biologics License Application, or BLA. After the FDA grants orphan drug designation to a product, the generic identity of the therapeutic agent and its potential orphan use are publicly disclosed by the FDA. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. If a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan exclusivity, which means that the FDA may not approve any other applications to market the same drug for the same indication for a period of seven years, except in limited circumstances such as greater effectiveness, greater safety, major contribution to patient care, or inadequate supply. Even though we have applied for orphan drug status, the FDA has determined that BiovaxID is ineligible for orphan drug designation in the absence of further information and clarification. Although we have successfully achieved the equivalent of Orphan Drug designation in the European Union, we have not yet determined whether we will continue to pursue orphan drug designation for BiovaxID in the U.S. Even if designated as an orphan drug, BiovaxID may not be

approved, or may not be approved before other applications, or granted orphan drug exclusivity if approved. Our competitors may obtain orphan drug exclusivity for products competitive with our product candidates before we do or even if we do not obtain such status, in which case we would be excluded from that market if the FDA deems the competitive drug to be the same drug as BiovaxID. Even if we obtain orphan drug exclusivity for BiovaxID, we may not be able to maintain it. For example, if a competitive product is shown to be clinically superior to our product, any orphan drug exclusivity we have obtained will not block the approval of such competitive product.

The commercialization of our product candidates may not be profitable.

In order for the commercialization of our product candidates to be profitable, our products must be cost-effective and economical to manufacture on a commercial scale. Furthermore, if our products do not achieve market acceptance, we may not be profitable. Subject to regulatory approval, we expect to incur significant sales, marketing, and manufacturing expenses in connection with the commercialization of SinuNase, BiovaxID, and our other product candidates. Even if we receive additional financing, we may not be able to complete planned clinical trials and the development, manufacturing, and marketing of any or all of our product candidates. Our future profitability will depend on many factors, including, but not limited to:

- the cost and timing of developing a commercial scale manufacturing facility or the costs of outsourcing our manufacturing of BiovaxID;
- the costs of filing, prosecuting, defending, and enforcing any patent claims and other intellectual property rights;
- the costs of establishing sales, marketing, and distribution capabilities;
- the effect of competing technological and market developments; and
- the terms and timing of any collaborative, licensing, and other arrangements that we may establish.

Even if we receive regulatory approval for BiovaxID, including regulatory approval of a commercial scale manufacturing facility, we may not ever receive significant revenues from BiovaxID. Additionally, although we currently receive licensing revenue from compounding pharmacies to produce antifungal solutions for CRS upon the prescription of licensed physicians, we may not receive significant revenues from an FDA-approved CRS therapy for many years. With respect to the products in our development pipeline that are being developed by third parties, our ability to generate revenues from those products will depend in large part on the efforts of those third parties. To the extent that we are not successful in commercializing our product candidates, our product revenues will suffer, we will incur significant additional losses and the price of our common stock will be negatively affected.

We have no experience manufacturing BiovaxID or any other immunotherapies for the number of patients and at a cost that would enable widespread commercial use.

To date, we have only manufactured BiovaxID in quantities necessary to support our ongoing clinical trials for BiovaxID. We have no experience in manufacturing BiovaxID, or any other immunotherapies, for the number of patients and at a cost that would support commercial use. In addition, since no other company has manufactured for commercial sale a patient-specific immunotherapeutic product derived from the patient's own cancer cells, there are no precedents from which we could learn. If we or a third-party are unable to manufacture sufficient quantities of BiovaxID at a reasonable cost to support commercial use, we will not be able to commercialize BiovaxID and generate revenue, despite significant development expenditures.

We may experience difficulties in manufacturing BiovaxID or in obtaining approval of the change in manufacturing site from the FDA, which could prevent us from completing our ongoing clinical trials and delay the commercialization of BiovaxID.

Manufacturing BiovaxID is complex and requires coordination internally among our employees as well as externally with physicians, hospitals and third-party suppliers and carriers. This process involves several risks that may lead to failures or delays in manufacturing BiovaxID, including:

- difficulties in obtaining adequate tumor samples from physicians;
- difficulties in timely shipping of tumor samples to us or in the shipping of BiovaxID to the treating physicians due to errors by third-party carriers, transportation restrictions or other reasons;
- destruction of, or damage to, tumor samples or BiovaxID during the shipping process due to the improper handling by third-party carriers, hospitals, physicians or us;
- destruction of, or damage to, tumor samples or BiovaxID during storage at our facility; and
- difficulties in ensuring the availability, quality, and consistency of materials provided by our suppliers.

If we experience any difficulties in manufacturing BiovaxID, or any other immunotherapies that we may develop, our ongoing clinical trials may be delayed and commercialization of BiovaxID, or any other immunotherapies that we may develop, may be delayed, resulting in delays in generating revenue and increased costs.

In addition, changes to the manufacturing process during or following the completion of clinical trials requires sponsors to demonstrate to the FDA that the product under new conditions is comparable to the product that was the subject of earlier clinical testing. This requirement applies to relocations or expansions of manufacturing facilities, such as the possible expansion to additional facilities that may be required for successful commercialization of the vaccine, resulting in increased costs.

A showing of comparability requires data demonstrating that the product continues to be safe, pure, and potent and may be based on chemical, physical, and biological assays and, in some cases, other non-clinical data. If we demonstrate comparability, additional clinical safety and/or efficacy trials with the new product may not be needed. The FDA will determine if comparability data are sufficient to demonstrate that additional clinical studies are unnecessary. If the FDA requires additional clinical safety or efficacy trials to demonstrate comparability, our clinical trials or FDA approval of BiovaxID may be delayed, which would cause delays in generating revenue and increased costs.

We are dependent on third-party development partners for the development and regulatory approval of some of our products and on third-party contract manufacturers for the supply of many of our products.

Some of the products in our development pipeline are being developed by third parties, and in some cases, these third parties are responsible for obtaining necessary regulatory approvals for the products. In addition, with the exception of BiovaxID, we currently rely, or will in the future rely, on third-party contract manufacturers to produce our currently marketed products and the product candidates in our pipeline. We are or will be substantially dependent on the following third-parties in connection with the following products:

- Collegium Pharmaceutical, Inc. is the developer of our AllerNase product, which is to be manufactured through a third-party contract manufacturer.
- The MD Turbo device was developed by Respirics, Inc., which was responsible for seeking regulatory clearance or approval of the product. Respirics will also be the exclusive supplier of MD Turbo to us, and Respirics will be responsible for engaging and managing one or more contract manufacturers for the product.
- ANI Laboratories is the exclusive manufacturer for our Respi~TANN product.

Our ability to commercialize the products that we develop with our partners and generate revenues from product sales depends on our partners' ability to assist us in establishing the safety and efficacy of our product candidates, obtaining and maintaining regulatory approvals and achieving market acceptance of the products once commercialized. Our partners may elect to delay or terminate development of one or more product candidates, independently develop products that could compete with ours, or fail to commit sufficient resources to the marketing and distribution of products developed through their strategic relationships with us. If our partners fail to perform as we expect, our potential for revenue from products developed through our strategic relationships with them could be dramatically reduced.

The risks associated with our reliance on contract manufacturers include the following:

- Contract manufacturers may encounter difficulties in achieving volume production, quality control, and quality assurance and also may experience shortages in qualified personnel and obtaining active ingredients for our products.
- If we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve these manufacturers in advance. This would involve testing and pre-approval inspections to ensure compliance with FDA and foreign regulations and standards.
- Contract manufacturers are subject to ongoing periodic, unannounced inspection by the FDA and corresponding state and foreign agencies or their designees to ensure strict compliance with cGMP and other governmental regulations and corresponding foreign standards. Other than through contract, we do not have control over compliance by our contract manufacturers with these regulations and standards. Our present or future contract manufacturers may not be able to comply with cGMP and other FDA requirements or similar regulatory requirements outside the United States. Failure of contract manufacturers to comply with applicable regulations could result in sanctions being imposed on us in some cases, including fines, injunctions, failure of regulatory authorities to grant marketing approval of our product candidates, delays, suspension or withdrawal of approvals, seizures or recalls of product candidates, operating restrictions, and criminal prosecutions, any of which could significantly and adversely affect our business.
- Contract manufacturers may breach the manufacturing agreements that we or our development partners have entered into with them because of factors beyond our control or may terminate or fail to renew a manufacturing agreement based on their own business priorities at a time that is costly or inconvenient for us.

If we are not able to obtain adequate supplies of our current and future products, it will be more difficult for us to develop our product candidates and compete effectively. If we or any of our third-party development partners are unable to continue to access sufficient supply from our third-party contract manufacturers, we may not be able to find another suitable source of supply that meets our need to manufacture the MD Turbo device or any of our other products. Dependence upon third parties for the manufacture of our product candidates may reduce our profit margins, if any, on the sale of our products and may limit our ability to develop and deliver products on a timely and competitive basis, which could delay our ability to generate revenue and increase costs.

Some of our specialty pharmaceutical products are not the subject of FDA-approved new drug applications.

New drugs must be the subject of an FDA-approved NDA, or ANDA, application demonstrating safety and effectiveness before they may be marketed in the United States. Some prescription and other drugs marketed by pharmaceutical companies are not the subject of an approved marketing application because new drug applications requiring demonstration of safety and effectiveness were not required at the time that these active ingredients were initially marketed. While the FDA reviewed classes of these products in the 1960s and 1970s as part of the Drug Efficacy Study Implementation (DESI) program, there are several types of drugs, including some cold and cough drugs, which the FDA has not yet evaluated and remain on the market without FDA approval.

Respi~TANN is marketed in the United States without an FDA-approved marketing application because it has been considered by us to be identical, related, or similar to products that have existed in the market without an NDA or ANDA. This product is marketed subject to the FDA's regulatory discretion and/or enforcement policies. FDA has adopted a risk-based enforcement policy concerning unapproved drugs. The agency has articulated that, in enforcing the new drug application requirements, it prioritizes drugs that pose potential safety risks, lack evidence of effectiveness and prevent patients from seeking effective therapies, and those that are marketed fraudulently. In addition, the FDA has indicated that approval of an NDA for one drug within a class of drugs marketed without FDA approval may also trigger agency enforcement of the new drug requirements. Once the FDA issues an approved NDA for one of the drug products at issue or completes the efficacy review for that drug product, it may require us to also file a NDA or ANDA application for that same drug in order to continue marketing it in the United States. While the agency generally provides sponsors a one year grace period, the agency is not statutorily required to do so. In addition, although we may be given time to submit a marketing application before the agency would take enforcement action, the time it takes us to complete the necessary clinical studies and submit an application to FDA may exceed this time period, resulting in an interruption of marketing. It is also possible that the FDA could disagree with our determination that this product is identical, related, or similar to products that have existed in the marketplace without an NDA or ANDA.

In addition, our Respi~TANN product contains a timed-release dosage mechanism utilizing tannic acid. In 1960, the FDA issued a policy stating that when a timed-release dosage feature is added to a drug, then an approved NDA is required in order to market the drug. While listed in the Code of Federal Regulations, this policy has never gone through the notice and comment rulemaking process required for the development of an FDA regulation. Additionally, numerous tannic-acid based medications have been introduced by other pharmaceutical companies since the FDA's pronouncement without an NDA. Consequently, in continuing to market this product, we rely on the FDA's enforcement discretion with respect to the product, but we cannot guarantee that the FDA will not in the future choose to require an NDA or ANDA for the product, notwithstanding the fact that similar products have been marketed for many years.

If we fail to enter into and maintain successful strategic relationships for our product candidates, we may have to reduce or delay our product candidate development or increase our expenditures.

Our strategy for developing, manufacturing, and commercializing products in certain therapeutic areas currently requires us to enter into and successfully maintain strategic relationships with pharmaceutical companies or other industry participants to advance our programs and reduce our expenditures on each program. In addition to our development partners for MD Turbo, AllerNase and Emezine, we have to date formed strategic relationships with Pharmaceutical Product Development, Inc. and other companies. We may not be able to negotiate additional strategic relationships on acceptable terms, if at all. If we are not able to maintain our existing strategic relationships or establish and maintain additional strategic relationships, we may have to limit the size or scope of, or delay, one or more of our product development programs or research programs, or undertake and fund these programs ourselves. If we elect to increase our expenditures to fund product development programs or research programs on our own, we will need to obtain additional capital, which may not be available on acceptable terms, or at all.

If we acquire other complementary technologies or companies, our financial performance could suffer, and such acquisitions involve a number of risks.

We may from time to time actively seek to identify and acquire companies, technologies, or pharmaceutical products with attributes complementary to our products and services. Acquisitions that we make may involve numerous risks, including:

- diverting management's attention from other business concerns;
- being unable to maintain uniform standards, controls, procedures, and policies;
- entering markets in which we have no direct prior experience;
- improperly evaluating new services and technologies or otherwise being unable to fully exploit the anticipated opportunity; and
- being unable to successfully integrate the acquisition.

Any of the factors listed above would adversely affect our results of operations.

We are not able to prevent third parties, including potential competitors, from developing and selling an anti-cancer vaccine for NHL having the same composition of matter as BiovaxID.

Our BiovaxID vaccine is based on research and studies conducted at Stanford University and the NCI. As a result of published studies, the concept of the vaccine and its composition of matter are in the public domain and cannot be patented by us, the NCI, or any other party. We have filed a PCT patent application on the type of cell media that is used to grow cell cultures in the production of our vaccine, and we have filed a PCT patent application on certain features of the integrated production and purification system used to produce and purify the vaccine in an automated closed system. However, we cannot prevent other companies using different manufacturing processes from developing active immunotherapies that directly compete with BiovaxID.

We are aware of several companies focusing on the development of active immunotherapies for NHL, including Genitope Corporation, Antigenics, Inc., Favrille, Inc., and Large Scale Biology Corporation. We believe none of these companies uses the hybridoma method to produce a patient-specific vaccine, and of these companies, only Genitope and Favrille have a product candidate in Phase 3 clinical trials. Several companies, such as Genentech, Inc., Curia Corporation, Biogen Idec, and Immunomedics, Inc., are involved in the development of passive immunotherapies for NHL. These passive immunotherapies include Rituxan, a monoclonal antibody, and Zevalin and Bexxar, which are passive radioimmunotherapy products. Competition could impair our ability to generate revenue and could increase costs.

Our proprietary rights may not adequately protect our technologies and product candidates.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our technologies and product candidates as well as successfully defending these patents against third-party challenges. We will only be able to protect our technologies and product candidates from unauthorized use by third parties to the extent that valid and enforceable patents or trade secrets cover them. Furthermore, the degree of future protection of our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage.

In addition to the patent applications that we have filed and the patent we hold relating to the method of producing BiovaxID, SinuNase is the subject of a patent that we license from MAYO that expires in 2018. The MD Turbo device is the subject of four issued U.S. patents and one pending U.S. application that are held by Respirics, Inc., our development partner for MD Turbo, and these patents expire in 2016.

The patent positions of life sciences companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in such companies' patents has emerged to date in the United States. The patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States or other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in our patents or in third-party patents. For example:

- we or our licensors might not have been the first to make the inventions covered by each of our pending patent applications and issued patents;
- we or our licensors might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;

- it is possible that none of our pending patent applications or the pending patent applications of our licensors will result in issued patents;
- our issued patents and issued patents of our licensors may not provide a basis for commercially viable products, or may not provide us with any competitive advantages, or may be challenged and invalidated by third parties;
- we may not develop additional proprietary technologies or product candidates that are patentable; or
- the patents of others may have an adverse effect on our business.

We also rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. While we use reasonable efforts to protect our trade secrets, our or our strategic partners' employees, consultants, contractors, or scientific and other advisors may unintentionally or willfully disclose our information to competitors. If we were to enforce a claim that a third party had illegally obtained and was using our trade secrets, it would be expensive and time consuming, and the outcome would be unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, if our competitors independently develop equivalent knowledge, methods, and know-how, it will be more difficult for us to enforce our patent rights and our business could be harmed.

If we are not able to defend the patent or trade secret protection position of our technologies and product candidates, then we will not be able to exclude competitors from developing or marketing competing products, and we may not generate enough revenue from product sales to justify the cost of development of our products and to achieve or maintain profitability.

We may find it difficult to prevent compounding pharmacies from preparing compounded formulations of amphotericin B solution for the treatment of CRS in violation of the patents that we license.

We hold an exclusive license to market and sell products made from amphotericin B based on MAYO's patented treatment method for CRS. Although amphotericin B has not been approved by the FDA for the treatment of CRS, a number of physicians currently prescribe a compounded formulation of amphotericin B solution for their CRS patients. These formulations are prepared by compounding pharmacies that are in the business of preparing custom-made solutions using FDA-approved active ingredients. While we have sublicensed our rights to the compounded variant of the product to compounding pharmacies, we are aware that other compounding pharmacies may be preparing similar compounded formulations in violation of one or more claims of our licensed patents. Because these patent violations may be sporadic and dispersed, we may not be able to easily identify the violations. In addition, because the patents that we license from MAYO relate to a method of treating CRS, if other amphotericin B solutions become commercially available for other indications, we may not be able to prevent physicians from prescribing such other solutions for CRS on an off-label basis. Such actions could hinder our ability to generate enough revenue to justify development costs and to achieve or maintain profitability.

If we are sued for infringing intellectual property rights of third parties, such litigation will be costly and time consuming, and an unfavorable outcome would have a significant adverse effect on our business.

Our ability to commercialize our products depends on our ability to sell such products without infringing the patents or other proprietary rights of third parties. Numerous United States and foreign issued patents and pending applications, which are owned by third parties, exist in the various areas in which we have products or are seeking to create products, including patents relating to specific antifungal formulations and methods of using the formulations to treat infections, as well as patents relating to serum-based vaccines and methods for detection of lymphoma. The interpretation of patent claims is complex and uncertain. The legal standards governing claim interpretations are evolving and changing. Thus, any significant changes in the legal standards would impact the way that we interpret the claims of third-party patents in our product areas. In addition, because patent applications can take several years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates may infringe. There could also be existing patents of which we are not aware that our product candidates may inadvertently infringe.

If a third party claims that we infringe on their patents or other proprietary rights, we could face a number of issues that could seriously harm our competitive position, including:

- infringement and other intellectual property claims which, with or without merit, can be costly and time consuming to litigate and can delay the regulatory approval process and divert management's attention from our core business strategy;
- substantial damages for past infringement which we may have to pay if a court determines that our products or technologies infringe upon a competitor's patent or other proprietary rights;
- a court prohibiting us from selling or licensing our products or technologies unless the holder licenses the patent or other proprietary rights to us, which it is not required to do;
- if a license is available from a holder, we may have to pay substantial royalties or grant cross licenses to our patents or other proprietary rights; and

- redesigning our process so that it does not infringe, which may not be possible or may require substantial time and expense.

Such actions could harm our competitive position and our ability to generate revenue and could result in increased costs.

If federal or state enforcement authorities characterize any portion of the fees payable to us by sublicenses of our CRS therapy as remuneration for recommending or referring business to the compounding pharmacies, then such fees could be challenged under federal and/or state anti-kickback laws.

We have sublicensed our rights to Mayo Clinic's patented CRS therapy to several compounding pharmacies that pay us a sublicensing fee each time they dispense an antifungal for CRS treatment under a physician's prescription. We may enter into additional sublicensing arrangements in the future with other compounding pharmacies and charge similar royalties. We also maintain a small group from our specialty pharmaceuticals business to educate physicians about Mayo Clinic's research and studies relating to the causes and potential treatment methods for CRS. We believe that the fees payable to us by sublicensed compounding pharmacies are payable solely for the grant of the sublicense to the Mayo Clinic's CRS therapy, and such sublicense fees are payable regardless of the source of the prescription. However, if federal or state enforcement authorities characterize any part of these sublicense fees as remuneration to us in exchange for arranging for or recommending the services of, or otherwise referring business to, these compounding pharmacies, then these sublicense fees could be challenged under federal and/or state anti-kickback laws. To the extent that enforcement is initiated, we could face fines and other penalties, which could harm our business.

The revenues that we receive from sublicensing the amphotericin B therapy for CRS to compounding pharmacies could be materially adversely impacted by FDA enforcement action.

Although we cannot market SinuNase until we obtain FDA approval, our license agreement with MAYO permits us to sublicense MAYO's patent rights related to amphotericin B for use as a therapy for CRS to compounding pharmacies under license agreements approved by MAYO. Such compounding pharmacies would then have the right to use the sublicense to compound the product for prescribing physicians. Pharmacy compounding is considered to be part of the practice of pharmacy, regulated by state pharmacy practice acts. The FDA does not typically exercise its enforcement authority against traditional pharmacy compounding whereby pharmacists extemporaneously compound and manipulate reasonable quantities of human drugs upon receipt of a valid prescription for an individually identified patient from a licensed practitioner. However, the FDA has taken enforcement action against pharmacies whose activities the FDA believes exceed the scope of the practice of pharmacy by engaging in the actual manufacturing of drug products. The FDA has identified that such activities may include, but not be limited to, compounding drugs in anticipation of receiving prescriptions, using commercial-scale manufacturing or testing equipment for compounding, failing to document individual medical need for the compounded product, and failing to operate in conformance with state law regulating the practice of pharmacy. In the event that the FDA takes an enforcement action against any of the compounding pharmacies to which we may sublicense the amphotericin B therapy, the revenues we receive could materially decline, which could harm our business. We have no assurance that the FDA will refrain from taking enforcement actions against any of the compounding pharmacies, nor can we assure you that laws related to the FDA's regulation of compounding pharmacies will not provide the FDA with additional enforcement authority against compounding pharmacies, all of which could result in a decline in our revenues which would harm our business. In addition, our representatives educate physicians about the availability of the compounding services, and while we believe that such information does not represent promotion of the product, the FDA may disagree, and we could be subject to enforcement action, including but not limited to a warning letter demanding that we cease the provision of such information.

Physicians may be reluctant to prescribe amphotericin B for treatment of CRS while it is an unapproved indication.

Physicians are permitted to prescribe drug for unapproved indications, sometimes referred to as "off-label" uses, as part of the practice of medicine. However, the federal Medicaid program, which provides significant reimbursement for prescription drugs, restricts the types and uses of drugs which may be paid for with federal funds. The Medicaid program primarily provides reimbursement only for drugs used for medically accepted indications. A medically accepted indication is defined as a use that has either been approved by the FDA or is supported by specific compendia set forth in the Medicaid statute, in which off-label usage is significantly restricted. Submission of a claim to federal or state governments for reimbursement of an off-label use of a drug not eligible for such reimbursement could be considered a false claim under the Federal False Claims Act, if such claim was submitted knowing it was false. Although the federal government has focused its attention in this area on the activities of drug manufacturers in promoting off-label uses of their products, these actions have been high profile and have involved substantial settlements. Such governmental activity has heightened concerns of physicians regarding off-label prescribing. This may result in a decline in prescriptions of amphotericin B for treatment of CRS. Such decline could cause our revenues to decline materially and harm the business of our company.

We currently depend on a sole-source supplier for KLH, a critical raw material used in the manufacture of BiovaxID, and physicians who administer BiovaxID depend on a sole-source supplier for GM-CSF, an immune system stimulant administered with BiovaxID.

We currently depend on single source suppliers for critical raw materials used in BiovaxID and other components used in the manufacturing process and required for the administration of BiovaxID. In particular, manufacturing of BiovaxID requires keyhole limpet hemocyanin, or KLH, a foreign carrier protein. We purchase KLH from BioSyn Arzneimittel GmbH, or BioSyn, a single source supplier. We have entered into a supply agreement with BioSyn, pursuant to which BioSyn has agreed to supply us with KLH. The supply agreement has an initial term of three years and is renewable for indefinite additional terms of five years each at our discretion, so long as we are not in default of our obligations pursuant to this agreement. Either party may terminate the supply agreement earlier upon a breach that is not cured within 60 days or other events relating to insolvency or bankruptcy. Under this agreement BioSyn is not contractually obligated to supply us with the amounts of KLH currently being supplied and necessary for our current clinical trial purposes or for commercialization. There may be no other supplier of KLH of suitable quality for our purposes.

When BiovaxID is administered, the administering physician uses a cytokine to enhance the patient's immune response, and this cytokine is administered concurrently with BiovaxID. The cytokine used by physicians for this purpose is Leukine® sargramostim, a commercially available recombinant human granulocyte-macrophage colony stimulating factor known as GM-CSF. This cytokine is a substance that is purchased by the administering physician and is administered with an antigen to enhance or increase the immune response to that antigen. The physicians who administer BiovaxID will rely on Berlex Inc., or Berlex, as a supplier of GM-CSF, and these physicians will generally not have the benefit of a long-term supply contract with Berlex. GM-CSF is not commercially available from other sources in the United States or Canada.

Establishing additional or replacement suppliers for these materials or components may take a substantial amount of time. In addition, we may have difficulty obtaining similar components from other suppliers that are acceptable to the FDA. If we have to switch to a replacement supplier, we may face additional regulatory delays and the manufacture and delivery of BiovaxID, or any other immunotherapies that we may develop, could be interrupted for an extended period of time, which may delay completion of our clinical trials or commercialization of BiovaxID, or any other immunotherapies that we may develop. If we are unable to obtain adequate amounts of these components, our clinical trials will be delayed. In addition, we will be required to obtain regulatory clearance from the FDA to use different components that may not be as safe or as effective. As a result, regulatory approval of BiovaxID may not be received at all. All these delays could cause delays in commercialization of BiovaxID, delays in our ability to generate revenue from BiovaxID, and increased costs.

Other than BioSyn, Berlex, and the exclusive supply relationships that we have for MD Turbo and Respi~TANN, we are not dependent on any sole-source suppliers.

The market may not be receptive to our products upon their introduction.

The biopharmaceutical products that we may develop may not achieve market acceptance among physicians, patients, health care payors, and the medical community. The degree of market acceptance will depend upon a number of factors, including

- the receipt of regulatory approvals;
- limited indications of regulatory approvals;
- the establishment and demonstration in the medical community of the clinical efficacy and safety of our products and their potential advantages over existing treatment methods;
- the prices of such products;
- reimbursement policies of government and third-party payors;
- market acceptance of patient-specific active immunotherapies, in the case of BiovaxID;
- the prevalence and severity of any side effects;
- potential advantages over alternative treatments;
- ability to produce our products at a competitive price;
- stocking and distribution;
- relative convenience and ease of administration;
- the strength of marketing and distribution support; and
- sufficient third-party coverage or reimbursement.

The failure of our product pipeline to gain market acceptance could impair our ability to generate revenue, which could have a material adverse effect on our future business, financial condition and results of operations.

The National Cancer Institute is not precluded from working with other companies on developing products that are competitive with BiovaxID.

Our BiovaxID vaccine is based on research and studies conducted at Stanford University and the NCI. The concept of producing a patient-specific anti-cancer vaccine through the hybridoma method from a patient's own cancer cells has been discussed in a variety of publications over a period of many years, and, accordingly, the general method and concept of such a vaccine is not eligible to be patented by us, the NCI, or any other party. Until November 2006, we were a party to a Cooperative Research and Development Agreement, or CRADA, with the NCI for the development of a hybridoma-based patient-specific idiotypic vaccine for the treatment of indolent follicular NHL. We gave notice of termination of the CRADA in September 2006, and the termination will be effective 60 days after notice. Although the NCI transferred sponsorship of the IND for BiovaxID to us in 2004, and although there are certain confidentiality protections for information generated pursuant to the CRADA, the CRADA does not prevent the NCI from working with other companies on other hybridoma-based idiotypic vaccines for indolent follicular NHL or other forms of cancer, and the NCI or its future partners may be able to utilize certain technology developed under our prior CRADA. If the NCI chooses to work with other companies in connection with the development of such a vaccine, such other companies may also develop technology and know-how that may ultimately enable such companies to develop products that compete with BiovaxID. Additionally, through their partnership with the NCI, these companies could develop immunotherapies for other forms of cancer that may serve as barriers to any future products that we may develop for such indications.

Risks Related to Our Industry

Our competitors may develop products that are less expensive, safer, or more effective, which may diminish or eliminate the commercial success of any future products that we may commercialize.

We compete with several biopharmaceutical companies, and our competitors may:

- develop product candidates and market products that are less expensive or more effective than our future products;
- commercialize competing products before we or our partners can launch any products developed from our product candidates;
- initiate or withstand substantial price competition more successfully than we can;
- have greater success in recruiting skilled scientific workers from the limited pool of available talent;
- more effectively negotiate third-party licenses and strategic relationships; and
- take advantage of acquisition or other opportunities more readily than we can.

We will compete for market share against large pharmaceutical and biotechnology companies and smaller companies that are collaborating with larger pharmaceutical companies, new companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors, either alone or together with their partners, may develop new product candidates that will compete with ours, and these competitors may, and in certain cases do, operate larger research and development programs or have substantially greater financial resources than we do.

If our competitors market products that are less expensive, safer or more effective than our potential products, or that reach the market sooner than our potential products, we may not achieve commercial success. In addition, the life sciences industry is characterized by rapid technological change. Because our research approach integrates many technologies, it may be difficult for us to stay abreast of the rapid changes in each technology. If we fail to stay at the forefront of technological change we may be unable to compete effectively. Our competitors may render our technologies obsolete by advances in existing technological approaches or the development of new or different approaches, potentially eliminating the advantages in our drug discovery process that we believe we derive from our research approach and proprietary technologies.

If we fail to comply with extensive regulations enforced by the FDA, EMEA, and other agencies, the sale of our current products, and the commercialization of our product candidates would be prevented or delayed.

Research, pre-clinical development, clinical trials, manufacturing, and marketing of our products are subject to extensive regulation by various government authorities. Neither we nor our partners have received marketing approval for SinuNase, BiovaxID or Emezine. The process of obtaining FDA, European Medicines Agency, or EMEA, and other required regulatory approvals is lengthy and expensive, and the time required for such approvals is uncertain. The approval process is affected by such factors as

- the severity of the disease;
- the quality of submission;
- the clinical efficacy and safety;

- the strength of the chemistry and manufacturing control of the process;
- the manufacturing facility compliance;
- the availability of alternative treatments;
- the risks and benefits demonstrated in clinical trials; and
- the patent status and marketing exclusivity rights of certain innovative products.

Any regulatory approvals that we or our partners receive for our product candidates may also be subject to limitations on the indicated uses for which the drug may be marketed or contain requirements for potentially costly post-marketing follow-up studies. The subsequent discovery of previously unknown problems with the drug, including adverse events of unanticipated severity or frequency, may result in restrictions on the marketing of the drug, and could include withdrawal of the drug from the market.

Our U.S. manufacturing, labeling, storage, and distribution activities also are subject to strict regulation and licensing by the FDA. Our biopharmaceutical manufacturing facilities are subject to periodic inspection by the FDA, the EMEA, and other regulatory authorities and from time to time, we may receive notices of deficiencies from these agencies as a result of such inspections. Our failure, or the failure of our biopharmaceutical manufacturing facilities, to continue to meet regulatory standards or to remedy any deficiencies could result in corrective action by the FDA or these other authorities, including the interruption or prevention of marketing, closure of our biopharmaceutical manufacturing facilities and fines or penalties.

Regulatory authorities also will require post-marketing surveillance to monitor and report to the FDA potential adverse effects of our products or product candidates. Congress or the FDA in specific situations can modify the regulatory process. Once approved, a product's failure to comply with applicable regulatory requirements could, among other things, result in warning letters, fines, suspension or revocation of regulatory approvals, product recalls or seizures, operating restrictions, injunctions, and criminal prosecutions.

The FDA's policies may change and additional government regulations may be enacted that could prevent or delay regulatory approval of our product candidates. We cannot predict the likelihood, nature or extent of adverse government regulation that may arise from future legislation or administrative action, either in the United States or abroad. If we are not able to maintain regulatory compliance, we might not be permitted to market our products and our business could suffer.

Although we do not have material sales of our biopharmaceutical products outside the U.S. today, our goal is to expand our global presence for these products. Distribution of our products outside the U.S. is subject to extensive government regulation. These regulations, including the requirements for approvals or clearance to market, the time required for regulatory review and the sanctions imposed for violations, vary from country to country. There can be no assurance that we will obtain regulatory approvals in such countries or that we will not be required to incur significant costs in obtaining or maintaining these regulatory approvals. In addition, the export by us of certain of our products that have not yet been cleared for domestic commercial distribution may be subject to FDA export restrictions. Failure to obtain necessary regulatory approvals, the restriction, suspension or revocation of existing approvals or any other failure to comply with regulatory requirements would impair our ability to generate revenue, increase our compliance costs, and have a material adverse effect on our future business, financial condition, and results of operations.

Our Respi~TANN product also contains pseudoephedrine. The DEA regulates pseudoephedrine, pursuant to the CSA and the Domestic Chemical Diversion Control Act of 1993, as a "listed chemical" because it can be used in the production of illicit drugs. There are two groups of listed chemicals, List I chemicals and List II chemicals; List I chemicals are more strictly regulated. Pseudoephedrine is a List I chemical. Persons or firms who manufacture, distribute, import, or export listed chemicals in amounts above specified threshold levels, or chemical mixtures that contain listed chemicals above specified threshold amounts, must fulfill certain requirements regarding, among other things, registration, recordkeeping, reporting, and security. Places where regulated persons or firms handle listed chemicals or chemical mixtures are subject to administrative inspections by the DEA. Failure to comply with relevant DEA regulations can result in civil penalties, refusal to renew necessary registrations, or initiating proceedings to revoke those registrations. In certain circumstances, violations can lead to criminal prosecution. Pseudoephedrine is subject to tighter controls than most other listed chemicals that are lawfully marketed under the Federal Food, Drug, and Cosmetic Act. Also, recent regulatory actions at the state level may affect future distribution, advertising, and promotion of pseudoephedrine-containing products.

The insurance coverage and reimbursement status of newly approved products is uncertain and failure to obtain or maintain adequate coverage and reimbursement for new or current products could limit our ability to market those products and decrease our ability to generate revenue.

There is significant uncertainty related to the insurance coverage and reimbursement of newly approved products. The commercial success of our potential products in both domestic and international markets is substantially dependent on whether third-party coverage and reimbursement is available for the ordering of our potential products by the medical profession for use by their patients. Medicare, Medicaid, health maintenance organizations, and other third-party payors are

increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement of new products, and, as a result, they may not cover or provide adequate payment for our potential products. Even our existing product line could face declining revenues if competitor products are perceived as providing a substantially equivalent therapeutic effect at a lower cost to the payor. They may not view our products as cost-effective and reimbursement may not be available to consumers or may not be sufficient to allow our products to be marketed on a competitive basis. Likewise, legislative or regulatory efforts to control or reduce healthcare costs or reform government healthcare programs could result in lower prices or rejection of our products. Changes in coverage and reimbursement policies or healthcare cost containment initiatives that limit or restrict reimbursement for our products may cause our revenue to decline.

We may not be able to maintain sufficient product liability insurance to cover claims against us.

Product liability insurance for the biopharmaceutical industry is generally expensive to the extent it is available at all. There can be no assurance that we will be able to maintain such insurance on acceptable terms or that we will be able to secure increased coverage if the commercialization of our products progresses, or that existing, or future claims against us will be covered by our product liability insurance. Moreover, there can be no assurance that the existing coverage of our insurance policy and/or any rights of indemnification and contribution that we may have will offset existing or future claims. We currently maintain product liability insurance of $10 million per occurrence and in the aggregate. We believe that this coverage is currently adequate based on current and projected business activities and the associated risk exposure, although we expect to increase this coverage as our business activities and associated risk grow. A successful claim against us with respect to uninsured liabilities or in excess of insurance coverage and not subject to any indemnification or contribution could have a material adverse effect on our future business, financial condition, and results of operations.

We could be negatively impacted by the application or enforcement of federal and state fraud and abuse laws, including anti-kickback laws and other federal and state anti-referral laws.

We are subject to various federal and state laws pertaining to healthcare fraud and abuse, including anti-kickback laws and physician self-referral laws. Violations of these laws are punishable by criminal and civil sanctions, including, in some instances, imprisonment and exclusion from participation in federal and state healthcare programs, including the Medicare, Medicaid and Veterans Administration health programs. Because of the far-reaching nature of these laws, we may be required to alter or discontinue one or more of our practices to be in compliance with these laws. Healthcare fraud and abuse regulations are complex, and even minor irregularities can potentially give rise to claims that a statute or prohibition has been violated. Any violations of these laws, or any action against us for violation of these laws, even if we successfully defend against it, could result in a material adverse effect on our business, financial condition and results of operations. If there is a change in law, regulation or administrative or judicial interpretations, we may have to change or discontinue our business practices or our existing business practices could be challenged as unlawful, which could have a material adverse effect on our business, financial condition and results of operations. In addition, we could become subject to false claims litigation under federal statutes, which can lead to treble damages based on the reimbursements by federal health care programs, civil money penalties (including penalties levied on a per false claim basis), restitution, criminal fines and imprisonment, and exclusion from participation in Medicare, Medicaid and other federal and state healthcare programs. These false claims statutes include the False Claims Act, which allows any person to bring suit on behalf of the federal government alleging the submission of false or fraudulent claims, or causing to present such false or fraudulent claims, under federal programs or contracts claims or other violations of the statute and to share in any amounts paid by the entity to the government in fines or settlement. These suits against biotechnology companies have increased significantly in recent years and have increased the risk that a healthcare company will have to defend a false claim action, pay fines or restitution, or be excluded from the Medicare, Medicaid or other federal and state healthcare programs as a result of an investigation arising out of such action. We cannot assure you that we will not become subject to such litigation or, if we are not successful in defending against such actions, that such actions will not have a material adverse effect on our business, financial condition and results of operations. In addition, we cannot assure you that the costs of defending claims or allegations under the False Claims Act will not have a material adverse effect on our business, financial condition and results of operations.

Risk Factors Related to Our Operations

The failure to attract and retain skilled personnel could impair our product development and commercialization efforts.

Our performance is substantially dependent on the performance of our senior management and key scientific and technical personnel, particularly Francis E. O'Donnell, Jr., M.D., our Chief Executive Officer and Chairman, Steven R. Arikian, M.D., our President and Chief Operating Officer, Biopharmaceutical Products and Services, and Alan M. Pearce, our Chief Financial Officer. We have entered into employment agreements with each of Messrs. O'Donnell, Arikian, and Pearce, although there is no assurance that they will remain in our employ for the entire term of such employment agreements. The loss of the services of any member of our senior management, scientific, or technical staff may significantly delay or prevent the achievement of product development and other business objectives by diverting management's attention to transition matters and identification of suitable replacements, and could have a material adverse effect on our business,

operating results, and financial condition. We do not maintain key man life insurance for any of Messrs. O'Donnell, Arikian, or Pearce. We are not aware of any plans by our key personnel to retire or leave us in the near future.

We also rely on consultants and advisors to assist us in formulating our research and development strategy. All of our consultants and advisors are either self-employed or employed by other organizations, and they may have conflicts of interest or other commitments, such as consulting or advisory contracts with other organizations, that may affect their ability to contribute to us.

In addition, we believe that we will need to recruit additional executive management and scientific and technical personnel. There is currently intense competition for skilled executives and employees with relevant scientific and technical expertise, and this competition is likely to continue. The inability to attract and retain sufficient scientific, technical, and managerial personnel could limit or delay our product development efforts, which would adversely affect the development of our product candidates and commercialization of our potential products and growth of our business.

We expect to expand our development, clinical research, and marketing capabilities, and as a result, we may encounter difficulties in managing our growth, which could disrupt our operations.

We expect to have significant growth in expenditures, the number of our employees and the scope of our operations, in particular with respect to those product candidates that we elect to commercialize independently or together with a partner. To manage our anticipated future growth, we must continue to implement and improve our managerial, operational, and financial systems, expand our facilities, and continue to recruit and train additional qualified personnel. Due to our limited resources, we may not be able to effectively manage the expansion of our operations or recruit and train additional qualified personnel. The physical expansion of our operations may lead to significant costs and may divert our management and business development resources. Any inability to manage growth could delay the execution of our business plans or disrupt our operations.

We have a limited operating history and financial results are uncertain.

We have a limited history as a consolidated company and face many of the risks of a new business. As a result of our limited operating history, it is difficult to accurately forecast our potential revenue. Our revenue and income potential is unproven and our business model is still emerging. Therefore, we cannot assure you that we will provide a return on investment in the future. An investor in our common stock must consider the challenges, risks, and uncertainties frequently encountered in the establishment of new technologies and products in emerging markets and evolving industries. These challenges include our ability to:

- execute our business model;
- create brand recognition;
- manage growth in our operations;
- create a customer base cost-effectively;
- retain customers;
- access additional capital when required; and
- attract and retain key personnel.

We cannot be certain that our business model will be successful or that it will successfully address these and other challenges, risks, and uncertainties.

Our relationship with BioDelivery Sciences and the relationship of several of our senior executive officers to BioDelivery Sciences creates potential for conflicts of interest.

Our company and several of our executive officers have relationships with BioDelivery Sciences International, Inc., or BioDelivery Sciences, a publicly traded drug delivery technology company, which may create conflicts of interest. An encochleated version of our SinuNase product is being developed under a license agreement with BioDelivery Sciences under which we have been granted exclusive worldwide rights to BioDelivery Sciences' encochleation technology for CRS and asthma products. Additionally, Emezine is being jointly developed with Arius Pharmaceuticals, Inc., or Arius, a wholly owned subsidiary of BioDelivery Sciences, under a distribution agreement that we entered into with Arius in March 2004.

Francis E. O'Donnell, Jr., M.D., is a principal stockholder and Chairman of the Board of both our company and BioDelivery Sciences. Previously, Dr. O'Donnell also served as the President and Chief Executive Officer of BioDelivery Sciences. Alan M. Pearce, our Chief Financial Officer, served as a director for BioDelivery Sciences until September 2005. Also, three of our employees are shared between BioDelivery Sciences and our company.

Our directors and executive officers owe a fiduciary duty of loyalty to us, and to the extent that they are also directors or officers of BioDelivery Sciences, they also owe similar fiduciary duties to BioDelivery Sciences. However, due to their responsibilities to serve both companies, there is potential for conflicts of interest. At any particular time, the needs of BioDelivery Sciences could cause one or more of these executive officers to devote attention to BioDelivery Sciences at the expense of our company. In addition, matters may arise that place the fiduciary duties of these individuals in conflicting positions. Such conflicts will be resolved by our independent directors and directors having no affiliation with BioDelivery Sciences. If conflicts occur, matters important to us could be delayed. The results of such delays are not susceptible to accurate predictions but could include, among other things, delay in the production of sufficient amounts of SinuNase to complete our clinical trials or to meet potential commercial demands. Such delays could increase our costs of development or reduce our ability to generate revenue. Our officers will use every effort to avoid material conflicts of interest generated by their responsibilities to BioDelivery Sciences, but no assurance can be given that material conflicts will not arise which could be detrimental to our operations and financial prospects.

The existence of minority stockholders in our Biovest subsidiary creates potential for conflicts of interest.

We directly own a majority of the outstanding capital stock of Biovest International, Inc., or Biovest, which is our subsidiary that is developing the BiovaxID vaccine, and the remaining Biovest stock is owned by approximately 500 stockholders of record. As a result, conflicts of interest may develop between us and the minority stockholders of Biovest. To the extent that our officers and directors are also officers or directors of Biovest, matters may arise that place the fiduciary duties of these individuals in conflicting positions. Although we intend that such conflicts will be resolved by independent directors of Biovest, if this occurs, matters important to us could be delayed. Francis E. O'Donnell, Jr., M.D., our Chairman and Chief Executive Officer, is also Vice Chairman and a director of Biovest, and Dr. Steven R. Arikian, a director and our President and Chief Operating Officer, Biopharmaceutical Products and Services, is the Chairman, CEO, and President of Biovest.

A total of 18 million shares of the Biovest stock held by us is transferable under debentures and warrants issued by us.

We hold approximately 78% of the shares of common stock of Biovest outstanding as of November 30, 2006. In September 2006, we entered into a private placement in which we issued to investors an aggregate of $25.0 million of 8% secured convertible debentures together with common stock purchase warrants. The convertible debentures issued by us in the private placement are convertible at the option of the holder into shares of our common stock or exchangeable for shares of Biovest stock held by us, and the warrants issued in the transaction are exercisable for our common stock or shares of Biovest stock held by us. In addition, we have pledged into an escrow account 18 million shares of the Biovest common stock held by us to secure the repayment of the convertible debentures. The total number of shares of Biovest common stock transferable by us to the investors in the private placement, whether pursuant to the exchange or exercise of the debentures and warrants or the exercise of rights under the pledge agreement, may not exceed 18 million shares in the aggregate. Accordingly, it is possible that our ownership of Biovest common stock could decrease by up to 18 million shares as a result of the September 2006 private placement. In such case, it is possible that we could cease to be the majority shareholder of Biovest.

In addition, we have issued a Warrant to Laurus Master Fund, Ltd. or Laurus to purchase up to 10 million shares of the Biovest common stock owned by us pursuant to an agreement dated October 31, 2006 The exercise price of these warrants is $0.01 per share of Biovest common stock.

We occasionally become subject to commercial disputes that could harm our business by distracting our management from the operation of our business, by increasing our expenses and, if we do not prevail, by subjecting us to potential monetary damages and other remedies.

From time to time we are engaged in disputes regarding our commercial transactions. These disputes could result in monetary damages or other remedies that could adversely impact our financial position or operations. Even if we prevail in these disputes, they may distract our management from operating our business and the cost of defending these disputes would reduce our operating results. If we do not prevail in these litigation matters or if we are required to expend a significant amount of resources defending such claims, our operating results, financial position, and cash flows could be adversely impacted.

Two of our customers generate a large portion of our revenue, and any reduction, delay, or cancellation of orders from these customers could reduce our revenues.

For the 2006 fiscal year, two of our customers, both wholesale distributors, accounted for more than 10% of our revenue. Revenues from Cardinal Health, McKesson Corporation, represented approximately 18.9% and 17.5% of our revenue for the years ended September 30, 2006. For the 2005 and 2004 fiscal years, two of our customers, both wholesale distributors, accounted for more than 10% of our revenue. Revenues from Cardinal Health represented approximately 25.0% and 15.3% of our revenue for the year ended September 30, 2005 and 2004, respectively, and revenues from McKesson Corporation

represented approximately 14.6% of our revenue for the year ended September 30, 2004. Any reduction, delay or cancellation of orders from this customer could reduce our revenue.

Our level of indebtedness reduces our financial flexibility and could impede our ability to operate.

As of December 10, 2006, our long-term debt excluding lines of credit was $33.8 million. Our long-term debt includes the following:

- $26.3 million in principal amount outstanding under our credit facilities with Laurus, consisting of two convertible term loans in the amounts of $8.7 million and $7.6 million, and a revolving credit line in the amount of $10.0 million. A portion of this credit facility is convertible into common stock as discussed under "MANAGEMENT DISCUSSION AND ANALYSIS"
- $4.0 million in principal amount outstanding under our revolving credit agreement with Southwest Bank of St. Louis f/k/a, Missouri State Bank ("Missouri State Bank").
- $2.0 million in principal amount outstanding under our term note with Pulaski Bank and Trust Company ("Pulaski Bank").
- $1.1 million in principal amount outstanding under our bridge note with Hopkins Capital II, LLC.
- $0.4 million in principal and interest under promissory notes issued by our Biovest subsidiary.

Under the $8.7 million term note with Laurus, assuming that Laurus does not convert the note, we are obligated to make equal monthly payments of principal and interest of $0.3 million each through the period ending in April 2008. Under the $7.6 million term notes with Laurus, assuming that Laurus does not convert the note, we are obligated to make equal monthly payments of principal and interest of $0.3 million each through the period ending in March 2009. Under the notes evidencing the revolving credit loan portion of our credit facility with Laurus, the $10.0 million principal amount will be due and payable in April 2008, with accrued interest being payable monthly. Under the revolving credit agreement with Missouri State Bank, the $4.0 million principal amount will become due and payable in January 2007, with accrued interest being payable monthly. Under the term note with Pulaski Bank, the $2.0 million principal amount will become due and payable in January 2007, with accrued interest being payable monthly. Under the bridge note issued to The Hopkins Capital II, LLC, the $1.1 million principal will become due and payable in August 2007, with accrued interest being payable monthly. The $0.4 million in principal and interest under the notes issued by Biovest will become due on various dates during 2006 and 2007. Our level of debt affects our operations in several important ways, including the following:

- a significant portion of our cash flow from operations is likely to be dedicated to the payment of the principal of and interest on our indebtedness;
- our ability to obtain additional financing in the future for working capital, capital expenditures or acquisitions may be limited;
- we may be unable to refinance our indebtedness on terms acceptable to us or at all;
- our cash flow may be insufficient to meet our required principal and interest payments; and

we may default on our obligations and the lenders may foreclose on their security interests that secure their loans.

Risks Related to Our Common Stock

Our stock price may be volatile, and your investment in our stock could decline in value.

The market prices for securities of biotechnology companies in general have been highly volatile and may continue to be highly volatile in the future. The following factors, in addition to other risk factors described in this section, may have a significant impact on the market price of our common stock:

- results from and any delays in the clinical trials programs;
- failure or delays in entering additional product candidates into clinical trials;
- failure or discontinuation of any of our research programs;
- delays in establishing new strategic relationships;
- delays in the development of our product candidates and commercialization of our potential products;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- actual and anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;

- issues in manufacturing our product candidates or products;
- market acceptance of our products;
- third-party healthcare reimbursement policies;
- FDA or other United States or foreign regulatory actions affecting us or our industry;
- litigation or public concern about the safety of our product candidates or products; and
- additions or departures of key personnel.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, in the past, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert the time and attention of our management.

If the ownership of our common stock continues to be highly concentrated, it may prevent you and other stockholders from influencing significant corporate decisions and may result in entrenchment of management or conflicts of interest that could cause our stock price to decline.

As of September 30, 2006, our executive officers, directors, greater-than-10% shareholders and their affiliates beneficially own or control approximately 71.25% of the outstanding shares of our common stock (after giving effect the exercise of all outstanding vested and unvested options and warrants). Accordingly, these persons and their affiliates, acting as a group, will have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of our assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of our company, even if such a change of control would benefit our other stockholders. The significant concentration of stock ownership may adversely affect the trading price of our common stock due to investors' perception that entrenchment of management or conflicts of interest may exist or arise.

Future sales of our common stock could lower the market price of our common stock.

Sales of substantial amounts of our shares in the public market could harm the market price of our common stock, even if our business is doing well. An aggregate of 31,717,467 shares of our common stock were outstanding as of November 30, 2006. Approximately 8,185,225 shares of our common stock outstanding as of November 30, 2006 were eligible for sale in the public market under SEC Rules 144, 144(k), and 701, subject in some cases to volume and other limitations. In addition, as of November 30, 2006:

- 3,732,014 shares issuable upon exercise of options and warrants to purchase our common stock were vested and eligible for sale;
- 2,648,482 shares issuable upon the conversion of convertible notes and the exercise of warrants held by Laurus are eligible for immediate sale under a currently effective registration statement covering the resale of such shares by Laurus (but only if Laurus elects to convert or exercise such notes and warrants and subject to certain volume limitations on conversion and exercise); and
- 12,751,585 shares issuable upon the conversion of convertible debentures and the exercise of warrants held by investors in our September 2006 private placement are eligible for immediate sale (but only if such investors elect to convert or exercise such debentures and warrants).

Due to the foregoing factors and due to registration rights held by other persons, sales of a substantial number of shares of our common stock in the public market could occur at any time. These sales, or the perception in the market that the holders of a large number of shares intend to sell shares, could reduce the market price of our common stock.

Evolving regulation of corporate governance and public disclosure may result in additional expenses and continuing uncertainty.

Changing laws, regulations and standards relating to corporate governance and public disclosure, including the Sarbanes-Oxley Act of 2002, new SEC regulations, and NASDAQ Global Market rules are creating uncertainty for public companies. As a result of these new rules, we will incur additional costs associated with our public company reporting requirements. In addition, these 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 this could make it difficult for us to attract and retain qualified persons to serve on our board of directors.

We are presently evaluating and monitoring developments with respect to new and proposed rules and cannot predict or estimate the amount of the additional costs we may incur or the timing of such costs. These new or changed laws, regulations, and standards are subject to varying interpretations, in many cases due to their lack of specificity, and as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

We are committed to maintaining high standards of corporate governance and public disclosure. As a result, we intend to invest resources to comply with evolving laws, regulations, and standards, and this investment may result in increased general and administrative expenses and a diversion of management time and attention from revenue-generating activities to compliance activities. If our efforts to comply with new or changed laws, regulations, and standards differ from the activities intended by regulatory or governing bodies due to ambiguities related to practice, regulatory authorities may initiate legal proceedings against us and we may be harmed.

We have limited experience attempting to comply with public company obligations, including Section 404 of the Sarbanes-Oxley Act of 2002.

As directed by Section 404 of the Sarbanes-Oxley Act of 2002, the SEC has adopted rules requiring public companies to include a report of management on the company's internal controls over financial reporting in their annual reports on Form 10-K. In addition, the public accounting firm auditing a public company's financial statements must attest to and report on management's assessment of the effectiveness of the company's internal controls over financial reporting. The requirement for a report of management, as currently in effect, will first apply to our annual report on Form 10-K for our fiscal year ending September 30, 2008. The requirement for our auditor to attest on management assessment will apply for the fiscal year ending September 30, 2009. If we are unable to conclude that we have effective internal controls over financial reporting, or if our independent auditors are unable to provide us with an unqualified report as to the effectiveness of our internal controls over financial reporting as required by Section 404 of the Sarbanes-Oxley Act of 2002, investors could lose confidence in the reliability of our financial statements, which could result in a decrease in the value of our securities.

We have never paid dividends on our common stock, and we do not anticipate paying any cash dividends in the foreseeable future.

We have paid no cash dividends on our common stock to date. We currently intend to retain our future earnings, if any, to fund the development and growth of our businesses, and we do not anticipate paying any cash dividends on our capital stock for the foreseeable future. In addition, the terms of existing or any future debts may preclude us from paying dividends on our stock. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

Some provisions of our amended and restated articles of incorporation, bylaws, and Florida law may inhibit potential acquisition bids that you may consider favorable.

Our corporate documents contain provisions that may enable our board of directors to resist a change in control of our company even if a change in control were to be considered favorable by you and other stockholders. These provisions include:

- the authorization of undesignated preferred stock, the terms of which may be established and shares of which may be issued without stockholder approval;
- advance notice procedures required for stockholders to nominate candidates for election as directors or to bring matters before an annual meeting of stockholders;
- limitations on persons authorized to call a special meeting of stockholders;
- a staggered board of directors;
- a requirement that vacancies in directorships are to be filled by a majority of directors then in office and the number of directors is to be fixed by the board of directors; and
- no cumulative voting.

These and other provisions contained in our amended and restated articles of incorporation and bylaws could delay or discourage transactions involving an actual or potential change in control of us or our management, including transactions in which our stockholders might otherwise receive a premium for their shares over then current prices, and may limit the ability of stockholders to remove our current management or approve transactions that our stockholders may deem to be in their best interests and, therefore, could adversely affect the price of our common stock.

In addition, we are subject to control share acquisitions provisions and affiliated transaction provisions of the Florida Business Corporation Act, the applications of which may have the effect of delaying or preventing a merger, takeover or other change of control of us and therefore could discourage attempts to acquire our company.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None

ITEM 2. PROPERTIES

Our principal executive office and administrative office is located in Tampa, Florida and consists of approximately 7,400 square feet pursuant to a lease agreement with a term of five years beginning April 1, 2005.

We have a sales and marketing office in Morrisville, North Carolina that consists of approximately 10,000 square feet. This office is occupied pursuant to a lease agreement that expires on April 30, 2007.

Our Analytica subsidiary leases approximately 13,800 square feet of office space in New York, New York, and approximately 22,500 square feet of office space in Lorrach, Germany. The New York office is occupied pursuant to a lease that will expire on August 31, 2010. The Lorrach lease will expire on November 1, 2011.

Our majority-owned Biovest subsidiary leases approximately 17,000 square feet in Worcester, Massachusetts, which it uses for contract cell production, offices, storage, and future expansion. The Worcester facility is occupied pursuant to a lease, and we have extended our lease term on this facility through February 28, 2010. Biovest also occupies a facility in Minneapolis, Minnesota that it uses for offices, a laboratory, manufacturing, warehousing, and contract cell culture services. This facility, which consists of approximately 33,000 square feet, is occupied pursuant to a lease agreement that is currently operating on a month-to-month basis. We historically have engaged in development activities for BiovaxID at our Minneapolis facility and have performed certain steps in the BiovaxID production process at this facility. However, we have consolidated all BiovaxID-related production activities into our Worcester facility.

Biovest leases approximately 24,000 square feet in St. Louis, Missouri, which it uses for the assembly, marketing and distribution of its AutovaxID instruments and associated cultureware. The lease term on this facility extends for three years.

We plan to continue to evaluate our requirements for facilities. We anticipate that as our development of SinuNase and BiovaxID advances and as we prepare for the future commercialization of these products, our facilities requirements will continue to change on an ongoing basis.

ITEM 3. LEGAL PROCEEDINGS

We are not a party to any material legal proceedings, and management is not aware of any threatened legal proceedings, that could cause a material adverse impact on our business, assets, or results of operations.

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

None.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market for Registrant's Common Stock

Our common stock is quoted on the Nasdaq Global Market, formerly known as the Nasdaq National Market under the symbol "ABPI" and has been quoted since our initial public offering on October 28, 2005. Prior to such date there was no public market for our common stock.

Market For Registrant's Common Equity And Related Stockholder Matters
Quarterly High / Low Company Stock Price - ABPI
FY 2006

	2006	
	High	Low
First Quarter	8.20	4.90
Second Quarter	8.86	5.12
Third Quarter	7.40	4.25
Fourth Quarter	4.35	2.35

Number of Common Shareholders

As of December 1, 2006, there were approximately 250 stockholders of record of our common stock.

Dividends

We have never declared or paid any dividends on our common stock. We currently intend to retain any future earnings to fund the development and expansion of our business, and therefore we do not anticipate paying cash dividends on our common stock in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors and will depend on our financial condition, results of operations, capital requirements, restrictions contained in future financing instruments, and other factors our board of directors deems relevant.

Equity Compensation Plan Information

Securities authorized for issuance under equity compensation plans as of September 30, 2006 (our last completed fiscal year end) were as follows:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants, and rights [a]	Weighted-average exercise price of outstanding options, warrants, and rights [b]	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in *column* [a]) [c]
Equity compensation plans approved by stockholders	2,186,992	$ 3.35	2,486,381
Equity compensation plans not approved by stockholders	—	N / A	—
Total	2,186,992	$ 3.35	2,486,381

Recent Sales of Unregistered Securities

During the fiscal year ended September 30, 2006, we did not issue any securities that were not registered under the Securities Act of 1933, as amended (the "Securities Act") except as disclosed in previous SEC filings.

ITEM 6. SELECTED FINANCIAL DATA

SELECTED CONSOLIDATED FINANCIAL DATA

The following selected consolidated financial data should be read in conjunction with our financial statements and the related notes thereto and "MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS" included elsewhere in this filing. The selected consolidated financial data as of September 30, 2006, 2005, 2004 and 2003 and for the years ended September 30, 2006, 2005, 2004 and 2003 have been derived from our audited consolidated financial statements included elsewhere in this filing. The selected financial data as of September 30, 2001 for the year ended September 30, 2001 of our predecessor, The Analytica Group, Ltd., have been derived from our predecessor's unaudited financial statements that are not included in this Annual Report.

	Years ended September 30,				From inception (April 3, 2002) through September 30,	Years ended September 30,	
						Pro forma	Predecessor
	(in thousands, except per share data)						
	2006	2005	2004	2003	2002	2002	2001
Consolidated Statements of Operations Data:							
Net sales	$ 25,058	$ 25,195	$ 25,936	$ 9,908	$ 2,761	$ 5,610	$ 2,440
Cost of sales	8,385	8,234	8,814	2,936	544	1,607	972
Gross margin	16,673	16,961	17,122	6,972	2,217	4,003	1,468
Operating expenses:							
Research and development	14,010	9,589	4,210	6,112	—	—	—
Research and development, related party	551	1,319	1,309	—	—	—	—
Sales and marketing	13,973	15,164	12,015	4,366	—	—	—
General and administrative	23,300	21,086	17,021	8,868	2,027	3,140	1,304
Royalties	1,460	1,717	387	—	—	—	—
Impairment charges	3,310	358	360	—	—	—	—
Other operating expense, related party	—	—	2,500	—	—	—	—
Total operating expenses	56,604	49,233	37,802	19,346	2,027	3,140	1,304
Operating income (loss)	(39,931)	(32,272)	(20,680)	(12,374)	190	863	164
Other income (expense):							
Interest (expense) income, net	(5,412)	(1,697)	(1,241)	(230)	(19)	(12)	16
Interest expense, net, related party	(1,092)	(2,120)	(1,485)	(338)	—	—	—
Derivative gain (loss)	1,241	(1,141)	—	—	—	—	—
Settlement expense	—	—	—	(1,563)	—	—	—
Loss on extinguishment of debt	—	(4,808)	—	—	—	—	—
Loss on extinguishment of debt, related party	—	(2,362)	—	—	—	—	—
Absorption of prior losses against minority interest	1,690	150	—	—	—	—	—
Other income (expense)	109	(56)	78	—	—	—	—
Net income (loss) from continuing operations before income taxes	(43,395)	(44,306)	(23,328)	(14,505)	171	851	180
Income tax benefit (expense)	—	—	—	180	(180)	(436)	—
Net income (loss) from continuing operations	(43,395)	(44,306)	(23,328)	(14,325)	(9)	415	180
Discontinued operations:							
Gain on sale of discontinued operations, net of income tax expense	—	—	1,618	—	—	—	—
Loss from discontinued operations, net of income tax benefit	—	(430)	(1,516)	(2,347)	(9,185)	(9,185)	—
Net income (loss)	(43,395)	(44,736)	(23,226)	(16,672)	(9,194)	(8,770)	180
Preferred stock dividends	(41)	(5,552)	(5,262)	—	—	—	—

Income (loss) attributable to common stockholders	$ (43,436)	$ (50,288)	$ (28,488)	$ (16,672)	$ (9,194)	$ (8,770)	$ 180
Weighted average shares outstanding, basic and diluted [1]	27,891	5,147	4,876	4,729	4,876	4,876	1,000
Per share amounts, basic and diluted [1]:							
Net Income (loss) per common share for:							
Continuing operations and minority interest	$ (1.56)	$ (9.69)	$ (5.86)	$ (3.01)	$ —	$ 0.08	$ 180
Discontinued operations	—	(0.08)	0.02	(0.51)	(1.89)	(1.87)	—
Net Income (loss) attributable to common stockholders	$ (1.56)	$ (9.77)	$ (5.84)	$ (3.52)	$ (1.89)	$ (1.79)	$ 180

(1) See Note 1 to our consolidated financial statements for a description of the method used to compute basic and diluted net loss per share and number of shares used in computing historical basic and diluted net loss per share.

(2) There were no cash dividends to common shareholders in the years ended September, 2006, 2005, 2004, 2003, 2002 and 2001.

	September 30,				
	2006	2005	2004[1]	2003[1]	2002
	(in thousands)				
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 15,392	$ 2,763	$ 1,905	$ 2,937	$ 569
Working capital	(20,469)	(40,623)	(31,462)	(23,104)	(88)
Total assets	57,136	36,681	28,133	23,387	6,891
Total liabilities	79,977	66,032	49,093	40,266	2,643
Non-controlling interest in variable interest entity	3,600	—	—	—	—
Total stockholders' deficit	(26,441)	(29,352)	(20,960)	(16,880)	(2,851)
Long-term obligations	29,391	15,319	9,976	7,654	—

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

When you read this section of this Form 10K, it is important that you also read the financial statements and related notes included elsewhere in this Form 10K. This section of this annual report contains forward-looking statements that involve risks and uncertainties, such as statements of our plans, objectives, expectations, and intentions. We use words such as "anticipate," "estimate," "plan," "project," "continuing," "ongoing," "expect," "believe," "intend," "may," "will," "should," "could," and similar expressions to identify forward-looking statements. Our actual results could differ materially from those anticipated in these forward-looking statements for many reasons, including the factors described below and in the "Risk Factors" section of this Form 10K.

Overview

We are a vertically integrated biopharmaceutical company focused on the development and commercialization of late-stage, targeted therapeutic clinical products in the areas of respiratory disease and oncology. We have two products with fast-track status in Phase 3 clinical trials. Our first such product candidate, SinuNase, is being developed as a treatment for CRS, which is a chronic inflammatory condition of the paranasal sinuses that results in nasal congestion, facial pain and pressure, nasal discharge, and headaches. SinuNase, is an amphotericin B suspension that is self-administered into a patient's nasal cavity for the treatment of CRS. We submitted an IND, with the FDA for SinuNase in April 2005 and we have commenced the first of two Phase 3 clinical trials for SinuNase for patients who have recurrent CRS. Our other late-stage product candidate, BiovaxID, is a patient-specific anti-cancer vaccine focusing on the treatment of follicular non-Hodgkin's lymphoma. BiovaxID was developed at the National Cancer Institute and is currently in a pivotal Phase 3 clinical trial. In addition to these product candidates, our specialty pharmaceutical business, Accentia Pharmaceuticals, currently markets respiratory products through our own dedicated specialty sales force. Our pharmaceutical product consulting business provides a broad range of services, including product candidate selection, outcomes research on the economic profiles of pharmaceuticals and biologics, pricing and market assessment on these products, reimbursement strategies and various services designed to expedite clinical trials to companies and institutions in the pharmaceutical, biotechnology, and medical markets as well as for our internal use. Our instrument business manufactures equipment used in the production of cells and other biologics based on the hollow-fiber production method and including our newly introduced automated instrument, AutovaxID and contract production of biologics for third-parties.

Our goal is to utilize our vertically integrated business structure to cost-effectively and efficiently develop, acquire, and commercialize innovative therapeutics that address significant unmet medical needs.

Corporate History and Structure

We were organized in 2002 to develop and commercialize biopharmaceutical products. We commenced business in April 2002 with the acquisition of The Analytica Group, Ltd., a provider of analytical and consulting services to the biopharmaceuticals industry, including clinical trial services, pricing and market assessment and outcomes research. We acquired Analytica in a merger transaction for $3.7 million cash, $1.2 million of convertible promissory notes, and the issuance of 8.1 million shares of Series B preferred stock. Analytica, which was founded in 1997, has offices in New York City and Lorrach, Germany.

In October 2002, Accent RX, Inc., a wholly owned subsidiary of our company, acquired the assets of American Prescription Providers, Inc. and American Prescription Providers of New York, Inc., collectively referred to as APP, which we operated under the name AccentRx after the acquisition. We acquired the assets and liabilities of APP for $0.2 million cash and the issuance of 10.3 million shares of common stock. We acquired assets of $10.6 million in the transaction and assumed liabilities of $10.4 million. At the time of acquisition, APP was controlled by our shareholders. AccentRx was a mail order specialty pharmacy focused on pharmaceuticals for AIDS patients and organ transplants. We sold the assets of AccentRx in December 2003 for $4.2 million cash.

In April 2003, we acquired, through a merger transaction, TEAMM Pharmaceuticals, Inc., a specialty pharmaceutical company founded in 2000 to market prescription pharmaceutical products. We acquired TEAMM for $7.9 million through the issuance of 9.7 million shares of Series D preferred stock, issuance of options to purchase 0.8 million shares of Series D preferred stock, issuance of warrants to purchase 2.1 million shares of Series D preferred stock, and the assumption of $13.7 million of liabilities. Through the TEAMM acquisition, we acquired an in-house sales force and a portfolio of prescription pharmaceutical products.

In June 2003, in exchange for an 81% interest in Biovest International, Inc., we invested $20.0 million in Biovest pursuant to an investment agreement with them. Under the investment agreement, as amended, we paid $2.5 million in cash at closing and $2.5 million by a 90-day note that has since been paid in full. The remaining $15.0 million was paid in the form of a non-interest-bearing promissory note. This note is payable in installments of $2.5 million on June 16, 2004, $2.5 million on June 16, 2005, and $5.0 million on June 16, 2006 and June 16, 2007. As of September 30, 2006, the $15.0 million non-interest-bearing note was fully paid in advance of its final due date. Because of our ownership interest in Biovest, this note is eliminated upon consolidation in our financial statements. Biovest is a biologics company that is developing our BiovaxID patient-specific vaccine for the treatment of follicular non-Hodgkin's lymphoma. Biovest also produces custom biologic products for a wide variety of customers, including biopharmaceutical and biotechnology companies, medical schools, universities, hospitals, and research institutions. The 18% minority interest in Biovest is held by approximately 500 shareholders of record. Biovest common stock is registered under Section 12(g) of the Securities Exchange Act of 1934, and Biovest therefore files periodic and other reports with the SEC.

In December 2003, we acquired substantially all of the assets and liabilities of Private Institute for Medical Outcome Research GmbH, or IMOR, for $0.6 million cash and assumption of $0.3 million of net liabilities. As part of the employment agreements with the two former owners of IMOR, we issued to them warrants to purchase 950,029 shares of Series B preferred stock that vest over five years and are exercisable at $2.63 per share. IMOR is a European-based provider of research, commercialization, and communications services similar to those provided by Analytica. Our acquisition of IMOR expanded the geographic reach of our analytical and consulting services business throughout the European Union and Asia, and provides us with additional capabilities that we believe will enable us to more effectively identify and attract partners with product candidates and to efficiently develop, clinically test, and market our products.

Business Segments

For financial reporting purposes, our business is divided into two segments: Biopharmaceutical Products and Services and Specialty Pharmaceuticals.

Biopharmaceutical Products and Services

Our Biopharmaceutical Products and Services segment develops late-stage innovative biopharmaceutical products with an emphasis on the respiratory and oncology therapeutic areas. The products currently being developed in this segment consist of SinuNase and BiovaxID. This segment also includes our consulting business, which provides a broad range of services relating to biopharmaceutical product development, and our biologics products business, which is engaged in the production of custom biologic products and cell culture instruments and systems for biopharmaceutical and biotechnology companies, medical schools, universities, hospitals, and research institutions.

Our Biopharmaceutical Products and Services segment is headquartered in New York City with an office in Lorrach, Germany and manufacturing facilities in Minneapolis, Minnesota, and Worcester, Massachusetts. Both manufacturing locations have laboratories, offices, and warehouse space for storage of supplies and inventories. The Minneapolis location is a 33,000 square foot building which includes laboratory and warehouse space. The Worcester facility, where we are developing the BiovaxID vaccine, has 17,500 square feet, primarily laboratories, and has approximately 3,500 square feet of warehouse.

Historically, our Minneapolis location has housed the National Cell Culture Center, or NCCC, which provides customized cell culture services for basic research laboratories under a grant from the National Institutes of Health. This contract, which expired in August 2005, but extended into 2006, generated approximately $0.7 million, $0.9 million, and $1.1 million in net sales for the years ended September 30, 2006, 2005 and 2004, respectively. As a result of the expiration of this contract, we no longer house the NCCC. Also at the Minneapolis facility, we generated approximately $4.6 million, $3.0 million, and $2.3 million in net sales for the years ended September 30, 2006, 2005 and 2004, respectively, from the manufacture of hollow fiber perfusion instruments used for the production of cell culture products and the sale of disposable products for use with these instruments. Additionally, the facility has provided contract cell line production services for research organizations, generating net sales of approximately $1.9 million, $0.9 million and $1.0 million for the years ended September 30, 2006, 2005 and 2004, respectively, using our hollow fiber perfusion instruments to manufacture monoclonal antibodies for use in diagnostics and other non-therapeutic applications. We also currently engage in development activities for instruments related to BiovaxID at our Minneapolis facility.

At our Worcester facility we currently produce vaccines for the BiovaxID clinical trial and also manufacture, on a selective basis, customized cell lines for external research organizations for their use in clinical trials in cases where we believe there may be promising potential future opportunities to license new product candidates from these research organizations. Net sales from contract production of custom cell lines were $0.03 million, $0.2 million and $1.1 million for the years ended September 30, 2006, 2005 and 2004, respectively. Furthermore, at this facility we oversee the design and manufacturing of our prototype AutovaxID systems, which automate the production and purification of patient-specific tumor antigens using fully enclosed sterile and disposable components for each patient treated. We anticipate that the second generation of these instruments will also incorporate conjugation and sterile fill of clinical material. We believe these systems will be integral to cost-effectively commercializing BiovaxID.

In December 2006, we entered into a lease of a facility in St. Louis, Missouri to locate the operations of the AutovaxID, Inc. subsidiary of Biovest, which will conduct the assembly, marketing and North American distribution of our AutovaxID systems.

Consolidated sales for our Analytica International subsidiary were $10.3 million, $10.1 million, and $7.2 million for the years ended 2006, 2005, and 2004, respectively.

Specialty Pharmaceuticals

Our Specialty Pharmaceuticals segment, which is based in Morrisville, North Carolina, markets and sells pharmaceutical products that are developed primarily by our third-party development partners. In this segment, we currently sell the Respi~TANN, CRSFungal Profile, MD Turbo products and have two additional products under development through development partners. Respi~TANN is a prescription antitussive decongestant for temporary relief of cough and nasal congestion, CRSFungal Profile is a test used in connection with the diagnosis of CRS, and MD Turbo is a breath-actuated inhaler device used by patients with asthma and chronic obstructive pulmonary disease. In this segment, we generated net sales of $7.5 million, $10.7 million and $11.9 million for the years ending September 30, 2006, 2005 and 2004, respectively

We license or obtain distribution or marketing rights to our specialty pharmaceutical products from third parties who are developing these products. We fund our partners' development activities primarily through milestone payments that are based on the partner achieving specified development goals. Milestone payments to our development partners were $2.0 million, $1.4 million and $2.9 million in the years ending September 30, 2006, 2005 and 2004, respectively.

Quarterly Results May Fluctuate

We anticipate that our quarterly results of operations will fluctuate for several reasons, including:

- the timing and extent of our development activities and clinical trials for SinuNase, BiovaxID, and any biopharmaceutical products that we may develop in the future;
- the timing and outcome of our applications for regulatory approval for our product candidates;
- the timing and extent of our adding new employees and infrastructure;
- the timing of any milestone payments, license fees, or royalty payments that we may be required to make; and
- seasonal influences on the sale of certain specialty pharmaceutical products sold primarily during the cough and cold season.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of our financial condition and results of operations is based on our consolidated financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements, as well as the reported net sales and expenses during the reporting periods.

The accounting policies discussed below are considered by our management to be critical to an understanding of our financial statements because their application depends on management's judgment, with financial reporting results relying on estimates and assumptions about the effect of matters that are inherently uncertain. On an ongoing basis, we evaluate our estimates and assumptions. We base our estimates on historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities that are not readily apparent from other sources. For all of these policies, management cautions that future events rarely develop exactly as forecast and that best estimates routinely require adjustment. Accordingly, actual results may differ from our estimates under different assumptions or conditions and could materially impact our financial condition or results of operations.

While our significant accounting policies are more fully described in Note 1 to our consolidated financial statements appearing at the end of this annual report on Form 10-K, we believe that the following accounting policies are the most critical to aid you in fully understanding and evaluating our reported financial results.

Revenue recognition

Biopharmaceutical Products and Services

We recognize revenue in our Biopharmaceutical Products and Services segment as follows:

Products. Net sales of cell culture instruments and disposables are recognized in the period in which the risk and rewards of ownership have passed (at point of shipment) to the buyer. We do not provide our customers with a right of return; however, deposits made by customers must be returned to customers in the event of non-performance by us.

Services. Service revenue in our Biopharmaceutical Products and Services segment is generated primarily by fixed-price contracts for cell culture production and consulting services. Such revenue is recognized over the contract term in accordance with the percentage-of-completion method based on the percentage of service cost incurred during the period compared to the total estimated service cost to be incurred over the entire contract. The nature and scope of our contracts often require us to make judgments and estimates in recognizing revenues.

Estimates of total contract revenues and costs are continuously monitored during the term of the contract, and recorded revenues and costs are subject to revision as each contract progresses. Such revisions may result in increases or decreases to revenues and income and are reflected in the consolidated financial statements in the periods in which they are first identified. Each month we accumulate costs on each contract and compare them to the total current estimated costs to determine the percentage of completion. We then apply this percentage to the total contract value to determine the amount of revenue that can be recognized. Each month we review the total current estimated costs on each contract to determine if these estimates are still accurate and, if necessary, we adjust the total estimated costs for each contract. As the work progresses, we might decide that original estimates were incorrect due to, among other things, revisions in the scope of work, and a contract modification might be negotiated with the customer to cover additional costs. If a contract modification is not agreed to, we could bear the risk of cost overruns. Losses on contracts are recognized during the period in which the loss first becomes probable and reasonably estimable. Reimbursements of contract-related costs are included in revenues. An equivalent amount of these reimbursable costs is included in cost of sales. Because of the inherent uncertainties in estimating costs, it is at least reasonably possible that the estimates used will change within the near term.

Service costs related to cell culture production include all direct materials and subcontract and labor costs and those indirect costs related to contract performance, such as indirect labor, insurance, supplies, and tools. We believe that actual cost incurred in contract cell production services is the best indicator of the performance of the contractual obligations, because the costs relate primarily to the amount of labor incurred to perform such services. The deliverables inherent in each of our cell culture production contracts are not output driven, but rather driven by a pre-determined production run. The duration of our cell culture production contracts range typically from 2 to 14 months.

Service costs relating to our consulting services consists primarily of internal labor expended in the fulfillment of our consulting projects and, to a lesser extent, outsourced research services. Service costs on a specific project may also consist of a combination of both internal labor and outsourced research service. Our consulting projects are priced and performed in phases, and the projects are managed by phase. As part of the contract bidding process, we develop an estimate of the total number of hours of internal labor required to generate each phase of the customer deliverable (for example, a manuscript or

database), and the labor cost is then computed by multiplying the hours dedicated to each phase by a standard hourly labor rate. We also determine whether we need services from an outside research or data collection firm and include those estimated outsourced costs in our total contract cost for the phase. At the end of each month, we collect the cumulative total hours worked on each contract and apply a standard labor cost rate to arrive at the total labor cost incurred to date. This amount is divided by the total estimated contract cost to arrive at the percentage of completion, which is then applied to the total estimated contract revenues to determine the revenue to be recognized through the end of the month. Accordingly, as hours are accumulated against a project and the related service costs are incurred, we concurrently fulfill our contract obligations. The duration of our consulting service contracts range typically from 1 to 12 months. Certain other professional service revenues, such as revenues from maintenance services on cell culture equipment, are recognized as the services are performed.

In our financial statements, unbilled receivables represents revenue that is recognizable under the percentage-of-completion method due to the performance of services for which billings have not been generated as of the balance sheet date. In general, amounts become billable pursuant to contractual milestones or in accordance with predetermined payment schedules. Under our consulting services contracts, the customer is required to pay for contract hours worked by us (based on the standard hourly rate used to calculate the contract price) even if the customer cancels the contract and elects not to proceed to completion of the project. Unearned revenues represent customer payments in excess of revenue earned under the percentage-of-completion method. Such payments are made in accordance with predetermined payment schedules set forth in the contract.

Specialty Pharmaceuticals

Revenue in our Specialty Pharmaceuticals segment is generated from the product sales. Revenue from product sales is recognized when all of the following occur: a purchase order is received from a customer; title and risk of loss pass to our customer upon the receipt of the shipment of the merchandise under the terms of FOB destination; prices and estimated sales provisions for product returns, sales rebates, payment discounts, chargebacks, and other promotional allowances are reasonably determinable; and the customer's payment ability has been reasonably assured. An estimate of three days from the time the product is shipped via common carrier until it reaches the customer is used for purposes of determining FOB destination. Revenues in connection with co-promotion agreements are recognized based on the terms of the agreements.

We make periodic adjustments to our monthly net sales for estimated chargebacks, rebates, and potential product returns we anticipate might ultimately be required. These adjustments are based on inventory quantity reports provided by our largest wholesale customers, sales activity reports generated by group purchase organizations with which we have rebate contracts, and sales activity data provided by a third-party provider of such data. Our net sales will typically reflect an adjustment of 8% of gross sales for charge-backs/rebates and 10% for product returns that we record in the form of a reserve. In the twelve months ended September 30, 2006, we made an additional adjustment to chargeback and return reserves of approximately 3% and 7%, respectively, to appropriately reflect reserves for specific returns, which had the effect of reducing our net sales by $3.2 million. This adjustment was required due to an additional amount of product returns for a specific product that has now been substantially returned and increased rebate activity for certain products. The percentage of adjustments to net sales will continue to be evaluated each quarter and modified when necessary.

Actual product returns, chargebacks, and other sales allowances incurred are dependent upon future events and may be different than our estimates. We continually monitor the factors that influence sales allowance estimates and make adjustments to these provisions when management believes that actual product returns, chargebacks, and other sales allowances may differ from established allowances.

Provisions for these sales allowances are presented in the consolidated financial statements as reductions to gross revenues and included as current accrued expenses in the balance sheet. These allowances approximated $3.2 million and $1.2 million for the years ended September 30, 2006 and 2005.

Inventories

Inventories are recorded at the lower of cost or market. We periodically review inventory quantities of raw materials, instrumentation components and disposables on hand, and completed pharmaceutical products in our third-party distribution center, and we record write-downs of inventories to market value based upon contractual provisions and obsolescence, as well as assumptions about future demand and market conditions. If assumptions about future demand change and/or actual market conditions are less favorable than those projected by management, additional write-downs of inventories may be required.

Inventory in our Biopharmaceutical Products and Services segment includes raw materials and component parts used in the assembly of instruments and cultureware for our Biovest subsidiary and totaled $0.2 million at September 30, 2006, an increase of $0.1 million from September 30, 2005. Estimates for obsolete and unsaleable inventory are determined by management and updated quarterly. We had a reserve of $0.6 million at September 30, 2006 and September 30, 2005 and a

reserve of $0.3 million at September 30, 2004 against the amounts of inventory classified as current for inventory that management has deemed obsolete and unsaleable.

Specialty Pharmaceuticals inventory consists primarily of trade products and samples, which totaled $1.3 million at September 30, 2006, an increase of $0.4 million from September 30, 2005. These inventories are warehoused at a third-party distribution center located in Memphis, Tennessee. All distribution, inventory control, and regulatory reporting are outsourced to this third party. Inventories are written-off if the product dating has expired or the inventory has no market value.

Valuation of Goodwill and Intangible Assets

Our intangible assets include goodwill, trademarks, product rights, non-compete agreements, technology rights, purchased customer relationships, and patents, all of which are accounted for based on Financial Accounting Standard Statement No. 142 *Goodwill and Other Intangible Assets* ("FAS 142"). As described below, goodwill and intangible assets that have indefinite useful lives are not amortized but are tested at least annually for impairment or more frequently if events or changes in circumstances indicate that the asset might be impaired. Intangible assets with limited useful lives are amortized using the straight-line method over their estimated period of benefit, ranging from two to eighteen and one-half years. We obtain a valuation of all intangibles purchased in any acquisition and undertake an annual impairment analysis. Goodwill is tested for impairment by comparing the carrying amount to the estimated fair value, in accordance with Statement of Financial Accounting Standards ("SFAS") No. 142. Impairment exists if the carrying amount is less than its estimated fair value, resulting in a write-down equal to the difference between the carrying amount and the estimated fair value. We have made no impairment adjustments to recorded goodwill. Our carrying value of goodwill at September 30, 2006 and 2005 was $1.2 million. The values recorded for goodwill and other intangible assets represent fair values calculated by accepted valuation methods. Such valuations require critical estimates and assumptions derived from and which include, but are not limited to: (i) information included in our business plan, (ii) estimated cash flows, (iii) discount rates, (iv) patent expiration information, (vi) terms of license agreements, and (vii) expected timelines and costs to complete any in-process research and development projects to commercialize our products under development.

We capitalized goodwill in the amount of $0.9 million in connection with our acquisition of Analytica in April 2002. In connection with the IMOR acquisition in December 2003, we initially capitalized goodwill in the amount of $0.6 million based on the fair value of the acquired assets net of assumed liabilities. Following this acquisition, we discovered that the assumed liabilities were $0.3 million in excess of the amount represented to us in the acquisition agreement. We recorded an impairment to goodwill in the amount of $0.3 million in the fiscal quarter in which the acquisition occurred.

Our major intangible assets with limited useful lives include product rights acquired in connection with our April 2003, acquisition of TEAMM and our June 2003 acquisition of Biovest, as well as a variety of patents, non-competition rights, and purchased customer relationships. We recorded amortization of intangible assets of $2.2 million, $2.5 million, and $2.0 million in the years ended September 30, 2006, 2005 and 2004, respectively. We amortize intangibles based on their expected useful lives and look to a number of factors for such estimations, including the longevity of our license agreements and the remaining life of patents on products currently being marketed. We recognized impairment losses of $3.3 million during the year ended September 30, 2006 in connection with our Xodol and pain technology. *See the explanation in Note 1 "Impairment of long-lived assets", in our Notes to Consolidated Financial Statements.* We have identified several trademarks and technology rights as intangible assets with indefinite lives. These assets were valued at $1.8 million as of September 30, 2006 and 2005.

Our carrying value of other intangible assets at September 30, 2006 and 2005 was $17.8 million and $21.2 million net of accumulated amortization of $7.8 million and $5.6 million, respectively. We begin amortizing capitalized intangibles on their date of acquisition, as further described in Note 7 to our consolidated financial statements included in this form 10K.

Impairment Testing

Our goodwill impairment testing is calculated at the reporting unit level. Our annual impairment test has two steps. The first identifies potential impairments by comparing the fair value of the reporting unit with its carrying value. If the fair value exceeds the carrying amount, goodwill is not impaired and the second step is not necessary. If the carrying value exceeds the fair value, the second step calculates the possible impairment loss by comparing the implied fair value of goodwill with the carrying amount. If the implied fair value of goodwill is less than the carrying amount, a write-down is recorded.

The impairment test for the other intangible assets is performed by comparing the carrying amount of the intangible assets to the sum of the undiscounted expected future cash flows.

In accordance with SFAS 144, which relates to impairment of long-lived assets other than goodwill, impairment exists if the sum of the future undiscounted cash flows is less than the carrying amount of the intangible asset or to its related group of assets.

We predominately use a discounted cash flow model derived from internal budgets in assessing fair values for our impairment testing. Factors that could change the result of our impairment test include, but are not limited to, different assumptions used to forecast future net sales, expenses, capital expenditures, and working capital requirements used in our cash flow models. In addition, selection of a risk-adjusted discount rate on the estimated undiscounted cash flows is susceptible to future changes in market conditions, and when unfavorable, can adversely affect our original estimates of fair values. In the event that our management determines that the value of intangible assets have become impaired using this approach, we will record an accounting charge for the amount of the impairment. We recognized impairment losses of $3.3 million during the year ended September 30, 2006 in connection with our Xodol and pain technology, in our Notes to Consolidated Financial Statements. We recognized impairment losses of $0.4 million during the year ended September 30, 2005 in connection with our SRL technology. We recognized impairment losses of $0.4 million during the year ended September 30, 2004 in connection with our European subsidiary.

Stock-Based Compensation

We account for stock-based awards to employees and non-employees using the accounting provisions of SFAS 123 — *accounting for Stock-Based Compensation,* which provides for the use of the fair value based method to determine compensation for all arrangements where shares of stock or equity instruments are issued for compensation. Shares of common and preferred stock issued in connection with acquisitions are also recorded at their estimated fair values. Fair values of equity securities issued are determined by management based upon independent valuations obtained by management.

In December 2004, the FASB revised its SFAS No. 123 ("SFAS No. 123R"). The revision establishes standards for the accounting of transactions in which an entity exchanges its equity instruments for goods or services, particularly transactions in which an entity obtains employee services in share-based payment transactions. The revised statement requires a public entity to measure the cost of employee services received in exchange for an award of equity instruments based on the grant-date fair value of the award. That cost is recognized over the period during which the employee is required to provide service in exchange for the award.

We use the Black-Scholes options-pricing model to determine the fair value of each option grant as of the date of grant for expense incurred. In applying the Black-Scholes options-pricing model during fiscal 2006, we assumed no dividend yield, risk-free interest rates ranging from 4.32% to 4.60%, expected option terms ranging from 6.0 to 6.5 years, a volatility factor of 89.53%, share prices ranging from $5.05 to $8.00, and option exercise prices ranging from $6.90 to $8.00.

We recorded stock-based compensation of $1.2 million in the twelve months ended September 30, 2006, which was related to employee and non-employee stock options. We recorded stock-based compensation of $0.4 million in the year ended September 30, 2005. In the year ended September 30, 2004, we recorded stock-based compensation of $3.3 million. In all periods, stock-based compensation is classified in various categories.

Fair value determination of privately-held equity securities

The fair values of the common and preferred stock as well as the common and preferred stock underlying options and warrants granted as part of acquisition purchase prices, financing transactions, or as compensation, issued during the period from April 2002 through September 2004 were originally estimated by our board of directors, with input from management. We did not obtain contemporaneous valuations until September 30, 2004. Subsequently, we reassessed the valuations of these securities during the respective periods by obtaining a valuation.

Determining the fair value of stock requires making complex and subjective judgments. We use the income and market approaches to estimate the value of the enterprise at each date on which securities are issued or granted. The income approach involves applying appropriate discount rates to estimated cash flows that are based on forecasts of revenue and costs. These forecasts are based on management's estimates of expected annual growth rates. There is inherent uncertainty in these estimates. However, the assumptions underlying the estimates are consistent with our business plan. The risks associated with achieving the forecasts were assessed in selecting the appropriate discount rates, which ranged from 15% to 45%. If different discount rates had been used, the valuations would have been different.

The enterprise value was then allocated to preferred and common shares taking into account the enterprise value available to all stockholders and allocating that value among the various classes of stock based on the rights, privileges and preferences of the respective classes.

The range of values is wide and somewhat varied by class of stock due to different distribution and liquidation preferences of such classes of stock.

Income Taxes

During the year ended September 30, 2006, we had a change in our consolidated group for income tax purposes. Since our initial acquisition of Biovest, we had an ownership interest in excess of 80%. This allowed Biovest to join with us in filing a consolidated federal income tax return. On December 7, 2005, our ownership interest in Biovest became less then 80%. Effective as of this date, Biovest is now required to file a separate federal income tax return. Additionally, due to this deconsolidation the net operating losses (NOLs) generated by Biovest during their time as a member of the consolidated group are now NOLs to which Biovest is entitled. The provision for income taxes has been prepared as if we filed a consolidated federal income tax return including Biovest.

We incurred net operating losses for the years ended September 30, 2006, 2005 and 2004, and consequently did not or will not be required to pay federal or foreign income taxes, but we did pay nominal state taxes in several states where we have operations. We have a federal net operating loss carryover of approximately $117.8 million as of September 30, 2006, which expires through 2026. Of this amount, $39.1 million is attributable to Biovest and will no longer be available to offset income generated by the other members of the group.

Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation" as defined, there are annual limitations on the amount of the net operating loss and other deductions which are available to us. Due to the acquisition transactions in which we have engaged in recent years, we believe that the use of these net operating losses will be significantly limited.

In addition, the utilization of our net operating loss carryforwards may be further limited if we experience a change in ownership of more than 50% subsequent to last change in ownership of September 30, 2003. As a result of our offering, we may experience another such ownership change. Accordingly, our net operating loss carryforward available to offset future federal taxable income arising before such ownership changes may be further limited.

We currently have limitations on at least $30.0 million of the NOLS based upon ownership changes through September 30, 2003. Of those losses subject to the limitations, $11.3 million is expected to expire before the losses can be utilized. Of the remaining amounts, the limitation is approximately $1.8 million per year through approximately the year ended September 30, 2012. After that, the annual limitation will decrease to approximately $0.2 million through September 30, 2024. We have not determined whether there has been another ownership change since September 30, 2003. As such, we may have further limitations that would limit the use of the NOLS even further.

Our ability to realize our deferred tax assets depends on our future taxable income as well as the limitations on usage discussed above. For financial reporting purposes, a deferred tax asset must be reduced by a valuation allowance if it is more likely than not that some portion or all of the deferred tax asset will not be realized prior to its expiration. Because we believe the realization of our deferred tax assets is uncertain, we have recorded a valuation allowance to fully offset them.

Additionally, since Biovest is no longer part of the consolidated group for income tax purposes, we could in the future have a net loss but we or Biovest could be subject to tax on our income since the losses may not be available to offset the income of the other entity.

Results of Operations

Year Ended September 30, 2006 Compared to the Year Ended September 30, 2005

Consolidated Results of Operations

Net Sales. Our net sales for the year ended September 30, 2006 were $25.1 million, a decrease of $0.1 million, or 0.5%, from the year ended September 30, 2005. This decrease in our consolidated net sales for the fiscal ended September 30, 2006, reflected a $3.2 million decrease in net sales in our Specialty Pharmaceuticals segment. This was offset by an increase of $3.1 million in net sales in our Biopharmaceutical Products and Services segment, primarily resulting from a $2.2 million increase in net sales of our Biovest subsidiary, a $1.4 million increase in net sales of our Analytica International subsidiary, and a $0.5 million decrease in our compounding subsidiary due to the discontinuance of its operations.

Cost of Sales. Our cost of sales for the year ended September 30, 2006 was $8.4 million, or 33% of net sales, compared to $8.2 million, or 33% of net sales, during the year ended September 30, 2005. This represented an increase of $0.2 million, or 2%, over the year ended September 30, 2005 attributable to the increase in corresponding sales.

Research and Development Expenses. Our research and development costs were $14.6 million in the year ended September 30, 2006 an increase of $3.7 million, or 33%, over the year ended September 30, 2005. This increase included $2.6 million in SinuNase development compared to $1.3 million in SinuNase development for the same period last year. Our Biovest subsidiary research and development expenses increased $2.1 million during the year ended September 30, 2006 due to increased emphasis on BiovaxID research and its phase 3 clinical trials from the same period last year. We expect that our research and development costs will continue to increase as we continue our clinical trials for BiovaxID and commence our clinical trials for SinuNase.

Sales and Marketing expenses. Our sales and marketing expenses were $14.0 million in the year ended September 30, 2006; a decrease of $1.2 million, or 8%, over the year ended September 30, 2005. This decrease was primarily due to a reduction in sales related personnel during FY2006. This decrease was offset in part due to higher costs of $0.3 million in our Specialty Pharmaceutical segment due in part to expenses related to the launch of MD Turbo and Xodol 7.5/300 and 5.0/300.

General and Administrative Expenses. Our general and administrative expenses were $23.3 million in the year ended September 30, 2006, an increase of $2.2 million, or 10%, over the year ended September 30, 2005. This increase was a result of increased expenses relating to the cost of maintaining our status as a public company.

Impairment Charges. We had impairment charges of $3.3 million in the year ended September 30, 2006 relating to our pain technology, while in the year ended September 30, 2005 we had $0.4 million in impairment charges associated with the acquisition of our subsidiary in Germany.

Interest Expense, net. In the twelve month periods ended September 30, 2006, our net interest expense was $6.5 million, an increase of $2.7 million over the year ended September 30, 2005. The increase was due primarily to interest on our existing Laurus term note, and increase to our existing Laurus revolver, and to the funding of our second Laurus term note, Pulaski term note, and convertible debentures. Interest income in both years was nominal.

Loss on extinguishment of debt. In the year ended September 30, 2006 we incurred no loss on extinguishment of debt. We incurred a $7.2 million loss on extinguishment of debt in the year ended September 30, 2005. This consisted of a loss on extinguishment of the, related party, in the amount of $2.4 million as a result of the conversion of shareholder debt and accrued interest into shares of our Series E preferred stock having an aggregate value in excess of the converted debt. The loss also incurred a $4.8 million loss on extinguishment of debt as a result of changing the accounting for freestanding warrants and embedded beneficial conversion option associated with the convertible notes from equity to recording these derivatives as liabilities at fair value at September 30, 2005.

Other income (expense). Other expense in the years ended September 30, 2006 and September 30, 2005 were nominal.

Derivative gain (loss). Derivative gain was $1.2 million for the year ended September 30, 2006 as compared to a loss of $1.1 million for the year ended September 30, 2005. This increase was related to the Laurus financing arrangement that commenced in the year ended September 30, 2005 and results primarily from the decrease in our common stock price on which the derivative liabilities are based.

Absorption of prior losses against minority interest. Absorption of prior losses against minority interest was $1.7 million in the year ended September 30, 2006, an increase of $1.5 million, primarily due to the conversion of Biovest notes into equity during 2006 against which previously absorbed Biovest losses could be recovered.

Preferred Stock Dividends. In the year ended September 30, 2006, we incurred dividend costs of $0.04 million, compared to $0.6 million in the year ended September 30, 2005. The dividend cost in the year ended September 30, 2006 and September 30, 2005 consisted of dividends accrued on our Series E preferred stock, which was converted to common stock early in fiscal 2006.

Segment Operating Results

	For the Year ended September 30,			
	2006		2005	
	Amount	% of Segment Net Sales	Amount	% of Segment Net Sales
Net Sales:				
Biopharmaceutical Products and Services-				
Biovest	$ 7,298,503		$ 5,077,305	
All other business units	10,310,783		9,424,673	
Total Biopharmaceutical Products and Services	17,609,286		14,501,978	
Specialty Pharmaceuticals	7,448,762		10,692,804	
Total Net Sales	$ 25,058,048		$ 25,194,782	
Cost of Sales:				
Biopharmaceutical Products and Services-				
Biovest	$ 3,889,277		$ 3,749,729	
All other business units	2,050,633		2,196,953	
Total Biopharmaceutical Products and Services	5,939,910	35%	5,956,682	41%

Specialty Pharmaceuticals	2,445,393	32%	2,276,643	21%
Total Cost of Sales	$ 8,385,303		$ 8,233,325	
Gross Margin:				
Biopharmaceutical Products and Services-				
Biovest	$ 3,409,226		$ 1,327,576	
All other business units	8,260,150		7,217,720	
Total Biopharmaceutical Products and Services	11,669,376	65%	8,545,296	59%
Specialty Pharmaceuticals	5,003,369	68%	8,416,161	79%
Total Gross Margin	$ 16,672,745		$ 16,961,457	
Research and Development Expenses:				
Biopharmaceutical Products and Services-				
Biovest	$ 12,019,543		$ 9,951,145	
All other business units	2,541,568		956,717	
Total Biopharmaceutical Products and Services	14,561,111	82%	10,907,862	75%
Specialty Pharmaceuticals	—	0%	—	0%
Total Research and Development Expenses	$ 14,561,111		$ 10,907,862	
Sales and Marketing Expenses:				
Biopharmaceutical Products and Services-				
Biovest	$ 146,258		$ 270,504	
All other business units	320,946		1,588,285	
Total Biopharmaceutical Products and Services	467,204	3%	1,858,789	13%
Specialty Pharmaceuticals	13,505,550	181%	13,305,278	124%
Total Sales and Marketing Expenses	$ 13,972,754		$ 15,164,067	

Biopharmaceutical Products and Services

Net Sales. Net sales in our Biopharmaceutical Products and Services segment for the year ended September 30, 2006, including net sales to related parties, were $17.6 million, an increase of $3.1 million, or 21%, from the year ended September 30, 2005. This increase was attributable primarily to an increase in net sales of $1.4 million in our Analytica subsidiary and an increase of $2.2 million is sales of instrument hardware and disposables, offset by a decrease in net sales of $0.5 million in our compounding activities.

Cost of Sales. Our cost of sales in the Biopharmaceutical Products and Services segment for the year ended September 30, 2006 was $5.9 million, or 34% of segment net sales, compared to $6.0 million, or 41% of segment net sales, for the year ended September 30, 2005. This increase was primarily due higher sales in our Analytica subsidiary and sales of instrument hardware and disposables.

Research and Development Expenses. Our research and development costs in the Biopharmaceutical Products and Services segment were $14.6 million in the year ended September 30, 2006; an increase of $3.7 million, or 33%, over the year ended September 30, 2005. This increase included additional $2.4 million in expense relating to our BiovaxID project, as well as $1.3 million in SinuNase development expenses.

Sales and Marketing Expenses. Our sales and marketing expenses in the Biopharmaceutical Products and Services segment were $0.5 million in the year ended September 30, 2006; a decrease of $1.4 million, or 75%, over the year ended September 30, 2005. This decrease was attributable to our shift in emphasis in the segment away from cell culture products and services and more toward the development of BiovaxID.

Specialty Pharmaceuticals

Net Sales. Net sales in the Specialty Pharmaceuticals segment for the year ended September 30, 2006, including net sales to related parties, were $7.4 million, a decrease of $3.2 million, or 30%, from the year ended September 30, 2005. This decrease was primarily attributable to a decrease in Histex I/E sales due to the manufacturer's voluntary recall of the product, and a decision to increase reserves for chargebacks, rebates, and returns. This additional reserve is considered necessary due to the potential for returns attributable to the Histex I/E recall and the FDA's guidance related to continued manufacturing of products containing carbinoxamine of which this segment promotes three products containing this ingredient under the Histex label.

Cost of Sales. Our cost of sales in the Specialty Pharmaceuticals segment for the year ended September 30, 2006 was $2.4 million, or 33% of net sales, compared to $2.3 million, or 21% of net sales, during the year ended September 30, 2005. The increase in cost of sales as a percentage of net sales, during the twelve months ended September 30, 2006 was attributable to a change of product sales mix due to the introduction of MD Turbo during the third fiscal quarter of 2006 which has a higher cost of goods, less sales of the Histex line with a lower coast of sales, and the decision to increase our reserves for chargebacks, rebates, and returns.

Research and Development Expenses. There were no research and development expenses in our Specialty Pharmaceuticals segment in either of the twelve-month periods ended September 30, 2006 or 2005.

Sales and Marketing Expenses. Our sales and marketing expenses in the Specialty Pharmaceuticals segment were $13.5 million in the year ended September 30, 2006; an increase of $0.2 million, or 2%, over the year ended September 30, 2005. This increase was primarily due to expenses related to the launch of MD Turbo in addition to the launch of Xodol 7.5/300 and 5.0/300.

Year Ended September 30, 2005 Compared to the Year Ended September 30, 2004

Consolidated Results of Operations

Net Sales. Our net sales for the year ended September 30, 2005 were $25.2 million, a decrease of $0.7 million, or 2.7%, from the year ended September 30, 2004. This decrease was attributable in part to an increase of $0.4 million in our reserve for chargebacks, rebates and returns on our cough, cold, and allergy products, due to an increase in generic competition for several of these products. The decrease in our consolidated net sales for the year ended September 30, 2005 reflected an increase of $0.5 million in net sales in our Biopharmaceutical Products and Services segment, primarily resulting from an increase in net sales of $0.9 million in our compounding activities.

Cost of Sales. Our cost of sales for the year ended September 30, 2005 was $8.2 million, or 32% of net sales, compared to $8.8 million, or 34% of net sales, during the year ended September 30, 2004. This represented a decrease of $0.6 million, or 7%, over the year ended September 30, 2004. The decrease in cost of sales is primarily due to a decrease in net sales of 2.7%, and improved margins in our Biovest Subsidiary.

Research and Development Expenses. Our research and development costs were $10.9 million in the year ended September 30, 2005, an increase of $5.4 million, or 98%, over the year ended September 30, 2004. This increase included $4.1 million of increased research and development activity associated with BiovaxID, and $1.3 million attributed to our SinuNase activity. Research and development costs incurred by our company in the year ended September 30, 2005 include expenses of $1.3 million attributable to the BiovaxID project paid to Pharmaceutical Product Development, Inc., one of our shareholders, under an agreement with them. In the year ended September 30, 2004 we also paid $1.3 million under the PPD agreement. We expect that our research and development costs will continue to increase as we continue our clinical trials for BiovaxID and commence our anticipated clinical trials for SinuNase.

Sales and Marketing expenses. Our sales and marketing expenses were $15.2 million in the year ended September 30, 2005; an increase of $3.1 million, or 26%, over the year ended September 30, 2004. This increase was due in part to an increase in headcount in our Specialty Pharmaceuticals segment, which resulted in $2.0 million of increased costs relating to the hiring of additional sales representatives in this segment. It was also due in part to $1.3 million of increased costs in our Biopharmaceutical Products and Services segment resulting from the addition of eight therapeutic specialists in this segment who participate in our CRS educational programs. The increased costs were offset by a $0.4 million decrease in sales and marketing expense in our Biopharmaceutical Product and Services segment resulting from our shift in emphasis in that segment away from cell culture products and services and more toward the development of BiovaxID. We expect that our sales and marketing expenses will continue to increase over the next 24 months upon the FDA approval and launch of additional products in our Specialty Pharmaceuticals segment that are now in our development pipeline.

General and Administrative Expenses. Our general and administrative expenses were $21.1 million in the year ended September 30, 2005, an increase of $4.1 million, or 24%, over the year ended September 30, 2004. This increase was a result of the growth of our corporate infrastructure to support an anticipated increase in our business activities. We expect that our general and administrative expenses will continue to increase as we hire new personnel and build up our corporate infrastructure necessary for the management of our business. The costs associated with being a public company may increase our general and administrative expenses.

Impairment Charges. We had impairment charges of $0.4 million in the year ended September 30, 2005 relating to our sustained release technology, while in the year ended September 30, 2004, we had $0.4 million in impairment charges associated with the acquisition of our subsidiary in Germany.

Interest Expense, net. In the twelve month periods ended September 30, 2005, our net interest expense was $3.8 million, an increase of $1.1 million over the year ended September 30, 2004. The increase was due primarily to interest relating to the Laurus funding in April 2005 and August 2005. Interest income in both years was nominal.

Other income (expense). In the year ended September 30, 2005, we recognized other expense of $2.4 million, compared to nominal other income in the year ended September 30, 2004. The other expense in the year ended September 30, 2005 consisted of a loss on extinguishment of debt in the amount of $2.4 million as a result of the conversion of shareholder debt and accrued interest into shares of our Series E preferred stock having an aggregate value in excess of the converted debt. In addition, there was a $4.8 million loss on extinguishment of debt related to the Laurus financing in August 2005.

Derivative loss. Derivative loss was $1.1 million for the year ended September 30, 2005 as compared to no derivative loss for the year ended September 30, 2004. This increase was due to the Laurus financing arrangement that commenced in the quarter ended June 30, 2005.

Preferred Stock Dividends. In the year ended September 30, 2005, we incurred dividend costs of $0.6 million, compared to $0.4 million in the year ended September 30, 2004. The dividend cost in the year ended September 30, 2005 and September 30, 2004 consisted of dividends accrued on our Series E preferred stock.

Segment Operating Results

	For the Year ended September 30,			
	2005		2004	
	Amount	% of Segment Net Sales	Amount	% of Segment Net Sales
Net Sales:				
Biopharmaceutical Products and Services-				
Biovest	$ 5,077,305		$ 5,705,544	
All other business units	9,424,673		8,290,987	
Total Biopharmaceutical Products and Services	14,501,978		13,996,531	
Specialty Pharmaceuticals	10,692,804		11,939,089	
Total Net Sales	$ 25,194,782		$ 25,935,620	
Cost of Sales:				
Biopharmaceutical Products and Services-				
Biovest	$ 3,657,972		$ 5,251,109	
All other business units	2,298,710		1,223,111	
Total Biopharmaceutical Products and Services	5,956,682	41%	6,474,220	46%
Specialty Pharmaceuticals	2,276,643	21%	2,339,370	20%
Total Cost of Sales	$ 8,233,325		$ 8,813,590	
Gross Margin:				
Biopharmaceutical Products and Services-				
Biovest	$ 1,419,333		$ 454,435	
All other business units	7,125,963		7,067,876	
Total Biopharmaceutical Products and Services	8,545,296	59%	7,522,311	54%
Specialty Pharmaceuticals	8,416,161	79%	9,599,519	80%
Total Gross Margin	$ 16,961,457		$ 17,121,830	
Research and Development Expenses:				
Biopharmaceutical Products and Services				
Biovest	$ 9,631,609		$ 5,508,961	
All other business units	1,276,253		10,197	
Total Biopharmaceutical Products and Services	10,907,862	75%	5,519,158	39%
Specialty Pharmaceuticals	—	0%	—	0%
Total Research and Development Expenses	$ 10,907,862		$ 5,519,158	
Sales and Marketing Expenses:				
Biopharmaceutical Products and Services				
Biovest	$ 270,504		$ 968,169	
All other business units	1,588,285		511,292	
Total Biopharmaceutical Products and Services	1,858,789	13%	1,479,461	11%
Specialty Pharmaceuticals	13,305,278	124%	10,535,583	88%
Total Sales and Marketing Expenses	$ 15,164,067		$ 12,015,044	

Biopharmaceutical Products and Services

Net Sales. Net sales in our Biopharmaceutical Products and Services segment for the year ended September 30, 2005, including net sales to related parties, were $14.5 million, a increase of $0.5 million, or 4%, from the year ended September 30, 2004. This increase was attributable primarily to an increase in net sales of $0.9 million in our compounding activities.

Cost of Sales. Our cost of sales in the Biopharmaceutical Products and Services segment for the year ended September 30, 2005 was $6.0 million, or 41% of segment net sales, compared to $6.5 million, or 46% of segment net sales, during the year ended September 30, 2004. This decrease was primarily due to a $0.3 million write-off of inventory consisting of cell production instruments and disposables in our Biopharmaceutical Products and Services segment.

Research and Development Expenses. Our research and development costs in the Biopharmaceutical Products and Services segment were $10.9 million in the year ended September 30, 2005; an increase of $5.4 million, or 98%, over the year ended September 30, 2004. This increase included $4.1 million of increased research and development activity associated with BiovaxID, and $1.3 million attributed to our SinuNase activity. Research and development costs incurred by our company in the year ended September 30, 2005 include expenses of $1.3 million attributable to the BiovaxID project paid to Pharmaceutical Product Development, Inc., one of our shareholders, under an agreement with them. In the year ended September 30, 2004 we paid $1.3 million under the PPD agreement.

Sales and Marketing Expenses. Our sales and marketing expenses in the Biopharmaceutical Products and Services segment were $1.9 million in the year ended September 30, 2005; an increase of $0.4 million, or 26%, over the year ended September 30, 2004. This increase was attributable to $1.1 million of increased costs resulting from the addition of 11 therapeutic specialists in this segment who participate in our CRS educational programs. The increased costs were offset by a $0.7 million decrease in sales and marketing expense in this segment resulting from our shift in emphasis from the segment's cell culture production business to the development of BiovaxID.

Specialty Pharmaceuticals

Net Sales. Net sales in the Specialty Pharmaceuticals segment for the year ended September 30, 2005, including net sales to related parties, were $10.7 million, a decrease of $1.2 million, or 10%, from the year ended September 30, 2004. This decrease was primarily attributable to a $1.0 million decrease in sales of our cough, cold and allergy products as a result of a later-than-normal onset of flue season in calendar year 2004 and increased competition from generic products. The decrease was also attributable to an increase of $3.8 million in charges for product returns, chargebacks and rebates on our cough, cold, and allergy products, which had the effect of reducing net sales. The decrease in net sales during the year ended September 30, 2005 was offset by an increase in sales of Respi~TANN, Xodol and our co-promotion revenues totaling $3.6 million.

Cost of Sales. Our cost of sales in the Specialty Pharmaceuticals segment for the year ended September 30, 2005 was $2.3 million, or 21% of net sales, compared to $2.3 million, or 20% of net sales, during the year ended September 30, 2004. The increase in cost of sales as a percentage of net sales was attributable to an increase in our reserve for chargebacks and rebates on our cough, cold, and allergy products and a large return of one of these products by a customer during the year ended September 30, 2005. The effect of the changes in these reserves is reflected in our revenues.

Research and Development Expenses. There were no research and development expenses in our Specialty Pharmaceuticals segment in either of the twelve-month periods ended September 30, 2005 or 2004.

Sales and Marketing Expenses. Our sales and marketing expenses in the Specialty Pharmaceuticals segment were $13.3 million in the year ended September 30, 2005; an increase of $2.8 million, or 26%, over the year ended September 30, 2004. This increase was due to an increase in sales force headcount in the segment and increased marketing efforts associated with new products under co-promotion agreements. We expect that our sales and marketing expenses in this segment will continue to increase over the next 24 months upon the FDA approval and launch of additional products that are now in our development pipeline.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through public and private placements of our capital stock, debt financing, conversions of debt to equity, and financing transactions with our strategic partners. These transactions are described throughout the following pages.

At September 30, 2006, our cash, cash equivalents and current and non-current restricted cash totals $25.3 million. Excluding restricted cash, our cash and cash equivalents were $15.4 million at September 30, 2006 compared with $2.8 million at September 30, 2005. Restricted cash for September 30, 2006 totals $9.9 million and includes $2.6 million which was released in December 2006, $5.0 million to be used for a debt payment due in early January 2007 and the $2.3 million classified as non-current cash held in escrow for payment of principal and interest coming due in 2008. There was no restricted cash as of September 30, 2005. On November 2, 2005, we closed our Initial Public Offering ("IPO") with gross and net proceeds of $19.2 million and $14.7 million, respectively.

Based on our current operating plans, we expect that our existing capital resources and cash flow from operations, together with borrowing availability under our lines of credit with Laurus and Hopkins Capital Group II, LLC. or Hopkins II, will be sufficient to fund our operations and development activities into the fourth quarter of fiscal year 2007 assuming Biovest receives its own financing. We are currently engaged in efforts to restructure certain of our existing indebtedness in order to increase available funds on a near-term basis, and we also intend to seek additional financing through one or more public or private equity offerings, additional debt financings, corporate collaborations or licensing transactions. We cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available from the foregoing

sources, we may consider additional strategic financing options, including sales of assets or business units (such as specialty pharmaceuticals, market services or cell culture equipment) that are non-essential to the ongoing development or future commercialization of SinuNase, or we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or curtail some of our commercialization efforts.

Our Biovest subsidiary is seeking financing through public or private equity offerings, debt financings, corporate collaborations, or licensing transactions. As of December 1, 2006, an aggregate of $6.8 million in intercompany demand notes payable to us by Biovest were outstanding, representing funds advanced to Biovest in excess to our funding commitment under the investment agreement plus intercompany obligations arising from the conversion of Biovest notes into our common stock in accordance with the terms of such notes. After the completion of a funding transaction by Biovest, if any, we do not anticipate that we will continue to finance Biovest's operations. In addition, upon the completion of such a Biovest financing transaction, we anticipate that Biovest may repay some or all of the outstanding demand notes. Additional sources of funding have not been established; however, additional financing is currently being sought from a number of sources, including the sale of Biovest equity or debt securities, strategic collaborations, recognized research funding programs, as well as domestic and/or foreign licensing of Biovest's vaccine. Biovest management is currently in the process of exploring various financing alternatives, and has hired investment consultants to assist in these efforts.

Capital Raised through Equity Issuances

We have received funding from our initial public offering, private placements of our common and preferred stock and from the exercise of warrants and options to purchase capital stock.

Debt Financing

We have also obtained debt financing from various sources to fund our operations.

Credit Facility with Laurus Master Fund, Ltd. On April 29, 2005, we entered into a credit facility with Laurus Master Fund, Ltd., or Laurus. The Laurus credit facility originally provided for total loan availability of $10 million, consisting of a $5 million term loan and a revolving credit facility of up to $5 million. As of September 30, 2005, a total of $5.0 million in principal amount was outstanding under the term loan portion of the credit facility, while $9.7 million in principal amount was outstanding under the revolving loan portion of the credit facility. On August 16, 2005, the credit facility was amended to increase the term loan portion of the credit facility from $5.0 million to $10.0 million in principal amount.

The term loan portion of the Laurus credit facility is evidenced by an amended and restated secured convertible term note, dated August 16, 2005, in the principal amount of $10 million. The revolving loan portion of the credit facility is evidenced by an amended and restated secured convertible minimum borrowing note in the amount of $2.5 million and a secured revolving note of up to $5 million, provided that the aggregate principal amount under both notes combined may not exceed $5 million. Both of the revolving loan notes are dated as of April 29, 2005. Under the revolving loan, we have the right to borrow up to the sum of 85% of all of eligible accounts receivable and 50% of eligible inventory pledged to secure the loan (with the eligibility criteria being set forth in the loan agreements), as well as 50% of the market value of publicly traded securities pledged by the Francis E. O'Donnell Irrevocable Trust #1. Our initial advance under the revolving loans was $5.0 million, of which $2.5 million was repaid in November 2005. Laurus waived our minimum collateral requirements under our borrowing base for a period of 180 days after April 29, 2005, provided that we pay an applicable over-advance interest rate of 10% per annum on any over-advanced amount.

In connection with the Laurus credit facility, as amended, we issued to Laurus a warrant to purchase a number of shares of our common stock that is equal to $8.0 million divided by our per share initial public offering price of $8.00. Based on the initial public

offering price of $8.00 per share, a total of 1,000,000 shares of our common stock are subject to this warrant agreement at an exercise price of $8.00 per share. The warrant will expire on the fifth anniversary of the date of warrant issuance. Laurus may exercise the warrant with cash, in a cashless exercise pursuant to the surrender of the warrant or shares issuable under the warrant, or any combination of the foregoing. We have the right to require Laurus to exercise this warrant so long as (i) there is an effective current registration statement in place covering the resale of all of the shares of our common stock issuable to Laurus pursuant to the credit facility and (ii) the average closing price of our common stock for the 20 consecutive trading days immediately preceding the forced exercise date is greater than 140% of our per share initial public offering price. As a part of the August 2005 amendment to the Laurus credit facility, we granted to Laurus an additional warrant to purchase up to 277,778 shares of our common stock at an exercise price of $.001 per share. This additional warrant is immediately exercisable and, except for the absence of a forced exercise provision, has substantially the same terms and conditions as the other warrant granted to Laurus.

The principal and accrued but unpaid interest under each of the Laurus notes were convertible at the option of Laurus into shares of our common stock at an initial conversion price of $6.95 per share. After the completion of our initial public offering, the conversion price became an amount equal to 85% of the per share initial public offering price or $5.91 per share.

However, these notes cannot be converted by Laurus until the earlier of 270 days after the date of the note or 180 days after our initial public offering. In connection with this credit facility, we entered into a registration rights agreement under which we agreed to register for public resale all of the shares of our common stock into which the amended and restated secured convertible term note, amended and restated secured convertible minimum borrowing note, and the warrants granted to Laurus are convertible or exercisable. However, these registration rights do not apply to the secured revolving note. At any time after the effectiveness of a registration statement covering the resale of the shares into which these notes are convertible, up to $2.5 million in principal amount under the secured revolving note may be transferred by Laurus to the amended and restated secured convertible minimum borrowing note, thereby making such portion of the principal amount subject to the registration rights agreement.

The amended and restated secured convertible term note accrues interest at a rate of the greater of 10% per annum or prime rate plus 4%. The amended and restated secured convertible minimum borrowing note and secured revolving note accrue interest at a rate equal to the greater of 7.75% per year or prime rate plus 2%. However, provided that (i) there is an effective registration statement in place covering the resale of the shares into which the notes are convertible and (ii) the market price of our common stock exceeds the conversion price by 25% for five consecutive trading days, then the interest rate will be reduced by 2% for each 25% of increase in the market price of our common stock above the conversion price.

The amended and restated secured convertible term note is payable through April 29, 2008 in equal monthly payments of principal and interest of $0.3 million. The secured revolving note and amended and restated secured convertible minimum borrowing note are due on April 29, 2008 with all accrued but unpaid interest payable monthly. We have the right to redeem the notes (other than the secured revolving note) at any time at a redemption price equal to 130% of the principal amount of the note plus all accrued but unpaid interest, subject to the right of Laurus to convert the note prior to a redemption. The secured revolving note may be prepaid at any time without penalty. On any date on which a payment is due under the amended and restated convertible term note, Laurus is required to convert the monthly payment amount into shares of common stock so long as and to the extent that (i) there is an effective current registration statement in place covering the resale of all of the shares of our common stock issuable to Laurus pursuant to the credit facility, (ii) the average closing price of our common stock for the five trading days immediately preceding the payment date is greater than 125% of the note conversion price, and (iii) the number of shares of common stock to be issued as payment does not exceed 25% of the aggregate dollar trading volume of our common stock during the 22 immediately preceding trading days. Under the amended and restated secured convertible term note and amended and restated secured convertible minimum borrowing note, Laurus is required to convert such note into a number of shares of our common stock equal to 20% of the aggregate trading volume of our common stock during the five immediately trading days at the conversion price provided that (i) there is an effective current registration statement in place covering the resale of all for the shares of our common stock issuable to Laurus pursuant to the credit facility, (ii) the average closing price of our common stock for the five trading days immediately preceding the conversion date is greater than 125% of the note conversion price, and (iii) the amount of the conversion does not exceed 20% of the aggregate dollar trading volume of our common stock during the 20 immediately preceding trading days.

The Laurus notes are secured by a first priority security interest in all of our tangible and intangible assets and our Analytica subsidiary (including the stock of their respective subsidiaries). This security interest does not extend to any assets of our Accentia Pharmaceuticals, Biovest, or IMOR subsidiaries. The notes are also secured by certain publicly traded securities owned by the Francis E. O'Donnell Jr. Irrevocable Trust #1.

On December 29, 2005, Laurus agreed to make a loan to us in excess of the Formula Amount under the Security Agreement dated April 29, 2005. This overadvance is in the amount of up to $2.5 million. In connection with this overadvance, we granted Laurus a warrant to purchase up to 51,000 shares of common stock at an exercise price of $0.01 per share.

On July 31, 2006, we repaid our loan to Harbinger Mezzanine Partners and increased the principal amount outstanding under our revolving credit line with Laurus to $7.5 million under an overadvance letter agreement with Laurus.

Credit Facility with Laurus Master Fund, Ltd., Biovest – On March 31, 2006, our majority-owned subsidiary, Biovest closed a financing transaction (the "Transaction") with Laurus, pursuant to which Laurus purchased from Biovest a secured promissory note in the principal amount of $7,799,000 (the "Note") and a warrant to purchase up to 18,087,889 shares of Biovest's common stock at an exercise price of $.01 per share (the "Warrant"). Since June 2003, we have been the primary source of financing for Biovest; however, this Transaction with Laurus represents the initial financing by Biovest from sources other than us.

The Note and Warrant were purchased pursuant to a Note and Warrant Purchase Agreement between Biovest and Laurus (the "Purchase Agreement"). The following describes certain material terms of the Biovest Transaction:

- Under the terms of the Note, $299,000 of the principal amount was disbursed at the closing of Laurus and other third parties to cover closing fees and expenses relating to the transaction, and $7,500,000 of the principal amount was deposited into a restricted bank account of Biovest (the "Restricted Account") pursuant to a restricted account agreement between Biovest and Laurus.

- Under otherwise agreed by Laurus is expected to authorize disbursements from the Restricted Account as the Company is able to secure additional working capital financing, including without limitation through financings involving New Market Tax Credits in the amounts and of the type more particularly described in the Transaction documents. On April 28, 2006, $2.5 million was released from the restricted account as part of a financing transaction involving New Market Tax Credits.
- The Note will become due and payable on March 31, 2009, provided that any portion of the principal amount not contained in the Restricted Account will be amortized in equal monthly payments of principal and interest beginning on July 1, 2006 and ending on the maturity date. The initial monthly payment amount will be $9,060.61 per month, provided that as amounts are released from the Restricted Account from time to time, such amounts will be added to the amortizing portion of the Note, and the monthly payments will increase accordingly. The Note can be prepaid by Biovest at any time without penalty.
- The outstanding principal amount of the Note will bear interest at a rate equal to the greater of the prime rate plus 2% or 9% per annum, except that any portion of the principal amount contained in the Restricted Account will bear interest at prime rate.
- Sixty-four percent (64%) of the Note is guaranteed by us. We also have a separate credit facility with Laurus pursuant to which we pledged our assets as collateral, and pursuant to the Transaction documents, this pledge of collateral by us will also secure our guarantee of the Note. Additionally, all of the assets of Biovest, including its intellectual property and the stock of Biovax, Inc. subsidiary, were pledged by Biovest as collateral of the Note and Obligations to Laurus.
- The Warrant provides that Laurus may purchase up to 18,087,889 shares of Biovest's common stock at an exercise price equal to $.01 per share. The Warrant will expire on March 31, 2021.
- In connection with the Transaction, Laurus and Biovest entered into a registration rights agreement providing that Laurus will have the right to require Biovest to file a registration statement with the U.S. Securities and Exchange Commission to register the resale of the shares issuable to Laurus pursuant to the exercise of the warrant. Biovest will be required to file such registration statement within sixty (60) days after written demand by Laurus, provided that in no event will Biovest be required to file such registration statement earlier than ninety (90) days after the closing of the Transaction.

The note payable provides for monthly payment provisions, a variable interest feature that includes a cap of 9.0% and a default put at 130% of face value for certain contingent events, including service defaults and changes in control, for the amortizing portion of the arrangement; these features are not present for unreleased, non-amortizing balances. We evaluated all terms and conditions of the amortizing notes for indications of embedded derivative financial instruments. While the interest rate cap was found to be clearly and closely related to the host instrument, we determined that the default put did not meet the clearly and closely related criteria as provided in FASB 133 Derivative Financial Instruments. Accordingly, upon release of funds underlying the first tranche, we reclassified an amount of $306,750 which represents the estimated fair value of the default put liability to derivative liability. Upon release of funds under the second tranche, we reclassified $122,700 to derivative liability. The default liability is initially and subsequently carried at fair value with changes recorded in income. Accordingly, $236,369 is recorded as a derivative liability in the accompanying balance sheet on September 30, 2006.

New Market Tax Credit Financing. On April 25, 2006, Biovest, through its wholly-owned subsidiary, Biovax, Inc. ("Biovax") became the recipient of $3.0 million in net-funds under a qualified New Market Tax Credit Program ("NMTC"). The NMTC was provided for in the Community Renewal Tax Relief Act of 2000 (the "Act") and is intended to induce investment capital in underserved and impoverished areas of the United States. The Act permits taxpayers (whether companies or individuals) to claim credits against their Federal income taxes for up to 39% of qualified investments in qualified, active low-income businesses or ventures. Biovax is a qualified, active low-income business and is eligible to receive investment capital under the NMTC.

NMTC investments are made though Community Development Entities ("CDE"); such entities are qualified for this purpose through the U.S. Department of the Treasury. The CDE investor in the Company's financing arrangement is Telesis CDE II, LLC, which was established solely for this investment. Telesis CDE II, LLC is managed and partially owned (0.01%) by Telesis CDE Corporation, which is a private financial institution. The remaining equity interest in Telesis CDE II, LLC (99.99%) is owned by Biovax Investments, LLC (the "Fund"), a company established solely for the purpose of facilitating this NMTC financing arrangement. The Fund equity is owned 99.99% by US Bancorp and 0.01% by Telesis CDE Corporation.

The fund was capitalized with $3.6 million equity from US Bancorp and a nominal equity investment by Telesis CDE Corporation. In addition, Biovest and the Company, through a consolidated subsidiary, loaned $8.5 million to the Fund pursuant to a 5.18%, annual rate, senior-secured, convertible note receivable, due in seven and one-half years. The note is convertible at the option of the Fund into shares of Biovest's common stock at a price based upon trading market prices of Biovest's common stock near the maturity date in seven and one-half years. These proceeds received by the Fund from the

aforementioned financing transactions were used to make a contemporaneous 99.99% equity investment in Telesis CDE II, LLC ($12.0 million) and payment for management, legal and accounting fees ($0.1 million).

Telesis CDE II, LLC, upon receipt of its equity funding, contemporaneously issued $11.5 million to Biovax for (a) a 1.0% convertible promissory note payable, due in seven and one-half years, (b) warrants to purchase 1.2 million shares of Biovest's common stock over a period of nine-years at a fixed price of $9.00 and (c) warrants to purchase 0.2 million shares of the Company's common stock over a period of seven years at a fixed price of $1.30. The convertible promissory note is convertible into common stock at the option of Telesis CDE II, LLC within 5 days of the maturity date at a conversion price equaling the then trading market price of the common stock. The overall arrangement provides that in the event Telesis CDE II, LLC converts the note payable, the aforementioned note receivable is subject to immediate conversion at the same conversion price.

Loans from Pulaski Bank. On September 5, 2006, Biovest closed a loan transaction with Pulaski Bank and Trust Company of St. Louis, MO ("Pulaski"), pursuant to which Pulaski loaned the sum of $2 million to Biovest pursuant to an unsecured Promissory Note (the "Note). The Note will become due and payable on January 5, 2007. The Note bears interest at prime rate minus .05%. The Note is guaranteed by entities and individuals that are stockholders, officers or directors of Biovest and/or Accentia. Biovest entered into Indemnification Agreements with each of the guarantors. As additional consideration, Biovest issued Pulaski a warrant (the "Warrant") to purchase 66,667 shares of Biovest Common Stock at an exercise price of $1.10 per share through September 5, 2011. Under the terms of the Warrant, Pulaski was granted piggy-back registration rights. The Note is an unsecured obligation of Biovest and is subordinated to Biovest's outstanding loan to Laurus.

Loans from McKesson Corporation. On September 29, 2006, we made a $0.4 million payment to the McKesson Corporation ("McKesson") to extinguish all remaining outstanding debt and accrued interest with the McKesson.

Bridge Loans from Hopkins Capital Group II, LLC. In June 2005, we borrowed an aggregate of $0.6 million in the form of a bridge loan from The Hopkins Capital Group II, LLC, otherwise referred to as Hopkins II. Dr. Francis E. O'Donnell, our Chief Executive Officer and Chairman, is the sole manager of Hopkins II, and several irrevocable trusts established by Dr. O'Donnell collectively constitute the largest equity owners of Hopkins II. The June 2005 bridge loan was evidenced by an unsecured interest-free promissory note that was due on the earlier of August 31, 2005 or the closing of this offering. A total of $0.6 million in principal was outstanding under this bridge loan as of June 30, 2005, and from July 1, 2005 through August 16, 2005, additional advances in the amount of $3.6 million were made by Hopkins II under this loan.

In August 2005, we entered into a new bridge loan agreement with Hopkins II that provides for aggregate borrowing availability of up to $7.5 million in principal amount at an interest rate of 4.25% per annum. In connection with this agreement, the $4.2 million advanced under the previous Hopkins II bridge loan was converted into an obligation under the new bridge loan agreement. The new bridge loan (including all accrued interest) will become due upon the earlier of August 16, 2007 or the completion by our company of a debt or equity financing that results in proceeds of more than $35.0 million (net of underwriting discounts, commissions, or placement agent fees). We may prepay the bridge loan at any time without penalty or premium. Notwithstanding the foregoing, on the date on which the bridge loan becomes due or on which we desire to prepay the loan, we must not be in default under our credit facility with Laurus, and the remaining balance under the Laurus credit facility at such time must be $2.5 million or less. If both of these conditions are not satisfied, then the bridge loan will not become due and cannot be paid until the first day on which both of these conditions are satisfied.

Under the August 2005 bridge loan agreement with Hopkins II, we have the unconditional right to borrow up to $5.0 million in the aggregate upon ten days' prior written notice to Hopkins II, provided that our right to borrow any amounts in excess of $5.0 million is conditioned upon us either being in default under our credit facility with Laurus or having less than $5.0 million cash on hand at the time of the advance. The loan is unsecured and bears interest at a rate equal to 4.25% per annum, simple interest. No payments of principal or interest are due until the maturity date of the loan. The Hopkins II bridge loan is subordinate to the Laurus credit facility and the McKesson loans, provided that we may repay the bridge loan prior to the full satisfaction of our obligations to Laurus so long as the above-described conditions are satisfied. On May 15, 2006, Hopkins Capital Group II, LLC elected to convert $3.3 million of debt and accrued interest into 412,892 shares at $8.00 per share. The outstanding balance on September 30, 2006 was $1.1 million.

Credit Facility with Southwest Bank of St. Louis f/k/a Missouri State Bank. In addition to the Laurus credit facility, in December 2005, we secured a $3.0 million subordinated revolving credit agreement with Southwest Bank of St. Louis f/k/a Missouri State Bank and Trust Company. In March of 2006 we were granted an incremental $1.0 million expansion of the existing credit facility, bringing to total credit facility to $4.0 million. This loan bears interest at prime per annum and has a January 2007 maturity date. The agreement is secured by the accounts receivable and inventory of our Accentia Pharmaceuticals subsidiary. Additionally, the agreement is secured by assets and personal guarantees of the Francis E. O'Donnell Jr. Irrevocable Trust #1, Steven Stogel and Dennis Ryll (directors and/or principal shareholders of our company). As of September 30, 2006, the entire $4.0 million credit facility had been drawn and was outstanding.

Our level of debt affects our operations in several important ways, including the following:

- a significant portion of our cash flow from operations is likely to be dedicated to the payment of the principal of and interest on our indebtedness;
- our ability to obtain additional financing in the future for working capital, capital expenditures or acquisitions may be limited;
- we may be unable to refinance our indebtedness on terms acceptable to us or at all;
- our cash flow may be insufficient to meet our required principal and interest payments; and

we may default on our obligations and the lenders may foreclose on their security interests that secure their loans.

Private Placement of Convertible Debentures

On September 29, 2006, we entered into definitive agreements relating to a private placement (the "Private Placement") of $25.0 million in principal amount of 8% Secured Convertible Debentures due September 29, 2010 (the "Debentures"). The Private Placement resulted in gross proceeds of $23.5 million after placement agent fees of $1.5 million but before other expenses associated with the transaction. To secure certain amounts payable by us to Laurus, our senior lender, a total of $7.3 million of the proceeds from the Private Offering were placed into an escrow account and paid to Laurus when certain amounts become due under our credit facility with Laurus.

The Debentures will be convertible at any time at the option of the holder into shares of our common stock at $2.60 per share, subject to adjustment for stock splits, stock dividends, and the like. In the event that we issue or grant in the future any rights to purchase any of our common stock, or other security convertible into our common stock, for an effective per share price less than the conversion price then in effect, the conversion price of all unconverted Debentures will be decreased to equal such lower price. The Debentures are also exchangeable for shares of common stock of Biovest held by us at an exchange price of $1.00 per share, subject to adjustment for stock splits, stock dividends, and the like, at any time after the earlier to occur of (i) September 29, 2007 or (ii) such time as the closing price of Biovest's common stock exceeds $2.25 for each of 20 consecutive trading days, subject to certain volume requirements and other conditions. In the event that Biovest issues or grants in the future any rights to purchase any of Biovest's common stock, or other security convertible into Biovest's common stock, for a per share price less than the exchange price then in effect, the exchange price for all unconverted Debentures will be decreased to equal such lower price. The above-described adjustments to the conversion price or exchange price for future stock issuances by us or Biovest will not apply to certain exempt issuances, including stock issuances pursuant to employee stock option plans and strategic transactions.

Prior to maturity the Debentures will bear interest at 8% per annum with interest payable quarterly in arrears in cash, or, at our option, in shares of our common stock. Our ability to pay interest with shares of our common stock will be subject to specified conditions, including the existence of an effective registration statement covering the resale of the shares issued in payment of interest and certain minimum trading volumes in the stock to be issued. Shares delivered in payment of interest will be valued at 90% of the average of the daily volume weighted average price of the shares for the 20 trading days prior to the interest payment date. From and after an event of default under the Debentures and for so long as the event of default is continuing, the Debentures will bear default interest at a rate of 18% per annum.

Beginning October 1, 2007, and on the 1st of each month thereafter, we will be required to redeem 1/37th of the face value of the Debentures in cash or, at our election, with shares of our common stock , shares of Biovest common stock held by us , or a combination thereof. Our ability to pay interest with shares of our or Biovest common stock will be subject to specified conditions, including the existence of an effective registration statement covering the resale of the shares issued in payment of the redemption amount and certain minimum trading volumes in the stock to be issued. Any payment in common stock of either us or Biovest may not exceed 15% of the total dollar traded volume in the applicable stock for the 20 trading days prior to the amortization payment. Any of our common stock or Biovest common stock delivered in satisfaction of an amortization payment will be valued at the lesser of (i) the conversion price or the exchange price, as the case may be, in effect at the time of the amortization payment or (ii) 90% of the average of the daily volume weighted average price of the applicable shares for the 20 trading days prior to the amortization payment. Any unconverted Debentures will become due on September 29, 2010.

In the event that the average of the daily volume weighted average price of the shares of our common stock for any 20 consecutive trading days exceeds $6.50, we will have the right, but not the obligation, to require the holders of the Debentures to convert into our common stock at the conversion price then in effect up to 50% of any outstanding Debentures (or 100% of any outstanding Debentures, in the event that the average of the daily volume weighted average price of the shares of our common stock for any 20 consecutive trading days exceeds 300% of the then-effective conversion price). Such a mandatory conversion is subject to specified conditions, including the existence of an effective registration statement covering the resale of the shares into which the Debentures are converted and certain minimum trading volumes in the stock to be issued. The registration statement was declared effective on November 17, 2006.

At any time beginning on the first anniversary of the effectiveness of a registration statement covering the resale of the shares of our common stock issuable upon conversion of the Debentures, we may redeem, subject to specified conditions and upon 20 trading days' written notice, any or all of the outstanding Debentures for a redemption price of (i) cash of 120% of par plus accrued and unpaid interest on the Debentures to be redeemed and (ii) warrants to subscribe for a number of shares of our common stock equal to the principal amount of the Debentures to be redeemed, divided by the conversion price then in effect. Such warrants will have an exercise price equal to the average of the daily volume weighted average price for the shares of our common stock for the 20 trading day period immediately preceding the redemption and a term equal to the weighted average remaining term of the Debentures.

As a part of the Private Placement, we issued Warrants to the purchasers of the Debentures giving them the right to purchase up to an aggregate of 3,136,201 shares of our common stock at an exercise price of $2.75 per share, provided that such Warrants may be alternatively exercised for shares of Biovest common stock held by us at an exercise price of $1.10 per share. The warrant exercise prices are subject to adjustment for stock splits, stock dividends, and the like. The Warrants may not be exercised for any shares of Biovest common stock until the earlier to occur of (i) September 29, 2007 or (ii) such time as the closing price of Biovest's common stock exceeds $2.25 for each of 20 consecutive trading days, subject to certain volume requirements and adjustments. In the event that we in the future issues or grants any rights to purchase any of our common stock, or other security convertible into our common stock, for a per share price less than the exercise price then in effect, the exercise price of the Warrant with respect to shares of our common stock will be reduced to equal such lower price and the number of shares of our common stock for which the Warrant may be exercised will be increased so that the total aggregate exercise price remains constant. In the event that Biovest in the future issues or grants any rights to purchase any of Biovest's common stock, or other security convertible into Biovest's common stock, for a per share price less than the exercise price then in effect, the exercise price of the Warrant with respect to shares of Biovest's common stock will be reduced to equal such lower price. The foregoing adjustments to the exercise price for both our common stock and Biovest's common stock for future stock issues will not apply to certain exempt issuances, including issuances pursuant to employee stock option plans and strategic transactions. In connection with the Private Placement, we also issued to the placement agent for the transaction warrants to purchase an aggregate of 545,455 shares of our common stock at an exercise price of $2.75 per share. All of the Warrants (including the warrants granted to the Placement Agent) will expire on September 29, 2011.

Unless and until shareholder approval of the Private Placement is obtained by us, the aggregate number of shares of our Common Stock issuable upon the conversion of any of the Debentures and upon the exercise of any of the Warrants is limited to 19.99% of the number of shares of our common stock outstanding on the date of the closing of the Private Placement. We agreed to include a proposal for shareholder approval of the Private Placement at its next annual meeting of shareholders, and shareholders holding more than 50% of our common stock have entered into voting agreements agreeing to vote their respective shares in favor of such proposal. In addition, the total number of shares of Biovest common stock held by us that may be transferred to the investors in the Private Placement pursuant to the Debentures or Warrants may not exceed 18,000,000 shares in the aggregate. Pursuant to a Pledge Agreement among us and all of the purchasers of the Debentures, the Debentures are also secured by these 18,000,000 shares of Biovest common stock held by the Company.

In connection with the Private Placement, we and the purchasers of the Debentures entered into a Registration Rights Agreement under which we are required, on or before November 1, 2006, to file a registration statement with the SEC covering the resale of the shares of our common stock issuable pursuant to the Debentures and Warrants and to use its best efforts to have the registration declared effective at the earliest date (but in no event later than 90 days after filing if there is no SEC review of the registration statement, or 120 days if there is an SEC review). We will be subject to certain monetary penalties, as set forth in the Registration Rights Agreement, if the registration statement is not filed or does not become effective on a timely basis. Biovest and the purchasers of the Debentures have entered into a similar registration rights agreement under which Biovest is required to file with the SEC and seek to have declared effective a registration statement covering the resale of the shares of Biovest common stock transferable by us pursuant to the Debentures and Warrants.

Cash Resources

At September 30, 2006, we had cash and cash equivalents of $15.4 million compared with cash and cash equivalents of $2.8 million at September 30, 2005.

We have lines of credit with Hopkins Capital Group II, LLC and with Laurus Master Funds, LP which subject to compliance with borrowing requirements may represent additional cash resources aggregating approximately $3.0 million.

Cash Flows for the Year Ended September 30, 2006

For the year ended September 30, 2006, we used $28.6 million in cash to fund our operating activities. This consisted primarily of a net loss of $43.4 million, derivative gain of $1.2 million, absorption of prior losses against minority interest of $1.7 million, reduced by non-cash charges of approximately $0.2 million related to a loss on sale of assets, $0.7 million of depreciation, $2.2 million in amortization of intangibles, $2.0 million accretion of debt discount, $1.2 million of stock-based compensation and the issuance of common stock warrants of $0.1 million. We also had $3.3 million in impairment charges

due to the sale of our pain products, valued in fiscal 2006, but sold subsequent to year end. This use of cash was offset by an increase in working capital of $8.0 million primarily due from $1.5 million accounts receivable, $2.5 million accounts payable, and $3.8 million accrued expenses.

We had net cash flows from investing activities of $2.9 million in the year ended September 30, 2006, primarily consisting of $5.2 million proceeds from restricted cash, offset by payments for product rights of $1.7 million, improvements to our Worcester laboratory facility of $0.5 million, and computer equipment and office improvements of $0.1 million.

We had net cash flows from financing activities of $38.3 million in the year ended September 30, 2006, consisting of $22.5 million in proceeds from the issuance of common stock, $16.1 million in proceeds from convertible debentures, net funding from lines of credit of $8.9 million, $3.0 million in net proceeds from a non-controlling investment in a variable interest entity, $2.0 million from the proceeds of long-term debt, and proceeds from the exercise of stock options of $0.1 million. We reduced our debt by $14.8 million, paid $0.4 million of stockholder notes, and paid related party payables of $0.2 million.

Our net working capital deficit at September 30, 2006 decreased from September 30, 2005 by $20.2 million to $20.5 million, which was attributed largely to the issuance of common stock at our Initial Public Offering, net debt proceeds, proceeds form restricted cash, and offset by our fiscal 2006 loss.

Funding Requirements

We expect to devote substantial resources to further our commercialization efforts for our late-stage clinical products in our Biopharmaceutical Products and Services division, including regulatory approvals of SinuNase and BiovaxID, as well as the commercial launch of Allernase. Our future funding requirements and our ability to raise additional capital will depend on factors that include:

- the timing and amount of expense incurred to complete our clinical trials;
- the costs and timing of the regulatory process as we seek approval of our products in development;
- the advancement of our products in development;
- the timing, receipt and amounts of milestone payments to our existing development partners;
- our ability to generate new relationships with industry partners whose business plans seek long-term commercialization opportunities which allow for up-front deposits or advance payments in exchange for license agreements;
- the timing, receipt and amount of sales, if any, from our products in development in our Biopharmaceutical Products and Services segment;
- the timing, receipt and amount of sales in our Specialty Pharmaceuticals segment;
- the cost of manufacturing (paid to third parties) of our licensed products, and the cost of marketing and sales activities of those products;
- the continued willingness of our vendors to provide trade credit on historical terms;
- the costs of prosecuting, maintaining, and enforcing patent claims, if any claims are made;
- our ability to maintain existing collaborative relationships and establish new relationships as we advance our products in development; and
- the receptivity of the financial market to biopharmaceutical companies.

Contractual Obligations and Off-Balance Sheet Arrangements

The following chart summarizes our contractual payment obligations as of September 30, 2006. The long- and short-term debt is reflected as liabilities on our balance sheet as of September 30, 2006. Operating leases are accrued and paid on a monthly basis.

The other contractual obligations reflected in the table include obligations to purchase product candidate materials contingent on the delivery of the materials and to fund various clinical trials contingent on the performance of services. These obligations also include long-term obligations, including milestone payments that may arise under agreements that we may terminate prior to the milestone payments being due. The table excludes contingent royalty payments that we may be obligated to pay in the future.

	Payments Due by Period				
	Less than One Year	One to Two Years	Three to Five Years	After Five Years	Total
			(in thousands)		
Long-term debt [a]	$ 12,243	$ 30,646	$ 8,880	$ —	$ 51,769
Cooperative research and development agreements	45	—	—	—	45
Employment agreements	3,209	4,399	221	—	7,829
License agreements	2,262	3,512	1,346	—	7,120
	$ 17,759	$ 38,557	$ 10,447	$ —	$ 66,763

(a) Includes interest on long-term debt.

The above table does not include any additional amounts that we may be required to pay under license or distribution agreements upon the achievement of scientific, regulatory, and commercial milestones that may become payable depending on the progress of scientific development and regulatory approvals, including milestones such as the submission of drug approval applications to the FDA and approval of such applications. While we cannot predict when and if such events will occur, depending on the successful achievement of such scientific, regulatory and commercial milestones, we may owe up to $4.0 million and $6.0 million in fiscal years 2007 and 2008, respectively.

Under the Biologics Distribution Agreement that we entered into with McKesson Corporation in February 2004, as described above, we granted McKesson exclusive distribution rights to our biologics products in exchange for a $3.0 million refundable deposit. McKesson has the right to terminate this agreement at any time upon 180 days' prior written notice, and upon such termination, we will be required to refund the $3.0 million deposit to McKesson.

Under the September 2004 Royalty Stream Purchase Agreement with Pharmaceutical Products Development ("PPD"), as described above, if PPD does not receive at least $2.5 million in royalties from SinuNase under this agreement by 2009, then PPD has the right to terminate the agreement. In the event of such a termination, we will be required to refund the $2.5 million that PPD paid to us upon the execution of the agreement in consideration of the future royalty rights granted to them under the agreement.

Under the promissory note that we issued to Biovest in connection with our June 2003 investment agreement with Biovest, a total of $15.0 million became payable to Biovest on various dates through June 2007. In August 2004, we entered into an amendment of the investment agreement under which we agreed to use reasonable efforts to make advances to Biovest under the note prior to the due date of the payments thereunder. We completed funding of our commitment under the note by September 30, 2005, and have advanced approximately $4.7 million in additional funds subsequent to that date through September 30, 2006.

We do not maintain any off-balance sheet financing arrangements.

Recent Accounting Pronouncements

The Financial Accounting Standards Board ("FASB") has recently announced a new interpretation, FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" (FIN 48), which will be effective for fiscal years beginning after December 15, 2006. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes". FIN 48 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. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company has not determined the impact of the adoption of FIN 48 on its consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 clarifies the definition of fair value, describes methods used to appropriately measure fair value, and expands fair value disclosure requirements. This statement is effective for fiscal years beginning after November 15, 2007. The Company is currently in the process of assessing the impact that SFAS 157 will have on the consolidated financial statements.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

We are exposed to various market risks as a part of our operations, and we anticipate that this exposure will increase as a result of our planned growth. In an effort to mitigate losses associated with these risks, we may at times enter into derivative financial instruments, although we have not historically done so. These may take the form of forward sales contracts, option contracts, foreign currency exchange contracts, and interest rate swaps. We do not, and do not intend to, engage in the practice of trading derivative securities for profit.

Interest Rates

Some of our funds may be invested in short-term, interest-bearing, investment grade securities. The value of these securities will be subject to interest rate risk and could fall in value if interest rates rise. Due to the fact that we hold our excess funds in cash equivalents, a 1% change in interest rates would not have a significant effect on the value of our cash equivalents.

Foreign Exchange Rates

While we have operations in Germany, these operations are not significant to our overall financial results. Therefore, we do not believe fluctuations in exchange rates would have a material impact on our financial results.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTAL DATA

The financial statements required by this item are located in Item 15 of this report.

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

Based on their evaluation, as of a date within 90 days prior to the date of the filing of this report, of the effectiveness of our disclosure controls and procedures, the Chief Executive Officer and Chief Financial Officer have each concluded that our disclosure controls and procedures are effective and sufficient to ensure that we record, process, summarize, and report information required to be disclosed by us in our periodic reports filed under the Securities Exchange Act within the time periods specified by the Securities and exchange Commission's rules and forms.

Subsequent to the date of their evaluation, there have not been any significant changes in our internal controls or in other factors to our knowledge that could significantly affect these controls, including any corrective action with regard to significant deficiencies and material weaknesses. The design of any system of controls and procedures is based in part upon certain assumptions about the likelihood of future events.

ITEM 9B. OTHER INFORMATION

None

PART III

ITEM 10. DIRECTORS AND EXECUTIVE OFFICERS

The information in response to this item is hereby incorporated by reference to the information under the captions "DIRECTORS AND EXECUTIVE OFFICERS" and "SECTION 16(a) BENEFICIAL OWNERSHIP REPORTING COMPLIANCE" presented in the Company's definitive proxy statement to be filed with the Securities and Exchange Commission and used in connection with the solicitation of proxies for our 2007 Annual Meeting of Shareholders (the "Proxy Statement").

ITEM 11. EXECUTIVE COMPENSATION

The information in response to this item is hereby incorporated by reference to the information under the captions "COMPENSATION OF EXECUTIVE OFFICERS", "DIRECTORS AND EXECUTIVE OFFICERS, "COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION", "REPORT ON EXECUTIVE COMPENSATION BY THE COMPENSATION COMMITTEE AND BOARD OF DIRECTORS" and "PERFORMANCE GRAPH presented in the Proxy Statement.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information in response to this item is located in ITEM 5 and is hereby incorporated by reference to the information under the caption "SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT" presented in the Proxy Statement.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

The information in response to this item is hereby incorporated by reference to the information under the caption "CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS" presented in the Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The information required by this item is incorporated by reference to the information under the caption "PRINCIPAL ACCOUNTANT FEES AND SERVICES" in the Proxy Statement.

PART IV

ITEM 15. EXHIBITSAND FINANCIAL STATEMENT SCHEDULES

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

(1) Financial Statements

See Index to Financial Statements on page F-1.

(2) Supplemental Schedules

Schedule II – Valuation and Qualifying Accounts (see last page of Consolidated Financial Statements)

All other schedules have been omitted because the required information is not present in amounts sufficient to require submission of the schedule, or because the required information is included in the consolidated financial statements or notes thereto.

(3) Exhibits

See Item 15(b) below.

(b) The following exhibits are filed as part of, or incorporated by reference into, this annual report on Form 10-K:

Number	Description of Document
2.1	Asset Purchase Agreement, dated as of October 27, 2006, among Accentia, TEAMM Pharmaceuticals, Inc. and Victory Pharma, Inc.
3.1	— Amended and Restated Articles of Incorporation, as amended (filed as Exhibit 3.1 to the Registration Statement on Form S-1 (Amendment No. 7) filed on September 2, 2005 (Registration No. 333-122769) and incorporated herein by reference).
3.2	— Amended and Restated Bylaws (filed as Exhibit 3.2 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).
4.1	— Reference is made to Exhibits 3.1 and 3.2.
4.2	— Form of Common Stock Certificate (filed as Exhibit 4.2 to the Registration Statement on Form S-1 (Amendment No. 3) filed on June 13, 2005 (Registration No. 333-122769) and incorporated herein by reference).
4.3	— Agreement of Merger and Plan of Reorganization, dated January 8, 2003, between Accentia, TEAMM Pharmaceuticals, Inc., and TEAMM Principals (filed as Exhibit 4.3 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).
4.4	— Amended and Restated Agreement of Merger and Plan of Reorganization, dated April 3, 2002, between Accentia, The Analytica Group, Ltd., and The Analytica Group, Inc. (filed as Exhibit 4.4 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).
4.5	— Merger Agreement, dated September 30, 2003, between Accentia and IMOR Private Institute for Medical Outcome Research GmbH (filed as Exhibit 4.5 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).
4.6	— Form of Investors' Rights Agreement and Form of Agreement and Waiver, between Accentia and certain investors named therein including The Joyce A. Aboussie Revocable Trust, Robert Carr, John P. Dubinsky, Charles R. and Ann T. Eveker, D&G Strategic Investments, Hopkins Capital Group, LLC, Lee Kling, McKesson Corporation, MOAB Investments, Gary Munson, DKR SoundShore Oasis Holding Fund, Ltd., John D. Prosperi, Nicholas G. and Linda P. Rallo, Dennis Ryll, MRB&B, LLC, Allen Family Partnership, Alan Hirmes, Harold Harris, Michael Fowler, Nathalie Rallo, Sophia Rallo, Tom MacDonald, Jim Varney, Jane Mingey, Jeffrey Lynford, Steve Kirby, Jeff Tobolski, George Vornas, Mayo Foundation, David Sabino, Donald L. Ferguson Living Trust, and Vincent Keating (filed as Exhibit 4.6 to the Registration Statement on Form S-1 (Amendment No. 2) filed on May 16, 2005 (Registration No. 333-122769) and incorporated herein by reference).
4.7	— Form of Investors' Rights Agreement and Form of Agreement and Waiver, between Accentia and certain investors named therein including Ronald E. Osman and Steve Stogel (filed as Exhibit 4.7 to the Registration Statement on Form S-1 (Amendment No. 2) filed on May 16, 2005 (Registration No. 333-122769) and incorporated herein by reference).

4.8 — Amended and Restated Investors' Rights Agreement, dated January 7, 2005, between Accentia and Pharmaceutical Product Development, Inc., as amended July 8, 2005 and August 11, 2005 (including Assignment and Assumption Agreement, dated June 28, 2005, among the Company, Pharmaceutical Product Development, Inc. and PPD International Holdings, Inc.) (filed as Exhibit 4.8 to the Registration Statement on Form S-1 (Amendment No. 7) filed on September 2, 2005 (Registration No. 333-122769) and incorporated herein by reference).

4.9 — Series E Convertible Preferred Stock Purchase Agreement, dated January 9, 2004, between Accentia and Pharmaceutical Product Development, Inc. (filed as Exhibit 4.9 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

4.10 — Series E Convertible Preferred Stock Purchase Agreement, dated April 15, 2004, between Accentia and Ronald E. Osman (filed as Exhibit 4.10 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

4.11 — Form of Series E Subscription Agreement between Accentia and certain investors named therein, including The Joyce A. Aboussie Revocable Trust, Robert Carr, John P. Dubinsky, Charles R. and Ann T. Eveker, D&G Strategic Investments, Hopkins Capital Group, LLC, Lee Kling, McKesson Corporation, MOAB Investments, Gary Munson, DKR SoundShore Oasis Holding Fund, Ltd., John D. Prosperi, Nicholas G. and Linda P. Rallo, Dennis Ryll, MRB&B, LLC, Allen Family Partnership, Alan Hirmes, Harold Harris, Michael Fowler, Nathalie Rallo, Sophia Rallo, Tom MacDonald, Jim Varney, Jane Mingey, Jeffrey Lynford, Steve Kirby, Jeff Tobolski, George Vornas, Mayo Foundation, David Sabino, Donald L. Ferguson Living Trust, Steve Stogel, and Vincent Keating (filed as Exhibit 4.11 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

4.12 — Registration Rights Agreement, dated April 3, 2002, between Accentia and Steven Arikian, M.D., John Doyle, Julian Casciano, and Roman Casciano, as amended by Amendment No. 1, dated March 30, 2005, and Amendment No. 2, dated April 29, 2005 (filed as Exhibit 4.12 to the Registration Statement on Form S-1 (Amendment No. 3) filed on June 13, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.1 — License Agreement, dated April 12, 2004, between Accentia and BioDelivery Sciences International, Inc., as amended pursuant to an Asset Purchase Agreement dated September 7, 2004 and as further amended by those certain letter agreements dated March 28, 2005 and April 25, 2005 (filed as Exhibit 10.1 to the Registration Statement on Form S-1 (Amendment No. 2) filed on May 16, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.2[(b)] — License Agreement, dated February 10, 2004, between Accentia and Mayo Foundation for Medical Education and Research ("MAYO"), as amended on December 12, 2004 (filed as Exhibit 10.2 to the Registration Statement on Form S-1 (Amendment No. 1) filed on April 6, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.3 — Exclusive Agreement, dated September 17, 2004, between Accentia and The Board of Trustees of the Leland Stanford Junior University (filed as Exhibit 10.3 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.4 — Investment Agreement, dated April 10, 2003, between Accentia and Biovest International, Inc. ("Biovest"), as amended (filed as Exhibit 10.4 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.5[(b)] — Distribution Agreement, dated March 12, 2004, between Accentia and Arius Pharmaceuticals, Inc. (filed as Exhibit 10.6 to the Registration Statement on Form S-1 (Amendment No. 3) filed on June 13, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.6 — Biologics Distribution Agreement, dated February 27, 2004, between Accentia and McKesson Corporation (filed as Exhibit 10.7 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.7[(b)] — Amended and Restated Distribution and Supply Agreement, dated August 12, 2005, between Accentia and Respirics, Inc. (filed as Exhibit 10.10 to the Registration Statement on Form S-1 (Amendment No. 7) filed on September 2, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.8[(b)] — Product Development Agreement, dated January 24, 2003, between Accentia and Respirics, Inc. (filed as Exhibit 10.11 to the Registration Statement on Form S-1 (Amendment No. 1) filed on April 6, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.9 — Cooperative Research and Development Agreement, dated May 27, 1999, between Accentia and The National Cancer Institute, as amended by that certain amendment dated April 6, 2005 (filed as Exhibit 10.12 to the Registration Statement on Form S-1 (Amendment No. 2) filed on May 16, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.10[b] — Supply Agreement, dated December 1, 2004, between Accentia and biosyn Arzeneimittel GmbH. (filed as Exhibit 10.14 to the Registration Statement on Form S-1 (Amendment No. 1) filed on April 6, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.11 — First Amended and Restated Royalty Stream Purchase Agreement, dated August 11, 2005, between Accentia and Pharmaceutical Product Development, Inc. (filed as Exhibit 10.15 to the Registration Statement on Form S-1 (Amendment No. 7) filed on September 2, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.12 — Office Lease, dated May 1, 2004, between Accentia, as Tenant, and AP Southeast Portfolio Partners, LP, as Landlord (filed as Exhibit 10.16 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.13 — Standard Form of Lease, dated April 1, 2004, between Accentia, as Tenant, and Pizzagalli Properties, LLC, as Landlord, as amended (filed as Exhibit 10.17 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.14 — Agreement of Lease, dated December 1998, between Accentia, as Tenant, and We're Associates Company, as Landlord (filed as Exhibit 10.18 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.15 — Agreement of Lease, dated February 26, 2002, between Accentia, as Tenant, and Heartland Rental Properties, LLC, as Landlord, as amended (filed as Exhibit 10.19 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.16 — Lease, dated March 22, 2005, between 460 Park Associates, as Landlord, and Accentia, as Tenant (filed as Exhibit 10.20 to the Registration Statement on Form S-1 (Amendment No. 3) filed on June 13, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.17 — Space Lease, dated October 26, 1995, between Accentia, as Tenant, and Worcester Business Development Corporation, as Landlord, as amended (filed as Exhibit 10.21 to the Registration Statement on Form S-1 (Amendment No. 1) filed on April 6, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.18 — Lease Agreement dated December 2003, between Accentia and IMOR Private Institute for Medical Outcome Research GmbH (filed as Exhibit 10.22 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.19[a] — 2003 Stock Option Plan, as amended (filed as Exhibit 10.23 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.20[a] — Employment Agreement, dated January 1, 2005, between Accentia and Dr. Francis E. O'Donnell (filed as Exhibit 10.24 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.21[a] — Employment Agreement, dated April 3, 2002, between Accentia and Dr. Steven R. Arikian, as amended (filed as Exhibit 10.25 to the Registration Statement on Form S-1 (Amendment No. 1) filed on April 6, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.22[a] — Second Amended and Restated Executive Employment Agreement, dated December 31, 2004, between Accentia and Martin G. Baum, as amended on February 10, 2005 (filed as Exhibit 10.26 to the Registration Statement on Form S-1 (Amendment No. 2) filed on May 16, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.23[a] — Employment Agreement, dated January 1, 2005, between Accentia and Alan M. Pearce (filed as Exhibit 10.27 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.24[a] — Employment Agreement, dated January 1, 2005, between Accentia and Samuel S. Duffey (filed as Exhibit 10.28 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.25 — Form of Director and Officer Indemnity Agreement (filed as Exhibit 10.29 to the Registration Statement on Form S-1 (Amendment No. 3) filed on June 13, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.26 — Form of Warrant for Purchase of Common Stock granted by Accentia to Common Stock Holder (filed as Exhibit 10.32 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.27[a] — Form of Non-Qualified Stock Option Agreement (filed as Exhibit 10.33 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.28[a] — Form of Incentive Stock Option Agreement (filed as Exhibit 10.34 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.29[a] — 2005 Equity Incentive Plan (filed as Exhibit 10.35 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.30 — Revolving Credit Agreement, dated March 30, 2004, between Missouri State Bank and Trust Company and Accentia, as amended on March 22, 2005 (filed as Exhibit 10.36 to the Registration Statement on Form S-1 (Amendment No. 1) filed on April 6, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.31 — Accentia Assumption of Debt and Security Agreement, dated December 31, 2003, between Accentia and McKesson Corporation, as amended by the First Amendment, dated February 9, 2005, and as modified on May 31, 2005, June 28, 2005, July 8, 2005, August 15, 2005, and September 13, 2005 (filed as Exhibit 10.39 to the Registration Statement on Form S-1 (Amendment No. 8) filed on October 3, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.32 — Forbearance Agreement, dated December 9, 2003, between Accentia, Accent Rx, Inc. and McKesson Corporation (filed as Exhibit 10.40 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.33 — Warrant Purchase Agreement, dated December 1, 1998, between Accentia and McKesson Corporation (filed as Exhibit 10.41 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.34 — Credit Agreement, dated November 30, 1998, between Accentia and McKesson Corporation (filed as Exhibit 10.42 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.35 — Security Agreement, dated November 30, 1998, between Accentia and McKesson Corporation (filed as Exhibit 10.43 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.36 — Lease Agreement, dated November 2004, between Accentia and Bay Villa Developers, Inc., as General Partner for Hyde Park Plaza Associates, Ltd. (filed as Exhibit 10.64 to the Registration Statement on Form S-1 (Amendment No. 1) filed on April 6, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.37 — Post Residential Rental Agreement, dated April 15, 2005, between Accentia and Post Apartment Homes, L.P. (filed as Exhibit 10.65 to the Registration Statement on Form S-1 (Amendment No. 1) filed on April 6, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.38[b] — Manufacturing and Supply Agreement, dated August 23, 2002, between Accentia and Kiel Laboratories (filed as Exhibit 10.66 to the Registration Statement on Form S-1 (Amendment No. 1) filed on April 6, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.39 — Securities Purchase Agreement, dated April 29, 2005, between Accentia and Laurus Master Fund, Ltd. ("Laurus") (filed as Exhibit 10.67 to the Registration Statement on Form S-1 (Amendment No. 2) filed on May 16, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.40 — Security Agreement dated April 29, 2005, between Accentia and Laurus (filed as Exhibit 10.68 to on Accentia's

Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.41 — Amended and Restated Secured Convertible Term Note, dated April 29, 2005, of Accentia payable to Laurus (filed as Exhibit 10.69 to the Registration Statement on Form S-1 filed on 2005March 6, 2006 (Registration No. 333-132237) and incorporated by reference).

10.42 — Amended and Restated Convertible Minimum Borrowing Note dated April 29, 2005, of Accentia and Laurus (filed as Exhibit 10.on2 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.43 — Secured Revolving Note dated April 29, 2005, of Accentia and Laurus (filed as Exhibit 10.on7 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.44 — Stock Pledge Agreement and InterCompany Note Pledge Agreement, dated April 29, 2005, between Accentia and Laurus (filed as Exhibit 10.72 to the Registration Statement on Form S-1 (Amendment No. 2) filed on May 16, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.45 — Amended and Restated Common Stock Purchase Warrant, dated August 16, 2005, granted by Accentia to Laurus (filed as Exhibit 10.73 to the Registration Statement on Form S-1 (Amendment No. 7) filed on September 2, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.46 — Subsidiary Guaranty, dated April 29, 2005, between Accentia and Laurus (filed as Exhibit 10.74 to the Registration Statement on Form S-1 (Amendment No. 2) filed on May 16, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.47 — Registration Rights Agreement, dated April 29, 2005, between Accentia and Laurus, as amended (filed as Exhibit 10.75 to the Registration Statement on Form S-1 (Amendment No. 8) filed on October 3, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.48 — Amended and Restated Registration Rights Agreement dated February 13, 2006 between Accentia and Laurus (filed as Exhibit 10.5 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.49 — Promissory Note, dated September 1, 2001, of Accentia payable to Dr. David DeFouw, as modified on January 18, 2005 (filed as Exhibit 10.77 to the Registration Statement on Form S-1 (Amendment No. 3) filed on June 13, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.50 — Unsecured Promissory Note, dated June 30, 2005, issued to The Hopkins Capital Group II, LLC (filed as Exhibit 10.79 to the Registration Statement on Form S-1 (Amendment No. 3) filed on June 13, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.51 — Unsecured Promissory Note, dated June 30, 2005, issued to The Hopkins Capital Group II, LLC (filed as Exhibit 10.80 to the Registration Statement on Form S-1 (Amendment No. 6) filed on July 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.52 — Omnibus Amendment and Consent, dated August 16, 2005, between Accentia and Laurus (filed as Exhibit 10.81 to the Registration Statement on Form S-1 (Amendment No. 7) filed on September 2, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.54 — Bridge Loan Agreement, dated August 16, 2005, between Accentia and The Hopkins Capital Group II, LLC, together with Bridge Loan Note, dated August 16, 2005 (filed as Exhibit 10.82 to the Registration Statement on Form S-1 (Amendment No. 7) filed on September 2, 2005 (Registration No. 333-122769) and incorporated herein by reference).

10.55[b] — Option Agreement, dated December 6, 2005, between Accentia and MAYO.

10.56[b] — Licensing and Distribution Agreement, dated November 22, 2005, between Accentia and Collegium Pharmaceuticals, Inc.

10.57 Promissory Note Dated September 30, 2005 (filed as Exhibit 10.85 to Accentia's Form 10-K filed December 29, 2005 and incorporated herein by reference).

10.58 Agreement with Collegium Pharmaceutical, Inc. (filed as Exhibit 10.84 to Accentia's Form 10-K filed December 29, 2005 and incorporated herein by reference).

10.59 Overadvance Letter Agreement and Additional Common Stock Purchase Warrant, dated December 29, 2005, between Accentia and Laurus (filed as Exhibit 10.86 to the Registration Statement on Form S-1 filed on March 6, 2006 (Registration No. 333-132237) and incorporated by reference).

10.60 Trust Ratification dated February 13, 2006 between Accentia and Laurus (filed as Exhibit 10.1 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.61 MSB Subordination Agreement dated February 13, 2006 between Accentia and Laurus (filed as Exhibit 10.3 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.62 Second Omnibus Amendment dated February 13, 2006 between Accentia and Laurus (filed as Exhibit 10.6 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.63 Joinder Agreement dated February 13, 2006 between TEAMM Pharmaceuticals, Inc. and Laurus (filed as Exhibit 10.8 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.64 Revolving Credit Agreement dated December 30, 2005 between Accentia and Missouri State Bank (filed as Exhibit 10.9 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.65 Revolving Credit Note dated December 30, 2005 between Accentia and Missouri State Bank (filed as Exhibit 10.10 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.66 Security Agreement dated December 30, 2005 between Accentia and Missouri State Bank (filed as Exhibit 10.11 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.67 Continuing Contract of Guaranty dated December 30, 2005 between Accentia, Missouri State Bank, and other parties (filed as Exhibit 10.12 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.68 Security Agreement dated December 30, 2005 between TEAMM Pharmaceuticals, Inc. and Missouri State Bank (filed as Exhibit 10.13 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.69 Stock Pledge Agreement dated December 30, 2005 between The Francis E. O'Donnell, Jr. Irrevocable Trust No. 1 dated May 25, 1990 and Missouri State Bank (filed as Exhibit 10.14 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.70 Securities Pledge and Security Agreement dated December 30, 2005 between Dennis L. Ryll and Missouri State Bank (filed as Exhibit 10.15 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.71 Form of Incentive Option Grant under 2005 Equity Incentive Plan (filed as Exhibit 10.16 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.72 Form of Non-Qualified Option Grant under 2005 Equity Incentive Plan (filed as Exhibit 10.17 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.73 Form of Non-Employee Directors Option Grant under 2005 Equity Incentive Plan (filed as Exhibit 10.18 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.74 Warrant dated February 13, 2006 from Accentia to Laurus (filed as Exhibit 10.19 to Accentia's Form 10-Q filed February 14, 2006 and incorporated herein by reference).

10.75 Amended and Restated Stock Pledge Agreement, dated as of April 29, 2005 and amended and restated as of April 25, 2006, among Laurus, Accentia, and each other Pledgor party thereto (filed as Exhibit 10.1 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.76 Demand Note, dated April 25, 2006, issued by Biovest to Laurus (filed as Exhibit 10.2 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.77 First Bank Subordination Agreement, dated as of April 25, 2006, by and among Laurus, First Bank ("First Bank") and Accentia (filed as Exhibit 10.3 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.78 Telesis Subordination Agreement, dated as of April 25, 2006, by and among Laurus, Telesis CDE Two, LLC ("Telesis CDE"), Biovax, Inc. ("Biovax"), Biovest and Accentia (filed as Exhibit 10.4 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.79 Promissory Note, dated April 25, 2006, issued by Biovax Investment LLC ("Leverage Fund") to Biolender, LLC ("Biolender") (filed as Exhibit 10.5 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.80 Loan and Security Agreement, dated as of April 25, 2006, between Leverage Fund and Biolender (filed as Exhibit 10.6 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.81 Subordinated Convertible Promissory Note, dated April 25, 2006, from Biovax to Telesis CDE (filed as Exhibit 10.7 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.82 Convertible Loan Agreement, dated as of April 25, 2006, by and among Biovax, Telesis CDE and Biovest (filed as Exhibit 10.8 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.83 Guaranty, dated April 25, 2006, made by Frances E. O'Donnell, Jr., Kathleen M. O'Donnell (as Trustee of the Frances E. O'Donnell, Jr. Irrevocable Trust), Dennis L. Ryll, Ronald Osman, Steven J. Stogel, Donald L. Ferguson, Donald L. Ferguson (as trustee of the Donald L. Ferguson Revocable Trust), Biovest and Accentia in favor of U.S. Bancorp Community Investment Corporation ("USBCIC") and Telesis CDE (filed as Exhibit 10.9 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.84 Limited Liability Company Agreement of Biolender, LLC, dated April 25, 2006, between Biovest and Accentia (filed as Exhibit 10.10 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.85 Put Option Agreement dated April 25, 2006, between Biovax IC, Leverage Fund, USBCIC and Biolender (filed as Exhibit 10.11 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.86 Purchase Option Agreement dated April 25, 2006, between Biovax IC, Leverage Fund, USBCIC and Biolender (filed as Exhibit 10.12 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.87 Common Stock Purchase Warrant, dated April 25, 2006, issued by Biovest to Telesis CDE (filed as Exhibit 10.13 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.88 Common Stock Purchase Warrant, dated April 25, 2006, issued by Accentia to Telesis CDE (filed as Exhibit 10.14 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.89 Tax Credit Reimbursement and Indemnity Agreement, dated as of April 25, 2006, between Biovax and USBCIC (filed as Exhibit 10.15 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.90 Asset Purchase Agreement dated April 18, 2006 between Biovest and Biovax (filed as Exhibit 10.16 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.91 Vaccine Purchase and Sale Agreement, dated as of April 28, 2006, between Biovax and Biovest (filed as Exhibit 10.17 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.92 Indemnification Agreement, dated as of April 25, 2006, from Biovest to Dennis Ryll (filed as Exhibit 10.18 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.93 Indemnification Agreement, dated as of April 25, 2006, from Biovest to Steven Stogel (filed as Exhibit 10.19 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.94 Indemnification Agreement, dated as of April 25, 2006, from Biovest to Donald Ferguson (filed as Exhibit 10.20 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.95 Indemnification Agreement, dated as of April 25, 2006, from Biovest to Ronald Osman (filed as Exhibit 10.21 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.96 Indemnification Agreement, dated as of April 25, 2006, from Biovest to Francis O'Donnell (filed as Exhibit 10.22 to Accentia's Form 8-K filed May 2, 2006 and incorporated herein by reference).

10.97 Note and Warrant Purchase Agreement, dated March 31, 2006, between Biovest and Laurus (filed as Exhibit 10.1 to Accentia's Form 8-K filed April 6, 2006 and incorporated herein by reference).

10.98 Secured Promissory Note, dated March 31, 2006, issued by Biovest to Laurus (filed as Exhibit 10.2 to Accentia's Form 8-K filed April 6, 2006 and incorporated herein by reference).

10.99 Restricted Account Agreement, dated March 31, 2006, among Biovest, Laurus, and North Fork Bank (filed as Exhibit 10.4 to Accentia's Form 8-K filed April 6, 2006 and incorporated herein by reference).

10.100 Restricted Account Letter Agreement, dated March 31, 2006, between Biovest and Laurus (filed as Exhibit 10.5 to Accentia's Form 8-K filed April 6, 2006 and incorporated herein by reference).

10.101 Stock Pledge Agreement, dated March 31, 2006, between Laurus and Accentia (filed as Exhibit 10.8 to Accentia's Form 8-K filed April 6, 2006 and incorporated herein by reference).

10.102 Securities Purchase Agreement, dated May 15, 2006, among Accentia and the parties identified as "Buyers" therein ("Securities Purchase Agreement") (filed as Exhibit 10.1 to Accentia's Form 8-K filed May 19, 2006 and incorporated herein by reference).

10.103 *Form of Common Stock Purchase Warrant, dated May 15, 2006, issued by Accentia pursuant to Securities Purchase Agreement (filed as Exhibit 10.3 to Accentia's Form 8-K filed May 19, 2006 and incorporated herein by reference).*

10.104 Registration Rights Agreement, dated May 15, 2006, among Accentia and Buyers under Securities Purchase Agreement (filed as Exhibit 10.2 to Accentia's Form 8-K filed May 19, 2006 and incorporated herein by reference).

10.105 Overadvance Letter Agreement, dated July 13, 2006, among Laurus, Accentia, The Analytica Group, Inc., and TEAMM Pharmaceuticals, Inc. (filed as Exhibit 10.1 to Accentia's Form 8-K filed July 19, 2006 and incorporated herein by reference).

10.106 Amendment to Option Agreement, dated July 20, 2006, between Accentia and MAYO together with Form of Common Stock Purchase Warrant. (filed as Exhibit 10.1 to Accentia's Form 8-K filed July 24, 2006 and incorporated herein by reference).

10.107 Amendment and Consent to Release between Biovest and Laurus dated August 2, 2006. (filed as Exhibit 10.8 to Accentia's Form 10-Q filed August 14, 2006 and incorporated herein by reference).

10.108[(b)] Second Amendment to License Agreement, dated August 22, 2006, between Accentia and MAYO (filed as *Exhibit 10.1 to Accentia's Form 8-K filed August 28, 2006 and incorporated herein by reference).*

10.109 Common Stock Purchase Warrant dated August 22, 2006, between Accentia and MAYO (filed as Exhibit 10.2 to Accentia's Form 8-K filed August 28, 2006 and incorporated herein by reference).

10.110 Side Letter dated August 22, 2006 between Accentia and MAYO (filed as Exhibit 10.3 to Accentia's Form 8-K filed August 28, 2006 and incorporated herein by reference).

10.111 Securities Purchase Agreement, dated as of September 29, 2006, among Accentia and each of the purchasers named therein (including form of Common Stock Purchase Warrant and form of Secured Convertible *Debenture issued thereunder) (filed as Exhibit 10.1 to Accentia's Form 8-K filed October 2, 2006 and* incorporated herein by reference).

10.112 Registration Rights Agreement, dated as of September 29, 2006, among Accentia and each of the purchasers of Secured Convertible Debentures. (filed as Exhibit 10.2 to Accentia's Form 8-K filed October 2, 2006 and incorporated herein by reference).

10.113 Registration Rights Agreement, dated as of September 29, 2006, among Biovest, and each of the purchasers of Secured Convertible Debentures (filed as Exhibit 10.3 to Accentia's Form 8-K filed October 2, 2006 and incorporated herein by reference).

10.114 Pledge Agreement, dated as of September 29, 2006, among Accentia, each of the purchasers of Secured Convertible Debentures, and American Stock Transfer & Trust Company. (filed as Exhibit 10.4 to Accentia's Form 8-K filed October 2, 2006 and incorporated herein by reference).

10.115 Asset Purchase Agreement, dated as of October 4, 2006, among Accentia, TEAMM Pharmaceuticals, Inc. and Tiber, Inc. (filed as Exhibit 10.1 to Accentia's Form 8-K filed October 31, 2006 and incorporated herein by reference).

10.116[(b)] Amendment No. 1 to the First Amended and Restated Royalty Stream Purchase Agreement between Pharmaco *Investments, Inc., dated October 9, 2006 (filed as Exhibit 10.1 to Accentia's Form 8-K filed October 19, 2006* and incorporated herein by reference).

10.117 Amendatory and Supplemental Letter Agreement, dated as of October 12, 2006, among Accentia and Argent Development Group, LLC.

10.118 Mutual Termination Agreement, dated as of October 25, 2006, among Accentia, TEAMM Pharmaceuticals, Inc. and Acheron Development Group, LLC.

10.119 Mutual Termination Agreement, dated as of October 25, 2006, among Accentia, TEAMM Pharmaceuticals, Inc.

and Ryan Pharmaceuticals, Inc.

10.120 Fifth Amendment to Distribution Agreement, dated as of October 25, 2006, among Accentia, TEAMM Pharmaceuticals, Inc. and Argent Development Group, LLC.

10.121 Sixth Amendment to Distribution Agreement, dated as of October 25, 2006, among Accentia, TEAMM Pharmaceuticals, Inc. and Argent Development Group, LLC.

10.122 Trademark Assignment, dated as of October 27, 2006, among Accentia, TEAMM Pharmaceuticals, Inc. and Victory Pharma, Inc.

10.123 Termination of Agreement Letter, dated as of October 27, 2006, among Accentia and Mikart, Inc.

10.124 Settlement of Employment and Compensation Related Matters Between Accentia and Martin G. Baum dated October 26, 2006.

10.125 Settlement of All Accentia Biopharmaceuticals, Inc. and Subsidiary Employment and Compensation Related Matters Between Accentia and Nicholas J. Leb dated October 31, 2006.

10.126 Royalty Agreement between Accentia and Biovest dated October 31, 2006.

10.127 Termination Agreement between Accentia and Biovest dated October 31, 2006.

10.128 Purchase Agreement of Biolender, LLC between Accentia and Biovest dated October 31, 2006.

10.129 Consent between Accentia and Laurus dated October 31, 2006.

10.130 Common Stock Purchase Warrant, dated October 31, 2006 from Accentia to Laurus.

10.131 License and Asset Purchase Agreement, dated as of December 8, 2006, between Biovest and AutovaxID, Inc. (filed as Exhibit 10.1 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.132 License Agreement, dated as of December 8, 2006, between Biovest and AutovaxID, Inc. (filed as Exhibit 10.2 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.133 Secured Promissory Note, dated as of December 8, 2006, made by Biovest for the benefit of Accentia (filed as Exhibit 10.3 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.134 Loan and Security Agreement, dated as of December 8, 2006, between Leverage Fund and Biolender II (filed as Exhibit 10.4 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.135 Promissory Note, dated December 8, 2006, issued by AutovaxID Investment LLC ("Leverage Fund") to Biolender II, LLC (filed as Exhibit 10.5 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.136 Subordinated Promissory Note, dated December 8, 2006, from AutovaxID to the CDE (filed as Exhibit 10.6 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.137 QLICI Loan Agreement, dated as of December 8, 2006, by and among AutovaxID, the CDE and Biovest (filed as Exhibit 10.7 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.138 Subordination Agreement, dated as of December 8, 2006, by and among Laurus, St. Louis New Markets Tax Credit Fund-II, LLC ("CDE"), US Bancorp Community Investment Corporation ("USBCIC"), AutovaxID and Biovest (filed as Exhibit 10.8 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.139 Second Lien Security Agreement, dated December 8, 2006, from AutovaxID to the CDE (filed as Exhibit 10.9 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.140 Tax Credit Reimbursement and Indemnity Agreement, dated as of December 8, 2006, between AutovaxID and USBCIC (filed as Exhibit 10.10 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.141 Guaranty, dated December 8, 2006, made by Hopkins Capital Group II, LLC, Frances E. O'Donnell, Jr., Kathleen M. O'Donnell (as Trustee of the Frances E. O'Donnell, Jr. Irrevocable Trust), Dennis L. Ryll, Ronald E. Osman, Alan M. Pearce, Steven R. Arikian, Steven J. Stogel, Donald L. Ferguson, Donald L. Ferguson (as trustee of the Donald L. Ferguson Revocable Trust)] and Biovest in favor of USBCIC and the CDE (filed as Exhibit 10.11 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.142 Limited Liability Company Agreement of Biolender II, LLC, dated December 8, 2006 (filed as Exhibit 10.12 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.143 Put Option Agreement dated December 8, 2006, between AutovaxID, Leverage Fund, USBCIC and Biolender II (filed as Exhibit 10.13 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.144 Purchase Option Agreement dated December 8, 2006, between AutovaxID, Leverage Fund, USBCIC and Biolender II (filed as Exhibit 10.14 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.145 Indemnification Agreement, dated as of December 8, 2006, from Biovest to Dennis Ryll (filed as Exhibit 10.15 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.146 Indemnification Agreement, dated as of December 8, 2006, from Biovest to Steven Stogel (filed as Exhibit 10.16 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.147 Indemnification Agreement, dated as of December 8, 2006, from Biovest to Donald Ferguson (filed as Exhibit 10.17 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.148 Indemnification Agreement, dated as of December 8, 2006, from Biovest to Ronald Osman (filed as Exhibit 10.18 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.149 Indemnification Agreement, dated as of December 8, 2006, from Biovest to Francis O'Donnell (filed as Exhibit 10.19 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.150 Indemnification Agreement, dated as of December 8, 2006, from Biovest to Alan Pearce (filed as Exhibit 10.20 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.151 Indemnification Agreement, dated as of December 8, 2006, from Biovest to Steven Arikian (filed as Exhibit 10.21 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.152 Subscription Agreement, dated December 8, 2006, between Biovest and SLDC (filed as Exhibit 10.27 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.153 Common Stock Purchase Warrant, dated December 14, 2006 issued by Biovest to Dennis Ryll (filed as Exhibit 10.28 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.154 Common Stock Purchase Warrant, dated December 14, 2006 issued by Biovest to Steven Stogel (filed as Exhibit 10.29 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.155 Common Stock Purchase Warrant, dated December 14, 2006 issued by Biovest to Donald Ferguson (filed as Exhibit 10.30 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.156 Common Stock Purchase Warrant, dated December 14, 2006 issued by Biovest to Ronald Osman (filed as Exhibit 10.31 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.157 Common Stock Purchase Warrant, dated December 14, 2006 issued by Biovest to Hopkins Capital Group II, LLC (filed as Exhibit 10.32 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.158 Common Stock Purchase Warrant, dated December 14, 2006 issued by Biovest to Alan Pearce (filed as Exhibit 10.33 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.159 Common Stock Purchase Warrant, dated December 14, 2006 issued by Biovest to Steven Arikian (filed as Exhibit 10.34 to Accentia's Form 8-K filed December 14, 2006 and incorporated herein by reference).

10.160 Notice to Exercise of Option to Terminate Services dated December 15, 2006 from Accentia to Pharmaco Investments, Inc. and Pharmaceutical Product Development, Inc.

21 Subsidiaries of the Accentia (filed as Exhibit 21 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference.

31.1 Certification of Chief Executive Officer pursuant to Rules 13a-14 and 15d-15 promulgated under the Securities Exchange Act of 1934.

31.2 Certification of Chief Financial Officer pursuant to Rules 13a-14 and 15d-15 promulgated under the Securities Exchange Act of 1934.

32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003.

32.2 Certificate of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2003.

(a) Indicates management contract or compensatory plan

(b) Portions of this exhibit have been omitted pursuant to a confidential treatment request. Omitted information has been filed separately with the Securities and Exchange Commission.

Reports on Form 8-K

Current Report on Form 8-K dated November 8, 2005

Current Report on Form 8-K dated November 14, 2005

Current Report on Form 8-K dated November 29, 2005

Current Report on Form 8-K dated December 1, 2005

Current Report on Form 8-K dated December 9, 2005

Current Report on Form 8-K dated January 5, 2006

Current Report on Form 8-K dated March 2, 2006

Current Report on Form 8-K dated April 6, 2006

Current Report on Form 8-K dated April 12, 2006

Current Report on Form 8-K dated May 2, 2006

Current Report on Form 8-K dated May 15, 2006

Current Report on Form 8-K dated May 16, 2006

Current Report on Form 8-K dated May 19, 2006

Current Report on Form 8-K dated July 10, 2006

Current Report on Form 8-K dated July 19, 2006

Current Report on Form 8-K dated August 28, 2006

Current Report on Form 8-K dated September 11, 2006

Current Report on Form 8-K dated September 26, 2006

Current Report on Form 8-K dated October 2, 2006

Current Report on Form 8-K dated October 19, 2006

Current Report on Form 8-K dated November 1, 2006

Current Report on Form 8-K dated November 3, 2006

Current Report on Form 8-K dated November 15, 2006

Current Report on Form 8-K dated December 14, 2006

Accentia Biopharmaceuticals, Inc.

INDEX TO FINANCIAL STATEMENTS

Accentia Biopharmaceuticals, Inc. and Subsidiaries Consolidated Financial Statements

Report of Independent Registered Public Accounting Firm

To the Board of Directors

Accentia Biopharmaceuticals, Inc. and Subsidiaries

Tampa, Florida

We have audited the accompanying consolidated balance sheets of Accentia Biopharmaceuticals, Inc. and Subsidiaries as of September 30, 2006 and 2005 and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years ended September 30, 2006, 2005 and 2004. In connection with our audits of the consolidated financial statements, we have also audited the financial statement schedule listed in Item 15. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements and financial statement schedule based on our audits.

We conducted our audits in accordance with standards of the Public Company Accounting Oversight Board (United States of America). Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the consolidated financial position of Accentia Biopharmaceuticals, Inc. and Subsidiaries as of September 30, 2006 and 2005 and the consolidated results of their operations and their cash flows for the years ended September 30, 2006, 2005 and 2004 in conformity with accounting principles generally accepted in the United States of America. Also, in our opinion, the related financial statement schedule, when considered in relation to the consolidated financial statements taken as a whole, presents fairly, in all material respects, the information contained therein.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company incurred cumulative net losses of approximately $111.4 million during the three years ended September 30, 2006, $34.2 million of which was attributable to its 72% owned subsidiary, and, as of that date, had a working capital deficiency of approximately $20.5 million. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are described in Note 2. The financial statements do not include any adjustments with respect to the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

/s/ AIDMAN, PISER & COMPANY, P.A.

Tampa, Florida
December 20, 2006

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED BALANCE SHEETS

	September 30, 2006	September 30, 2005
ASSETS		
Current assets:		
Cash and cash equivalents	$ 15,391,799	$ 2,763,452
Cash, restricted, net of $2.3 million non-current portion	7,550,817	—
Accounts receivable:		
Trade, net of allowance for doubtful accounts of $366,309 and $345,458 at September 2006 and 2005, respectively	2,719,280	3,715,488
Stockholder	170,510	676,752
Inventories	1,500,185	1,013,896
Inventory deposits	997,149	844,740
Unbilled receivables	1,087,159	690,886
Prepaid expenses and other current assets	700,490	385,241
Total current assets	30,117,389	10,090,455
Cash, restricted, non-current	2,328,584	—
Goodwill	1,193,437	1,193,437
Other intangible assets:		
Product rights	19,914,707	21,216,334
Non-compete agreements	2,104,000	2,104,000
Trademarks	1,634,659	1,631,474
Purchased customer relationships	1,268,950	1,268,950
Other intangible assets	648,288	648,040
Accumulated amortization	(7,783,227)	(5,631,122)
Total other intangible assets	17,787,377	21,237,676
Furniture, equipment and leasehold improvements, net	1,535,978	1,775,819
Deferred offering costs	—	821,573
Deferred finance costs	4,109,028	1,497,012
Other assets	64,449	64,621
	$ 57,136,242	$ 36,680,593

(Continued)

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(CONTINUED)

	September 30, 2006	September 30, 2005
LIABILITIES AND STOCKHOLDERS' DEFICIT		
Current liabilities:		
Current maturities of long-term debt:		
Related party	$ —	$ 7,414,742
Other	5,652,152	8,888,847
Lines of credit:		
Related party	1,060,497	—
Other	13,925,473	5,052,604
Accounts payable (including related party of $688,135 and $346,423 at September 30, 2006 and 2005, respectively)	8,016,559	5,519,626
Accrued expenses (including related party accrued interest of $-0- and $147,983 at September 2006 and 2005, respectively)	10,160,946	6,917,721
Unearned revenues	1,395,098	863,096
Product development obligations (including $-0- and $200,000 due to related party at September 30, 2006 and 2005, respectively)	—	500,000
Dividends payable	479,452	575,447
Stockholder advances and notes	—	350,000
Customer deposits	1,025,404	828,050
Deposits, related party	3,000,000	3,000,000
Derivative liability	5,870,088	10,802,825
Total current liabilities	50,585,669	50,712,958
Long-term debt, net of current maturities:		
Related party	—	3,661,917
Other	27,021,205	4,902,666
Line of credit, related party	—	4,180,000
Other liabilities, related party	2,370,200	2,574,865
Total liabilities	79,977,074	66,032,406

(Continued)

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(CONTINUED)

	September 30, 2006	September 30, 2005
Non-controlling interest in variable interest entities	3,600,000	—
Commitments and contingencies (Notes 17 and 18)	—	—
Stockholders' deficit:		
Common stock, $0.001 par value; 300,000,000 shares authorized; 31,716,279 and 5,170,421 shares issued and outstanding at September 30, 2006, and 2005, respectively	31,716	5,170
Preferred stock, Series A, $1.00 par value; 10,000,000 shares authorized; -0- and 2,937,013 shares issued and outstanding at September 30, 2006, and 2005	—	6,183,000
Preferred stock, Series B, $1.00 par value; 30,000,000 shares authorized; -0- and 3,895,888 shares issued and outstanding at September 30, 2006, and 2005, respectively	—	239,919
Preferred stock, Series C, $1.00 par value; 10,000,000 shares authorized; -0- and 3,562,607 shares issued and outstanding at September 30, 2006, and 2005, respectively	—	7,500,000
Preferred stock, Series D, $1.00 par value; 15,000,000 shares authorized; -0- and 4,672,482 shares issued and outstanding at September 30, 2006 and 2005, respectively	—	219,769
Preferred stock, Series E, $1.00 par value; 60,000,000 shares authorized; -0- and 20,506,178 shares issued and outstanding at September 30, 2006 and 2005, respectively	—	49,789,554
Additional paid-in capital	135,102,051	24,851,870
Accumulated deficit	(161,574,599)	(118,141,095)
Total stockholders' deficit	(26,440,832)	(29,351,813)
	$ 57,136,242	$ 36,680,593

See notes to consolidated financial statements.

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ending September 30,		
	2006	2005	2004
Net Sales			
Products	$ 10,163,780	$ 10,882,685	$ 10,528,756
Services	12,414,319	10,460,011	11,632,343
Related party, products	2,479,949	3,766,586	3,774,521
Related party, services	—	85,500	—
Total net sales	25,058,048	25,194,782	25,935,620
Cost of sales:			
Products	4,660,605	4,479,395	3,852,880
Services	3,724,698	3,753,930	4,960,710
Total cost of sales (exclusive of amortization of acquired product rights)	8,385,303	8,233,325	8,813,590
Gross margin	16,672,745	16,961,457	17,122,030
Operating expenses:			
Research and development	14,009,947	9,588,677	4,210,058
Research and development, related party	551,164	1,319,185	1,309,100
Sales and marketing	13,972,754	15,164,067	12,015,044
General and administrative	23,299,945	21,086,188	17,021,219
Royalties	1,460,268	1,717,291	387,130
Impairment charges	3,309,932	357,931	359,445
Other operating expense, related party	—	—	2,500,000
Total operating expenses	56,604,010	49,233,339	37,801,996
Operating loss	(39,931,265)	(32,271,882)	(20,679,966)
Other income (expense):			
Interest expense	(5,411,804)	(1,696,964)	(1,240,906)
Interest expense, net, related party	(1,092,388)	(2,119,621)	(1,485,616)
Derivative gain (loss)	1,241,019	(1,140,732)	—
Loss on extinguishment of debt	—	(4,808,782)	—
Loss on extinguishment of debt, related party	—	(2,361,894)	—
Absorption of prior losses against minority interest	1,690,010	150,000	—
Other income (expense)	109,524	(56,384)	78,164
Loss from continuing operations before income taxes	(43,394,904)	(44,306,259)	(23,328,324)
Income tax benefit	—	—	—
Net loss from continuing operations	(43,394,904)	(44,306,259)	(23,328,324)
Discontinued operations:			
Gain on sale of discontinued operations, net of $0 income tax expense	—	—	1,618,400
Loss from discontinued operations, net of $0 income tax benefit	—	(430,110)	(1,516,017)
Net loss	(43,394,904)	(44,736,369)	(23,225,941)
Constructive preferred stock dividend	—	(4,949,031)	(4,906,612)
Preferred stock dividends, other	(40,739)	(603,097)	(355,367)
Loss attributable to common stockholders	$ (43,435,643)	$ (50,288,497)	$ (28,487,920)
Weighted average shares outstanding, basic and diluted	27,890,825	5,147,222	4,875,683
Per share amounts, basic and diluted:			
Loss attributable to common stockholders per common share for:			
Continuing operations and minority interest	$ (1.56)	$ (9.69)	$ (5.86)
Discontinued operations	(0.00)	(0.08)	0.02
Loss attributable to common stockholders	$ (1.56)	$ (9.77)	$ (5.84)

See notes to consolidated financial statements.

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
YEARS ENDED SEPTEMBER 30, 2006, 2005 AND 2004

	Common Stock		Preferred Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balances, September 30, 2003	4,875,641	$ 10,264	13,308,715	$ 10,410,844	$ 12,063,693	$ (39,364,368)	$ (16,879,567)
Issuance of preferred stock for cash	—	—	7,500,000	15,789,000	—	—	15,789,000
Exercise of stock options and warrants	687	1	3,947	8,309	(3,434)	—	4,876
Series E preferred stock dividends	—	—	—	—	4,906,612	(5,262,289)	(355,677)
Stock-based compensation	—	—	—	—	3,707,132	—	3,707,132
Net loss for the year	—	—	—	—	—	(23,225,941)	(23,225,941)
Balances, September 30, 2004	4,876,328	$ 10,265	20,812,662	$ 26,208,153	$ 20,674,003	$ (67,852,598)	$ (20,960,177)

(Continued)

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
YEARS ENDED SEPTEMBER 30, 2006, 2005 AND 2004

	Common Stock		Preferred Stock		Additional Paid-In Capital	Accumulated Deficit	Total
Balances, September 30, 2004	4,876,328	$ 10,265	20,812,662	$ 26,208,153	$ 20,674,003	$ (67,852,598)	$ (20,960,177)
Issuances of common stock for cash	294,093	611	—	—	617,567	—	618,178
Issuance of preferred stock for cash	—	—	12,220,367	25,754,535	(100,297)	—	25,654,238
Issuance of preferred stock in exchange for debt	—	—	1,401,105	5,311,954	—	—	5,311,954
Issuance of preferred stock in payment of licensing rights	—	—	1,140,034	6,657,600	—	—	6,657,600
Issuance of warrants for product rights	—	—	—	—	200,000	—	200,000
Stock-based compensation	—	—	—	—	434,583	—	434,583
Repurchase of preferred stock warrants	—	—	—	—	(2,000,000)	—	(2,000,000)
Preferred stock dividends	—	—	—	—	4,949,031	(5,552,128)	(603,097)
Net loss for the year	—	—	—	—	—	(44,736,369)	(44,736,369)
Reclassification of derivative liability to equity	—	—	—	—	71,277	—	71,277
Effect of 1-for-2.1052 reverse stock split	—	(5,706)	—	—	5,706	—	—
Balances, September 30, 2005	5,170,421	$ 5,170	35,574,168	$ 63,932,242	$ 24,851,870	$ (118,141,095)	$ (29,351,813)

(Continued)

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
YEARS ENDED SEPTEMBER 30, 2006, 2005 AND 2004

	Common Stock		Preferred Stock		Additional Paid-In Capital	Accumulated Deficit	Total
Balances, September 30, 2005	5,170,421	$5,170	35,574,168	$63,932,242	$24,851,870	$(118,141,095)	$(29,351,813)
Conversion of preferred shares to common stock	20,910,908	20,911	(35,574,168)	(63,932,242)	63,911,331	—	—
Issuance of common stock for cash at initial public offering, net of offering costs	2,400,000	2,400	—	—	14,738,962	—	14,741,362
Issuance of common stock in private equity transaction, net of offering costs	1,647,000	1,647	—	—	7,719,073	—	7,720,720
Issuance of common stock for finance costs	100,000	100	—	—	349,900	—	350,000
Issuance of common stock for cash – options exercised	30,872	31	—	—	74,387	—	74,418
Issuance of common stock in cashless warrant exercise	533,253	533	—	—	(391)	—	142
Issuance of common stock warrants for deferred financing costs	—	—	—	—	5,714,967	—	5,714,967
Issuance of common stock warrants for services	—	—	—	—	82,740	—	82,740
Issuance of common stock warrants for intangible assets	—	—	—	—	793,306	—	793,306
Issuance of common stock upon conversion of notes payable and accrued interest	906,734	907	—	—	7,043,023	—	7,043,930
Series E Preferred Stock dividends converted to common stock	17,091	17	—	—	136,717	—	136,734
Other comprehensive income	—	—	—	—	—	2,139	2,139
Stock-based compensation	—	—	—	—	1,218,813	—	1,218,813
Preferred stock dividends	—	—	—	—	—	(40,739)	(40,739)
Reclassification of derivative liability to equity	—	—	—	—	8,467,353	—	8,467,353
Net loss for the year	—	—	—	—	—	(43,394,904)	(43,394,904)
Balances, September 30, 2006	31,716,279	$31,716	—	$—	$135,102,051	$(161,574,599)	$(26,440,832)

(Continued)

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
YEARS ENDED SEPTEMBER 30, 2006, 2005 AND 2004

(continued)

	Preferred Stock										
	Series A		Series B		Series C		Series D		Series E		
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount	Total
Balances, September 30, 2003...	1,298,214	$ 2,733,000	3,835,390	$ 80,742	3,562,607	$ 7,500,000	4,612,504	$ 97,102	—	$ —	$ 10,410,844
Issuance of preferred stock for cash.....	641,269	1,350,000	—	—	—	—	—	—	6,858,731	14,439,000	15,789,000
Exercise of stock options and warrants....	—	—	—	—	—	—	3,947	8,309	—	—	8,309
Balances, October 1, 2004.....	1,939,483	4,083,000	3,835,390	80,742	3,562,607	7,500,000	4,616,451	105,411	6,858,731	14,439,000	26,208,153
Issuance of preferred stock for cash.....	340,110	716,000	60,498	159,177	—	—	56,031	114,358	11,763,728	24,765,000	25,754,535
Issuance of preferred stock for extinguishment of debt.....	657,420	1,384,000	—	—	—	—	—	—	743,685	3,927,954	5,311,954
Issuance of preferred stock for licensing rights.....	—	—	—	—	—	—	—	—	1,140,034	6,657,600	6,657,600
Balances, October 1, 2005.....	2,937,013	6,183,000	3,895,888	239,919	3,562,607	7,500,000	4,672,482	219,769	20,506,178	49,789,554	63,932,242
Conversion of preferred shares to common stock	(2,937,013)	(6,183,000)	(3,895,888)	(239,919)	(3,562,607)	(7,500,000)	(4,672,482)	(219,769)	(20,506,178)	(49,789,554)	(63,932,242)
Balances, September 30, 2006...	—	$ —	—	$ —	—	$ —	—	$ —	—	$ —	$ —

See notes to consolidated financial statements.

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ending September 30,		
	2006	2005	2004
Cash flows from operating activities:			
Net loss	$ (43,394,904)	$ (44,736,369)	$ (23,225,941)
Adjustments to reconcile net loss to net cash flows from operating activities:			
Loss on sale of property and equipment	179,940	—	—
Depreciation	687,035	705,959	593,256
Amortization	2,152,105	2,448,916	1,969,779
Stock-based cost of disposal of business	—	—	2,581,600
Stock-based compensation	1,218,812	434,583	683,236
Accretion of debt discounts	1,963,348	1,181,952	—
Derivative (gain) loss	(1,241,019)	1,140,732	—
Issuance of common stock warrants for services	82,740	—	—
Absorption of prior losses against minority interest	(1,690,010)	—	—
Other non-cash charges	2,141	(69,600)	95,350
Loss on extinguishment of debt	—	7,170,676	—
Impairment charges	3,309,932	357,931	359,445
Default interest charged	—	—	748,149
Increase (decrease) in cash resulting from changes in:			
Accounts receivable	1,502,450	(1,153,984)	1,625,247
Inventories	(486,289)	265,159	293,356
Inventory deposits	(152,409)	(844,740)	—
Unbilled receivables	(396,273)	(46,405)	(474,891)
Prepaid expenses and other current assets	(315,249)	33,059	270,880
Other assets	961,816	(268,567)	(13,078)
Accounts payable	2,496,933	(1,147,670)	(1,650,915)
Accrued expenses	3,788,415	1,996,248	(3,546,190)
Unearned revenues	532,002	(428,055)	405,497
Due to affiliate	—	—	113,981
Customer deposits	197,354	(32,048)	633,317
Net cash flows from operating activities	(28,601,130)	(32,992,223)	(18,537,922)
Cash flows from investing activities:			
Cash paid in business acquisition	—	—	(600,874)
Proceeds from sale of property and equipment	13,804	—	—
Release of restricted cash	5,248,183	—	1,270,823
Acquisition of furniture, equipment, and leasehold improvements	(640,938)	(478,743)	(784,524)
Cash paid for acquisition of product rights and other intangibles	(1,718,433)	(4,600,593)	(2,940,345)
Net cash flows from investing activities	2,902,616	(5,079,336)	(3,054,920)
Cash flows from financing activities:			
Deferred offering costs	821,573	(821,573)	—
Payments on notes payable and long-term debt	(14,765,226)	(2,268,616)	(5,250,004)
Proceeds from deposits and other liabilities	—	—	5,500,000
Proceeds from issuance of common stock, net of offering cost of $4,922,917	22,462,082	618,178	1
Proceeds from issuance of preferred stock	—	25,654,178	15,793,874
Proceeds from the exercise of stock options	74,418	—	—
Proceeds from non-controlling investment in variable interest entity	3,000,000	—	—
Payment of Series E preferred stock dividends	—	(316,311)	(67,015)
Proceeds (payments) on related party loans	(204,665)	4,180,000	2,943,299
Proceeds from convertible debentures (net of $7.3 million cash restricted in 2006 for debt payments)	16,121,416	10,000,000	—
Proceeds from long-term debt	2,000,000	—	524,531

Repayment of amounts due to stockholders	(439,025)	—	(885,418)
Proceeds from line of credit, net (net of $7.8 million cash restricted in 2006 for debt payments)	8,906,288	1,734,217	3,272,587
Issuance of common stock for finance costs	350,000	—	—
Proceeds from minority interest investment	—	150,000	—
Net cash flows from financing activities	38,326,861	38,930,073	21,831,855
Net change in cash and cash equivalents	12,628,347	858,514	239,013
Cash and cash equivalents at beginning of period	2,763,452	1,904,938	1,665,925
Cash and cash equivalents at end of period (net of $9.9 million cash restricted at September 30, 2006)	$ 15,391,799	$ 2,763,452	$ 1,904,938
Supplemental cash flow information:			
Cash paid for:			
Interest	$ 2,899,562	$ 3,424,730	$ 1,258,149
Income taxes	—	—	—

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(CONTINUED)

Supplemental Disclosure of Non-cash Investing and Financing Activities:

2006:

- The Company issued warrants valued at $0.8 million for product rights.
- An aggregate of $0.04 million in preferred dividends were declared but unpaid during the year ended September 30, 2006.
- The Company paid for $5.7 million of Capitalized Finance Costs through the issuance of common stock warrants.
- The Company converted $7.0 million in debt into equity in 2006.
- The Company incurred $0.2 million in debt to reduce accrued expenses in 2006.
- The Company borrowed $7.8 million from Laurus in 2006 which was restricted cash at the time of the transaction. $5.2 million of those restricted funds were released in 2006.
- $7.3 million of the proceeds from the Convertible Debenture financing are held in escrow and classified as restricted cash.
- During 2006, $8.5 million of derivative liabilities were reclassified to equity.

2005:

- The Company issued warrants valued at $0.2 million for product rights.
- The Company issued 1.1 million shares of Series E preferred stock with a fair value of $6.7 million in exchange for $6.6 million in product rights and $0.1 million for general and administrative expenses.
- The Company issued 743,685 shares of Series E preferred stock and 657,420 shares of Series A preferred stock with a fair value of $5.3 million in settlement of $2.9 million of related party debt obligations (including interest) resulting in a $2.4 million loss on extinguishment of debt, related party.
- The Company repurchased 1,424,074 warrants at a cost of $2.0 million, which was financed by a $2.0 million increase in notes payable.
- An aggregate of $0.3 million in preferred dividends were accrued but unpaid in 2005.
- The Company repaid $3.0 million net advances from the Missouri State Bank line of credit with a portion of the Laurus Master Fund Ltd. note proceeds.
- In 2005, the Company recognized $4.0 million in discounts associated with warrants and beneficial conversion feature for convertible feature for convertible debentures.

2004:

- The Company assumed net liabilities aggregating $0.3 million in connection with its acquisition of its Germany subsidiary.
- In connection with the acquisition of product rights of $4.4 million, the Company entered into short-term financing arrangements with the seller for a like amount.
- The Company has issued warrants to purchase 1,008,120 shares of Series A and D preferred stock with a fair value of $0.8 million in connection with certain financing arrangements that have been accounted for as discounts on notes payable.
- An aggregate of $0.3 million in preferred dividends were accrued and were paid in December 2004.
- In 2004, the Company recognized a constructive dividend in the amount of $4.9 million in connection with a beneficial conversion feature for Series E preferred stock issued with warrants.

See notes to consolidated financial statements.

1. Description of business and summary of significant accounting policies

Business and organization

Accentia Biopharmaceuticals, Inc. and its subsidiaries, Analytica International, Inc. ("Analytica"), TEAMM Pharmaceuticals, Inc. ("TEAMM"), Accent RX, Inc. ("AccentRx"), Biovest International, Inc. ("Biovest"), and Accentia Specialty Pharmacy ("ASP") (collectively referred to as the "Company" or "Accentia") is a vertically integrated specialty biopharmaceutical company. The Company is focused on the development and commercialization of late-stage clinical products in the therapeutic areas of respiratory disease and oncology. The Company has two product candidates entering or in Phase 3 clinical trials. The first product candidate, SinuNase™, has been developed as a novel application and formulation of a known therapeutic to treat chronic rhinosinusitis. The second product candidate, BiovaxID™, is a patient-specific cancer vaccine focusing on the treatment of follicular non-Hodgkin's lymphoma. BiovaxID is currently in a pivotal Phase 3 clinical trial.

Segment reporting

The Company has operations in two business segments and, as a result, has adopted Statement of Financial Accounting Standards No. 131—Disclosures about Segments of an Enterprise and Related Information ("FAS 131"). FAS 131 establishes standards for reporting information about operating segments in annual financial statements. Operating segments are defined as components of an enterprise about which separate financial information is available and is evaluated on a regular basis by the chief operating decision maker or decision making group, in deciding how to allocate resources to an individual segment and in assessing performance of the segment. The Company has identified these segments based on the nature of business conducted by each. They are described as follows:

The Biopharmaceutical Products and Services segment ("Biopharmaceutical Segment") of the Company is focused on the research and development of contract cell production and biologic drug development and ownership, the production and contract manufacturing of biologic drugs and products and provides pre-market research, pharmacoeconomics and outcomes analyses to its pharmaceutical and biopharmaceutical partners and clients. This segment's two primary products are SinuNase and BiovaxID. This segment also develops, manufactures and markets patented cell culture systems and equipment to pharmaceutical, diagnostic and biotechnology companies, as well as leading research institutions worldwide, and has provided contract cell production services to those institutions. Additionally, this segment provides strategic services prior to product launch, such as technology assessment and valuation, and formulary and strategic reimbursement planning.

The Specialty Pharmaceuticals segment markets and sells pharmaceutical products that are developed primarily through third-party development partners. This segment currently sells a portfolio of ten pharmaceutical products and has a pipeline of additional products under development by our development partners. Currently marketed specialty pharmaceutical products include Respi-TANN®, a prescription antitussive decongestant for temporary relief of cough and nasal congestion, and MD Turbo.

Principles of consolidation

The accompanying consolidated financial statements include the accounts of Accentia, its three wholly-owned subsidiaries, its 72% owned subsidiary, and certain entities that qualify as variable interest entities where the Company or a consolidated subsidiary are considered the primary beneficiary (see Variable interest entities, below). All intercompany accounts and transactions have been eliminated. The Company does not currently recognize a minority interest in its 72% owned subsidiary pursuant to Accounting Research Bulletin 51, Consolidated Financial Statements. Where losses applicable to the minority interest in a subsidiary exceed the minority interest in the equity capital of the subsidiary, such excess and any further losses applicable to the minority interest shall be charged against the majority interest, as there is no obligation of the minority interest to make good such losses. However, if future minority equity or earnings do materialize, the majority interest will be credited to the extent of such losses previously absorbed. The Company currently records any equity raised through Biovest as Absorption of Prior Losses Against Minority Interest in the Other Income section on the Consolidated Statement of Operations. The Company will continue to record these transactions in this manner until losses applicable to Biovest no longer exceed the minority interest in the equity capital of Biovest.

Variable interest entities

The Company evaluates all significant arrangements and relationships for indications of variable interest entities pursuant to Financial Accounting Standards Board Interpretation 46R, *Consolidation of Variable Interest Entities* As discussed in Note 19, during April 2006, the Company and Biovest entered into a financing arrangement that involved entities that met the definition of variable interest entities. As a result, the Company was required to consolidate these entities and reflect the non-controlling interest of $3,600,000 in its financial statements.

Use of estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States of America requires management to make judgments, assumptions and estimates that affect the amounts reported in the financial statements and accompanying notes. Actual results could differ materially from those estimates.

Cash and cash equivalents

The Company considers all highly-liquid investments purchased with an original maturity of three months or less to be cash equivalents.

Concentrations of credit risk and customer and vendor concentrations

Financial instruments that subject the Company to concentrations of credit risk include cash and accounts receivable. The Company places its cash in several high-quality financial institutions. Such amounts are insured by the FDIC up to $100,000 per institution.

Accounts receivable are customer obligations due under normal trade terms. The Company sells its products to pharmaceutical distribution companies and retail organizations nationwide. The Company performs ongoing credit evaluations of customers' financial condition and does not require collateral.

Management reviews accounts receivable on a monthly basis to determine collectibility. Balances that are determined to be uncollectible are written off to the allowance for doubtful accounts. The allowance for doubtful accounts contains a general accrual for estimated bad debts and had a balance of approximately $0.4 million and $0.3 million at September 30, 2006 and 2005 respectively, which management considers adequate; however actual write-offs may exceed the allowance.

As set forth below, two customers in the Specialty Pharmaceuticals segment accounted for approximately 36% of consolidated net sales for the year ended September 30, 2006. One of these customers (McKesson) accounted for approximately 6% of the Company's trade accounts receivable balance as September 30, 2006. They are as follows:

	Sales
Customer 1	19%
Customer 2 (McKesson)	17%
	36%

As set forth below, one customers in the Specialty Pharmaceuticals segment accounted for approximately 25% of consolidated net sales for the year ended September 30, 2005. This customer accounted for approximately 19% of the Company's trade receivables as of September 30, 2005.

	Sales
Customer 1	25%
	25%

As set forth below, three customers in the Specialty Pharmaceuticals segment accounted for approximately 40% of consolidated net sales for the year ended September 30, 2004. They are as follows:

	Sales
Customer 1	15%
Customer 2 (McKesson)	15%
Customer 3	10%
	40%

One vendor in the Specialty Pharmaceuticals segment provided approximately 14% of total product purchases during the year ended September 30, 2006.

Two vendors in the Specialty Pharmaceuticals segment provided approximately 27% of total product purchases during the year ended September 30, 2005. They are as follows:

	Purchases
Vendor 1	16%
Vendor 2	11%
	27%

Two vendors in the Specialty Pharmaceuticals segment provided approximately 21% of total product purchases during the year ended September 30, 2004. They are as follows:

	Purchases
Vendor 1	11%
Vendor 2	10%
	21%

Inventories

Inventories consist primarily of trade pharmaceutical products, supplies/parts used in instrumentation assembly and related materials. Inventories are stated at the lower of cost or market with cost determined using the first-in first-out ("FIFO") method. In evaluating whether inventory is stated at the lower of cost or market, management considers such factors as the amount of inventory on hand and in the distribution channel, estimated time required to sell such inventory, remaining shelf life and current and expected market conditions, including levels of competition. As appropriate, a provision is recorded to reduce inventories to their net realizable value.

Furniture, equipment and leasehold improvements

Furniture, equipment and leasehold improvements are stated at cost, less accumulated depreciation. Depreciation is determined using straight-line and accelerated methods over the estimated useful lives of three to seven years for furniture and equipment. Amortization of leasehold improvements is over the shorter of the improvements' estimated economic lives or the related lease terms.

Goodwill and intangible assets

Intangible assets include trademarks, product rights, noncompete agreements, technology rights, purchased customer data relationships and patents, and are accounted for based on Financial Accounting Standard Statement No. 142 *Goodwill and Other Intangible Assets* ("FAS 142"). In that regard, goodwill and intangible assets that have indefinite useful lives are not amortized but are tested at least annually for impairment, or more frequently if events or changes in circumstances indicate that the asset might be impaired. The Company has identified certain trademarks, and purchased customer relationships as intangible assets with indefinite lives and, therefore, these assets are not amortized.

Intangible assets with finite useful lives are amortized over the estimated useful lives from the date of acquisition as follows:

Noncompete agreements	2 to 4 years
Customer relationships	10 years
Software	3 years
Patents	3 years
Product rights	4.5 to 20.5 years

Deferred finance costs

Deferred finance costs will be amortized over the term of the related financial instrument. Approximate future amortization of deferred finance costs:

Year ending September 30,	
2007	$ 1,568,000
2008	1,020,000
2009	612,000
2010	606,000
Thereafter	304,000
	$ 4,110,000

Advertising expense

The Company expenses the costs of advertising, which includes promotional expenses, as incurred. For the years ended September 30, 2006, 2005, and 2004, advertising expenses were nominal.

Income taxes

Deferred income tax assets and liabilities are computed annually for differences between the financial statements and income tax bases of assets and liabilities that will result in taxable or deductible amounts in the future, based on enacted tax laws and rates applicable to the periods in which the differences are expected to affect taxable income. Valuation allowances are established when necessary to reduce deferred tax assets to the amount expected to be realized.

Financial instruments

Financial instruments, as defined in Financial Accounting Standard No. 107 Disclosures about Fair Value of Financial Instruments (FAS 107), consist of cash, evidence of ownership in an entity and contracts that both (i) impose on one entity a contractual obligation to deliver cash or another financial instrument to a second entity, or to exchange other financial instruments on potentially unfavorable terms with the second entity, and (ii) conveys to that second entity a contractual right (a) to receive cash or another financial instrument from the first entity or (b) to exchange other financial instruments on potentially favorable terms with the first entity. Accordingly, the Company's financial instruments consist of cash and cash equivalents, accounts receivable, accounts payable, accrued liabilities, long-term debt, derivative financial instruments, and convertible debentures.

The Company carries cash and cash equivalents, accounts receivable, accounts payable, and accrued liabilities at historical costs; their respective estimated fair values approximate carrying values due to their current nature. The Company also carries notes payable and convertible debt, included in long-term debt, at historical cost; however, fair values of these debt instruments are estimated for disclosure purposes based upon the present value of the estimated cash flows at market interest rates applicable to similar instruments. The fair value of the Company's historical cost debt instruments, including deposits and other liabilities, if recalculated based on current interest rates (*11.25% current* borrowing rate) would be approximately $30.5 million or $3.3 million lower than the recorded amounts at September 30, 2006. The Company carries its convertible debentures at fair value pursuant to Financial Accounting Standard No. 155 Accounting for Certain Hybrid Financial Instruments (FAS 155).

In February 2006, the FASB issued Statement of Financial Accounting Standard (SFAS) No. 155 (SFAS No. 155), "Accounting for Certain Hybrid Financial Instruments—An Amendment Of FASB Statements No. 133 and 140", to simplify and make more consistent the accounting for certain financial instruments. Specifically, SFAS No. 155 amends SFAS No. 133, "Accounting for Derivative Instruments and Hedging Activities", to permit fair value re-measurement for any hybrid financial instrument with an embedded derivative that otherwise would require bifurcation provided that the whole instrument is accounted for on a fair value basis. Prior to fair value measurement, however, interests in securitized financial assets must be evaluated to identify interests containing embedded derivatives requiring bifurcation. SFAS No. 155 applies to all financial instruments acquired or issued after the beginning of an entity's first fiscal year that begins after September 15, 2006, with earlier application allowed.

The Company generally does not use derivative financial instruments to hedge exposures to cash-flow, market or foreign-currency risks. However, the Company and its consolidated subsidiaries have entered into certain other financial instruments and contracts, such as debt financing arrangements and freestanding warrants with features that are either (i) not afforded equity classification, (ii) embody risks not clearly and closely related to host contracts, or (iii) may be net-cash settled by the counterparty. Except as provided in FAS 155, these instruments are required to be carried as derivative liabilities, at fair value, in our financial statements. In instances, where the Company elects not to bifurcate embedded derivative features, the entire hybrid instrument is carried at fair value in the financial statements.

The Company estimates fair values of derivative financial instruments using various techniques (and combinations thereof) that are considered to be consistent with the objective measuring fair values. In selecting the appropriate technique(s), management considers, among other factors, the nature of the instrument, the market risks that it embodies and the expected means of settlement. For less complex derivative instruments, such as free-standing warrants, the Company generally uses the Black-Scholes-Merton option valuation technique because it embodies all of the requisite assumptions (including trading volatility, estimated terms and risk free rates) necessary to fair value these instruments. For complex derivative instruments, such as embedded conversion options, the Company generally uses the Flexible Monte Carlo valuation technique because it embodies all of the requisite assumptions (including credit risk, interest-rate risk and exercise/conversion behaviors) that are necessary to fair value these more complex instruments. For forward contracts that contingently require net-cash settlement as the principal means of settlement, management projects and discounts future cash flows applying probability-weightage to multiple possible outcomes. Estimating fair values of derivative financial instruments requires the development of significant and subjective estimates that may, and are likely to, change over the duration of the instrument with related changes in internal and external market factors. In addition, option-based techniques are highly volatile and sensitive to changes in the Company's trading market price which has high-historical volatility. Since derivative financial instruments are initially and subsequently carried at fair values, the Company's income will reflect the volatility in these estimate and assumption changes.

The following tabular presentation reflects the components of derivative financial instruments on the Company's balance sheet at:

	September 30,	
	2006	2005
Embedded derivative instruments that have been bifurcated	$ —	$ 4,707,955
Freestanding derivatives (principally warrants)	5,633,719	6,094,870
Default Put Liability	236,369	—
	$ 5,870,088	$ 10,802,825

The following tabular presentation reflects the number of common shares into which the aforementioned derivatives are indexed as of:

	September 30,	
	2006	2005
Common shares indexed:		
Embedded derivative instruments that have been bifurcated	—	2,674,975
Freestanding derivatives (principally warrants)	3,136,201	1,018,797
Default Put Liability	—	—
	3,136,201	3,693,772

Derivative income (expense) in the accompanying statement of operations is related to the individual derivatives as follows:

	Year Ending September 30,		
	2006	2005	2004
Embedded derivative instruments	$ 2,090,963	$ (230,709)	$ —
Freestanding derivatives (warrants)	(1,043,025)	(910,023)	—
Default Put Liability	193,081	—	—
	$ 1,241,019	$ (1,140,732)	$ —

Foreign currency translation

The Company translates the assets and liabilities of its non-U.S. functional currency subsidiary into dollars at the current rates of exchange in effect at the end of each reporting period, while net sales and expenses are translated using the average exchange rate. Foreign currency translation adjustments were nominal during the period and, as such, no adjustments have been recognized in the accompanying consolidated financial statements.

Impairment of long-lived assets

Indefinite lived assets, including goodwill, are tested for impairment at least annually. The Company will perform this test annually, effective as of the last day of the fourth fiscal quarter of each year. The Company recognized impairment losses of $3.3 million, $0.4 million and $0.4 million during the years ended September 30, 2006, 2005 and 2004, respectively. See Note 15 for further discussion.

Revenue recognition

Biopharmaceutical Products and Services

The Company recognizes revenue in its Biopharmaceutical Products and Services segment as follows:

Services

Service revenue is generated primarily by fixed price contracts for cell culture production and consulting services. Such revenue is recognized over the contract term based on the percentage of services cost incurred during the period compared to the total estimated service cost to be incurred over the entire contract. The nature and scope of the Company's contracts often require the Company to make judgments and estimates in recognizing revenues. Estimates of total contract revenues and costs are continuously monitored during the term of the contract, and recorded revenues and costs are subject to revision as each contract progresses. Such revisions may result in increases or decreases to revenues and income and are reflected in the consolidated financial statements in the periods in which they are first identified. Each month the Company accumulates costs on each contract and compares them to the total current estimated costs to determine the percentage of completion. The Company then applies this percentage to the total contract value to determine the amount of revenue that can be recognized. Each month the Company reviews the total current estimated costs on each contract to determine if these estimates are still accurate and, if necessary, the Company adjusts the total estimated costs for each contract. As the work progresses, the Company might decide that original estimates were incorrect due to, among other things, revisions in the scope of work, and a contract modification might be negotiated with the customer to cover additional costs. If a contract modification is not agreed to, the Company could bear the risk of cost overruns. Losses on contracts are recognized during the period in which the loss first becomes probable and reasonably estimable. Reimbursements of contract-related costs are included in revenues. An equivalent amount of these reimbursable costs is included in cost of sales. Because of the inherent uncertainties in estimating costs, it is at least reasonably possible that the estimates used will change within the near term.

Contract costs related to cell culture production include all direct material, subcontract and labor costs and those indirect costs related to contract performance, such as indirect labor, insurance, supplies and tools. The Company believes that actual cost incurred in contract cell production services is the best indicator of the performance of the contractual obligations, because the costs relate primarily to the amount of labor incurred to perform such services. The deliverables inherent in each of the Company's cell culture production contracts are not output driven, but rather driven by a pre-determined production run. The duration of the Company's cell culture production contracts range typically from 2 to 14 months.

Revenues stemming from consulting services are recognized based on the percentage of service cost incurred during the period compared to the total estimated service cost to be incurred over the entire contract. Service costs relating to the Company's consulting services consist primarily of internal labor expended in the fulfillment of the Company's consulting projects and, to a lesser extent, outsourced research services. Service costs on a specific project may also consist of a combination of both internal labor and outsourced research service. The Company's consulting projects are priced and performed in phases, and the projects are managed by phase. As part of the contract bidding process, the Company develops an estimate of the total number of hours of internal labor required to generate each phase of the customer deliverable (for example, a manuscript or database), and the labor cost is then computed by multiplying the hours dedicated to each phase by a standard hourly labor rate. The Company also determines whether the Company needs services from an outside research or data collection firm and includes those estimated outsourced costs in the Company's total contract cost for the phase. At the end of each month, the Company collects the cumulative total hours worked on each contract and applies a standard labor cost rate to arrive at the total labor cost incurred to date. This amount is divided by the total estimated contract cost to arrive at the percentage of completion, which is then applied to the total estimated contract revenues to determine the revenue to be recognized through the end of the month. Accordingly, as hours are accumulated against a project and the related service costs are incurred, the Company concurrently fulfills its contract obligations. The duration of the Company's consulting

service contracts range typically from 1 to 6 months. Certain other professional service revenues are recognized as the services are performed.

The asset unbilled receivables represents revenue that is recognizable under the percentage of completion method due to the performance of services for which billings have not been generated as of the balance sheet date. In general, amounts become billable pursuant to contractual milestones or in accordance with predetermined payment schedules. Under the Company's consulting services contracts, the customer is required to pay for contract hours worked by the Company (based on the standard hourly rate used to calculate the contract price) even if the customer cancels the contract and elects not to proceed to completion of the project.

Pursuant to these contracts, the project is typically billed in two or three equal installments at different times over the duration of the engagement, and therefore it is possible that contractually prescribed billing date will occur after the hours are worked. There are instances in which the scope of a project may be reduced (or increased) after work has commenced. In order to ensure proper revenue recognition, the Company evaluates changes in the scope of all open projects on a monthly basis in order to determine whether the estimated revenues and costs at completion are valid in light of current contractual and customer expectations. In cases in which the scope of a project is reduced, the Company documents the understanding with its customer regarding the scope reduction as well as the revised total amounts billable under the contract. The Company then evaluates revenues recognized to date based on the old estimates; revises the total estimated contract costs, revenues, and percentage of completion to date; and applies this revised percentage to the new estimated total contract revenue. If the amount of revenue recognizable based on the new estimates is less than revenues recognized to date, the Company reverses the excess revenue in the period of the change and accordingly reduces receivables in accordance with generally accepted accounting principles.

Unearned revenues represent customer payments in excess of revenue earned under the percentage of completion method. Such payments are made in accordance with predetermined payment schedules set forth in the contract.

Products

Net sales of instruments and disposables are recognized in the period in which the rewards of ownership have passed (at point of shipment) to the buyer. The Company does not provide its customers with a right of return; however, deposits made by customers must be returned to customers in the event of non-performance by the Company.

Specialty Pharmaceuticals

Revenue from product sales is recognized when all of the following occur: a purchase order is received from a customer; title and risk of loss pass to the Company's customer upon the receipt of the shipment of the merchandise under the terms of FOB destination; prices and estimated sales provisions for product returns, sales rebates, payment discounts, chargebacks, and other promotional allowances are reasonably determinable; and the customer's payment ability has been reasonably assured. An estimate of three days from the time the product is shipped via common carrier until it reaches the customer is used for purposes of determining FOB destination. Revenues in connection with co-promotion agreements are recognized based on the terms of the agreements.

Concurrently with the recognition of revenue, the Company records estimated sales provisions for estimated product returns, sales rebates, payment discounts, chargebacks, and other sales allowances. Estimates are established base upon consideration of a variety of factors, including but not limited to, historical relationship to revenues, historical payment and return experience, estimated customer inventory levels, customer rebate arrangements, and current contract sales terms with wholesale and indirect customers.

Actual product returns, chargebacks and other sales allowances incurred are, however, dependent upon future events and may be different than the Company's estimates. The Company continually monitors the factors that influence sales allowance estimates and makes adjustments to these provisions when management believes that actual product returns, chargebacks and other sales allowances may differ from established allowances.

Provisions for these sales allowances are presented in the consolidated financial statements as reductions to net revenues and included as current accrued expenses in the balance sheet. These allowances approximated $ 0.4 million, $0.2 million, $1.7 million as of September 30, 2006, 2005 and 2004.

During 2004, the Company entered into an agreement with Pharmaceutical Product Development, Inc. ("PPD"), a common stockholder (see Note 10 for a full discussion of the agreement). In connection with the agreement, PPD acquired future royalty rights in exchange for $2.5 million received by the Company in September 2004; however, the agreement provides for return of the net purchase price ($2.5 million less royalty payments remitted to date) should royalties received by PPD through December 2009 be less than $2.5 million. In addition, there are certain other default provisions that would require the Company's return of the net funds received. As a result, Accentia will recognize revenue in the future as royalties are

remitted to PPD. As of September 30, 2006 and September 2005, the balance of this liability is $2.4 million, reflecting royalties payable to PPD accrued as of the date (included in other liabilities, related party on the balance sheets).

Cost of sales

Cost of sales excludes amortization of acquired product rights of $2.2 million, $1.5 million, $0.4 million in 2006, 2005, and 2004, respectively.

Shipping and handling costs

Shipping and handling costs are included as a component of cost of sales in the accompanying consolidated statements of operations.

Research and development

The Company expenses research and development costs as incurred. Such costs include payroll and related costs, facility costs, consulting and professional fees, equipment rental and maintenance, lab supplies, and certain other indirect cost allocations that are directly related to research and development activities. The Company incurred total research and development expenses of $14.6 million in the year ended September 30, 2006, $10.9 million in the year ended September 30, 2005 and $5.5 million in the year ended September 30, 2004.

Stock-based compensation

The Company has adopted the accounting provisions of Statement of Financial Accounting Standards No. 123R—Accounting for Stock-Based Compensation ("FAS 123R"), which requires the use of the fair-value based method to determine compensation for all arrangements under which employees and others receive shares of stock or equity instruments (warrants and options). The Company uses the Black-Scholes options-pricing model to determine the fair value of each option grant.

In applying the Black-Scholes options-pricing model, assumptions are as follows:

2006	Range of values	Weighted Avg.
Dividend yield	$0	$ 0
Expected volatility	89.53%	89.53%
Risk free interest rate	4.32 – 4.60%	4.50%
Expected life	6.0 to 6.50 years	6.25 years

2005	Range of values	Weighted Avg.
Dividend yield	$0	$ 0
Expected volatility	0% to 50%	12.83%
Risk free interest rate	2.05 – 3.53%	2.38%
Expected life	0.5 to 5 years	0.71 years

2004:	Range of values	Weighted Avg.
Dividend yield	$0	$ 0
Expected volatility	0% to 45.174%	1.35%
Risk free interest rate	1.62 – 3.93%	2.48%
Expected life	1 to 5 years	1.96 years

Net loss per common share

The Company had net losses for all periods presented in which potential common shares were in existence. Diluted loss per share assumes conversion of all potentially dilutive outstanding common stock options and warrants. Potential common shares outstanding are excluded from the calculation of diluted loss per share if their effect is anti-dilutive. As such, dilutive loss per share is the same as basic loss per share for all periods presented as the effect of all options outstanding is anti-dilutive.

The following table sets forth the calculations of basic and diluted net loss per share:

	September 30,		
	2006	2005	2004
Numerator:			
Net loss applicable to common stockholders	$ (43,435,643)	$ (50,288,497)	$ (28,487,920)
Denominator:			
For basic loss per share—weighted average shares	27,890,825	5,147,222	4,875,683
Effect of dilutive securities	—	—	—
Weighted average shares for dilutive loss per share	27,890,825	5,147,222	4,875,683
Net loss per share applicable to common stockholders, basic and diluted	$ (1.56)	$ (9.77)	$ (5.84)
EPS effect of preferred dividends	$ 0.00	$ (1.08)	$ (2.16)

The effect of common stock equivalents and common shares indexed to our convertible debt securities are not considered in the calculation of diluted loss per share because the effect would be anti-dilutive. They are as follows:

	2006	2005	2004
Options and warrants to purchase common stock	8,302,147	3,027,933	1,933,158
Convertible debt instrument	11,263,867	1,790,882	—
Preferred stock convertible to common stock	—	35,574,154	20,812,662
Preferred stock options and warrants convertible to preferred which is then convertible to common	—	1,211,502	15,307,015

Reclassification:

Certain amounts in the 2005 and 2004 financial statements have been reclassified to conform with the 2006 presentation.

Deferred offering costs:

Deferred offering costs at September 30, 2005 represent legal, accounting and other costs associated with the initial public offering that were charged to additional paid-in capital in fiscal 2006 upon completion of the initial public offering.

Recent accounting pronouncements

The Financial Accounting Standards Board ("FASB") has recently announced a new interpretation, FASB Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" (FIN 48), which will be effective for fiscal years beginning after December 15, 2006. FIN 48 clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements in accordance with FASB Statement No. 109, "Accounting for Income Taxes". FIN 48 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. FIN 48 also provides guidance on derecognition, classification, interest and penalties, accounting in interim periods, disclosure and transition. The Company has not determined the impact of the adoption of FIN 48 on its consolidated financial statements.

In September 2006, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 157, "Fair Value Measurements" ("SFAS 157"). SFAS 157 clarifies the definition of fair value, describes methods used to appropriately measure fair value, and

expands fair value disclosure requirements. This statement is effective for fiscal years beginning after November 15, 2007. The Company is currently in the process of assessing the impact that SFAS 157 will have on the consolidated financial statements.

2. Liquidity and management's plans

The accompanying financial statements have been prepared on a going concern basis, which assumes Accentia will realize its assets and discharge its liabilities in the normal course of business. As reflected in the accompanying consolidated financial statements, the Company incurred net losses of $111.3 million and used cash from operations of $79.8 million during the three years ended September 30, 2006, and has a working capital deficit of $20.5 million at September 30, 2006. The Company projects operating deficits for fiscal 2007 before consideration of potential funding sources for this same period. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Funding to date of the Company's working capital requirements has resulted principally from the issuance of common and preferred stock and proceeds from debt.

A breakdown of the losses between Accentia and Biovest is as follows:

	(in millions)		
	2006	2005	2004
Accentia	$ 29.7	$ 33.2	$ 14.2
Biovest	$ 13.7	$ 11.5	$ 9.0
Consolidated	$ 43.4	$ 44.7	$ 23.2

Since the Company's inception, operations have been funded primarily through its Initial Public Offering ("IPO") which closed on November 2, 2005, with gross and net proceeds of $19.2 million and $14.7 million, private placements of capital stock, debt financing, conversions of debt to equity, and financing transactions with strategic partners. In May 2006 we closed a private placement of common stock with 19 institutional investors with gross and net proceeds of $8.2 million and $7.7 million respectively. In September 2006, we closed a private placement of convertible and exchangeable debentures with 10 institutional investors with gross and net proceeds of $25.0 million and $23.5 million respectively. These transactions are described throughout the footnotes.

The Company has $3.3 million available under the Hopkins II line of credit.

While the Company is currently engaged in efforts to restructure certain existing indebtedness (including $4.0 million line of credit and $2.0 million term note obligations due in January 2007 – see Notes 9 and 10) in order to increase available funds on a near-term basis, and they also intend to seek additional financing during the next six months through one or more public or private equity offerings, additional debt financings, corporate collaborations, or licensing transactions, the Company cannot be certain that additional funding will be available on acceptable terms, or at all. If adequate funds are not available, the Company may be required to delay, reduce the scope of, or eliminate one or more of the research or development programs or commercialization efforts.

The Company further anticipates that Biovest will seek additional financing during the next six months through public and private equity offerings, debt financings, corporate collaborations, or licensing transactions. As of December 1, 2006, an aggregate of $6.8 million intercompany demand notes payable to Accentia by Biovest are outstanding, representing funds advanced to Biovest in excess of the funding commitment under the investment agreement plus intercompany obligations arising from the conversion of Biovest notes into common stock of Accentia in accordance with the terms of such notes. Management does not anticipate that Accentia will continue to finance Biovest's operations. In addition, upon the completion of a Biovest financing transaction, Management anticipates that Biovest may repay some or all of the outstanding demand notes.

There are currently no commitments in place for these debt and equity transactions, nor can assurances be given that such financing will be available. While management is confident that they will raise the capital necessary to fund operations and achieve successful commercialization of the products under development, there can be no assurances in that regard. The financial statements do not include any adjustments that may arise as a result of this uncertainty.

3. Acquisitions and dispositions

Acquisition

On December 10, 2003 and effective October 1, the Company through its newly formed subsidiary IMOR-Analytica, GmbH, entered into an agreement to purchase certain assets and liabilities of Private Institute for Medical Outcome Research GmbH ("IMOR") for €0.5 million ($0.6 million). Pursuant to this agreement, Analytica International, Inc. leases a building and has the option to purchase such real estate located in Lorrach, Germany. This lease and option expires on November 30, 2008. Pursuant to the purchase, employment agreements were executed with the two prior owners of IMOR, which include annual compensation of €0.3 million and options to purchase 950,029 shares of Series B preferred stock at an exercise price of $1.25. The options converted to common stock options at our IPO. The purchase price was allocated as follows: purchased customer relationships $0.2 million; software $0.1 million; and goodwill $0.3 million (after taking into account the impairment charge described below). The allocation was based on a review by management based on the estimated relative fair value of the assets acquired and liabilities assumed. The net assets acquired consisted of all of IMOR's business activities, intangible assets, and software. IMOR provides strategic services prior to product launch, including clinical trials management, technology assessment and valuation, and formulary and strategic reimbursement planning. In connection with the IMOR acquisition, the Company initially capitalized goodwill in the amount of $0.6 million based on the fair value of the acquired assets net of assumed liabilities. Following this acquisition, the Company discovered that the assumed liabilities were $0.3 million in excess of the amount represented in the acquisition agreement. Because the Company has been unable to negotiate a post-closing purchase price adjustment as a result of this excess liability, the Company recorded an impairment to goodwill in the amount of $0.3 million in the fiscal quarter in which the acquisition occurred.

The pro forma effects of this acquisition were considered immaterial. In addition the effect of the retroactive effective date was also nominal.

Disposition

On December 8, 2003, the Company entered into an agreement to sell certain assets of AccentRx for $4.2 million in cash. The sale agreement provided for the sale of AccentRx's trademarks, customer lists and goodwill associated with the AccentRx pharmacy business, none of which had a cost basis, and were therefore not recorded on the Company's balance sheet. All proceeds reduced current liabilities. Furthermore, during December 2003, the Company renegotiated the terms of certain indebtedness to McKesson in the Assumption of Debt and Security Agreement, which amendment was required as a condition of McKesson's approval of the AccentRx sale. Subsequently, this agreement was amended to, among other things, grant McKesson warrants to purchase up to 1,425,043 million shares of Series E preferred stock of Accentia. Accordingly, the fair value of these warrants computed using the Black Scholes pricing model is $2.6 million, which was offset against the gain on the sale transaction. The McKesson indebtedness was paid off in September 2006.

Revenues and pre-tax income (loss) reported as discontinued operations are as follows:

	2006	2005	2004
Revenues	$ —	$ —	$ 3,745,688
Pre-tax loss	$ —	$ (430,110)	$ (1,516,017)

Continuing cash flows in 2005 from discontinued operations resulted from the resolution of lease matters.

4. Restricted Cash

Funds from Convertible Debenture transaction held in escrow to pay down Laurus debt:

- $5.0 million to be released in January 2007 to reduce Laurus line of credit balance
- $2.3 million to be released throughout 2008 to for final payoff of Laurus Term Note

Funds from New Market Tax Credit financings:

- $2.6 million released in December 2006 upon the completion of the second New Market Tax Credit transaction

5. Inventories

Inventories consist of the following:

	September 30,	
	2006	2005
Pharmaceutical products held for sale	$ 1,266,732	$ 814,862
Finished goods, other, net of $0.3 million allowance for obsolescence	34,253	35,787
Work-in-process	102,228	120,977
Raw materials	96,972	42,270
	$ 1,500,185	$ 1,013,896

6. Unbilled receivables and unearned revenues

Unbilled receivables and unearned revenues are as follows:

	September 30,	
	2006	2005
Costs incurred on uncompleted service contracts	$ 9,026,436	$ 7,020,113
Estimated earnings	8,084,874	7,286,296
	17,111,310	14,306,409
Less billings to date	(17,419,249)	(14,478,619)
	$ (307,939)	$ (172,210)

6. Unbilled receivables and unearned revenues (continued):

These amounts are presented in the accompanying balance sheets under the following captions:

	September 30,	
	2006	2005
Unbilled receivables	$ 1,087,159	$ 690,886
Unearned revenues	(1,395,098)	(863,096)
	$ (307,939)	$ (172,210)

7. *Other intangible assets*

Intangible assets, other than goodwill, consist of the following:

	September 30,		Weighted Average Amortization Period
	2006	2005	
Indefinite-life intangible assets:			
Trademarks	$ 1,525,433	$ 1,525,433	
Purchased customer relationships	225,137	225,137	
	1,750,570	1,750,570	
Amortizable intangible assets:			
Noncompete agreements	2,104,000	2,104,000	3.5 years
Patents	149,871	149,624	3.5 years
Purchased customer relationships	1,043,813	1,043,813	9.5 years
Product rights	19,914,707	21,216,334	14.3 years
Software	498,416	498,416	3.5 years
Trademarks	109,227	106,041	7.5 years
	23,820,034	25,118,228	
Less accumulated amortization	(7,783,227)	(5,631,122)	
	16,036,807	19,487,106	
Other intangible assets	$ 17,787,377	$ 21,237,676	

	Balances Sep. 30, 2003	Acquired in Imor Bus Acq. In 2004	Acquired in 2004	2004 Amortization	Balances Sep. 20, 2004
Indefinite-life intangibles:					
Trademarks	$ 1,525,433				$ 1,525,433
Goodwill	893,000	300,437			1,193,437
Purchased customer relationships	225,137				225,137
	2,643,570				2,944,007
Amortizable intangible assets:					
Noncompete agreements	2,104,000				2,104,000
Patents	103,248		43,365		146,613
Purchased customer relationships	803,463	240,350			1,043,813
Software	438,329	60,087			498,416
Trademarks	104,000				104,000
Product rights	7,296,829		7,306,811		14,603,640
Less accumulated amortization	(1,354,496)			(1,969,779)	(3,324,275)
	9,495,373	$ 600,874	$ 7,350,176	$ (1,969,779)	15,176,207
Total	$ 12,138,943				$ 18,120,214

	Balances Sep. 30, 2004	Acquired in 2005	2005 Amortization and Removal of Impaired Asset	Balances Sep. 20, 2005
Indefinite-life intangibles:				
Trademarks	$ 1,525,433			$ 1,525,433
Goodwill	1,193,437			1,193,437
Purchased customer relationships	225,137			225,137
	2,944,007			2,944,007
Amortizable intangible assets:				
Noncompete agreements	2,104,000			2,104,000
Patents	146,613	$ 3,011		149,624
Purchased customer relationships	1,043,813			1,043,813
Software	498,416			498,416
Trademarks	104,000	2,041		106,041
Product rights	14,603,640	8,082,694	$ (1,470,000)	21,216,334
Less accumulated amortization	(3,324,275)		(2,306,847)	(5,631,122)
	15,176,207	$ 8,087,746	$ (3,776,847)	19,487,106
Total	$ 18,120,214			$ 22,431,113

	Balances Sep. 30, 2005	Acquired in 2006	2006 Amortization	2006 Impairment	Balances Sep. 30, 2006
Indefinite-life intangibles:					
Trademarks	$ 1,525,433				$ 1,525,433
Goodwill	1,193,437				1,193,437
Purchased customer relationships	225,137				225,137
	2,944,007				2,944,007
Noncompete agreements	2,104,000				2,104,000
Patents	149,624				149,624
Purchased customer relationships	1,043,813	$ 247			1,044,060
Software	498,416				498,416
Trademarks	106,041	3,186			109,227
Product rights	21,216,334	2,008,305		$ (3,309,932)	19,914,707
Less accumulated amortization	(5,631,122)		$ (2,152,105)		(7,783,227)
	19,487,106	$ 2,011,738	$ (2,152,105)	$ (3,309,932)	16,036,807
Total	$ 22,431,113				$ 18,980,814

Product rights by product are as follows:

	Licensor		Developer if product under development at Sept 2006	Balance 30-Sep-05	Impairment Fiscal Year	Purchased Fiscal Year 2006	2006 Amortization	Balance 30-Sep-06	Product obligation 30-Sep-06
Product Rights:									
Chronic rhinosinusitis	Mayo	(g)	Accentia	$ 8,873,902	$ —	$ 958,305	$ (471,419)	$ 9,832,207	$ —
Histex	Andrx		Product in market	999,000	—	—	(222,000)	999,000	—
Respitan			Product in market	607,000	—	—	(60,996)	607,000	—
Alcotin/Novacort	Primus		Product in market	250,000	—	—	(82,996)	250,000	—
Emezine	Arius	(b)	Arius	1,600,000	—	—	(85,363)	1,600,000	—
Xodol	Ryan	(c)	Product in market	2,192,000	(108,928)	—	(368,688)	2,083,072	—
Pain	Argent	(d)	Mikart	1,457,940	(1,778,816)	550,000	(128,322)	229,124	—
Pain	Acheron	(e)	Mikart	1,883,000	(1,422,186)	—	(131,661)	460,814	—
MD Turbo	Respirics	(f)	Respirics	2,932,000	(2)	—	(145,414)	2,931,998	—
AllerNase	Collegium	(a)	Collegium	300,000	—	500,000	(44,999)	800,000	—
Other				121,492	—	—	(28,758)	121,492	—
				21,216,334	$ (3,309,932)	$ 2,008,305		19,914,707	$ —
Less accumulated amortization				(2,740,168)			$ (1,770,616)	(4,510,784)	
				$ 18,476,166				$ 15,403,923	

	Licensor	Developer if product under development at Sept 2006	Balance 30-Sep-04	Removal of Impaired Asset Fiscal Year	Purchased Fiscal Year 2005	2005 Amortization	Balance 30-Sep-05	Product obligation 30-Sep-05
Product Rights:								
Chronic rhinosinusitis	Mayo	Accentia	$ 2,155,000	$ —	$ 6,718,902	$ (302,994)	$ 8,873,902	$ —
Histex	Andrx	Product in market	999,000	—	—	(222,000)	999,000	—
Respitan		Product in market	607,000	—	—	(60,996)	607,000	—
Alcotin/Novacort	Primus	Product in market	250,000	—	—	(125,004)	250,000	—
Sustained release	SRL	N/A technology	1,470,000	(1,470,000)	—	(101,379)	—	—
Asthma	Mayo	Mayo & Accentia	—	—	—	—	—	—
CRS Worldwide	Mayo	Accentia	—	—	—	—	—	—
Emezine	Arius	Arius	1,300,000	—	300,000	(68,902)	1,600,000	200,000
Xodol	Ryan	Product in market	2,192,000	—	—	(368,688)	2,192,000	300,000
Pain	Argent	Mikart	814,148	—	643,792	(70,649)	1,457,940	—
Pain	Acheron	Mikart	1,883,000	—	—	(131,661)	1,883,000	—
MD Turbo	Respirics	Respirics	2,812,000	—	120,000	(142,168)	2,932,000	—
AllerNase	Collegium	Collegium	—	—	300,000	(3,333)	300,000	—
Other			121,492	—	—	(26,999)	121,492	—
			14,603,640	$ (1,470,000)	$ 8,082,694		21,216,334	$ 500,000
Less accumulated amortization			(1,269,224)			$ (1,624,773)	(2,740,168)	
			$ 13,334,416				$ 18,476,166	

Continued

	Licensor	Developer if product under development at Sept 2006	Balance 30-Sep-03	Purchased Fiscal Year 2004	2004 Amortization	Balance 30-Sep-04	Product obligation 30-Sep-04
Product Rights:							
Chronic rhinosinusitis	Mayo	Accentia	$ —	$ 2,155,000	$ (48,000)	$ 2,155,000	$ 1,005,000
Histex	Andrx	Product in market	999,000	—	(222,000)	999,000	—
Respitan		Product in market	607,000	—	(61,000)	607,000	—
Alcotin/Novacort	Primus	Product in market	—	250,000	(42,000)	250,000	—
Sustained release	SRL	N/A technology	—	1,470,000	(50,690)	1,470,000	1,360,000
Asthma	Mayo	Mayo & Accentia	—	—	—	—	—
CRS Worldwide	Mayo	Accentia	—	—	—	—	—
Emezine	Arius	Arius	—	1,300,000	(31,707)	1,300,000	1,000,000
Xodol	Ryan	Product in market	1,692,000	500,000	(172,130)	2,192,000	270,000
Pain	Argent	Mikart	—	814,148	(30,154)	814,148	756,750
Pain	Acheron	Mikart	1,883,000	—	(131,662)	1,883,000	—
MD Turbo	Respirics	Respirics	2,112,000	700,000	(120,973)	2,812,000	—
Other			3,829	117,663	(27,000)	121,492	—
			7,296,829	$ 7,306,811		14,603,640	$ 4,391,750
Less accumulated amortization			(331,908)		$ (937,316)	(1,269,224)	
			$ 6,964,921			$ 13,334,416	

All products being developed are currently FDA approved chemical entities being developed in different dosage strengths or formulations under FDA guidelines, with the exception of MD Turbo, was is being developed under predicate device FDA guidelines. Development and approval paths are expected to average approximately 24 months:

(a) Represents exclusive licensing and distribution rights from a third-party under a licensing and distribution agreement for one product, with expected sNDA submission to the FDA in the first quarter of 2007 and expected approval in the third quarter of 2007.

(b) Represents exclusive U.S. rights for distribution of anti-emetic therapy for treatment of nausea and vomiting acquired from a third-party.

(c) Represents exclusive U.S. distribution rights acquired from a third-party under a distribution agreement. Product was approved by FDA in June 2004, and amortization of acquired product cost is being recognized commencing in fiscal 2004. This product achieved approval within 10 months of filing. These rights were sold subsequent to September 30, 2006.

(d) Represents exclusive U.S. distribution rights acquired from third-party under a distribution agreement for nine products. These rights were sold subsequent to September 30, 2006.

(e) Represents exclusive U.S. distribution rights acquired from a third-party under a distribution agreement for one product. These rights were sold subsequent to September 30, 2006.

(f) Represents distribution rights acquired from a third-party for a medical device that can be used in the administration of multiple products. Commercial launch commenced in fiscal year 2006.

(g) The Mayo Clinic has approved patents supporting these products.

See Notes 11 and 17 for detailed discussions relating to acquisition of these intangibles.

Estimated future amortization of amortizable intangible assets with finite lives is as follows:

Year ending September 30,	
2007	$ 1,640,553
2008	1,375,764
2009	1,328,212
2010	943,048
2011	941,723
Thereafter	9,807,507
	$ 16,036,807

8. Furniture, equipment and leasehold improvements

Furniture, equipment and leasehold improvements consist of the following:

	September 30,	
	2006	2005
Furniture	$ 261,469	$ 253,130
Office and laboratory equipment	2,420,217	2,737,291
Leasehold improvements	1,184,313	791,687
	3,865,999	3,782,108
Less: accumulated depreciation and amortization	(2,330,021)	(2,006,289)
	$ 1,535,978	$ 1,775,819

9. Lines of credit

Lines of credit consist of the following:

	September 30,	
	2006	2005
Related Party:		
Bridge note related party, interest at 4.25%, unsecured, matures August 2007 (a)	$ 1,060,497	$ 4,180,000
Other:		
Secured revolving note, of which $2.5 million is convertible, due to Laurus Master Fund, Ltd., interest at prime plus 2% (10.25% at September 30, 2006); matures April 2008; principal and accrued interest convertible at fixed conversion price of $6.80 per share (See Note 9)	9,925,473	5,052,604
Revolving credit agreement, interest at prime rate (8.25% at September 30, 2006); matures January 2007; secured by Company's accounts receivable and guarantee of major stockholder	4,000,000	—
	14,985,970	9,232,604
Less current maturities	14,985,970	5,052,604
	$ —	$ 4,180,000

(a) This note was amended to provide up to $4.0 million in available borrowings from Hopkins II. The Company may prepay the bridge loan at any time without penalty or premium. However, on the date on which the bridge loan becomes due or on which the Company desires to prepay the loan, the Company must not be in default under its credit facility with Laurus Master Fund, Ltd., and the remaining balance under the Laurus credit facility at such time must be $2.5 million or less. If both of these conditions are not satisfied, then the bridge loan will not become due and cannot be paid until the first day on which both of these conditions are satisfied.

The Company has the unconditional right to borrow up to $4.0 million in the aggregate upon ten days' prior written notice to Hopkins II. The Company's right to borrow any amounts in excess of $4.0 million is conditioned upon the Company either being in default under its credit facility with Laurus or having less than $5.0 million cash on hand at the time of the advance. As of September 30, 2006, $1.1 million is outstanding under this bridge loan after conversion of $3.2 million in principal into common stock in May 2006, leaving potentially available borrowing capacity of $2.9

million. The loan is unsecured and bears interest at a rate equal to 4.25% per annum, simple interest. No payments of principal or interest are due until the maturity date of the loan.

Dr. Francis E. O'Donnell, the Company's Chief Executive Officer and Chairman, is the sole manager of Hopkins II, and several irrevocable trusts established by Dr. O'Donnell collectively constitute the largest equity owners of Hopkins II.

Weighted average interest on all short-term borrowings aggregated 9.29%, 6.42%, and 5.30% at September 30, 2006, 2005 and 2004, respectively. At September 30, 2006, the Company has an aggregate of $2.9 million available under its lines of credit.

10. Long-term debt

Long-term debt consists of the following:

	September 30, 2006	September 30, 2005
Related party:		
Term loan due to McKesson, a holder of shares of common stock and major supplier, payable at 10% contract rate (a)	$ —	$ 3,900,000
Note due to McKesson, interest payable monthly at 10% (a)	—	2,095,414
Notes payable, former Biovest management, interest at 7%; due in 2006 (b)	—	4,439,328
Accrued interest (b)	—	641,917
		11,076,659
Less current maturities	—	(7,414,742)
	$ —	$ 3,661,917
Other:		
Face value $25,000,000 convertible debentures, at fair value(g)	$ 21,727,869	$ —
Convertible amortizing term note, due to Laurus Master Fund, Ltd., interest payable monthly at prime rate plus 4%; due April 2008(c)(e)	6,166,670	6,496,127
Note payable, Harbinger Mezzanine Partners, LP, net of discount; secured by assets of TEAMM; interest payable monthly at 13.5%; $5.0 million principal balance matures August 2006 (a)	—	6,589,854
Convertible notes payable, Biovest bridge financing, due in 2006(a)	—	100,000
Convertible notes payable, Biovest 2000 bridge financing, interest at 10%, due in 2006(d)	114,499	175,469
Convertible amortizing term note, due to Laurus Master Fund, Ltd., interest payable monthly at the greater of prime rate plus 2% or 10.25%, due March 31, 2009 (e)	2,354,128	—
Term note, Pulaski Bank and Trust Company, interest payable monthly at prime rate minus 0.05% or 8.20%, due January 5, 2007 (f)	2,000,000	—
Note payable, former employee settlement	119,950	—
Other	104,263	119,050
Long term accrued interest(b)	85,978	311,013
	32,673,357	13,791,513
Less current maturities	(5,652,152)	(8,888,847)
	$ 27,021,205	$ 4,902,666

Footnotes to long-term debt

(a) Re-paid in fiscal 2006.

(b) Notes collateralized by certain assets of Biovest; convertible at the option of the holder into Biovest common stock (at $0.50 per share) or Accentia common stock (at either discounts ranging from zero to $1.60 of the $8 IPO offering price). During the fiscal year ended September 30, 2006, $0.5 million of the debt was paid down, and $3.9 million of the debt was converted to equity.

(c) Note is convertible into shares of common stock at $6.80 per share, exercisable through April 2008.

(d) Notes are convertible into shares of Biovest common stock at $1.00 per share and include warrants to purchase 50,000 shares of Biovest common stock at an exercise price of $1.25 per share, exercisable through September 2007.

(e) Discounts on long-term debt include the value of warrants issued in conjunction with long-term debt and are accreted over the life of the related debt. The debt provides for monthly payment provisions, a variable interest feature that includes a cap of 9.0% and a default put at 130% of face value for certain contingent events, including service defaults

and changes in control, for the amortizing portion of the arrangement; these features are not present for unreleased, non-amortizing balances. The Company evaluated all terms and conditions of the amortizing notes for indications of embedded derivative financial instruments. While the interest rate cap was found to be clearly and closely related to the host instrument, the Company determined that the default put did not meet the clearly and closely related criteria as provided in FASB 133 Derivative Financial Instruments. Accordingly, upon release of funds underlying the first tranche, the Company reclassified an amount of $306,750 on the date of release, which represents the estimated fair value of the default put liability to derivative liability. Upon release of funds under the second tranche, the Company reclassified $122,700 to derivative liability. The default liability is initially and subsequently carried at fair value with changes recorded in income. Accordingly, $236,369 is recorded as a derivative liability in the accompanying balance sheet on September 30, 2006.

(f) Upon issuance of the note, $50,000 of the principal amount was disbursed at the closing to Pulaski to cover closing fees relating to the loan transaction. The note will become due and payable on January 5, 2007 but may be prepaid by the Biovest at any time without penalty. The outstanding principal amount of the note will bear interest at the rate of the prime rate minus .05% (7.75% per annum initially). Monthly payments of accrued interest only shall be due and payable monthly on the 5th day of each month commencing on October 5, 2006. The note is an unsecured obligation of Biovest and is subordinated to Biovest's outstanding obligation to Laurus. The note is guaranteed by entities and individuals affiliated with the Biovest or Accentia Biopharmaceuticals, Inc., the majority stockholder of the Biovest. Biovest has entered into Indemnification Agreements that hold the guarantors harmless from all claims and losses with respect to enforcement of the guarantees provided the guarantors fulfill certain notice conditions and waiting periods. Biovest issued to Pulaski a warrant to purchase up to 66,667 shares of Biovest's Common Stock, par value $0.01 per share, at an exercise price of $1.10 per share. The warrant will expire on September 5, 2011. The warrant provides Pulaski with piggy-back registration rights for the shares underlying the warrant.

(g) Private Placement of $25.0 million in principal amount of 8% Secured Convertible Debentures due September 29, 2010, resulting in gross proceeds of $23.5 million after placement agent fees of $1.5 million but before other expenses associated with the transaction. A total of $7.3 million of the proceeds from the Private Offering were placed into an escrow account and will be paid to Laurus when certain amounts become due under the Company's credit facility with Laurus. The Debentures are convertible at any time, at the option of the holder, into shares of the Company's common stock at $2.60 per share, subject to adjustment for stock splits, stock dividends, and the like. Debentures bear interest at 8% per annum with interest payable quarterly in arrears in cash, or, at the Company's option, in shares of Company common stock. The Debentures will bear default interest at a rate of 18% per annum.

Beginning October 1, 2007, and on the 1st of each month thereafter, the Company will be required to redeem 1/37th of the face value of the Debentures in cash or, at the Company's election, with shares of Company common stock, shares of Biovest common stock held by the Company, or a combination thereof. Any unconverted Debentures will become due on September 29, 2010

As a part of the Private Placement, the Company issued Warrants to the purchasers of the Debentures giving them the right to purchase up to an aggregate of 3,136,201 shares of the Company's common stock at an exercise price of $2.75 per share, provided that such Warrants may be alternatively exercised for shares of Biovest common stock held by the Company at an exercise price of $1.10 per share. All of the Warrants (including the warrants granted to the Placement Agent) will expire on September 29, 2011.

Unless and until shareholder approval of the Private Placement is obtained by the Company, the aggregate number of shares of the Common Stock of the Company issuable upon the conversion of any of the Debentures and upon the exercise of any of the Warrants is limited to 19.99% of the number of shares of Company common stock outstanding on the date of the closing of the Private Placement.

Future maturities of long-term debt are as follows as of September 30, 2006:

Years ending September 30,	
2007	$ 8,135,610
2008	17,718,224
2009	9,392,333
2010	8,508,503
	43,754,670
Less unamortized discount and adjustment to fair value on convertible debentures	11,081,313
	$ 32,673,357

Laurus Master Funds, Ltd.

On April 29, 2005, the Company obtained an aggregate total of $10.0 million in debt financing from Laurus Master Funds, Ltd. ("Laurus"). The term loan portion of the Laurus credit facility is evidenced by a secured convertible term note in the principal amount of $5.0 million. The revolving loan portion of the credit facility is evidenced by a secured convertible

minimum borrowing note in the amount of $2.5 million and a secured revolving note of up to $5.0 million, provided that the aggregate principal amount under both notes combined may not exceed $5.0 million.

In August 2005, the term loan portion of the Laurus credit facility was amended and restated secured convertible term note, dated August 16, 2005, in the principal amount of $10.0 million (an increase of $5.0 million).

The amended and restated secured convertible term note accrues interest at a rate of the greater of 10% per annum or prime rate plus 4%. The secured convertible minimum borrowing note and secured revolving note accrue interest at a rate equal to the greater of 7.75% per year or prime rate plus 2%.

Certain repayment terms were conditional based on timing of the initial public offering. As a result of completion of the offering, the amended and restated secured convertible term note is payable over three years in equal monthly payments of principal and interest of $0.3 million. The secured revolving note and secured convertible minimum borrowing note are due on the third anniversary of the notes with all accrued but unpaid interest payable monthly.

In connection with the Laurus credit facility, the Company issued to Laurus a warrant to purchase a number of shares of our common stock that is equal to $8.0 million divided by our per share initial public offering price ($8.00) (1,000,000 warrants), and such warrant has an exercise price equal to our per share initial public offering price ($8.00). The warrant will expire on the 5th anniversary of the date of warrant issuance.

As a part of the August 2005 amendment to the Laurus credit facility, the Company granted Laurus an additional warrant to purchase up to 277,778 shares of the Company's common stock at an exercise price of $0.001 per share. This additional warrant is immediately exercisable and, except for the absence of a forced exercise provision, has substantially the same terms and conditions as the other warrant granted to Laurus.

The principal and accrued but unpaid interest under each of the Laurus notes is convertible at the option of Laurus into shares of our common stock at an initial conversion price of $6.95 per share, provided that from after the completion of our initial public offering, the conversion price will be an amount equal to 85% of our per share initial public offering price or $6.80 per share.

On August 2, 2006, Biovest entered into an Amendment and Consent to Release (the "Amendment") with Laurus. The Amendment amends the Restricted Account Agreement and Side Letter Agreement entered into by Biovest and Laurus on March 31, 2006 (the "Agreements") to permit the release to Biovest from the Restricted Account of the sum of $2,500,000 (the "Release") prior to the satisfaction of the preconditions for such Release as set forth in the Agreements.

The Laurus financings included registration rights and certain other terms and conditions related to share settlement of the embedded derivatives and the warrants that Biovest has determined are not within its control. In addition, certain features associated with the financings, such as anti-dilution protection afforded the financing agreements render the number of shares issuable to be indeterminate. In these instances, EITF 00-19 Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock, requires allocation of the proceeds between the various instruments and the derivative elements carried at fair values. The following represents the allocation of the proceeds:

Principle balance of Laurus notes:	$ 20,000,000
Less reduction for:	
Fair value of beneficial conversion of options	(4,413,514)
Fair value of warrants	(3,989,610)
Recorded at closing	11,596,876
Accretion of discount (interest expense) through September 30, 2006 using effective interest method	1,299,390
Loss on extinguishment of debt resulting from the August 2005 amendment	4,808,782
Debt payments	(1,612,907)
Carrying value at September 30, 2006	$ 16,092,141

As presented on balance sheet:	
Current maturities of long term debt-other	$ 2,740,753
Lines of credit-current	9,925,473
Long-term debt, net of current maturities-other	3,425,915
	$ 16,092,141

The discount to the debt instruments resulting from the aforementioned allocation is being amortized through periodic charges to interest expense using the effective method for the Notes.

The fair value of convertible notes for disclosure purposes only are estimated based upon the present value of the estimated cash flow at credit risk adjusted interest rates for convertible instruments. As of September 30, 2006, estimated fair values and respective carrying values for debt instruments are as follows:

	Fair Value	Carrying Value
$10,000,000 Face Value Convertible Secured Term Note	$ 8,709,677	$ 7,828,923
$10,000,000 Revolving Line of Credit	$ 10,000,000	$ 8,988,764

Private Placement of Convertible Debentures

On September 29, 2006, the Company entered into definitive agreements relating to a private placement (the "Private Placement") of $25.0 million in principal amount of 8% Secured Convertible Debentures due September 29, 2010 (the "Debentures"). The funds raised in the Private Placement were disbursed from escrow to the Company on October 2, 2006. The principal purposes of the Private Placement was to raise additional funding for working capital to support the commercialization of the Company's specialty pharmaceutical products and to continue the development of the Company's proprietary intranasal antifungal therapy for chronic sinusitis and to repay certain short-term debt. The Private Placement resulted in gross proceeds of $23.5 million after placement agent fees of $1.5 million but before other expenses associated with the transaction. To secure certain amounts payable by the Company to Laurus, the Company's senior lender, a total of $7.3 million of the proceeds from the Private Offering were placed into an escrow account and will be paid to Laurus when certain amounts become due under the Company's credit facility with Laurus.

The Debentures are convertible at any time at the option of the holder into shares of the Company's common stock at $2.60 per share, subject to adjustment for stock splits, stock dividends, and the like. In the event that the Company issues or grants in the future any rights to purchase any of the Company's common stock, or other security convertible into the Company's common stock, for an effective per share price less than the conversion price then in effect, the conversion price of all unconverted Debentures will be decreased to equal such lower price. The Debentures are also exchangeable for shares of common stock of Biovest held by the Company at an exchange price of $1.00 per share, subject to adjustment for stock splits, stock dividends, and the like, at any time after the earlier to occur of (i) September 29, 2007 or (ii) such time as the closing price of Biovest's common stock exceeds $2.25 for each of 20 consecutive trading days, subject to certain volume requirements and other conditions. Biovest is a majority-owned subsidiary of the Company. In the event that Biovest issues or grants in the future any rights to purchase any of Biovest's common stock, or other security convertible into Biovest's common stock, for a per share price less than the exchange price then in effect, the exchange price for all unconverted Debentures will be decreased to equal such lower price. The above-described adjustments to the conversion price or exchange price for future stock issuances by the Company or Biovest will not apply to certain exempt issuances, including stock issuances pursuant to employee stock option plans and strategic transactions.

Prior to maturity the Debentures will bear interest at 8% per annum with interest payable quarterly in arrears in cash, or, at the Company's option, in shares of Company common stock. The Company's ability to pay interest with shares of Company common stock will be subject to specified conditions, including the existence of an effective registration statement covering the resale of the shares issued in payment of interest and certain minimum trading volumes in the stock to be issued. Shares delivered in payment of interest will be valued at 90% of the average of the daily volume weighted average price of the shares for the 20 trading days prior to the interest payment date. From and after an event of default under the Debentures and for so long as the event of default is continuing, the Debentures will bear default interest at a rate of 18% per annum.

Beginning October 1, 2007, and on the 1st of each month thereafter, the Company will be required to redeem 1/37th of the face value of the Debentures in cash or, at the Company's election, with shares of Company common stock, shares of Biovest common stock held by the Company, or a combination thereof. The Company's ability to pay interest with shares of Company or Biovest common stock will be subject to specified conditions, including the existence of an effective registration statement covering the resale of the shares issued in payment of the redemption amount and certain minimum trading volumes in the stock to be issued. Any payment in common stock of either the Company or Biovest may not exceed 15% of the total dollar traded volume in the applicable stock for the 20 trading days prior to the amortization payment. Any common stock of the Company or Biovest delivered in satisfaction of an amortization payment will be valued at the lesser of (i) the

conversion price or the exchange price, as the case may be, in effect at the time of the amortization payment or (ii) 90% of the average of the daily volume weighted average price of the applicable shares for the 20 trading days prior to the amortization payment. Any unconverted Debentures will become due on September 29, 2010

In the event that the average of the daily volume weighted average price of the shares of the Company's common stock for any 20 consecutive trading days exceeds $6.50, the Company will have the right, but not the obligation, to require the holders of the Debentures to convert into Company common stock at the conversion price then in effect up to 50% of any outstanding Debentures (or 100% of any outstanding Debentures, in the event that the average of the daily volume weighted average price of the shares of the Company's common stock for any 20 consecutive trading days exceeds 300% of the then-effective conversion price). Such a mandatory conversion is subject to specified conditions, including the existence of an effective registration statement covering the resale of the shares into which the Debentures are converted and certain minimum trading volumes in the stock to be issued. The registration statement was declared effective on November 17, 2006.

At any time beginning on the first anniversary of the effectiveness of a registration statement covering the resale of the shares of Company common stock issuable upon conversion of the Debentures, the Company may redeem, subject to specified conditions and upon 20 trading days' written notice, any or all of the outstanding Debentures for a redemption price of (i) cash of 120% of par plus accrued and unpaid interest on the Debentures to be redeemed and (ii) warrants to subscribe for a number of shares of the Company's common stock equal to the principal amount of the Debentures to be redeemed, divided by the conversion price then in effect. Such warrants will have an exercise price equal to the average of the daily volume weighted average price for the shares of the Company's common stock for the 20 trading day period immediately preceding the redemption and a term equal to the weighted average remaining term of the Debentures.

As a part of the Private Placement, the Company issued Warrants to the purchasers of the Debentures giving them the right to purchase up to an aggregate of 3,136,201 shares of the Company's common stock at an exercise price of $2.75 per share, provided that such Warrants may be alternatively exercised for shares of Biovest common stock held by the Company at an exercise price of $1.10 per share. The warrant exercise prices are subject to adjustment for stock splits, stock dividends, and the like. The Warrants may not be exercised for any shares of Biovest common stock until the earlier to occur of (i) September 29, 2007 or (ii) such time as the closing price of Biovest's common stock exceeds $2.25 for each of 20 consecutive trading days, subject to certain volume requirements and adjustments. In the event that the Company in the future issues or grants any rights to purchase any of the Company's common stock, or other security convertible into the Company's common stock, for a per share price less than the exercise price then in effect, the exercise price of the Warrant with respect to shares of the Company's common stock will be reduced to equal such lower price and the number of shares of the Company's common stock for which the Warrant may be exercised will be increased so that the total aggregate exercise price remains constant. In the event that Biovest in the future issues or grants any rights to purchase any of Biovest's common stock, or other security convertible into Biovest's common stock, for a per share price less than the exercise price then in effect, the exercise price of the Warrant with respect to shares of Biovest's common stock will be reduced to equal such lower price. The foregoing adjustments to the exercise price for both the Company's common stock and Biovest's common stock for future stock issues will not apply to certain exempt issuances, including issuances pursuant to employee stock option plans and strategic transactions. In connection with the Private Placement, the Company also issued to the placement agent for the transaction warrants to purchase an aggregate of 545,455 shares of Company common stock at an exercise price of $2.75 per share. All of the Warrants (including the warrants granted to the Placement Agent) will expire on September 29, 2011.

Unless and until shareholder approval of the Private Placement is obtained by the Company, the aggregate number of shares of the Common Stock of the Company issuable upon the conversion of any of the Debentures and upon the exercise of any of the Warrants is limited to 19.99% of the number of shares of Company common stock outstanding on the date of the closing of the Private Placement. The Company has agreed to include a proposal for shareholder approval of the Private Placement at its next annual meeting of shareholders, and shareholders holding more than 50% of the Company's common stock have entered into voting agreements agreeing to vote their respective shares in favor of such proposal. In addition, the total number of shares of Biovest common stock held by the Company that may be transferred to the investors in the Private Placement pursuant to the Debentures or Warrants may not exceed 18,000,000 shares in the aggregate. Pursuant to a Pledge Agreement among the Company and all of the purchasers of the Debentures, the Debentures are also secured by these 18,000,000 shares of Biovest common stock held by the Company.

In connection with the Private Placement, the Company and the purchasers of the Debentures entered into a Registration Rights Agreement under which the Company is required, on or before November 1, 2006, to file a registration statement with the SEC covering the resale of the shares of Company common stock issuable pursuant to the Debentures and Warrants and to use its best efforts to have the registration declared effective at the earliest date (but in no event later than 90 days after filing if there is no SEC review of the registration statement, or 120 days if there is an SEC review). The Company will be subject to certain monetary penalties, as set forth in the Registration Rights Agreement, if the registration statement is not filed or does not become effective on a timely basis. Biovest and the purchasers of the Debentures have entered into a similar registration rights agreement under which Biovest is required to file with the SEC and seek to have declared effective a

registration statement covering the resale of the shares of Biovest common stock transferable by the Company pursuant to the Debentures and Warrants. The registration statements were filed on November 17, 2006.

On the inception date of the Convertible Debenture and Warrant financing, the Company evaluated the terms and conditions of the transaction and determined (i) the convertible debentures possessed certain features, including the conversion provision, redemption rights and certain other features, that were not clearly and closely related to the host debt instrument and (ii) the terms of the warrants did not provide for all of the conditions necessary for equity classification.

When a hybrid debt instrument, such as the convertible debentures, embodies derivative features that are not clearly and closely related to the host instrument, current accounting standards afford the Company an option to bifurcate from the hybrid instrument one "compound" derivative financial instrument that would be carried as a derivative liability at fair value (the FAS133 Context) or carry the entire hybrid financial instrument at fair value (the FAS155 Context). See the Financial Instruments Policy Note for information on these standards. After reviewing the terms and conditions of the arrangement in its entirety, the Company elected to apply the FAS155 Context to the convertible debentures. Accordingly, proceeds from the financing were allocated to the convertible debentures based upon their fair value of $21,727,869. The Company valued the hybrid instrument as a forward contract (that is, the present value of the future cash flows including cash flows projected from redemption features and penalties at market interest rates) enhanced by a conversion option. The company valued the conversion option component of the hybrid instrument using the Flexible Monte Carlo technique because it reflects all of the requisite assumptions (including credit risk, interest-rate risk and exercise/conversion behaviors) that are necessary to fair value these more complex instruments. The hybrid instrument will continue to be adjusted to fair value at the end of each reporting period until it matures, is converted or is redeemed.

Since, as previously noted, the Warrants did not achieve all of the conditions necessary for equity classification, the Company allocated proceeds of $5,057,227 to the detachable warrants based upon their fair value using the Black-Scholes-Merton valuation technique.

The aforementioned allocation resulted in the recognition of a day-one derivative loss of $1,835,097. That means that the fair value of the hybrid debt instrument and warrants exceeded the net proceeds that the Company received from the arrangement and, accordingly, the Company was required to record a loss to record the financial instruments at fair value. The Company did not enter into any other financing arrangements during the periods reported that reflected day-one losses.

11. Related party transactions

Related party transactions

In order to induce additional investment in the Company, two principal stockholders entered into the following agreements:

In connection with the sale of 1,187,536 shares of Series E preferred stock (subsequently converted to common stock), a party related to a principal stockholder of the Company (the "Trust") has pledged shares of a publicly traded company to secure obligations pursuant to a Put Call Agreement ("PCA"). The PCA provides that, for a period of two years, the preferred stockholder has the right to require the Trust to repurchase up to 1,187,536 shares of Series E preferred stock at $2.11 per share plus 5% per year. In addition, for a period of two years, the Trust has the right to repurchase 593,768 of said shares at $2.11 per share plus 5% per year; however, in May 2005, the Trust irrevocably waived this right.

In connection with equity transactions in the first quarter of 2005, two principal stockholders assigned an aggregate of 237,507 warrants to purchase shares of Series E preferred stock to a Series E preferred stockholder. These warrants were then exercised.

Accounts receivable, stockholder

Accounts receivable stockholder consists of amounts due from McKesson, a holder of common stock. These amounts are due in accordance with customary trade terms in the Specialty Pharmaceuticals segment.

Stockholder advances and notes

The Stockholder Note at September 30, 2005 is an unsecured 6% convertible note in the amount of $0.4 million, and was repaid in 2006.

See Notes 8 and 9 for related party notes payable

Related party license agreement

Background

On February 10, 2004, the Company entered into a license agreement with Mayo Foundation for Medical Education and Research ("MAYO") for the license of certain technology as it relates to development of therapeutic products for the treatment of chronic rhinosinusitis ("CRS"). The license grants the Company a) an exclusive license under the patent rights to use, offer for sale, sell, develop, manufacture, and have manufactured amphotericin-B and derivatives thereof as an FDA Product in the United States and European Union; b) an exclusive license in the United States and European Union to use, offer for sale, sell, import and manufacture, but not have manufactured, products, excluding FDA Products, for the treatment of CRS; and c) a nonexclusive license to use the technical information and data provided by MAYO to the Company that relate to the treatment of CRS to develop, manufacture, use and sell products and FDA products for the treatment of CRS. The agreement expires on the last to expire claim within the patent rights covered under the agreement, some of which are pending at September 30, 2006 and September 30, 2005.

In connection with the Mayo agreement, Accentia agreed to acquire or obtain all rights owned or licensed by BioDelivery Sciences International, Inc. ("BDSI") (a company related to the Company through partial common ownership and control) to develop an FDA product under the Mayo license based on cochleated amphotericin-B without interference from BDSI.

During the year ended September 30, 2005, the Company's agreement with MAYO was amended to provide for the following:

- Expansion of territory to worldwide;
- Reduction of minimum royalties;
- Milestone royalties increased;
- Licensing of and addition of asthma milestone royalties; and
- Payment of 1,140,034 shares of Series E preferred stock as an up-front, non-refundable royalty.

Related party license agreement and sale of royalty rights

On April 12, 2004, the Company entered into a license agreement (as licensee) with BDSI relating to certain products. Accentia's responsibilities included paying the costs associated with any of the commercial aspects, in keeping with its business plan (utilization of sales force, education of the public and prescribing population, etc.). In connection therewith, BDSI is entitled to royalties of 12% for sales of all products covered under the MAYO agreement including but not limited to topical antifungal products that do not require FDA approval and 14% of licensed products. The royalty obligations shall continue for each product for the term of the last to expire of the licensed patent rights covering the product.

Pharmaceutical Product Development, Inc. ("PPD"), a holder of our common stock, expressed an interest in purchasing certain royalty rights that BDSI possessed in connection with its April 12, 2004 arrangement with the Company, but PPD did not wish to deal directly with BDSI since the original technology was licensed to the Company from MAYO. As a result the Company entered into an agreement to acquire 50% of the royalty rights back from BDSI for $2.5 million.

Simultaneous with the BDSI transaction, the Company entered into an agreement whereby PPD purchased from the Company 50% of said royalty rights based on the sale of certain products. The royalty rights are defined as 6% of net sales for all non-FDA products and 7% of all FDA product sales, which is 50% of the initial royalty calculations, respectively. The sales price for these royalty rights was $2.5 million.

PPD acquired only the royalty rights and did not assume any liability or obligation of the Company. Further, pursuant to the agreement, the Company has agreed to make minimum royalty payments through December 2009 of $2.5 million. Failure to make such minimum payments is deemed a material breach. In connection therewith, Accentia may make up such shortfall to cure the breach. In addition, termination of the "enabling agreements" (BDSI and MAYO) constitutes a default as well as failure to maintain market exclusivity and failure to enforce Mayo Patent Rights. In the event of termination, the Company is required to refund the purchase price less the aggregate royalties paid prior to termination, except that if aggregate royalties exceed $2.5 million, the Company has no obligation to refund the purchase price. As discussed in Note 1, the $2.5 million received from PPD is recorded as "other liabilities, related party" in the accompanying consolidated balance sheet as of September 30, 2006 and 2005. As such, other liabilities, related party includes $2.37 million and $2.44 million associated with this transaction at September 30, 2006 and 2005, respectively (net of royalties earned through those respective dates). Further, as a result of the sale to PPD of the purchased future royalties from BDSI and the fact that the Company has no recourse against BDSI if these royalties do not materialize, the $2.5 million paid to BDSI in connection with the acquisition thereof has been expensed as "other operating expense, related party" in the accompanying 2004 consolidated statement of operations. If royalties do materialize, they must be paid to PPD, at which time revenue from the sale of these rights to PPD would be recognized.

Distribution agreement with Arius

On March 12, 2004, the Company entered into a distribution agreement with Arius Pharmaceuticals, Inc. ("Arius") which grants the Company an exclusive perpetual license to market and sell a central nervous system product called Emezine ™ in the United States. Pursuant to the distribution agreement, as consideration for the distribution rights, the Company is obligated to pay: a) $0.1 million upon execution of the distribution agreement; b) $0.2 million upon the confirmation of NDA requirements; c) $1.0 million upon the initiation of clinical studies; d) $0.3 million upon FDA filing and acceptance; e) $0.4 million upon NDA approval; and f) perpetual royalties on net product sales, subject to annual minimum royalties of $2.0 million in year one and $4.0 million for every year thereafter, pro rated for any portion thereof, until the initial sale of a generic competitor to the product. The agreement expires at the termination or expiration of Arius's master license agreement with Reckitt Benckiser Healthcare (UK) Ltd., (January 2014) unless terminated for causes as defined in the agreement.

An aggregate of $1.6 million in acquired product rights were purchased from Arius (see a, b, c and d above), $-0- and $0.2 million of which is accrued and included in "product development obligations" in the accompanying 2006 and 2005 consolidated balance sheets, respectively.

Subsequent to the above referenced March transaction, Arius was acquired by BDSI and became a related party through common ownership and control.

Biologics distribution agreement with McKesson

In February 2004, the Company signed a biologics distribution agreement with McKesson ("McKesson") Corporation to convey to McKesson exclusive rights to distribute all current and future biologic products developed or acquired by the Company in the United States, Mexico and Canada. Pursuant to the agreement, McKesson remitted a $3.0 million non-interest bearing refundable deposit upon execution of the agreement and, as of September 30, 2006 and 2005, has been included in the accompanying consolidated balance sheets as "deposits, related party". The refundable deposit will be returned to McKesson upon termination of the agreement and McKesson will then cease to have the exclusive distribution rights. The Company may repurchase the rights granted McKesson prior to FDA approval of the Company's first biologic product upon payment of the greater of $6.0 million or 3% of the shareholders' equity of the Company at the time of termination. Pursuant to the agreement, the Company will pay a monthly royalty on all net revenues of all biologic products licensed by the Company and reimburse McKesson for all costs of distribution, as defined in the agreement. The agreement shall continue until the first to occur of 1) mutual written termination, 2) written notice of material breach, not cured, 3) 180 days after McKesson requests termination, or 4) repurchase of the distribution rights by Accentia prior to FDA approval. There were no biologics product sales subject to this agreement in 2006 and 2005.

12. Income taxes -

The Company's deferred tax assets and liabilities consist of the following:

	September 30, 2006	September 30, 2005
Deferred tax assets:		
Accrued expenses deductible in future	$ 3,927,000	$ 2,991,000
Allowance for doubtful accounts	30,000	45,000
Basis difference in assets	776,000	359,000
Inventory valuation allowance	497,000	318,000
Stock based compensation	755,000	755,000
Intangibles	1,628,000	1,628,000
Net operating loss carryforward	44,716,000	31,849,000
Other	623,000	—
Valuation allowance	(52,335,000)	(35,668,000)
	617,000	2,277,000
Deferred tax liabilities:		
Intangibles	(617,000)	(2,277,000)
	$ —	$ —

Income tax (expense) benefit consists of the following:

	Year ended September 30, 2006	2005	2004
Current	$ —	$ —	$ —
Deferred	(3,799,000)	(352,000)	218,000
Benefit of net operating loss carryover	(12,868,000)	(13,816,000)	(8,253,000)
Increase in valuation allowance	16,667,000	14,168,000	8,035,000
	$ —	$ —	$ —
Allocation between continuing and discontinued operations:			
Continuing operations	$ —	$ —	$ —
Discontinued operations	—	—	—
	$ —	$ —	$ —

The expected income tax benefit at the statutory tax rate differed from income taxes in the accompanying statements of operations as follows:

	2006	2005	2004
Statutory tax rate	34%	34%	34%
State taxes	4%	4%	4%
Acquisition adjustments	—	—	—
Other	—	(2)%	—
Change in valuation allowance	(38)%	(36)%	(38)%
Effective tax rate in accompanying statement of operations	0%	0%	0%

During the year ended September 30, 2006, we had a change in our consolidated group for income tax purposes. Since our initial acquisition of Biovest, we had an ownership interest in excess of 80%. This allowed Biovest to join with us in filing a consolidated federal income tax return. On December 7, 2005, our ownership interest in Biovest became less then 80%.

Effective as of this date, Biovest is now required to file a separate federal income tax return. Additionally, due to this deconsolidation the net operating losses (NOLs) generated by Biovest during their time as a member of the consolidated group are now NOLs to which Biovest is entitled. The provision for income taxes has been prepared as if we filed a consolidated federal income tax return including Biovest.

Deferred tax assets are reduced by a valuation allowance if, based on the weight of available evidence, it is more likely than not (a likelihood of more than 50 percent) that some portion or all of the deferred tax assets will not be realized. The

valuation allowance should be sufficient to reduce the deferred tax asset to the amount that is more likely than not to be realized. As a result, the Company recorded a valuation allowance with respect to all the Company's deferred tax assets.

Under Section 382 and 383 of the Internal Revenue Code, if an ownership change occurs with respect to a "loss corporation", as defined, there are annual limitations on the amount of the net operating loss and other deductions, which are available to the Company. Due to the acquisition transactions in which the Company has engaged in recent years, the Company believes that the use of these net operating losses will be significantly limited. As a consequence of the initial public offering, the Company may experience another such ownership change. Accordingly, our net operating loss carryforward arising before such ownership changes may be also limited to offset future federal taxable income.

The Company has a federal net operating loss carryover of approximately $117.8 million as of September 30, 2006, which expires through 2026, and of which $30.0 million is subject to various Section 382 limitations based upon ownership changes that occurred through September 30, 2003. Of those losses subject to the limitations, $11.3 million is expected to expire before the losses can be utilized. Of the remaining amounts, the limitation is approximately $1.8 million per year through approximately the year ended September 30, 2012. After that, the annual limitation will decrease to approximately $0.2 million through September 30, 2024. We have not determined whether any ownership changes have occurred since September 30, 2003 and therefore, our NOLs may be limited even beyond the amounts described above. Of the total NOLs, $39.1 million is attributable to Biovest.

13. Stockholders' equity

During the year ended September 30, 2006, the following common shares were issued:

Shares of common stock issued upon conversion of preferred shares	20,910,908
Shares of common stock issued for cash at initial public offering, net of offering costs	2,400,000
Shares of common stock issued in private equity transaction, net of offering costs	1,647,000
Shares of common stock issued for finance costs	100,000
Shares of common stock issue for cash upon the exercise of options	30,872
Shares of common stock issued in cashless exercise	533,253
Shares of common stock issued upon conversion of notes payable and accrued interest	906,734
Shares of common stock issued upon conversion of Series E preferred stock dividends	17,091

During the year ended September 30, 2005, the following shares were issued:

Shares of common stock issued for cash	294,093
Shares of Series A preferred stock for cash	340,110
Shares of Series A preferred stock for extinguishment of debt	657,420
Total shares of Series A preferred issued	997,530
Shares of Series B preferred stock for cash	60,498
Shares of Series D preferred stock for cash	56,031
Shares of Series E preferred stock for cash	11,763,728
Shares of Series E preferred stock for extinguishment of debt	743,685
Shares of Series E preferred stock for licensing rights	1,140,034
Total Series E preferred shares issued	13,647,447

During the year ended September 30, 2004, the following shares were issued:

Shares of common stock issued for cash	686
Shares of Series A preferred stock issued for cash	1,235,037
Shares of Series E preferred stock issued for cash	3,633,859
Shares of Series E preferred stock issued for extinguishment of debt	2,037,336

Common stock

The Company has one class of common stock with an aggregate authorization of three hundred million shares. Each share of common stock carries equal voting rights, dividend preferences, and a par value of $.001 per share.

Preferred stock

The Company has an aggregate of one hundred twenty-five million authorized shares of convertible preferred stock designated in five series (the "preferred stock"), each at a par value of $1.00 per share as follows:

Convertible Preferred Shares authorized:

Series A	10,000,000
Series B	30,000,000
Series C	10,000,000
Series D	15,000,000
Series E	60,000,000
	125,000,000

Series E preferred stock was generally issued with Class A and Class B warrants. These warrants were exercisable for Series E preferred stock at an exercise price of $2.11 per share. These warrants expired upon closing of the initial public offering. The Company has recorded a constructive dividend in 2005 of $4.9 million attributable to the fair value of warrants issued in connection therewith. The preferred stock was converted into shares of common stock during the year ended September 30, 2006.

Fair value determination of privately-held equity securities

The fair values of the common and preferred stock as well as the common and preferred stock underlying options and warrants granted as part of acquisition purchase prices or as compensation, issued during the period from April 2002 through September 2004 were originally estimated by the board of directors, with input from management. The Company did not obtain contemporaneous valuations by an unrelated valuation specialist until September 30, 2004. Subsequently, the Company reassessed the valuations of these securities during the respective periods.

Determining the fair value of stock requires making complex and subjective judgments. The Company used the income and market approaches to estimate the value of the enterprise at each date on which securities were issued/granted. The income approach involves applying appropriate discount rates to estimated cash flows that are based on forecasts of revenue and costs. Revenue forecasts were based on expected annual growth rates ranging from 9% to 177% based on management's estimates. There is inherent uncertainty in these estimates. The assumptions underlying the estimates were consistent with the Company's business plan. The risks associated with achieving the forecasts were assessed in selecting the appropriate discount rates, which ranged from 15% to 45%. If different discount rates had been used, the valuations would have been different.

The enterprise value was then allocated to preferred and common shares taking into account the enterprise value available to all stockholders and allocating that value among the various classes of stock based on the rights, privileges and preferences of the respective classes.

Stock options and warrants

The company provides for two option plans, the 2003 Stock Option Plan ("2003") per its second amendment on February 27, 2004, and the 2005 Equity Incentive Plan ("2005"). Both plans provide for the issuance of qualified and non-qualified options as those terms are defined by the Internal Revenue Code.

The 2003 Plan, as amended, provides for the issuance of 3,500,000 shares of common stock, and 762,571 shares of Series D Preferred Stock. At September 30, 2006, all Series D Preferred options have been converted into common share options. All options issued, pursuant to the 2003 Plan, cannot have a term greater than ten years. Options granted under this plan vest over periods established in the option agreement. As of September 30, 2006, 1,673,373 options are outstanding under the 2003 Plan.

On February 1, 2005, the Company's board of directors adopted the Accentia Biopharmaceuticals, Inc. 2005 Equity Incentive Plan. The 2005 Plan provides for the issuance of 3,000,000 shares of common stock. All options issued, pursuant to the 2005 Plan, cannot have a term greater than ten years. Options granted under this plan vest over periods established in the option agreement. As of September 30, 2006, 513,619 options are outstanding under the 2005 Plan. The Company may, at any time, amend or modify the Plan without limitation.

Stock options and warrants issued, redeemed and outstanding during the years ended September 30, 2006, 2005 and 2004 are as follows:

	Outstanding Options and Warrants to Acquire						Average Exercise price per share
	Common Stock	Preferred Series A	Preferred Series B	Preferred Series C	Preferred Series D	Preferred Series E	
Options and warrants outstanding September 30, 2003	793,192	—	—	712,521	1,560,643	—	0.72
Options issued	811,179		950,029	—	30,194	—	2.11
Options terminated/forfeited	(71,914)	—	—	—	(18,378)	—	1.77
Warrants issued in connection with preferred stock	—	—	—	—	—	9,642,789	2.11
Warrants issued in connection with services	401,387	760,023	—	—	248,097	1,425,043	2.11
Options exercised	(686)	—	—	—	(3,946)	—	1.05
Options and warrants outstanding, September 30, 2004	1,933,158	760,023	950,029	712,521	1,816,610	11,067,832	1.89
Activity for the year ended September 30, 2005:							
Warrants issued	1,375,854	—	—	—	—	3,874,903	3.15
Options issued	71,737	—	—	—	—	—	3.16
Options terminated/forfeited	(58,882)	—	—	(712,589)	(14,678)	—	1.16
Warrants terminated	—	—	—	—	(1,424,209)	(4,372,635)	1.62
Warrants exercised	(292,921)	(760,095)	—	—	(42,755)	(10,571,148)	2.10
Options exercised	(1,201)	—	(60,498)	—	(13,279)	—	2.33
Rounding differences resulting from reverse split	188	72	91	68	191	1,048	
Options and warrants outstanding, September 30, 2005	3,027,933	—	889,622	—	321,880	—	3.48
Activity for the year ended September 30, 2006:							
Options converted to common options	320,967	—	(332,510)	—	(321,880)	—	3.23
Warrants issued	5,115,156	—	—	—	—	—	3.60
Options issued	513,619	—	—	—	—	—	6.70
Options terminated/forfeited	(74,243)	—	—	—	—	—	5.37
Warrants terminated	(179,775)	—	(557,112)	—	—	—	4.91
Warrants exercised	(390,638)	—	—	—	—	—	0.01
Options exercised	(30,872)	—	—	—	—	—	2.41
Options and warrants outstanding, September 30, 2006	8,302,147	—	—	—	—	—	4.06
Options outstanding	2,186,992	—	—	—	—	—	3.35
Warrants outstanding	6,115,155	—	—	—	—	—	4.32
Options and warrants outstanding, September 30, 2006	8,302,147	—	—	—	—	—	4.06

The weighted average grant date fair values of stock options and warrants granted during the years ended September 30, 2006, 2005, and 2004 were as follows:

	Weighted Average Grant Date Fair Value Options	Warrants
Year ended September 30, 2006	$ 5.26	$ 1.70
Year ended September 30, 2005	$ 1.05	$ 2.69
Year ended September 30, 2004	$ 0.13	$ 1.68

Stock-based compensation was approximately $1.2 million during the year ended September 30, 2006.

The following table summarizes information for options and warrants outstanding and exercisable at September 30, 2006:

	Options and Warrants Outstanding				Exercisable		
Range of Exercise Prices	Number	Weighted average remaining life	Intrinsic Value	Weighted average exercise price	Number	Weighted average exercise price	Intrinsic Value
$0.00-1.05	600,990	6.54 years	$	1.05	600,990	$ 1.05	
$1.06-2.11	583,851	7.04 years		2.11	565,224	2.11	
$2.12-2.63	273,136	7.07 years		2.44	245,978	2.42	
$2.64-9.00	6,844,170	5.17 years		4.56	6,127,274	4.41	
	8,302,147	5.46 years	$ 1,239,083	$ 4.06	7,539,466	$ 3.91	$ 1,230,234

The following table summarizes information for options and warrants outstanding and exercisable at September 30, 2005:

	Options and Warrants Outstanding			Exercisable		
Range of Exercise Prices	Number	Weighted average remaining life	Weighted average exercise price	Number	Weighted average exercise price	
$1.05	1,174,136	8.09 years	$ 0.80	1,174,114	$ 0.80	
$1.06-2.11	703,691	8.00 years	2.11	494,332	2.11	
$2.12-2.63	1,064,734	8.24 years	2.63	214,385	2.63	
$2.64-5.33	317,562	8.91 years	4.77	241,083	5.28	
$5.33-8.169	979,312	4.88 years	8.17	979,312	8.17	
	4,239,435			3,103,226		

A summary of the status of the Company's nonvested options as of September 30, 2006, and changes during the year ended September 30, 2006, is summarized as follows:

Nonvested Shares	Shares	Weighted-Average Grant-Date Fair Value	Intrinsic Value
Nonvested at October 1, 2005	367,942		
Granted	513,619		
Vested	(409,773)		
Forfeited	(37,855)		
Nonvested at September 30, 2006	433,933	$ 3.45	8,849

The total unearned compensation cost of $ 1,868,878 relating to the 433,933 nonvested options as of September 30, 2006 will be recognized over a weighted average period of two years.

14. Employee benefit plans

The Company maintains defined contribution benefit plans qualified under Section 401(k) of the Internal Revenue Code. Any employee who has met minimum service requirements may enroll. Participants may contribute a percentage of their compensation within certain limits. Employer contributions are discretionary. The Company contributed approximately $0.1 million, $0.04 million, and $0.09 million, to the plan for the years ended September 30, 2006, 2005, 2004, respectively. Participants are always 100% vested in their contributions and earnings. Employer contributions are fully vested after three years of service.

15. Operational results for Biovest

	For the year ended September 30,			
	2006		2005	
	Biovest	Consolidated without Biovest	Biovest	Consolidated without Biovest
Net sales	$ 7,298,503	$ 17,759,545	5,077,305	20,117,477
Cost of sales	3,889,277	4,496,026	3,749,729	4,483,596
Gross margin	3,409,226	13,263,519	1,327,576	15,633,881
Operating expenses	15,425,283	37,868,798	12,388,878	36,844,468
Loss from operations	(12,016,057)	(24,605,279)	(11,061,303)	(21,210,579)
Interest income (expense)	(1,876,644)	(4,627,548)	(395,271)	(3,421,314)
Other income (expense)	240,922	(2,200,308)	(22,737)	(8,775,165)
Absorption of prior losses against minority interest	—	1,690,010	—	150,000
Net loss	(13,651,779)	(29,743,125)	(11,479,311)	(33,257,058)
Dividends	—	(40,739)	—	(5,552,128)
Loss attributable to common stockholders	(13,651,779)	(29,783,864)	(11,479,311)	(38,809,186)
Weighted average shares outstanding, basic and diluted	27,890,825	27,890,825	5,147,222	5,147,222
Loss attributable to common stockholder per common share	(0.49)	(1.07)	(2.23)	(7.54)

16. Segment information

We define our segment operating results as earnings (loss) before general and administrative costs, interest expense, interest income, other income, discontinued operations and income taxes. Inter-segment sales of $0.3 million, $1.6 million, and $0.3 million for the years ended September 30, 2006, 2005 and 2004 respectively, representing the sale of services from the Biopharmaceutical Products and Services segment to the Specialty Pharmaceuticals segment have been eliminated from segment sales.

Segment information for the year ended September 30, 2006 is as follows:

	Biopharmaceutical Products and Services	Specialty Pharmaceuticals	Total
Net sales:			
Products	$ 5,194,967	$ 7,448,762	$ 12,643,729
Services	12,414,319	—	12,414,319
Total net sales	17,609,286	7,448,762	25,058,048
Cost of sales:			
Products	2,215,212	2,445,393	4,660,605
Services	3,724,698	—	3,724,698
Total cost of sales	5,939,910	2,445,393	8,385,303
Gross margin	11,669,376	5,003,369	16,672,745
Sales and marketing	467,204	13,505,550	13,972,754
Research and development	14,561,111	—	14,561,111
Total assets	46,361,926	10,774,316	57,136,242
Goodwill	1,193,437	—	1,193,437

Segment information for the year ended September 30, 2005 is as follows:

	Biopharmaceutical Products and Services	Specialty Pharmaceuticals	Total
Net sales:			
Products	$ 3,956,467	$ 10,692,804	$ 14,649,271
Services	10,545,511	—	10,545,511
Total net sales	14,501,978	10,692,804	25,194,782
Cost of sales:			
Products	2,202,752	2,276,643	4,479,395
Services	3,753,930	—	3,753,930
Total cost of sales	5,956,682	2,276,643	8,233,325
Gross margin	8,545,296	8,416,161	16,961,457
Sales and marketing	1,858,789	13,305,278	15,164,067
Research and development	10,907,862	—	10,907,862
Total assets	23,631,924	13,048,669	36,680,593
Goodwill	1,193,437	—	1,193,437

Segment information for the year ended September 30, 2004 is as follows:

	Biopharmaceutical Products and Services	Specialty Pharmaceuticals	Total
Net sales:			
Products	$ 2,364,188	$ 11,939,089	$ 14,303,277
Services	11,632,343	—	11,632,343
Total net sales	13,996,531	11,939,089	25,935,620
Cost of sales:			
Products	1,513,510	2,339,370	3,852,880
Services	4,960,710	—	4,960,710
Total cost of sales	6,474,220	2,339,370	8,813,590
Gross margin	7,522,311	9,599,719	17,122,030
Sales and marketing	1,479,461	10,535,583	12,015,044
Research and development	5,519,158	—	5,519,158
Total assets	14,375,796	13,756,838	28,132,634
Goodwill	1,193,437	—	1,193,437

Domestic and foreign operations

As discussed in Note 3, during 2004, the Company made an insignificant acquisition of a foreign entity, IMOR. Total assets and net losses of this operation were insignificant; however, total revenues aggregated approximately 22% of total revenues of the Company since its acquisition. This entity, which is based in Germany, operates in the Biopharmaceutical Products and Services Segment and its general segment data is included therein. Segment information on a geographic basis for the year ended September 30, 2006 is as follows:

	Domestic	International (Europe)	Total
Net sales	$ 20,674,822	$ 4,383,226	$ 25,058,048
Net loss	(43,113,303)	(281,601)	(43,394,904)
Total Assets	54,333,106	2,803,136	57,136,242
Goodwill	893,000	300,437	1,193,437

Segment information on a geographic basis for the year ended September 30, 2005 is as follows:

	Domestic	International (Europe)	Total
Net sales	$ 20,468,614	$ 4,726,168	$ 25,194,782
Net income (loss)	(45,195,115)	458,746	(44,736,369)
Total Assets	34,177,901	2,502,692	36,680,593
Goodwill	893,000	300,437	1,193,437

Segment information on a geographic basis for the year ended September 30, 2004 is as follows:

	Domestic	International (Europe)	Total
Net sales	$ 22,584,668	$ 3,350,952	$ 25,935,620
Net loss	(22,765,858)	(460,083)	(23,225,941)
Total Assets	25,577,634	2,555,000	28,132,634
Goodwill	893,000	300,437	1,193,437

17. Product rights and obligations

a) Product rights and obligations

The Company has entered into certain product development and licensing agreements which provide for the acquisition of product rights and performance payments based on achievement of milestones as it relates to product development.

Parties to these agreements are as follows:

- Mayo Foundation for Medical Education and Research ("MAYO")
- Arius Pharmaceuticals, Inc. ("Arius")
- Respirics, Inc. ("Respirics")
- Mikart, Inc. ("Mikart")

b) Stanford

In September 2004, the Company entered into an agreement with Stanford University ("Stanford") providing for worldwide rights to use two proprietary hybridoma cell lines that are used in the production of BiovaxID. These are the same cell lines that been used by researchers at Stanford and the National Cancer Institute to perform their studies of the hybridoma idiotype vaccine in non-Hodgkins Lymphoma. This agreement gives the Company exclusivity to this cell line through 2019 in the fields of B-cell and T-cell cancers, and it provides non-exclusive rights in such fields of use at all times thereafter. The agreement also gives the Company the right to sublicense or transfer the licensed biological materials to collaborators in the licensed fields. Under the agreement with Stanford, the Company is obligated to pay Stanford an up-front license fee of $15,000 within 30 days following the execution of the agreement, and an annual maintenance fee of $10,000 thereafter. If BiovaxID is approved by the FDA, the agreement provides for a $100,000 payment to Stanford upon approval, and following approval, Stanford will receive a royalty of the greater of $50.00 per patient or 0.05% of the amount received by us for each BiovaxID patient treated using this cell line. This running royalty will be creditable against the yearly maintenance fee. The agreement with Stanford obligates the Company to diligently develop, manufacture, market, and sell BiovaxID and to provide progress reports to Stanford regarding these activities. The Company can terminate this agreement at any time upon 30 days prior written notice, and Stanford can terminate the agreement upon a breach of the agreement by the Company that remains uncured for 30 days after written notice of the breach from Stanford.

18. Commitments and contingencies

a) Operating leases

The Company has operating leases for various facilities, automobiles, machinery, and equipment, which expire at various times through 2012. The annual aggregate rental commitments under non-cancelable leases are as follows:

Year ending September 30,	
2007	$ 2,261,882
2008	1,847,287
2009	1,665,041
2010	930,342
2011	383,304
Thereafter	31,942
	$ 7,119,798

The annual aggregate future rental income from sub-leases is as follows:

Year ending September 30,	
2007	$ 476,431
2008	493,106
2009	187,751
	$ 1,157,288

Rent expense for all operating leases was approximately $3.2 million, $2.5 million, and $1.9 million for the years ended September 30, 2006, 2005, and 2004 respectively. Rental income from subleases aggregated $0.1million, $0.4 million, and $0.4 million for the years ended September 30, 2006, 2005 and 2004, respectively, and has been included in loss from discontinued operations in the accompanying statements of operations.

b) Cooperative research and development agreement

In September 2001 Biovest entered into a definitive Cooperative Research and Development Agreement ("CRADA") with the National Cancer Institute ("NCI") for the development and ultimate commercialization of patient-specific vaccines for the treatment of non-Hodgkin's low-grade follicular lymphoma. The terms of the CRADA, as amended, included, among other things, a requirement to pay $0.5 million quarterly to NCI for expenses incurred in connection with the ongoing Phase 3 clinical trials. Since the transfer to Biovest of the IND for development of this vaccine, which occurred in April 2004, these payments to NCI were reduced to approximately $580,000 annually. Failure to remit these reduced payments will constitute the Company's unilateral termination of the CRADA and Biovest will lose the rights to commercialize the results of its collaborative research. The Company has funded the continuing development costs as described above, including the renovation of our Worcester facility to meet FDA requirements. Successful development of the vaccine, if approved by the FDA, from Phase 3 clinical trials through commercialization will commit Biovest to several years of significant expenditures before revenues will be realized, if ever. The agreement was unilaterally terminated by the Company effective November 25, 2006.

The terms of the CRADA provide for the Company to be granted an exclusive option to negotiate with the NCI for a license to commercialize certain intellectual property resulting from the research conducted pursuant to the CRADA. There can be no assurance that research under the CRADA will be successful or, if it is successful, that the Company will be able to negotiate a license on favorable terms. In addition, the Company may not be able to derive any revenue from a license for a number of years.

c) Government regulation

Government authorities in the United States at the federal, state, and local levels and foreign countries extensively regulate, among other things, the research, development, testing, manufacture, labeling, promotion, advertising, distribution, sampling, marketing, and import and export of pharmaceutical products, biologics, and medical devices. All of our products in development will require regulatory approval by government agencies prior to commercialization. In particular, human therapeutic products are subject to rigorous preclinical and clinical trials 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, safety, labeling, storage, and record-keeping related to such products and their marketing. The process of obtaining these approvals and the subsequent process of maintaining substantial compliance with appropriate federal, state, local, and foreign statutes and regulations require the expenditure of substantial time and financial resources. In

addition, statutes, rules, regulations, and policies may change and new legislation or regulations may be issued that could delay such approvals.

d) Product liability

The contract production services for the Company's therapeutic products offered exposes the Company to an inherent risk of liability as the proteins or other substances manufactured, at the request and to the specifications of customers, could potentially cause adverse effects. The Company obtains agreements from contract production customers indemnifying and defending the Company from any potential liability arising from such risk. There can be no assurance, however, that the Company will be successful in obtaining such agreements in the future or that such indemnification agreements will adequately protect the Company against potential claims relating to such contract production services. The Company may also be exposed to potential product liability claims by users of its products. A successful partial or completely uninsured claim against the Company could have a material adverse effect on the Company's operations. Management believes that insurance coverage is adequate to cover risks inherent in the business.

e) Litigation

The Company's Analytica subsidiary is a party to a litigation brought against a former employee, alleging breach of covenants not to compete, breach of confidentiality agreements and misappropriation of proprietary information. This matter is pending in the Supreme Court of New York, New York County. The defendant has filed an Answer containing counterclaims against Analytica, the Company and an officer of the Company. The Company has filed a motion seeking to dismiss all claims naming the Company and the Company's officer personally, and to dismiss certain claims against all defendants. The Company has indicated that it plans to pursue its affirmative claims in this matter vigorously and will assert all available defenses against the counterclaims, which the Company believes are without merit.

Further, from time to time the Company is subject to various legal proceedings in the normal course of business, some of which is covered by insurance. Management believes that these proceedings will not have a material adverse effect on the financial statements.

f) Employment agreements

The Company has employment agreements with certain officers and executives, which extend from 18 to 60 months. These agreements provide for base levels of compensation and separation benefits.

Future minimum payments under these employment agreements are as follows:

Year ending September 30,	
2007	$ 3,209,000
2008	2,413,000
2009	1,986,000
2010	221,000
	$ 7,829,000

19. New Market Tax Credit Financing

On April 25, 2006, Biovest, through its wholly-owned subsidiary, Biovax, Inc. ("Biovax") became the recipient of $3.0 million in net-funds under a qualified New Market Tax Credit Program ("NMTC"). The NMTC was provided for in the Community Renewal Tax Relief Act of 2000 (the "Act") and is intended to induce investment capital in underserved and impoverished areas of the United States. The Act permits taxpayers (whether companies or individuals) to claim credits against their Federal income taxes for up to 39% of qualified investments in qualified, active low-income businesses or ventures. Biovax is a qualified, active low-income business and is eligible to receive investment capital under the NMTC.

NMTC investments are made though Community Development Entities ("CDE"); such entities are qualified for this purpose through the U.S. Department of the Treasury. The CDE investor in the Company's financing arrangement is Telesis CDE II, LLC, which was established solely for this investment. Telesis CDE II, LLC is managed and partially owned (0.01%) by Telesis CDE Corporation, which is a private financial institution. The remaining equity interest in Telesis CDE II, LLC (99.99%) is owned by Biovax Investments, LLC (the "Fund"), a company established solely for the purpose of facilitating this NMTC financing arrangement. The Fund equity is owned 99.99% by US Bancorp and 0.01% by Telesis CDE Corporation.

The fund was capitalized with $3.6 million equity from US Bancorp and a nominal equity investment by Telesis CDE Corporation. In addition, Biovest and the Company, through a consolidated subsidiary, loaned $8.5 million to the Fund pursuant to a 5.18%, annual rate, senior-secured, convertible note receivable, due in seven and one-half years. The note is convertible at the option of the Fund into shares of Biovest's common stock at a price based upon trading market prices of Biovest's common stock near the maturity date in seven and one-half years. These proceeds received by the Fund from the aforementioned financing transactions were used to make a contemporaneous 99.99% equity investment in Telesis CDE II, LLC ($12.0 million) and payment for management, legal and accounting fees ($0.1 million).

Telesis CDE II, LLC, upon receipt of its equity funding, contemporaneously issued $11.5 million to Biovax for (a) a 1.0% convertible promissory note payable, due in seven and one-half years, (b) warrants to purchase 1.2 million shares of Biovest's common stock over a period of nine-years at a fixed price of $9.00 and (c) warrants to purchase 0.2 million shares of the Company's common stock over a period of seven years at a fixed price of $1.30. The convertible promissory note is convertible into common stock at the option of Telesis CDE II, LLC within 5 days of the maturity date at a conversion price equaling the then trading market price of the common stock. The overall arrangement provides that in the event Telesis CDE II, LLC converts the note payable, the aforementioned note receivable is subject to immediate conversion at the same conversion price.

Other salient terms and conditions of the NMTC financing arrangement are as follows:

1. The new market tax credits arising from this transaction were fully assigned to US Bancorp. Biovest, its subsidiaries and certain related parties have entered into an indemnification agreement directly with US Bancorp that provides for indemnification in the event of tax credit recapture from events caused by the Company. Examples of events that would cause recapture are relocation out of the qualified zone or disqualification from changes in Biovax's employment mix. An example of an event that would not cause a recapture is a change in the Internal Revenue Code that results in such recapture. The total indemnification amount could be $4.7 million (representing 39% of the $12.0 million qualified investment). However, in accordance with Financial Interpretation 45 Guarantor's Accounting and Disclosure Requirements for *Guarantees, including Indirect* Guarantees of the Indebtedness of Others, the conditions and events that could result in recapture are within Biovest's control. Therefore, the financial statements do not reflect a liability for this indemnification at September 30, 2006.
2. In connection with the NMTC financing, the Company and US Bancorp entered into a put option wherein US Bancorp will have the right to put it's investment in the Fund to Biovest near the maturity of the instruments at a price of $180,000. The counterparties also extended a purchase option to Biovest to purchase US Bancorp's interest in the fund near the maturity date at fair value. These instruments were evaluated pursuant to the provisions of FAS133 and it was concluded that the put liability required recognition in Biovest's financial statements because it is highly probable that, upon maturity, US Bancorp will put its investment in the Fund to the Company.
3. Biovest, its subsidiaries and certain related parties have entered into a guarantee arrangement with Telesis CDE II, Inc. for the debt service of Biovax. In addition, the Company has partially guaranteed debt service with limitations established at no greater than $60,000 each year the instrument is outstanding. Biovest issued warrants to purchase 1.0 million shares of common stock to the related parties as compensation for their guarantees. The guarantees were treated in a manner similar to contributed service and the fair value of the warrants issued for consideration was charged to expense upon issuance.

Accounting for the NMTC financing arrangement:

The Company evaluated the structure of the NMTC financing arrangement and entities so involved under the context of FIN46. FIN46 provides a framework for determining whether certain entities should be consolidated (irrespective of equity ownership) based upon a variable interests model. This model determines the control and consolidation based upon potential variability in gains and losses of the entity being evaluated for consolidation. Generally, a variable interest holder that absorbs a majority of the entity's expected losses, if they occur, receives a majority of the entity's expected residual return, if they occur, or both is identified as the primary beneficiary for consolidation purposes.

The Company concluded that the Fund and Telesis CDE II, LLC met the definition of variable interest entity. However, for Biovest to be required to apply the provisions of the Interpretation, it must have a variable interest in the entity. Variable interests in a variable interest entity are contractual, ownership or other money interests in an entity that change with changes in the value of the net assets of the entity. The following table illustrates the variable interests have been identified in each of the entities considered by the Company and the related holder:

Variable Interest Holder	Variable Interests Fund	Variable Interests Telesis CDE II, LLC
Biovest and its Related Parties	Senior beneficial interest Guaranty Agreement Indemnification Agreement Put (VIE Equity) Call (VIE Equity)	Senior beneficial interest Guarantee Agreement Call (Biovest Equity)
Fund		VIE Equity (99.9%)
US Bancorp	VIE Equity (99.9%)	Tax Credit Rights
Biovest Investment Corp.	VIE Equity (0.01%)	
Telesis CDE, Inc.		VIE Equity (0.01%)

The above table illustrates the weight of the variable interests that are held by Biovest. In addition, in performing quantitative valuation, the Company afforded significant weight to the guarantee agreement, indemnification and put feature, the preponderance of which limit the equity investor's risk of loss on the venture. In evaluating both qualitative and quantitative considerations, the Company has concluded that its variable interests in the entity absorb most of the entities' losses and should, therefore, consolidate the entities under the scope of FIN46.

The assets and liabilities of the variable interest entities, identified above, are limited to the instruments referred to in the description of the NMTC financing arrangement above. In accordance with consolidation principles, these assets and liabilities are eliminated in consolidation leaving the non-controlling interests of US Bancorp and Telesis CDE Corporation reflected on Biovest's and therefore Accentia's consolidated balance sheet. All intercompany accounts will continue to be eliminated so long as (i) the entities meet the definition of variable interest entities and (ii) Biovest is the primary beneficiary.

20. Quarterly financial data

2006

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Net sales	$ 6,817,966	$ 7,053,925	$ 5,726,527	$ 5,459,630
Gross profit	4,942,193	4,403,310	3,360,552	3,966,690
Net loss	(317,026)	(13,797,533)	(12,131,710)	(17,148,635)
Net loss per share available to common stockholders	$ (0.02)	$ (0.47)	$ (0.40)	$ (0.54)

2005

	Quarter 1	Quarter 2	Quarter 3	Quarter 4
Net sales	$ 4,517,119	$ 7,575,192	$ 5,608,307	$ 7,494,164
Gross profit	2,302,788	5,402,034	3,664,055	5,592,580
Net loss	(11,032,146)	(7,649,767)	(9,919,840)	(16,134,616)
Net loss per share available to common stockholders	$ (3.12)	$ (1.53)	$ (1.93)	$ (3.12)

21. Subsequent Events

Amendments to PPD Agreements.

On October 9, 2006, the Company entered into an agreement with Pharmaco Investments, Inc. ("PPD") titled "Amendment No. 1 to the First Amended and Restated Royalty Stream Purchase Agreement" (the "Amendment"), amending the Royalty Stream Purchase Agreement dated September 7, 2004 and the First Amended and Restated Royalty Stream Purchase Agreement dated August 11, 2005 (collectively the Royalty Stream Agreements"). The Amendment contains a provision allowing either the Company or PPD to elect to terminate the Amendment at any time prior to December 31, 2006 upon written notice to the other party. In the event of such termination, the Company would be required to pay to PPD, upon receipt of a proper invoice, for all direct labor costs incurred in the provision of the Services, as defined in the Agreement. Upon such a termination and the payment of the invoiced direct labor costs, the royalty rate for future sales of SinuNase shall revert to a 7% rate as defined in the Royalty Stream Agreements.

On December 15, 2006, the Company gave notice to PPD of its election to exercise its option to terminate services in accordance with the provisions contained in Amendment #1 to the First Amended and Restated Royalty Stream Purchase Agreement dated as of September 26, 2006. The election was effective as of the close of business on December 28, 2006. As a result of this termination, upon satisfaction of certain conditions, the amount of the "Royalty Stream" to be paid by the Company as defined in the applicable agreements will be reduced to 7%.

Asset sale

On October 27, 2006, the Company entered into an amendment and termination of its Distribution Agreements with Argent Development Group, LLC ("Argent") and Ryan Pharmaceuticals, Inc. ("Ryan"). Under those agreements, the Company held a license to three formulations of pain products marketed under the name "Xodol" (the "Xodol Products"). Under the amendment and termination, the Company relinquished its license to the Xodol products. In addition, the Company terminated its rights in and to certain other formulations of pain products licensed from Argent and Ryan.

Simultaneously, on October 27, 2006, the Company entered into an Asset Purchase Agreement with a non-affiliate third-party purchaser (the "Purchaser") whereby the Purchaser purchased from the Company all rights to market and distribute the Xodol Products in North America, and the Company terminated all of its rights pursuant to a Supply Agreement with Mikart, Inc. ("Mikart") for the Xodol Products. In connection with this transaction, the Company agreed to make payment for specific quantity of returned Xodol Products being received from Cardinal Health while the Purchaser has agreed to assume responsibility for all future returned products, discounts and chargebacks associated with the Xodol Products.

New Markets Tax Credits

On December 8, 2006, the Company's majority-owned subsidiary, Biovest, through its wholly owned subsidiary, AutovaxID, Inc. ("AutovaxID") closed a financing transaction (the "Transactions") that was structured in an effort to obtain certain perceived advantages and enhancements from the New Markets Tax Credit regulations adopted under the auspices of the United States Department of the Treasury in 2002 to provide incentive for investing in businesses located in "qualifying census tracts," or areas with a median income below the poverty line. AutovaxID is presently located in a qualifying census tract, and the New Plant (as defined below) will be located in a qualifying census tract.

In the Transaction, AutovaxID entered into a QLICI Loan Agreement where St. Louis New Markets Tax Credit Fund-II, LLC (the "CDE") made a loan to AutovaxID, evidenced by a Subordinated Promissory Note dated as of December 8, 2006, in the principal amount of $7,700,000 ("CDE Loan"). The CDE Loan has a maturity date of December 8, 2036 and is described in more detail below, qualified entirely by the QLICI Loan Agreement attached as an exhibit. The following parties were involved in the Transaction: AutovaxID, the Company, Biovest's majority shareholder, Biolender II, LLC ("Biolender II"), the CDE, St. Louis Development Corporation ("SLDC"), AutovaxID Investment LLC ("Leverage Fund"), U.S. Bancorp Community Investment Corporation ("USBCIC") and Laurus Master Fund, Ltd. ("Laurus").

Under a License and Asset Purchase Agreement dated as of December 8, 2006, Biovest granted a nonexclusive license to the intellectual property enabling AutovaxID to manufacture and sell automated cell culture instruments in the United States, Canada and Mexico (the "License"), which license will become exclusive upon the occupancy by AutovaxID of a space located at 1031 Macklind Avenue, St. Louis, Missouri (the "New Plant"). Biovest also agreed to sell AutovaxID certain equipment (the "Equipment") to AutovaxID upon the occupancy by AutovaxID of the New Plant. AutovaxID must use its best efforts to occupy the New Plant by March 31, 2007, and must occupy the new plant by June 15, 2007. As full purchase price for the License and related business opportunity, AutovaxID paid Biovest $5,600,000. Upon the attainment of occupancy of the New Plant, AutovaxID will pay Biovest fair market value for the Equipment, which is estimated to be $896,100.

On December 8, 2006, we loaned to Biovest $3,100,000 pursuant to a Secured Promissory Note (the "Accentia Note") in order to facilitate Biovest's ability to close the Transaction. Under the terms of the Accentia Note, interest shall accrue at a rate equal to prime rate, payable upon demand of the Company. Biovest shall pay principal and interest as follows: (a) $1,100,000 was paid to the Company upon the closing of the Transaction and (b) the remaining $2,000,000 of principal and all accrued and unpaid interest shall be paid by Biovest upon demand by the Company.

All amounts payable by AutovaxID under the CDE Loan are guaranteed by Biovest. In addition, Biovest and certain officers, directors and shareholders of Biovest and/or the Company (and related trusts) ("Individual Guarantors") guarantee the payment of all obligations under AutovaxID's indemnity to USBCIC. The Individual Guarantors' obligations are proportionate and provide for a maximum aggregate liability for each of the Individual Guarantors as set forth in the Guaranty Agreement. Biovest entered into Indemnity Agreements with the Individual Guarantors, and, in consideration of such guaranties, has granted warrants to the Individual Guarantors for the purchase of a total of 2,629,543 shares of Biovest's common stock at $1.10 per share in proportion to the amounts of their guaranties.

SLDC has used a portion of the credits allocation transaction fee it received from Biovest in order to purchase 326,098 shares of Biovest's common stock, valued at $1.10 per share. Biovest issued its shares to SLDC under a transaction that was exempt from registration under the Securities Act of 1933, as amended (the "Securities Act"), by virtue of Rule 506 of Regulation D under the Securities Act. Such sale and issuance did not involve a public offering, was made without general solicitation or advertising, and St. Louis Development Corporation is an accredited investor with access to all relevant information necessary to evaluate the investment, representing to Biovest that the common stock was being acquired for investment.

Restructure of Intercompany Agreements with Biovest

- The Company and Biovest entered into a Royalty Agreement that terminated and superseded the Biologics Products Commercialization Agreement (the "Biologics Commercialization Agreement"), dated August 17, 2004, between the two companies. The Biologics Commercialization Agreement had provided that the Company was the exclusive commercialization partner for Biovest's biologic products and was entitled to 49% of Biovest's net profits from the sale of biologic products. Net revenue as used in the Biologics Commercialization Agreement included all receipts from the sale, license, sub-license, joint venture or other receipts from each Biovest biologic product less all expenses including the costs of product acquisition, research, manufacture, sales, distribution, commercialization and governmental regulation. The new Royalty Agreement provides that the Company is no longer Biovest's exclusive commercialization partner and replaces the share of net profits with a 19.5% royalty based on net sales of biologics products. The products and territory subject to the Royalty Agreement remain identical to those terms as previously contained in the Biologics Commercialization Agreement. In consideration for the Company entering into this Royalty Agreement, Biovest agreed to issue to the Company five million new shares of Biovest common stock, representing the independently appraised value to Biovest of the new agreement.
- The Company and Biovest entered into a Termination Agreement under which the Company agreed to immediately terminate its absolute anti-dilution rights that were granted to the Company pursuant to the First Right of Refusal Agreement dated June 16, 2003 with Biovest. In consideration of the Company's termination of the First Right of Refusal Agreement, Biovest issued to the Company five million additional new shares of Biovest common stock.
- The Company and Biovest entered into a Purchase Agreement whereby Biovest purchased the Company's 70.5% ownership interest in Biolender, LLC ("Biolender"). Biolender is the entity that was formed by Biovest and the Company to participate in Biovest's New Market Tax Credit enhanced financing that closed on April 25, 2006. Biolender's principal assets is a promissory note in principal amount of $8.5 million which is anticipated to be repaid in approximately seven years when Biovest is required to repay the loan that it received as part of this New Market Tax Credit enhanced financing. In consideration of the sale of this interest in Biolender, Biovest agreed to issue to the Company ten million additional new shares of Biovest common stock, representing the negotiated value of the purchased interest.
- In order to consummate the foregoing transactions, the Company was required to obtain the consent of its senior lender, Laurus Master Fund, Ltd. ("Laurus"), under the Company's loan agreements with Laurus. In consideration for providing such consent, the Company entered into an agreement with Laurus pursuant to which Laurus consented to the above-described agreements and the Company issued to Laurus a warrant to purchase 10 million outstanding shares of Biovest common stock owned by the Company at an exercise price of $.01 per share. The warrant expires in October 2012.

SIGNATURES

Pursuant to the requirements of Section 13 of the Securities Exchange Act of 1934, the Company has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

ACCENTIA BIOPHARMACEUTICALS, INC.

By: /s/ Francis E. O'Donnell, Jr.
Chairman and Chief Executive Officer
(Principal Executive Officer)

By: /s/ Alan M. Pearce
Chief Financial Officer
(Principal Financial Officer and Principal Accounting Officer)

Date: December 29, 2006

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Company and in the capacities and as of the date indicated:

Signature	Title	Date
By: /s/ Francis E. O'Donnell, Jr., M.D. Francis E. O'Donnell, Jr., M.D.	Chief Executive Officer; Chairman ofthe Board; Director (Principal Executive Officer)	December 29, 2006
By: /s/ Alan M. Pearce Alan M. Pearce	Chief Financial Officer; Director (Principal Financial Officer and Principal Accounting Officer)	December 29, 2006
By: /s/ Steven R. Arikian, M.D. Steven R. Arikian, M.D.	Director; President and Chief Operating Officer, Biopharmaceutical Products and Services	December 29, 2006
By: /s/ David M. Schubert David M. Schubert	Director	December 29, 2006
By: /s/ John P. Dubinsky John P. Dubinsky	Director	December 29, 2006
By: /s/ Todd D. Thomason Todd D. Thomason	Director	December 29, 2006
By: /s/ Edmund C. King Edmund C. King	Director	December 29, 2006

Registrar and Transfer Agent

American Stock Transfer & Trust Company
59 Maiden Lane
New York, New York 10038
(800) 937-5449
www.amstock.com

Stock *Trading* Symbol

Accentia's shares trade on the The Nasdaq Stock Market® under the symbol "ABPI"

Annual Meeting

Accentia's 2007 Annual Meeting of Shareholders will be held on February 28, 2007, at 11:00 a.m. (local time). The meeting will be held at the St. Louis Club, 7701 Forsyth Blvd., Clayton, Missouri 63105.

Independent Registered Public Accounting Firm

Aidman, Piser & Company
401 East Jackson St., Suite 3400
Tampa, Florida 33602
(813)222-8555
www.apcpa.com

Corporate Headquarters

324 South Hyde Park Ave., Suite 350
Tampa, Florida 33606
(813) 864-2544
www.accentia.net

Investor Relations Firm

The Investor Relations Group
11 Stone St., 3rd Floor
New York, New York 10004
(212) 825-3210
www.investorrelationsgroup.com

Quarterly reports on Form 10-Q and the Form 10-K Annual Report filed with the Securities and Exchange Commission are available in the "Investor Relations" section of Accentia's website at www.accentia.net and can be obtained by calling Accentia's investor relations firm, The Investor Relations Group, at 212-825-3210.

Forward-Looking Statements

Statements in this Annual Report, including the letter from our CEO, that are not strictly historical in nature constitute "forward-looking statements." Such statements include, but are not limited to, statements about our products, product candidates, and product development programs. Such statements may include, without limitation, statements with respect to the Company's plans, objectives, expectations and intentions and other statements identified by words such as "may," "could," "would," "should," "believes," "expects," "anticipates," "estimates," "intends," "plans" or similar expressions. Such forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause the actual results of Accentia to be materially different from historical results or from any results expressed or implied by such forward-looking statements. These factors include, but are not limited to, risks and uncertainties related to the progress, timing, cost, and results of clinical trials and product development programs; timing of product launches, difficulties or delays in obtaining regulatory approval for product candidates; competition from other pharmaceutical or biotechnology companies; and the additional risks discussed in filings

ACCENTIA BIOPHARMACEUTICALS

END

Corporate Headquarters

324 South Hyde Park Ave., Suite 350

Tampa, Florida 33606

telephone: (813) 864-2554

fax: (813) 258-6912

www.accentia.net