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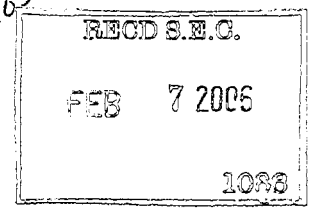

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ACCENTIA BIOPHARMACEUTICALS INC.

2005 ANNUAL REPORT

To Our Shareholders

We are pleased to present our first annual report as a public company and share with you the important developments that occurred at Accentia during fiscal 2005. We have spent the last several years working to build an innovative platform for the development and commercialization of late-stage product candidates in the respiratory and oncology fields. This activity primarily consisted of business acquisitions and the in-licensing of products. Fiscal 2005 presented us with challenges, yet we were able to accomplish our key objectives and lay a solid foundation for the future. We believe that Accentia is now positioned as a young and dynamic publicly held biopharmaceutical company with remarkable product candidates. In particular, we are optimistic about our SinuNase™ product for the treatment of chronic sinusitis and our BiovaxID™ product for the treatment of follicular non-Hodgkin's lymphoma. We look forward to working on your behalf to harvest the potential value of these product candidates, as well as the other products in our pipeline.

> > > Looking Back on Fiscal 2005

Fiscal 2005 was an important year for Accentia, as we accomplished the following key objectives:

Financial Foundation

During fiscal 2005, we expended considerable effort toward the completion of our initial public offering (IPO). Although the IPO was not finalized until after the end of the fiscal year, the arduous process consumed much of our time and focus throughout the year. In the biotechnology and pharmaceutical sectors, the market conditions for such offerings have been unfavorable, impacting the size and price of our IPO. Nevertheless, we were able to achieve IPO status at a time when other biotech companies in the industry could not, and Accentia is now traded on the NASDAQ National Market. Divergent from the traditional biotech business model, Accentia is a commercial-stage enterprise with growing revenue in its two operating segments, Biopharmaceutical Products and Services, and Specialty Pharmaceuticals. Our Biopharmaceutical Products and Services division primarily focuses on the development of our product candidates, while the Specialty Pharmaceuticals segment directs the marketing and sale of products licensed from our development partners. These are the two core competencies that

drive success and position us as an attractive partner for late-stage products in the respiratory and oncology markets. We consolidate our financials with our majority-owned subsidiary, Biovest International, Inc. (OTCBB:BVTI), which is spending heavily on its pivotal Phase 3 clinical trial for BiovaxID. We are also developing SinuNase, and have established a variety of partnerships with third-party drug developers that are paid based on milestones achieved. Accordingly, additional financing will be necessary to continue our development programs, and losses will continue to be incurred for the foreseeable future; but we believe the completion of our IPO affords us more financial options and better situates us to attract investors.

Product Development Programs

We made significant advances in our product-development program during fiscal 2005, principally in regard to the development of SinuNase and BiovaxID. We filed the IND for SinuNase, a potential blockbuster product, and partnered with Pharmaceutical Product Development, Inc., a major Accentia investor and a leading clinical-research organization with a successful track-record of conducting clinical trials. As for BiovaxID, we completed the development of AutovaxID™, a highly automated production unit. This technology is equipped to produce BiovaxID, and other customized proteins. In addition, after the transfer of the IND from the National Cancer Institute (NCI), we expanded the number of U.S. clinical investigative sites from 5 to 22. We also reported the long-term follow-up results of the NCI Phase 2 study of BiovaxID, which produced an encouraging overall survival rate of 95% at a median follow-up of 9.2 years.

Accentia Product Pipeline Highlights

Drug	Drug Application	Regulatory Status	Anticipated Launch
MD Turbo	*Device for metered dose inhalers in asthma and COPD*	*510(k) Approved*	*FY06*
emezine (prochlorperazine maleate)	*Treatment of severe nausea and vomiting*	*505(b)(2) Pending Approval*	*FY06*
Allernase	*Seasonal and perennial allergic rhinitis*	*sNDA Planned*	*FY07*
SinuNase (amphotericin B)	*Treatment of chronic sinusitis*	*IND Filed*	*FY08*
BIOVAXID	*Treatment of indolent follicular non-Hodgkin's Lymphoma*	*Phase 3 Ongoing*	*FY08*

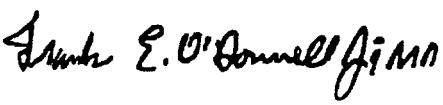
From within our Specialty Pharmaceuticals pipeline, two products, MD Turbo™ and Emezine™, are expected to be launched in fiscal 2006. Our development partner received FDA clearance for our MD Turbo product, a unique host device intended to provide breath-activated, reliable delivery of most metered dose inhalers (MDIs) used for treating asthma and chronic obstructive pulmonary disease. Additionally, our development partner BioDelivery Sciences International filed an NDA for Emezine, the first and only buccal tablet in the U.S for the treatment of severe nausea and vomiting related to influenza, chemotherapy, migraines, surgery, etc. We anticipate launching these, our first truly unique products, this fiscal year.

> > > Looking Forward

Fiscal 2005 was a year of substantial accomplishments for Accentia, yet many challenges lie ahead. We will continue to navigate the complex regulatory approval process for our product candidates, as well as secure additional financing to meet our objectives. With the expected launch of MD Turbo and Emezine and the successful development of SinuNase and BiovaxID, we believe Accentia has never been in a better position.

We would like to note the extraordinary efforts throughout fiscal 2005 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, 2005

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 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 an accelerated filer (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

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 October 28, 2005, 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 National Market, was approximately $88,223,080. The registrant has elected to use October 28, 2005 as the calculation date because on March 31, 2005 (the last business date of the registrant's second fiscal quarter), the registrant was a privately held concern.

As of December 1, 2005, there were 29,121,951 shares of the registrant's Common Stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's definitive Proxy Statement for the 2006 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 1. BUSINESS" 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 "2005" or "fiscal 2005" means the 12-month period that ended September 30, 2005.

Overview

We are a biopharmaceutical company focused on the development and commercialization of late-stage clinical products in the therapeutic areas of respiratory disease and oncology. We have two product candidates entering or in Phase 3 clinical trials. Our first product candidate, SinuNase™, has been developed as a treatment for chronic rhinosinusitis, also commonly referred to as chronic sinusitis, and is based on a novel application and formulation of a known therapeutic previously approved for other indications. Chronic rhinosinusitis, or CRS, is a long-term inflammatory condition of the paranasal sinuses for which there is currently no FDA-approved therapy. Our Investigational New Drug Application, or IND, for SinuNase was accepted by the FDA in May 2005, and we expect to initiate clinical trials for the product in early 2006. Our second product candidate, BiovaxID™, is a patient-specific anti-cancer vaccine focusing on the treatment of follicular non-Hodgkins lymphoma. BiovaxID is currently in a pivotal Phase 3 clinical trial. In addition to these product candidates, we have a growing specialty pharmaceutical business with a portfolio of ten currently marketed products and a pipeline of products under development by third parties. Our goal is to utilize our vertically integrated business structure to cost-effectively and efficiently develop and commercialize innovative therapeutics that address significant unmet medical needs.

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 initiate clinical trials for SinuNase and continue our pivotal Phase 3 clinical trials for BiovaxID. We also plan to aggressively pursue regulatory approvals for both products.

- Exploiting our specialty pharmaceutical business and its product pipeline to help commercialize SinuNase, BiovaxID, and future late-stage product opportunities. We are building a specialty pharmaceutical business based on our currently marketed products and also on new product candidates being developed by third parties that we believe can be approved and introduced to the market more quickly than SinuNase and BiovaxID. We intend to exploit our specialty pharmaceutical business to provide a platform upon which to commercialize SinuNase, BiovaxID, and other innovative therapeutics. However, we will continue to evaluate our strategy for our specialty pharmaceutical business in light of market conditions, our future financial requirements and our long-term objectives related to our lead products such as SinuNase.

- *Identifying and acquiring additional late-stage clinical products and technologies with an emphasis on respiratory disease and oncology.* We intend to pursue the acquisition of late-stage products that could increase the value of our development pipeline and complement our existing products and product candidates. 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 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. On November 29, 2005 we announced the commercial introduction of a patented, non-invasive test, CRSFungal Profile, to assist in the diagnosis of Chronic Sinusitis in-licensed from IMMCO Diagnostics Inc. On December 6, 2005 we announced the in-licensing from Collegium Pharmaceuticals of a branded intranasal steroid intended for treatment of seasonal and perennial allergic rhinitis. Collegium is preparing to submit its Supplemental New Drug Application (sNDA) in 2006, and the Company has exclusive rights to the US market for the intranasal steroid.

- *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 development and commercialization services, biologics production capabilities, and dedicated sales force 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 opportunities for our current and future products and product candidates.

Our Product Development Pipeline

We currently have 14 product candidates in various stages of clinical development. Of these product candidates, we have direct primary responsibility for the development and regulatory approval of our late-stage biopharmaceutical products, SinuNase and BiovaxID, while various third-party development partners have primary responsibility for the development and approval of our specialty pharmaceutical product candidates. The following table summarizes our current product candidates:

Biopharmaceutical Products

Product	Indication	Current Status	Milestones
SinuNase	Chronic Rhinosinusitis (CRS)	IND submitted in April 2005 and accepted in May 2005; Phase 3 trials expected to commence in early 2006	Completion of Phase 3 trials expected in 2006
BiovaxID	Follicular B-Cell Non-Hodgkin's Lymphoma (NHL)	Phase 3 in progress	Completion of enrollment expected in calendar year 2007

Specialty Pharmaceutical Products

Product	Therapeutic Area	Current Status	Development Partner
AllerNase	Seasonal and perennial allergic rhinitis	sNDA expected to be filed in 2006	Collegium Pharmaceutical, Inc.
MD Turbo	Asthma and Chronic Pulmonary Obstructive Disease	510(k) clearance received in June 2005	Respirics, Inc.
Emezine	Nausea	505(b)(2) submitted in April 2005 and oral notification of acceptance for filing received from the FDA in June 2005	Arius Pharmaceuticals, Inc.
Pain Products (9 products)	Pain/Oncology	Six ANDAs filed in 2005 and three ANDAs expected to be filed in 2006	Argent Development Group, LLC, Acheron Development Group, LLC, and Mikart, Inc.

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 becomes inflamed and swells, 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 could be substantially relieved using an intranasal application of low-dose antifungals. Mayo Foundation for Medical Education and Research has been issued a U.S. patent relating to this treatment method and has filed a European counterpart patent application for the therapy. In February 2004, we acquired a license from Mayo Foundation that, as amended, gives us the exclusive worldwide license to commercialize this therapy using amphotericin B. Our license from Mayo Foundation also includes the use of amphotericin B solution as a topical therapy for asthma. In December 2005, we entered into an Option Agreement with Mayo Foundation giving us the exclusive right until December 2006, without obligation, to seek to negotiate a license for all anti-fungals in addition to Amphotericin B.

Amphotericin B in other formulations has been approved for many years in the U.S. and the European Union for other indications. We selected amphotericin B, rather than another antifungal agent available for our CRS therapy, for the following reasons:

- Amphotericin B is the only antifungal used to date by Mayo Clinic and others in their reported clinical studies relating to the therapy, and such studies have demonstrated that an intranasal application of amphotericin B reduces paranasal inflammation in CRS patients.
- Amphotericin B is classified as fungicidal, meaning it is powerful enough to kill the fungi, whereas most other approved antifungals are fungistatic, meaning that they can impair growth of the fungi but not kill them.
- Amphotericin B, when applied topically, has minimal absorption into a patient's mucus membrane, which makes it possible to apply an effective dose to the fungi in the mucus with a low risk for systemic exposure to the patient.
- Amphotericin B is generally recognized as being very unlikely to induce drug resistance among fungi, as there are not any published studies reporting such induced resistance.
- There is a significant body of historical safety data available for the topical application of amphotericin B, as amphotericin B has been prescribed as an anti-fungal for other indications for over 40 years. Additionally, the published clinical studies with intranasal amphotericin B have not disclosed any serious adverse events to date.

Market Opportunity

Rhinosinusitis is one of the most commonly reported chronic diseases in the U.S., affecting an estimated 14% of the population. Approximately 35 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 some of these studies:

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 nostril • 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. Our IND for SinuNase was initially assigned to the FDA's Division of Special Pathogens and Transplant Products (DSPTP), although we were notified in November 2005 by representatives of DSPTP that our IND for SinuNase may be transferred from their division to the FDA's Division of Pulmonary and Allergy Products (DPAP). Based on our communications with the FDA, we understand that this transfer has not yet occurred and that there is currently uncertainty as to whether a transfer will ultimately occur. We currently believe that this uncertainty will be resolved during the first calendar quarter of 2006.

Upon the filing of our IND in May 2005, the FDA gave us permission to proceed directly to Phase 3 clinical trials for SinuNase, and we originally intended to commence two concurrent Phase 3 clinical trials for SinuNase in late calendar year 2005 in patients who have recurrent CRS despite a history of sinus surgery. In September 2005, we originally submitted a request for a Special Protocol Assessment, or SPA, to the DSPTP regarding our first planned Phase 3 clinical trial for SinuNase. The SPA process provides for official FDA evaluation of a Phase 3 clinical trial and provides a product sponsor with a binding agreement, unless circumstances change, confirming that the design and size of the Phase III study will be appropriate to form the primary basis of an effectiveness claim for an NDA if the study is performed according to the SPA. However, an SPA is not a guarantee than an NDA for SinuNase will be approved. In August 2005, the DSPTP advised us orally and in a non-binding draft communication that it agreed in principle with the principal terms that we had proposed to include in our SPA for SinuNase. In particular, as a part of our August 2005 communications with the DSPTP, the DSPTP advised us that the proposed primary endpoint consisting of the major, or cardinal, symptoms of chronic sinusitis for our SinuNase Phase 3 trials was agreeable to the division. Our proposed endpoint for these studies was the measurement of improvement in the symptoms associated with CRS, namely sinus headaches, facial pain or pressure, post-nasal drip, and nasal congestion. We proposed that this endpoint would be measured with an independently developed published patient questionnaire. These endpoints, together with other suggestions made by the DSPTP concerning our Phase 3 primary endpoints and validation of the measurements used to confirm these endpoints, were reflected in our request for an SPA that we filed with the DSPTP in September 2005.

Upon the notification in November 10, 2005 that our IND may be transferred by DSPTP to DPAP, we voluntarily withdrew our request for an SPA from DSPTP. We currently intend to consult with DPAP and DSPTP concerning the potential submission of a SinuNase SPA request to the appropriate division of the FDA once the uncertainty regarding the transfer is resolved. Because an SPA is not necessary in order to commence and complete the clinical trials and to submit an NDA for SinuNase, we may elect not to submit an SPA for SinuNase. As a consequence of the uncertainty regarding the potential transfer of our IND between FDA divisions, we did not commence our Phase 3 clinical trials during calendar year 2005.

If we ultimately request and receive an SPA for our Phase 3 SinuNase clinical trials, any change by us to the terms of the SPA or to the protocol for our Phase 3 trial included in the SPA would require FDA approval, which could delay our ability to implement such change. Also, the SPA generally could not be changed by the FDA without our permission except where the director of the reviewing division at the FDA discovers a substantial scientific issue essential to determining the safety or effectiveness of SinuNase after testing has begun.

We are currently negotiating with manufacturers for production of amphotericin B suspension that will be used for purposes of the IND and clinical trials. 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.

We filed an application for Fast-Track status with the FDA in April 2005 for SinuNase. Products with Fast-Track designation are eligible for approval based on surrogate endpoints that are not well-established and generally would not be an acceptable basis for approval and for early or rolling acceptance of the marketing application for review by the agency. In June 2005, the FDA informed us in writing that the agency needs additional information to evaluate whether SinuNase satisfies the criteria for Fast-Track designation. We cannot predict the ultimate impact, if any, that Fast-Track designation would have on the timing or likelihood of FDA approval of SinuNase, and we cannot guarantee that Fast-Track status will be formally granted.

Our initial IND for SinuNase is for an amphotericin B suspension that is self-administered by squirting the 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 our affiliate BioDelivery Sciences, under which we have been granted exclusive worldwide rights to BioDelivery Sciences' 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

In February 2004, we entered into a license agreement with Mayo Foundation under which we acquired an exclusive license in the U.S. and European Union to Mayo Foundation's patent rights relating to intranasal amphotericin B therapy for CRS. In December 2004, this license agreement was amended to add asthma as a licensed indication and to also expand the geographic scope of the CRS license to give us worldwide exclusive rights. In December 2005, we entered into an Option Agreement with Mayo Foundation giving us the exclusive right until December 2006 without obligation, to seek to negotiate a license for all anti-fungals in addition to Amphotericin B. Mayo Foundation holds an issued U.S. patent that will expire in 2018 and a European Union counterpart patent application for the use of intranasal antifungals for the treatment of CRS. It also holds a U.S. patent for the use of muco-administered antifungals for the treatment of asthma, and it has filed an additional U.S. patent application relating to this family of patents.

Under our license agreement with Mayo Foundation, we have the exclusive right under Mayo Foundation's patents to use, sell, develop, manufacture, and have manufactured amphotericin B and its derivatives for use as a therapeutic for CRS on a worldwide basis. This includes the exclusive right and duty to pursue FDA approval and commercialize one or more therapies based on the patents using amphotericin B. Prior to FDA approval of any licensed therapies, we have the right to sublicense the therapy to compounding pharmacies that are approved by Mayo Foundation, provided that such licenses are granted only on a year-to-year basis and the sublicensees agree not to seek FDA approval for the therapy. If we receive FDA approval of the therapy, we are prohibited from sublicensing the therapy in the U.S. and can only sublicense it in the European Union with Mayo Foundation's written permission. Under the license agreement, we are required to pay Mayo Foundation royalties based on our net sales of the products and on any sublicense revenue. In addition, the agreement provides for the payment by us to Mayo Foundation of minimum royalties, milestone payments for SinuNase that will become due upon the achievement of various milestones relating to FDA approval and commercial launch of the product, and other fees.

Our license agreement with Mayo Foundation terminates upon the last-to-expire claim contained within the licensed patents. However, Mayo Foundation may terminate the agreement earlier if we commit a material breach of the agreement and fail to cure such breach within 30 days of written notice of the breach. Mayo Foundation may also terminate the agreement if we fail to file the NDA for SinuNase on or before February 10, 2009 or do not pay Mayo Foundation $10.0 million, exclusive of previously paid royalties or fees, by February 17, 2009. Additionally, Mayo Foundation may terminate the agreement if we, before we become a publicly held company, are acquired without Mayo Foundation's written consent, experience a change in ownership of a majority of our voting securities, or enter into a material reorganization in which our core competency is no longer the commercialization of pharmaceutical products in the U.S. Additionally, Mayo Foundation will have the right to convert the

license to a non-exclusive license if we fail to meet various milestones that are specified in a development schedule included in the agreement and if the parties cannot agree on a modified development schedule within ten days of notification of such failure.

Under our April 2004 license agreement with BioDelivery Sciences, BioDelivery Sciences granted us an exclusive license to make, use, or sell its encochleated formulation of amphotericin B for topical treatments for CRS and asthma in the U.S. and European Union. The agreement originally provided for royalties to BioDelivery Sciences in the amount of 14% of our net sales of any FDA-approved antifungal products for CRS or asthma that utilize BioDelivery Sciences' technology, and 12% of our net sales of any unapproved antifungal CRS products that are based on the license from Mayo Foundation. The agreement also provided for a sublicense royalty equal to the greater of 50% of our sublicense revenue on licensed products (after deduction of any royalties payable by us to Mayo Foundation) or 8% of our sublicensees' net sales (regardless of royalty amounts payable to Mayo Foundation), provided that we are not permitted to sublicense the technology except for in the European Union with BioDelivery Sciences' prior written consent. In September 2004, we entered into an asset purchase agreement with BioDelivery Sciences under which we paid BioDelivery Sciences a fee of $2.5 million to expand the geographic scope of the license to make it worldwide and to reduce the royalty percentages to 7% on approved antifungal CRS therapies (but not asthma therapies) that utilize BioDelivery Sciences' technology and 6% on any unapproved antifungal CRS therapies based on the Mayo Foundation license.

Our license agreement with BioDelivery Sciences provides that we will conduct and bear the full expense for the regulatory approvals and clinical trials of the licensed products. The license agreement will expire upon the last-to-expire claim contained in any of BioDelivery Sciences' patents covering its encochleation technology, provided that either party may terminate the agreement earlier if the other party materially breaches the agreement and fails to cure the breach within 60 days after written notice of the breach. In addition, BioDelivery Sciences may terminate the entire agreement if we have not filed an NDA for a licensed product within five years of the agreement date or if our license agreement with Mayo Foundation is terminated. Also, BioDelivery Sciences has the right to convert our exclusive license to its encochleation technology to a non-exclusive license if our rights under the Mayo Foundation license agreement become non-exclusive.

Sales, Marketing, and Manufacturing

If the FDA approves SinuNase for the initial indication of recurrence of CRS after sinus surgery, we anticipate that we will market and sell the product through our own sales force directly to otolaryngologists (ear, nose, and throat surgeons) who are treating CRS patients. There are approximately 10,500 ear, nose, and throat specialists in the U.S., and we currently market other products to these specialists. 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, disposable plastic applicator to administer the suspension into the nasal cavity through each nostril. We expect that the product will be manufactured by a third-party contract manufacturer that will be selected by us in the near future, and we believe that there are a variety of qualified contract manufacturers that could be suitable for this purpose.

On June 30, 2005, we entered into an exclusive commercialization agreement with IMMCO Diagnostics, Inc. under which we have been granted the exclusive right in the U.S. to market IMMCO's 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. The proprietary test involves taking a mucus sample of the patient and delivering it to an IMMCO clinical reference laboratory for testing. It is not sold as a diagnostic kit. This test has been patented by Mayo Clinic and has been exclusively licensed to IMMCO. We began marketing this test in November 2005 under the name CRSFungal Profile™, and we have filed a federal trademark registration application for this name. We believe that the CRSFungal Profile could be used to complement the marketing of SinuNase if SinuNase is approved by the FDA.

BiovaxID

BiovaxID is an injectable patient-specific vaccine that we are developing in conjunction with the NCI to treat the follicular form of non-Hodgkin's lymphoma, or NHL. 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 International, Inc., 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 $1.5 billion in 2004.

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 1I clinical trial and selected our Biovest subsidiary to produce the vaccine for the trial. In 2001, Biovest entered into a cooperative research and development agreement, or CRADA, with the NCI under which we jointly conducted the Phase 3 clinical trial. The NCI filed the Investigational New Drug application, or IND, for BiovaxID in 1994, and in April 2004, sponsorship of the IND was formally transferred from the NCI to us.

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 considering the future potential 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 6 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. As of September 30, 2005, there were 23 clinical sites and 200 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, 2005:

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 1n progress	Enrolling patients to treatment phase; 200 have been enrolled (150 of which have 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 II	Open label, single arm	20	Followup period exceeded 8 years as of September, 2005: 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 3-4 follicular NHL, Grades I-IIIa, which are the indolent slowly progressing forms of the disease that historically have been incurable. Of the 375 patients in a complete remission planned to take part in the BiovaxID or control arm of the 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. 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 vaccinations administered over a six-month period. Each vaccination is accompanied by a series of four injections of GM-CSF. 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. 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 2005 meeting of this board, no safety concerns regarding the trial were identified. We are seeking to complete enrollment for our Phase 3 clinical trial in calendar year 2007. To complete enrollment in calendar year 2007, 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 are considering various opportunities, such as enrolling patients in international venues and adding additional domestic sites. 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 II 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 II 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.

We have applied to the FDA 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. 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. Even though we have applied for orphan drug status, BiovaxID may be deemed by the FDA not to be eligible for orphan drug status. Even if designated as an orphan drug, BiovaxID may not be approved before other applications or granted orphan drug exclusivity if approved. 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.

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, our development relationship with the NCI, 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. We also hold a patent on the cycling technology that is used in the vaccine production machinery, although this patent will expire in 2006. An application has also been filed for the registration of the trademark BiovaxIDTM.

Our CRADA with the NCI provides that we will have exclusive ownership rights to any inventions that arise under the CRADA solely through the efforts of our employees, and we will have a first option to exclusively license any other technology within the scope of the CRADA that may be developed under the CRADA by the parties jointly or solely by the NCI. The specific scope of the CRADA is the clinical development of hybridoma-based idiotypic vaccines for treatment of follicular B-cell lymphoma. In light of the recent transfer of the BiovaxID IND to us, we believe that any future developed patentable inventions under the CRADA will likely be developed solely by our own employees. The CRADA also provides for confidentiality obligations with respect to any new data, technology, or inventions that may be patentable.

Under the CRADA and for the duration of the CRADA, we are obligated to provide the NCI, at no charge to the NCI, sufficient quantities of the vaccine to enable the NCI to complete its ongoing studies relating to the vaccine. The CRADA will continue to remain in effect for so long as the development efforts under the CRADA are ongoing, provided that the CRADA can be terminated by either us or the NCI at any time upon at least 60 days prior written notice. If we terminate the agreement, we would be 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. Also, if we terminate the development of BiovaxID, then we are obligated to grant the NCI a nonexclusive royalty-free license to any invention relating to BiovaxID that was developed under the CRADA, unless we transfer our development efforts to another party. The CRADA obligates us to commit 50 to 60 persons per year to permit the execution of the CRADA

study plan, and the agreement also obligates us to reimburse the NCI approximately $580,000 per year for the duration of the CRADA for the NCI's expenses in carrying out the study plan.

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 within 30 days following the execution of the agreement, and we 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 we obtain regulatory approval for BiovaxID, 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 exclusive distribution rights for all of our biologic products, which include BiovaxID, antigens, monoclonal antibodies, and cell cultures.

Specialty Pharmaceutical Products

We have a specialty pharmaceutical business through which we currently sell a portfolio of ten pharmaceutical products and have a pipeline of additional products under development by third parties. We currently intend to exploit our specialty pharmaceutical business to provide a platform upon which to commercialize SinuNase, BiovaxID, and other innovative therapeutics. However, we are evaluating our strategy for our specialty pharmaceutical business in light of our future financial requirements, market conditions, and our long-term objectives.

Currently Marketed Products

We currently market and sell ten pharmaceutical products in the respiratory and pain markets. Each of these products is manufactured exclusively for us by third-party pharmaceutical manufacturers. Our current product portfolio includes the following products:

Xodol. Xodol is a pain formulation that was approved by the FDA in June 2004 and introduced to the market in August 2004. Xodol is sold in the form of tablets that contain a combination of hydrocodone and acetaminophen and are indicated for the relief of moderate to moderately severe pain. Xodol provides physicians with the ability to prescribe a high dose of hydrocodone with a low dose of acetaminophen. Xodol, which is listed in the FDA Orange Book as having no therapeutic equivalent, is being marketed through our in-house sales force primarily to surgeons, pain management specialists, primary-care physicians, internal medicine physicians, oral surgeons, and otolaryngologists. The main branded competitors of Xodol are Lortab, Lorcet, and Norco, all of which contain a 10 mg dose of hydrocodone and have similar indications for pain. Xodol was developed exclusively for us by Ryan Pharmaceuticals, and we have exclusive distribution rights to the product in the U.S. Under our May 2003 distribution agreement with Ryan Pharmaceuticals, as amended in October 2004, we acquired the exclusive perpetual right to sell, market, promote, and distribute Xodol in the U.S. in consideration of a running royalty based on our net sales of Xodol, subject to remaining annual minimum royalties payable through September 2007 in the aggregate amount of $0.4 million. Ryan Pharmaceuticals was also granted a warrant to purchase 106,878 shares of our common stock under this agreement at an exercise price of $3.89 per share. The agreement requires us to assign a specified number of sales representatives to market Xodol to certain types of physicians in the U.S. The term of the agreement is perpetual, provided that any party can terminate it if the other party becomes insolvent, enters bankruptcy or receivership, or materially breaches the agreement and fails to cure the breach

within 30 days of notice of breach. Xodol is exclusively manufactured for us by Mikart, Inc. Under a June 2003 manufacturing and supply agreement with Mikart, we have minimum purchase requirements for Xodol aggregating approximately $1.2 million over a five-year period beginning in June 2004.

Respi~TANN™. Respi~TANN™ is a unique decongestant for temporary relief of cough and nasal congestion accompanying respiratory tract conditions associated with the common cold, influenza, sinusitis, and bronchitis. Respi~TANN is unique in that it contains a proprietary Tannate Conversion Technology that, by including tannic acid in the product, enables twice-a-day dosing with delayed and consistent drug delivery. In August 2002, we entered into a five-year manufacturing and supply agreement with Kiel Laboratories, or Kiel, providing for the exclusive manufacture and supply by Kiel of Respi~TANN, and we started marketing and selling Respi~TANN in January of 2003. As provided in this agreement, Kiel owns exclusive rights to the Tannate Conversion Technology utilized in Respi~TANN, and we are obligated to purchase all of our requirements of Respi~TANN from Kiel. The agreement also sets forth the prices that we will pay for the product and minimum purchase volume obligations. The agreement will expire in August 2007, unless the parties mutually agree to renew the agreement, although the agreement can be terminated by either party prior to the expiration date if, among other things, the other party materially breaches the agreement and fails to cure the default within 15 days of written notice of default or the other party fails to function for any reason in the ordinary course of business for a period of 10 consecutive business days. During the term of the agreement, Kiel is precluded from manufacturing the product for any party other than us.

Histex Heritage Products. Since 2003, we have marketed and sold a line of allergy, cough, and cold medicines that we refer to as our Histex™ Heritage Products. The Histex Heritage Products consist of Histex HC, Histex PD, Histex Liquid, and Histex SR. Histex SR is indicated for the relief of multiple symptoms of nasal congestion, sneezing, runny nose, and watery eyes associated with seasonal and perennial nasal allergies. Histex HC is indicated for symptomatic relief when coughing, congestion, and rhinorrhea, or runny nose, are associated with respiratory infections. Histex PD is indicated for the relief of nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis, and Histex Liquid is indicated for a wide range of respiratory conditions. We acquired exclusive marketing rights to the Histex Heritage Product line in June 2002 from Andrx Laboratories under an asset purchase agreement.

Histex I/E. Since May 2003, we have marketed and sold Histex I/E, which is a prescription medicine indicated for the relief of seasonal and perennial allergic rhinitis for patients 12 years of age and older. The active ingredient in this product is carbinoxamine maleate, a type of antihistamine that is a strong anticholinergic but that is recognized to be less sedating than equivalent products. Histex I/E utilizes a proprietary Dynamic Variable Release™ technology to allow release of the medication at specified intervals to enhance the efficacy and safety.

Histex Pd 12. Histex Pd 12 is indicated for the relief of nasal and non-nasal symptoms of seasonal and perennial allergic rhinitis and hives. Histex Pd 12 contains carbinoxamine maleate and carbinoxamine tannate, a tannated antihistamine, to deliver an immediate-release benefit for quick relief, as well as sustained relief due to the sustained-release profile of the tannate-based portion of the product. Histex Pd 12 utilizes a patent-pending delivery technology called Dynamic Polymorphic Dissociation, which delivers a specified amount of the active agent immediately and another portion over an extended period of time. Histex Pd 12 was introduced in October 2003.

Specialty Pharmaceutical Products Under Development

In addition to our currently marketed products, we have a pipeline of 12 specialty pharmaceutical products currently under development, consisting of AllerNase, MD Turbo™, Emezine™, and nine narcotic pain products.

AllerNase

Product Background. AllerNase is a novel formulated suspension of an intranasal topical steroid indicated for the treatment of allergic and non-allergic rhinitis. This product is being developed by Collegium Pharmaceutical, Inc.

Marketing Opportunity/Sales & Marketing. An estimated 35 million Americans have allergic rhinitis. The intranasal steroid market in the United States is estimated at more than $2.7 billion in sales annually. Flonase®, Nasonex®, Rhinocort Aqua®, Nasacort AQ®, Beconase AQ® , and Nasarel® are among the intranasal steroid products currently available. Our marketing of AllerNase will target primary care, allergy, and ENT prescribers. AllerNase will be a prescription-only product that we intend to market and sell through our sales force.

Development Status. Under our exclusive licensing and distribution agreement, Collegium has primary responsibility for completing the development of AllerNase and obtaining regulatory approval. Following product approval, Accentia is responsible for completing a Phase IV growth study as required by FDA guidelines. Collegium plans to file a Supplemental New Drug Application (sNDA) in 2006 for this patent-pending aqueous nasal spray formulation. Collegium will own all rights to all filings with and approvals received from the FDA. FDA guidelines allow companies to make changes to drugs or their labels after they

have been approved. To change a label, market a new dosage or strength of a drug, or change the way it manufactures a drug, a company must submit a supplemental new drug application (sNDA).

Proprietary Rights and Manufacturing. Under our exclusive perpetual agreement with Collegium, we have the exclusive right to sell, market, promote, and distribute AllerNase in the United States. Under this agreement, we have royalty and annual minimum royalty obligations. It is anticipated that AllerNase will be produced by a third-party contract manufacturer to be selected.

MD Turbo

Product Background. 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. MD Turbo, which is being developed for us by Respirics, Inc., is a device into which most MDIs can be inserted in order to provide more efficient delivery of medication.

Studies have shown that MDIs are frequently used improperly due to the high velocity of the aerosol particles when exiting the mouthpiece. This particle velocity often results in, among other problems, difficulty in coordinating the timing of actuation and inhalation. It has been demonstrated that, with improper technique, 50% of patients can be expected to get reduced or no clinical benefit from the prescribed medication, as less of the medication reaches the lungs. Physicians currently prescribe spacers or holding chambers to help relieve the effects of improper timing, but these devices are large and are often not well-received by patients. To counter these problems, our MD Turbo device has a patented inspiratory pressure trigger that, upon insertion of the MDI into the device, provides breath-actuation, meaning that inhalation triggers the release of the medication from the canister. Additionally, MD Turbo incorporates a dosage counter to better measure the effectiveness of patient use.

MD Turbo is compatible with most albuterol generics, Ventolin™/Ventolin™ HFA, Proventil™ (but not Proventil™ HFA), Flovent™, Atrovent™, Combivent™, and Alupent™. The dosage counter on the device is battery-operated, and it contains a self-elimination feature that renders it unusable after dispensing a specified volume of medication, usually amounting to approximately one year of usage. The device also features a mechanical over-ride so a timely dose can be delivered regardless of electronic triggering.

Market Opportunity/Sales and Marketing. An estimated 40 million prescriptions are written for MDIs each year. Over 1.25 million prescriptions are filled for spacers or holding chambers each year. Maxair™, marketed by 3M Corporation, is the only competitive breath-actuated inhaler device, but Maxair is compatible with only one drug, pirbuterol, which limits therapeutic options for patients. Maxair generated an estimated $71.5 million in annual sales in 2003. Our marketing of MD Turbo will target allergists, pulmonologists, general practitioners, respiratory therapists, pharmacists, managed care organizations, and consumers. MD Turbo will be a prescription-only device that we intend to market and sell through our own sales force and through a third-party sales force after entering into a co-promotion agreement.

Development Status. We are developing MD Turbo in conjunction with Respirics under a product development agreement that we entered into with Respirics in January 2003. Respirics is a developer of pulmonary drug delivery devices and holds two issued U.S. patents and two U.S. patent applications relating to MD Turbo. Under the development agreement, Respirics has primary responsibility for completing the development of the product and obtaining regulatory clearance or approval, and we are responsible for paying Respirics a total of $1,070,000 in development fees in installments against the delivery of various development milestones. As of September 30, 2005, we have paid Respirics all of this amount. Respirics submitted a 510(k) pre-market notification to the FDA in February 2005 for the product, with the product being classified as a Class II prescription-only medical device. A 510(k) pre-market notification is a type of application that is available for medical devices that are substantially equivalent in intended use and in safety and effectiveness to a previously approved device. In June 2005, the FDA notified Respirics that MD Turbo was cleared to be marketed as a device to assist with the delivery of aerosolized medications when used in conjunction with MDIs and to count the number of doses remaining in the MDI.

Proprietary Rights and Manufacturing. Under a distribution agreement with Respirics that we entered into in January 2003 and amended in August 2005, we have the exclusive right to sell, market, promote, and distribute MD Turbo in the U.S. Under this agreement, Respirics is the exclusive supplier of MD Turbo to us. The agreement provides that Respirics will sell the product to us at a specified price per unit (subject to increases based on verified increases in Respirics' costs), and we are obligated to pay a royalty to Respirics based on the number of units purchased by us. The agreement also sets forth minimum purchase requirements that, based on the expected cost of the product, we anticipate will aggregate to $2.9 million in purchases during each of the two years following commercial launch of the product, $4.0 million in purchases during the third year, and approximately $6.3 million per year thereafter during the term of the agreement. The distribution agreement terminates upon the expiration of the last-to-expire of the U.S. patents covering MD Turbo. However, the agreement can be terminated earlier by either party if the other party becomes insolvent, declares bankruptcy, or materially breaches the agreement and fails to cure the breach within 30 days of written notice of breach. Upon such a termination, Respirics will continue to own all intellectual property relating to MD Turbo,

and the agreement provides that we will not sell any products that are competitive with MD Turbo for a period of two years following the termination.

Emezine

Product Background. In March 2004, we obtained exclusive U.S. distribution rights to Emezine, a product for control of nausea and vomiting. Emezine is 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.

Prochlorperazine maleate is a commonly used anti-nausea and anti-vomiting medication, but in the U.S., it is not available in transbuccal form. A product identical to Emezine (except for packaging and dosing strength) is currently approved for marketing in the United Kingdom and is manufactured, marketed, and sold there under the name Buccastem by Reckitt Benckiser Healthcare (UK) Ltd., a United Kingdom pharmaceuticals company. We believe that, as a transbuccal product, Emezine could provide an attractive alternative to other prochlorperazine maleate products currently sold in the U.S.

Market Opportunity/Sales and Marketing. The market for products that control nausea and vomiting is estimated to exceed $1.7 billion in annual sales. Sales are split between the hospital/clinic setting and the retail market. Competitive products with Emezine will include Zofran, prochlorperazine (Compazine), Phenergan, and Promethazine. We expect to market Emezine though our sales force and through a third-party sales force after entering into a co-promotion agreement. The marketing efforts will be directed to primary care physicians, oncologists, radiation oncologists, anesthesiologists, neurologists, and surgeons.

Development Status. Emezine is being jointly developed with Arius, the exclusive U.S. licensee of the product and a wholly-owned subsidiary of BioDelivery Sciences, under a distribution agreement that we entered into with Arius in March 2004. Under this distribution agreement, Arius is required to use commercially reasonable efforts to obtain FDA approval of Emezine. We are responsible for paying Arius up to a total of $1.9 million in development fees, payable in installments against the delivery of various development milestones. As of September 30, 2005, we have paid Arius $1.5 million of this amount.

Arius filed an NDA with the FDA for Emezine in May 2005, and in June 2005 Arius was orally notified by the FDA that the NDA was accepted for filing as a 505(b)(2) application. In general, a 505(b)(2) application can be filed by a drug sponsor whenever a new drug represents a limited variation of a previously approved drug, and the 505(b)(2) application process enables the sponsor of a drug to rely on the FDA's previous findings of safety and efficacy for the previously approved drug.

Proprietary Rights and Manufacturing. Arius holds an exclusive license to the Emezine product for the U.S. from Reckitt Benckiser. Under our distribution agreement with Arius, we have the exclusive right to market, promote, and distribute Emezine in the U.S. for the duration of the distribution agreement, which expires upon expiration of Arius' license agreement with Reckitt Benckiser in 2014. Under our distribution agreement, Arius is the exclusive supplier of the product to us with specified minimum purchase obligations, and Reckitt Benckiser is the manufacturer of the product. The agreement provides that Arius will sell the product to us at its cost, although we are obligated to pay Arius a royalty based on our net sales of the product. The agreement also provides for the payment by us of milestone payments of up to $2.0 million, of which $1.6 million has been paid through September 30, 2005, with the balance being due upon the achievement of various milestones relating to the FDA approval process. In addition, minimum annual royalties of $2.0 million will be due for the first twelve months after product approval, with minimum annual royalties of $4.0 million due thereafter until a generic competitive product is introduced to the market. During the term of the agreement, we may not sell any product other than Emezine for the treatment of nausea and vomiting in the U.S. without Arius' written consent. If Emezine is approved by the FDA, we are obligated under the agreement to use commercially reasonable efforts to launch Emezine within 90 days of approval, and the agreement specifies certain required annual marketing expenditures by us in connection with Emezine. We are also obligated to assign a specified number of sales representatives to market the product to hospitals and oncologists. The agreement can be terminated by either party prior to its scheduled expiration if the other party becomes insolvent, declares bankruptcy, or materially breaches the agreement and fails to cure the breach within 90 days of written notice of breach.

Pain Products

Product Background. In conjunction with Mikart, Argent, and Acheron, we are developing a portfolio of ten narcotic pain products for the treatment of moderate to moderately severe pain. Each of these products represents a unique combination of hydrocodone and a non-steroidal anti-inflammatory drug (NSAID), hydrocodone and a non-NSAID analgesic or oxycodone and a non-NSAID analgesic. Each new pain product will be differentiated through a separate Abbreviated New Drug Application, or ANDA, filed with the FDA. The first of our pain products, Xodol™, was approved by the FDA in June 2004 and introduced to the market in August 2004. Our goal is to obtain FDA approval of and launch our other nine new pain products over the next 18 to 24 months.

Market Opportunity/Sales and Marketing. Over 50 million Americans suffer from chronic pain, and nearly 25 million Americans experience acute pain each year due to injuries or surgery. As a result, the prescription pharmaceutical market for the treatment of pain was projected to be in excess of $24 billion in sales in the U.S. in 2004. In 2003, an estimated 89 million prescriptions were written for hydrocodone/acetaminophen products. Currently, general and family practitioners and internal medicine practitioners collectively write more than 50% of all prescriptions in the pain category. Although the pain product market is crowded and very competitive, we believe that recently launched products by other companies in this market have been able to generate substantial sales due to product differentiation, focused promotion to key prescribers, and the significant size of the pain market. Our goal is to leverage our complementary and differentiated pain products in development, as well as our relationships with prescribers and current market presence, to gain market share within the pain category.

Our pain products will be marketed and sold for a wide range of pain indications, including post-operative surgery, musculoskeletal and connective tissue conditions, sprains, strains, and fractures. We anticipate marketing our pain products through our sales force directly to primary care physicians, pain specialists, orthopedic surgeons, and other selected specialties that practice in outpatient settings. These products may also be marketed to oncologists in conjunction with our other critical care or oncology products, such as Emezine and BiovaxID (if they are approved), and to otolaryngologists in connection with SinuNase (if it is approved). We believe that our different pain products can be marketed in a complementary manner in order to leverage the relative advantages of each such product.

Development Status. The ANDA filings for these pain products have occurred or are expected to occur at various times during the 2005 or 2006 calendar years. As of December 20, 2005, a total of six of these ANDAs have been filed with the FDA, and the remaining three ANDAs are expected to be filed by early calendar year 2006. Under distribution agreements that we entered into with Argent in June 2004 (as amended in August 2005) and with Acheron in May 2003, Argent and Acheron have primary responsibility for the development of these products and, together with Mikart, will be responsible for obtaining regulatory approval of the products. The ANDAs for these products will be filed in the name of Mikart. In addition, Mikart is developing proprietary process and formulation patents that may provide additional protection from generic products.

Under the Argent and Acheron agreements, we will be required to pay running royalties based on our net sales of the product formulations developed under these agreements. In addition, the Argent agreement provides for the payment by us of minimum royalties upon product approval, milestone payments, and other fees of up to $6.3 million, of which $1.6 million has been paid through September 30, 2005. The Acheron agreement provides for the payment by us of minimum royalties upon product approval and milestone payments of up to $2.0 million, of which $0.1 million has been paid through September 30, 2005. The remaining payments under these agreements will be due upon the achievement of various milestones relating to the product development, approval, and launch process for the product formulations covered by the agreements. In addition, we issued warrants to purchase up to 330,135 shares of our common stock to the designees of Argent and Acheron under these agreements at an exercise price of $2.11 or $5.33 per share.

Once products covered by these agreements are approved by the FDA, we are obligated to launch the products within 90 days of the approval date and to assign a specified number of sales representatives to market the products to certain types of physicians. The term of these agreements is perpetual, provided that any party can terminate the agreements for cause if the other party becomes insolvent, enters bankruptcy or receivership, or materially breaches the agreement and fails to cure within 30 days of notice of breach or if the other party is dissolved, liquidated, or files a petition under bankruptcy or insolvency law. Upon the termination of the agreement, Argent and Acheron will retain all rights to the developed products, subject to royalty payments to us on sales of the products by them.

Proprietary Rights. Our rights to these products (other than Xodol) are based on our agreements with Argent and Acheron, which give us exclusive perpetual rights to market and sell the products developed by them under the agreement in the U.S., and a June 2003 manufacturing and supply agreement with Mikart, who will serve as our exclusive manufacturer and supplier for our pain products (including Xodol). Under our agreement with Mikart, Mikart has agreed not to manufacture any products having an identical formulation as our pain products for any party other than us. The agreement sets forth the prices at which we will buy the products and imposes certain annual minimum purchase requirements on us. The term of the agreement is for five years after Mikart achieves certain manufacturing testing and validation milestones and renews automatically for successive one-year terms thereafter unless either party delivers six months' prior written notice of termination. The agreement can be terminated earlier by either party upon a material breach by the other party that remains uncured for 60 days after written notice of breach or if the other party is dissolved, liquidated, or files a petition under bankruptcy or insolvency law. Upon termination under certain circumstances, Mikart is required to transfer its ANDAs for the products to us at the fair market value of such ANDAs.

Our Development and Commercialization Capabilities

We provide a broad range of analytical, consulting, and clinical development 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.

Biologics Production

We commercially produce biologic products such as mammalian cells, proteins, monoclonal antibodies, and other cell culture products. We provide these products and related services for a fee to a wide variety of customers, including biopharmaceutical and biotechnology companies, medical schools, universities, research facilities, hospitals, and public and private laboratories. We also manufacture and sell instruments and disposables used for the production of cell cultures. Our biologics business is conducted through Biovest, our majority owned subsidiary, which is also the developer and manufacturer of our BiovaxID vaccine.

Sales and Marketing

We maintain a sales force that, as of September 30, 2005, consisted of approximately 106 full-time employees for the marketing and sale of our current specialty pharmaceutical products. Because of our sales force's focus and experience in the respiratory and primary care market, we expect that we will continue to use, and perhaps expand, our sales force to market and sell SinuNase, AllerNase, MD Turbo, Emezine, and our pain products, provided that they are approved by the FDA. If we obtain regulatory approval for BiovaxID, we plan to build a small, highly-focused sales and marketing force 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 likely 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 AllerNase, we will compete with the other intransal corticosteroids currently marketed including Flonase®, Nasonex®, Rhinocort Aqua®, Nasacort AQ®, and Nasarel®

- 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 MD Turbo, we will compete with 3M Corporation's MaxairTM 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 MaxairTM 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 Xodol and our pain products in development, we will compete with other products approved for marketing in the U.S. that contain a combination hydrocodone bitartrate or oxycodone with ibubrofen or acetaminophen, including branded and generic versions of Lortab® 10, Lorcet® 10, Norco®, and Vicodin® HP. As of December 2003, we believe that Lortab® 10 represented about 41% and Lorcet® 10 represented about 30% of the market for hydrocodone/acetaminophen brands that, like Xodol, contain a 10 mg dose of hydrocodone.

- For Respi~TANN and our Histex products, we compete with a wide variety of branded and generic prescription cough, cold, and allergy medications, such as Tussionex®, Allegra®, Clarinex®, and Zyrtec®. Our Histex Pd and Histex Pd 12 products compete in the prescription liquid antihistamine market, in which Zyrtec Syrup has the largest market share at around 84%. Our Histex I/E product competes in the solid antihistamine market, in which Allegra® and Zyrtec® are the largest competitors with about 42% and 37% of the market, respectively. Our Respi~TANN product competes in the antihistamine 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. In addition, our ability to compete may be affected because insurers and other third-party payors in some cases seek to encourage the use of generic products making branded products less attractive, from a cost perspective, to buyers.

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 Involves 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, that 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.

We filed an application for Fast-Track status for SinuNase with the FDA in April 2005. In June 2005, the FDA informed us in writing that the agency needs additional information to evaluate whether SinuNase satisfies the criteria for Fast-Track designation. We cannot predict the ultimate impact, if any, the Fast-Track designation would have on the timing or likelihood of FDA approval of SinuNase, and we cannot guarantee that Fast-Track status will be formally granted.

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, including Mikart, 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 1V 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 prospectus.

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, the pain products in our development pipeline, 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 own manufacturing facility in Worcester, Massachusetts. We historically have performed certain steps in the BiovaxID production process at our Minneapolis, Minnesota facility. However, we are in the process of completing the consolidation of all BiovaxID-related production activities into our Worcester facility and are considering divesting the remaining business conducted at Minneapolis. We believe that our Worcester facility is sufficient to produce the vaccine required for the product's clinical trials, and 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 prospectus.

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 Foundation holds one issued U.S. patent relating to the treatment of CRS with intranasal anti-fungals and another U.S. patent relating to the treatment of asthma through muco-administration of anti-fungals. 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 Foundation.

- 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. We also hold an issued U.S. patent, as well as various foreign counterpart patents, on our hollow-fiber cell culture device and the method of operation of the device, although this patent will expire in February 2006 in the U.S., and the European and Japanese counterparts will expire in October 2005.

- 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™, and Xodol™. Respi~TANN® is a registered trademark of TEAMM Pharmaceuticals, Inc., our wholly owned subsidiary. We use Histex™ and AllerNase™ as trademarks in the U.S. and other countries.

Customers

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, 2005, we had 264 full-time employees. 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, 2005:

Name	Age	Position
Francis E. O'Donnell, Jr., M.D.	55	Chairman of the Board; Chief Executive Officer; Director
Steven R. Arikian, M.D.	47	President and Chief Operating Officer, Biopharmaceutical Products and Services; Director
Martin G. Baum	39	President and Chief Operating Officer, Specialty Pharmaceuticals; Director
Alan M. Pearce	56	Chief Financial Officer; Director
Samuel S. Duffey	60	General Counsel

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.

Martin G. Baum began serving as one of our directors and as our President and Chief Operating Officer of Commercial Operations and Business Development in June 2003. In February 2005, his title was changed to President and Chief Operating Officer, Specialty Pharmaceuticals. He has also served as Chairman, President and Chief Executive Officer of our TEAMM subsidiary since its founding in July 2000. Prior to that, Mr. Baum served as Senior Vice President of Commercial Operations at DJ Pharmaceuticals, Inc., a specialty pharmaceutical company, since January 1999. Since June 2003, Mr. Baum has also been a director of Biovest International, Inc., our majority owned, publicly held subsidiary. Mr. Baum is a graduate of The University of Toledo, where he received B.S. degrees in Pre-Med and Business.

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, or Georgia Tech, the 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. 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.

Samuel S. Duffey, Esq. has served as a director and our General Counsel since April 2003. Prior to that, Mr. Duffey practiced business law with Duffey and Dolan P.A. beginning in 1992. From February 2000, to September 2003, Mr. Duffey served as the non-executive chairman and as a member of the board of directors of Invisa, Inc., a small publicly held safety company, and from October 2001 to May 2004, Mr. Duffey also served as the non-executive chairman and as a member of the board of directors of FlashPoint International, Inc., a publicly held automotive parts company which is currently named Navitrak International Corporation. Mr. Duffey received his B.A. and J.D. degrees from Drake University.

Available Information

We were incorporated in the State of Florida in 2002. Our principal executive offices are located at 324 South Hyde Park Ave., 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.

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.

Prior to the commencement of our Phase 3 clinical trials for SinuNase, we sought a Special Protocol Assessment, or SPA, with the FDA regarding our Phase 3 clinical trials. The SPA process provides for official FDA evaluation of a Phase 3 clinical trial and provides a product sponsor with a binding agreement, unless circumstances change, confirming that the design and size of the Phase 3 study will be appropriate to form the primary basis of an effectiveness claim for an NDA if the study is performed according to the SPA. However, an SPA is not a guarantee that an NDA for SinuNase will be approved. Any change to the protocol for our Phase 3 trial included in the SPA would require FDA approval, which could delay our ability to implement such change. The FDA had advised us orally and in a non-binding draft communication that it agreed in principle with the principal terms that we propose to include in an SPA for SinuNase. In August 2005, the FDA advised us orally and in a non-binding draft communication that it agreed in principle with the principal terms that we had proposed to include in our SPA for SinuNase. In particular, as a part of our August 2005 communications with the FDA, the FDA advised us that the proposed primary endpoint for our SinuNase Phase 3 trials was agreeable to the FDA. Our proposed endpoint for these studies was the measurement of improvement in the symptoms associated with CRS, namely sinus headaches, facial pain or pressure, post-nasal drip, and nasal congestion. This measurement would be accomplished through an independently developed published patient questionnaire. FDA review personnel have made several suggestions concerning our Phase 3 primary endpoints and validation of the measurements used to confirm these endpoints, and our agreement to these recommendations is reflected in our request for an SPA that we filed

with the FDA in September 2005. On November 10, 2005, representatives of the Division of Special Pathogens and Transplant Products (DSPTP) of the FDA notified us by telephone that our IND for SinuNase would likely be transferred from their division to the FDA's Division of Pulmonary and Allergy Products (DPAP). As the result of these discussions, on November 11, 2005, we voluntarily withdrew our request for a Special Protocol Assessment (SPA) for SinuNase. We currently intend to consult with DPAP and DSPTP concerning the potential submission of a SinuNase SPA request to the appropriate division of the FDA. Because an SPA is not necessary in order to commence and complete the clinical trials and to submit a New Drug Application for SinuNase, we may elect not to submit an SPA for SinuNase. At least in part as the result of these developments, we did not commence our Phase 3 clinical trials during calendar year 2005. If we request and receive an SPA, any change by us to the terms of the SPA or to the protocol for our Phase 3 trial included in the SPA would require FDA approval, which could delay our ability to implement such change. There is no guarantee that an SPA will ultimately be granted for SinuNase or that, even if an SPA is granted, that an NDA for SinuNase will be approved.

We expect that "505(b)(2)" applications, which rely in part on investigations not performed for or by the applicant, and for which the applicant has not obtained a right of reference, and Abbreviated New Drug Applications, or ANDAs, will be submitted for our specialty pharmaceutical products under development. No assurances can be given that all of our specialty pharmaceutical products will be suitable for, or approved under, such application procedures. Certain 505(b)(2) application procedures have been the subject of petitions filed by brand name manufacturers which seek changes in the FDA's approval process for such 505(b)(2) applications. These requested changes include, among other things, disallowance of the use by an applicant of a 505(b)(2) application with data considered proprietary by the original manufacturer that was submitted to the FDA as part of an original NDA. We are unable to predict at this time whether the FDA will make any changes to its application procedures as a result of such petitions or the effect that such changes or challenges may have on us.

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 must 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 Foundation 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 $1 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, 2005 and 2004 was $39.4 million and $23.2 million, respectively. , As of September 30, 2005, we had an accumulated deficit of $112.8 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.

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 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, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or 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 be certain that we will receive "Fast-Track" status from the FDA for SinuNase.

In April 2005, we filed an application for the FDA's "Fast-Track" review designation for SinuNase, which, if granted, means that SinuNase may be eligible for expedited review procedures by the FDA. In June 2005, the FDA informed us in writing that the agency needs additional information to evaluate whether SinuNase satisfies the criteria for Fast-Track designation. We cannot predict the impact, if any, that the Fast-Track designation would have on the duration of regulatory approval process for SinuNase if the product is approved by the FDA, and we cannot guarantee that Fast-Track status will be formally granted. If Fast-Track status is not granted, the time to market for SinuNase could increase, which could impair our ability to generate revenue from SinuNase for a longer period of time. Even if Fast-Track status is granted, the FDA may deny regulatory approval of SinuNase.

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 trials. To complete enrollment of our Phase 3 clinical trial for BiovaxID in calendar year 2007, as anticipated, we will need to continue our efforts to significantly increase the rate at which we are enrolling patients in that trial. 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. Delays in planned patient enrollment may result in increased costs and harm our ability to complete our clinical trials and obtain regulatory approval.

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 intend to commence two concurrent Phase 3 clinical trials for SinuNase in early 2006. 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 prior to, or 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 Data Monitoring and Safety Board for BiovaxID, which reviews all adverse event reports related to BiovaxID, has not expressed any concerns to date about the safety of the vaccine. However, 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 Foundation for antifungals other than amphotericin B in the treatment of CRS, then Mayo Foundation 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 Foundation for Medical Education and Research. Our license agreement with Mayo Foundation gives us the exclusive worldwide right to commercialize Mayo Foundation'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 Foundation'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 Foundation giving us the exclusive right until December 2006, without obligation, to seek to negotiate a license for all anti-

fungals in addition to Amphotericin B. In the event that we are not successful in negotiating such additional licenses, Mayo Foundation 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 Foundation 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 currently expect that we and our Biovest subsidiary will need expend at least $2.8 million to complete our clinical trials for SinuNase and at least $20.0 million to complete our clinical trials for BiovaxID, respectively. 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, 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 may not be able to obtain or maintain orphan drug exclusivity for BiovaxID, and our competitors may obtain orphan drug exclusivity prior to us.

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, FDA has sought additional information from us as to whether the indication for BiovaxID meets the legal definition of orphan disease or condition and may decide that BiovaxID is ineligible for orphan drug designation. 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, 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.

Inability to obtain approval of a supplemental IND for SinuNase in its encochleated form may delay the approval and commercialization of the encochleated version of SinuNase.

We submitted an IND for SinuNase in April 2005 for an amphotericin B suspension that is self-administered by squirting the 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 suspension for administration with a pump spray. Encochleation is a proprietary process in which a phospholipid 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 medium. The encochleated version of the product is being developed by us 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 using topical amphotericin B.

Changes to the drug product and to certain manufacturing processes during or following the completion of clinical trials require 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. 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, the FDA may not require additional clinical safety and/or efficacy trials with the encochleated

amphotericin B suspension. If the FDA requires additional clinical safety or efficacy trials to demonstrate comparability, our clinical trials or FDA approval of the encochleated version of SinuNase may be delayed, which would cause delays in generating revenue and increased costs. We cannot guarantee that the FDA will permit us to file a supplemental IND for the encochleated version of SinuNase, in which case we would be required to file a separate IND for the product, thus causing a delay in the clinical trials and approval of the product.

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 to be selected in the future.

- The MD Turbo device is being developed by Respirics, Inc., which is 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.

- Emezine is being developed by Arius Pharmaceuticals, Inc., which is responsible for obtaining regulatory approval of the product. Under our agreements with Arius, Arius will be the exclusive supplier of Emezine, and Arius is obligated to have Emezine exclusively manufactured by Reckitt Benckiser Healthcare (UK) Ltd., a United Kingdom pharmaceuticals company. Arius will manage the relationship with Reckitt Benckiser.

- Under a manufacturing and supply agreement with Mikart, Inc., Mikart will serve as the exclusive manufacturer of our pain products, including Xodol. Mikart is also responsible for obtaining regulatory approval of these products. Argent Development Group, LLC and Acheron Development Group, LLC are our exclusive development partners for the pain products that are still under development.

- Kiel 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, that the FDA has not yet evaluated and remain on the market without FDA approval.

Respi~TANN® and our Histex line of products are marketed in the United States without an FDA-approved marketing application because they have been considered by us to be identical, related, or similar to products that have existed in the market without an NDA or ANDA. These products are 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 for a product 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 some or all of these products are identical, related, or similar to products that have existed in the marketplace without an NDA or ANDA.

The FDA has approved an NDA for a competitor of our Histex Pd 12 product, although to date, we have not received any indication that the agency plans to take enforcement action with respect to this drug. Our ability to market Histex Pd 12 may be affected if the FDA takes enforcement action and requires that we submit an NDA or ANDA application to continue to market this product. Any change in the FDA's enforcement discretion and/or policies could alter the way we currently conduct our business, and any such change could impact our future profitability.

In addition, our Respi-TANN, Histex I/E, Histex SR, Histex PD 12 products contain a timed-release dosage mechanism utilizing tannic acid or timed-release beads. 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 or bead-based timed-release medications have been introduced by other pharmaceutical companies since the FDA's pronouncement without an NDA. Consequently, in continuing to market these products, we rely on the FDA's enforcement discretion with respect to these products, but we cannot guarantee that the FDA will not in the future choose to require an NDA or ANDA for these products, 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 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, Emezine, and our pain product formulations, 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 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.

In connection with our acquisitions to date, we do not believe that we have been materially impacted by any of the factors listed above, although we are still in the process of integrating our acquired businesses and cannot guarantee that we will not experience any material problems in connection with such integration in the future. If we are unable to accurately assess any newly acquired businesses or technologies, our business could suffer. Future acquisitions may involve the assumption of obligations or large one-time write-offs and amortization expenses related to goodwill and other intangible assets. Any of the factors listed above would adversely affect our results of operations.

In addition, in order to finance any future acquisition, we may need to raise additional funds through public or private financings. In this event, we could be forced to obtain equity or debt financing on terms that are not favorable to us and that may result in dilution to our stockholders.

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., Corixa 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 Foundation 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 Foundation'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 Foundation 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 sublicensees 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 Foundation permits us to sublicense Mayo Foundation's patent rights related to amphotericin B for use as a therapy for CRS to compounding pharmacies under license agreements approved by Mayo Foundation. 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, Emezine, Respi~TANN, and our pain products, 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. We are currently 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. The CRADA provides that we have the first right to negotiate an exclusive license to any inventions conceived or first actually reduced to practice by NCI employees, either solely or jointly with our employees, in the course of their performance of the research plan under the CRADA. However, the agreement does not give us an automatic right to such a license, and therefore it is possible that such an invention could ultimately be licensed to a third-party, including a competitor. Additionally, although the NCI has transferred sponsorship of the IND for BiovaxID to us, 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 has the right to terminate the CRADA at any time upon 30 days prior written notice. If the NCI chooses to work with other companies in connection with the development of such a vaccine, such other companies may 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;

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. The 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 Pearce, our Chief Financial Officer, served as a director for BioDelivery Sciences until September 2005. Also, four 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 81% of the outstanding capital stock of Biovest International, Inc., or Biovest, our subsidiary that is developing the BiovaxID vaccine, and the remaining 19% of 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 Arikian, a director and our President and Chief Operating Officer, Biopharmaceutical Products and Services, is the Chairman, CEO, and President of Biovest. Also, Martin G. Baum, our President and Chief Operating Officer, Specialty Pharmaceuticals, is a director of Biovest.

Some of the minority stockholders of our Biovest subsidiary have indicated that they believe that they have a claim against Biovest and/or our company in connection with the investment agreement between us and Biovest.

We acquired our 81% interest in Biovest pursuant to a June 2003 investment agreement with Biovest. The investment agreement with Biovest provides that, within 12 months of the date of our investment in Biovest, Biovest was required to file all necessary documents and take all necessary actions to permit the public trading of all outstanding shares of Biovest common stock that are not subject to restriction on sale or transfer under the applicable securities laws. Since August 2005, Biovest's common stock has been quoted on the OTC Bulletin Board under the symbol BVTI.OB. Although Biovest common stock was not quoted on the OTC Bulletin Board prior to August 2005, Biovest believes that, by filing all reports required to be filed by it under the Securities Exchange Act of 1934 at all times since the date of the investment agreement, it timely filed all required documents and reports and timely took all action within its control necessary to permit such stock to trade publicly during the 12-month period following our investment in Biovest. Prior to the commencement of the quotation of Biovest's common stock on the OTC Bulletin Board, an attorney representing a group of approximately 13 Biovest shareholders orally communicated to us that such shareholders believe that they have a claim against Biovest and/or our company as a result of the fact that Biovest common stock had not yet started trading publicly and no repurchase offer for Biovest stock had yet made under the investment agreement between Biovest and our company. To date, Biovest has not received any written notice of such claims, and no further oral communications regarding these claims have been received subsequent to the date on which Biovest's common stock began being quoted on the OTC Bulletin Board. We believe that any such claim, if formally asserted, would probably be based on the investment agreement. We currently cannot predict whether these Biovest shareholders will file any action against Biovest and/or our company, and if such an action is filed, we cannot predict what the timing and precise nature of their claims will be.

Under the Biovest investment agreement, should it be determined that Biovest should have filed additional documents or taken additional action to permit the trading of its shares, Biovest would, upon 90 days' written notice with a right to cure, be obligated to make an offer to purchase the following number of shares of its outstanding stock (other than stock held by us) as of each of the following dates, provided that Biovest common stock had not started trading by then: 980,000 shares at the first anniversary of the date of our investment in Biovest, 1,960,000 shares at the second anniversary, 2,940,000 shares at the third anniversary of the investment, and 3,920,000 shares at the fourth anniversary, with each such repurchase being at a price of $2.00 per share. If these Biovest shareholders file a claim against us and/or Biovest and we do not prevail in the matter, we may be required to undertake a repurchase offer or otherwise pay monetary damages, in which case our operating results, financial position, and cash flows could be adversely impacted. Even if we prevail in the matter, we may be required to expend significant amounts in defending against the action, and such expenditures could adversely impact our financial position and cash flows.

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. We are currently a party to the disputes described in Item 3 of this Form 10-K under the caption "LEGAL PROCEEDINGS." 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 generates a large portion of our revenue, and any reduction, delay, or cancellation of orders from these customers could reduce our revenues.

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. 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 20, 2005, our long-term debt was $13.9 million. Our long-term debt includes the following:

- $11.9 million in principal amount outstanding under our credit facility with Laurus, consisting of a term loan in the amount of $9.7 million and a revolving credit line in the amount of $2.2 million (which replaced an existing credit line); A portion of this credit facility is convertible into common stock as discussed under "MANAGEMENT DISCUSSION AND ANALYSIS"
- $4.7 million in principal and interest as of December 20, 2005 under a loan from Harbinger Mezzanine Partners, LP (net of a debt discount relating to warrants issued in connection with the loan); and
- $0.8 million in principal and interest as of December 20, 2005 under convertible promissory notes issued by our Biovest subsidiary after conversion to stock in November and December, 2005.
- $4.2 million in principal amount outstanding under our bridge note with Hopkins Capital II, LLC.

Under the $10.0 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 notes evidencing the revolving credit loan portion of our credit facility with Laurus, the $4.7 million principal amount will be due and payable in April 2008, with accrued interest being payable monthly. The entire principal amount of the Harbinger loan will become due in June 2006 (with $2.0 million becoming due within 30 days of the completion of our initial public offering). The $0.8 million in principal and interest under the notes issued by Biovest will become due on various dates during 2006 and 2007. The $4.2 million bridge note issued to The Hopkins Capital Group II, LLC will become due on the earlier of August 16, 2007 or the completion by our company of a debt or equity financing that results in more that $35.0 million in proceeds (net of underwriting discounts, commissions, or placement agent fees). 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 December 20, 2005, our executive officers, directors, and their affiliates beneficially own or control approximately 26% of the outstanding shares of our common stock (after giving effect to the conversion of all outstanding convertible preferred stock and the exercise of all outstanding vested and unvested options and warrants). Accordingly, these executive officers, directors, 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.

A significant portion of our total outstanding shares are restricted from immediate resale but may be sold into the market in the near future. This could cause the market price of our common stock to drop significantly, even if our business is doing well.

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. We have outstanding 29,121,951 shares of common stock as of December 1, 2005. The shares that were sold in our IPO may be resold in the public market immediately, and 25,623,325 shares that are currently restricted as a result of securities laws or lock-up agreements will be able to be sold in the near future as set forth below.

Number of Shares and % of Total Outstanding After Offering	Date Available for Sale Into Public Market
24,138,245 shares, or 84%	On April 25, 2006, which is 181 days after the date of our initial public offering due to the lock-up agreements between the holders of these shares and the underwriters, provided that this lock-up period is subject to extension for up to 17 days under specified circumstances. However, the underwriters can waive the provisions of these lock-up agreements and allow these stockholders to sell their shares at any time. Sales of these shares by "affiliates" and sales of these shares by non-"affiliates" who have held such shares for less than 2 years are subject to the volume limitations, manner of sale provisions, and public information requirements of Rule 144.
1,485,080 shares, or 5%	Between 182 and 365 days after the date of our initial public offering, depending on the requirements of the federal securities laws. Sales of these shares by "affiliates" and sales of these shares by non-"affiliates" who have held such shares for less than 2 years are subject to the volume limitations, manner of sale provisions, and public information requirements of Rule 144.

In addition to the foregoing, we had options to purchase 1,226,767 shares of common stock outstanding and exercisable as of December 1, 2005, after the automatic conversion of preferred stock options into common stock options upon the closing of the IPO. We intend to register the shares of common stock issuable or reserved for issuance under our equity plans within 180 days after the date of closing of the IPO.

Up to 2,166,723 shares of our common stock will become issuable to Laurus Master Fund, Ltd. upon the conversion of convertible notes issued to Laurus in connection with our credit facility with Laurus (excluding the conversion of accrued interest), and up to 1,277,778 shares are or will become issuable to Laurus under warrants granted to Laurus under this credit facility.

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 National 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. This requirement will first apply to our annual report on Form 10-K for our fiscal year ending September 30, 2007. 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 of September 30, 2007 and future year ends 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 2. PROPERTIES

Our principal executive office and administrative office is located in Tampa, Florida and consists of approximately 6,500 square feet. We moved our principal executive and administrative office to this new location in April 2005 after entering into a new lease agreement for five years beginning April 1, 2005. Our former office at a different location in Tampa, Florida consisted of approximately 5,300 square feet and was occupied pursuant to a lease agreement that expired on April 30, 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 17,500 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 agreement that expires in February 28, 2006, and we intend to negotiate a renewal of this lease prior to its expiration. 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 We are considering divesting the remaining business conducted at Minneapolis. However, , in the absence of such divestiture and prior to any such divestiture, we may continue to engage in certain development and other activities at our Minneapolis facility, or any replacement facility selected for our Minneapolis facility, relating to our BiovaxID automated production and purification system.

We anticipate that our facilities will meet our needs for approximately the next three months. 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

In October 2002, our subsidiary, Accent RX, Inc, acquired the assets and certain liabilities of American Prescription Providers, Inc. and American Prescription Providers of New York, Inc., collectively referred to as APP, which at the time of purchase operated a mail-order specialty pharmacy focused on filling prescriptions for AIDS patients and organ transplants. Commencing in late 1998, Dr. Francis E. O'Donnell (our Chairman and Chief Executive Officer) was the Chairman of the Board of APP, Dr. Dennis L. Ryll (a director of our company) was a director of APP, and McKesson Corporation was APP's principal lender. Also beginning in late 1998, The Hopkins Capital Group, LLC, an entity in which Dr. O'Donnell is the manager, and MOAB Investments, LP, an entity in which Dr. Ryll is a limited partner, were principal stockholders of APP. Following the purchase of APP's assets, Accent RX operated the mail-order business until it sold the assets of this business in December 2003 to a third-party in an arm's length transaction. All of the sale proceeds from the disposition of this business were used to pay debts of Accent RX, including to reduce the outstanding balance of the McKesson loan. After the sale of the APP assets, Accent RX ceased to engage in business, and Accent RX currently has nominal assets.

APP learned in May 2002 that the U.S. Department of Justice was conducting an industry-wide investigation under anti-kickback laws and other laws and regulations relating to purchases and sales of Serostim, an AIDS-wasting drug manufactured by Serono, Inc., from 1997 through 2000. As part of this investigation, in May 2002, APP received a subpoena from the U.S. Attorney's Office for the District of Massachusetts, and in March 2004, it received a federal grand jury subpoena seeking records related to Serostim prescriptions dispensed by APP, reimbursement claims submitted to Medicaid for Serostim, and APP's relationships with Serono. We are not aware of any investigation into the acts of Accent RX or our company with regard to the conduct of the mail-order pharmacy business following Accent RX's purchase of APP's assets. While we are uncertain as to the amount or measure of damages, if any, that may be sought from APP, based on information currently available to us, we estimate that, from the commencement of business by APP on December 1, 1998 through 2000, Serono paid APP approximately $500,000 under a program for data collection, and during this same period, Medicaid reimbursed APP approximately $6,000,000 for Serostim prescriptions filled by APP. We estimate that the majority of these payments from Serono and reimbursements from Medicaid were not attributable to APP's mail-order business, but rather were attributable to APP's retail pharmacies, which APP sold to a third party in February 2001 and were therefore not acquired by Accent RX as a part of the 2002 acquisition of APP's assets. In May 2005, the U.S. Attorney's Office notified APP that it believes that APP has significant potential liability as a result of allegedly unlawful rebates and discounts paid to them by Serono between 1997 and 2000. In August 2005, the U.S. Attorney's Office orally and informally indicated to our legal counsel that, as a result of these allegedly unlawful rebates and discounts, it was considering instituting a civil action against Accent RX, our company, APP (which has since dissolved and been liquidated), and shareholders of APP who received APP assets as a part of the liquidation of APP. However, it is not possible to predict the outcome of this investigation and whether the government will formally commence any action challenging any of APP's prior programs and practices or APP's liability or exposure as a result thereof. We are uncertain if any such action would be under the False Claims Act or other civil or criminal causes of action. In the event of litigation, we believe that APP will have defenses that will be vigorously asserted.

We cannot predict whether Accent RX or our company could be held liable for the prior acts of APP as a result of Accent RX's purchase of APP's assets or whether the government will commence any actions against Accent RX. However, we believe that it is unlikely that our company, which has always been operated as a distinct legal entity from Accent RX, will have material financial exposure in the event that Accent RX or APP incurs a material penalty in connection with this matter. Similarly, we do not believe that any adverse legal or regulatory determinations regarding APP, our company, or Accent RX or any persons associated with APP, our company, or Accent RX would have any material effect on the ability of our company and its subsidiaries to conduct their current or expected business operations. On October 17, 2005, the U.S. Department of Justice announced a settlement of criminal and civil allegations against Serono. According to the terms of the settlement, Serono, together with its U.S. subsidiaries and related entities, agreed to pay $704 million in connection with illegal schemes to promote, market, and sell its drug Serostim. We cannot predict the impact, if any, that this settlement will have on the government's investigation relating to APP's purchases and sales of Serostim.

Matters Relating to Biovest

We acquired our 81% interest in Biovest pursuant to a June 2003 investment agreement with Biovest. The investment agreement with Biovest provides that, within 12 months of the date of our investment in Biovest, Biovest was required to file all necessary documents and take all necessary actions to permit the public trading of all outstanding shares of Biovest common stock that are not subject to restriction on sale or transfer under the applicable securities laws. Since August 2005, Biovest's common stock has been quoted on the OTC Bulletin Board under the symbol BVTI.OB. Although Biovest common stock was not quoted on the OTC Bulletin Board prior to August 2005, Biovest believes that, by filing all reports required to be filed by it under the Securities Exchange Act of 1934 at all times since the date of the investment agreement, it timely filed all required documents and reports and timely took all action within its control necessary to permit such stock to trade publicly during the 12-month period following our investment in Biovest. Under the Biovest investment agreement, should it be determined that Biovest should have filed additional documents or taken additional action to permit the trading of its shares, the agreement provides that Biovest would, upon 90 days' written notice with a right to cure, be obligated to make an offer to purchase the following number of shares of its outstanding stock (other than stock held by us) as of the following dates, provided that Biovest common stock had not started trading by then: 980,000 shares at the first anniversary of the date of our investment in Biovest, 1,960,000 shares at the second anniversary, 2,940,000 shares at the third anniversary of the investment, and 3,920,000 shares at the fourth anniversary, with each such repurchase being at a price of $2.00 per share. Under the terms of the investment agreement, all of the above-described obligations are imposed solely on Biovest. Biovest stock is held by approximately 500 shareholders of record, and the shareholders of Biovest are not a party to the investment agreement.

Prior to the commencement of the quotation of Biovest's common stock on the OTC Bulletin Board, an attorney representing a group of approximately 13 Biovest shareholders orally communicated to us that such shareholders believe that they have a claim against Biovest and/or our company as a result of the fact that Biovest common stock had not yet started trading publicly and no repurchase offer had yet been made under the investment agreement. To date, Biovest has not received any written notice of such claims, and no further oral communications regarding these claims have been received subsequent to the date on which Biovest's common stock began being quoted on the OTC Bulletin Board. We believe that any such claim, if formally asserted, would probably be based on the investment agreement. Currently, we cannot predict whether these Biovest shareholders will file any action against Biovest and/or our company, and if such an action is filed, we cannot predict what the timing and precise nature of their claims will be. We have informed the Biovest shareholders that we do not believe any such claim, if asserted, would have merit and that we would defend such claim.

On January 24, 2005, Dr. Robert Pfeffer filed an action against our Biovest subsidiary in United States District Court in New Jersey alleging that Dr. Pfeffer has an employment agreement with Biovest under which Biovest owes him approximately $600,000 and options to purchase 120,000 shares of Biovest common stock. Biovest disputes the alleged employment agreement and the alleged services and Biovest intends to defend this litigation. Additionally, Dr. Pfeffer alleges that Biovest breached its obligation to purchase 168,836 shares of Biovest common stock owned by him for $2.00 per share pursuant to the investment agreement between Biovest and us. Biovest intends to defend this claim. Biovest has asserted defenses and counterclaims against Dr. Pfeffer in this litigation, which has now been transferred to the United States District Court for the Southern District of New York.

Except for the foregoing, 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

During the three-month period ended September 30, 2005, the following matters were submitted to a vote of our stockholders: In July 2005 the shareholders approved the adoption of Amended and Restated Articles of Incorporation in preparation for our initial public offering, and a further amendment thereto was approved by the shareholders in September, 2005.

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 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.

Number of Common Shareholders

As of December 1, 2005 there were approximately 218 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, 2005 (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	1,601,133	$ 1.85	5,260,326
Equity compensation plans not approved by stockholders	—	N/A	—
Total	1,601,133	$ 1.85	5,260,326

Recent Sales of Unregistered Securities

During the fiscal year ended September 30, 2005, we issued the following securities that were not registered under the Securities Act of 1933, as amended (the "Securities Act"):

1. In May 2005, Hutchison & Mason, a law firm, exercised 42,751 warrants to purchase shares of our former Series D preferred stock at an exercise price of $0.00211 per share, resulting in the issuance of 42,751 shares of our Series D preferred stock to its affiliate, H+M Holdings, LLC.

2. In October 2004, we granted warrants to purchase up to an aggregate of 118,754 shares of our common stock at an exercise price of $5.33 per share to Kenneth Greathouse, Patricia Ryan, and Brian Smith. These warrants were granted in connection with certain product development programs of our company. In June 2005, Stuart Rose exercised 7,885 warrants, resulting in the issuance of 7,885 shares of our common stock.

3. Prior to our 2005 fiscal year, in October 2003, we issued warrants to purchase an aggregate of 380,011 shares of our Series A preferred stock at an exercise price of $2.11 per share to The Hopkins Capital Group, LLC, MOAB Investments, LP, Alan MacInnis and RAM Holdings, LLC. The consideration for these warrants was the extension of loans to our company by these parties in an aggregate principal amount of $3,000,000. In December 2003 and February 2004, we issued to Hopkins Capital Group, LLC, MOAB Investments, LP, RAM Holdings, LLC, and Alan MacInnis additional warrants entitling them to purchase an aggregate of 380,011 additional shares of Series A preferred stock at an exercise price of $2.11 per share. The additional warrants were granted in consideration for extending the due date of the loans made by them. In November 2004, 233,707 of these warrants were exercised, resulting in the issuance of an aggregate of 233,707 shares of our Series A preferred stock. The exercise price of these warrants was paid by reducing the indebtedness owing to these parties. In December 2004, an additional 526,316 of these warrants were exercised, resulting in the issuance of an aggregate of 526,316 shares of our Series A preferred stock, and $216,000 of the aggregate exercise price for these shares was paid in cash, with the remaining $892,000 being paid through the reduction of indebtedness owing to the exercising parties.

4. Between September 2004 and December 2004, we issued and sold a total of 2,602,286 shares of our Series E preferred stock, together with warrants to purchase an additional 5,204,573 shares of our Series E preferred stock, at an exercise price

of $2.11 per share to a total of 21 accredited investors. The consideration for these issuances was $2.11 in cash per each investment unit consisting of one share and two warrants.

5. In November 2004, we issued and sold 237,507 shares of our Series A preferred stock to Alan Pearce for a cash purchase price of $2.11 per share.

6. In December 2004, we issued 1,140,034 shares of Series E preferred stock to Mayo Foundation for Medical Education and Research. These shares were granted in consideration of Mayo Foundation's execution of an amendment to our license agreement with them in which they agreed to expand the scope of our license.

7. Between December 2004 and February 2005, we issued 8,195,075 shares of our Series E Preferred stock to 21 holders of outstanding warrants in consideration of the exercise of certain of their warrants at an exercise price of $2.11 per share. $1,565,606 of the aggregate exercise price was paid by The Hopkins Capital Group, LLC and MOAB Investments, LP through the cancellation of outstanding indebtedness owing to them under previously issued promissory notes. The balance of the aggregate exercise price was paid in cash by the various holders of such warrants, which included Pharmaceutical Product Development, Inc., or PPD, and Ronald Osman. In addition, in August 2005, PPD International Holdings, Inc., as assignee of PPD, exercised a warrant for the purchase of 2,375,071 shares of our Series E preferred stock.

8. On April 29, 2005, we entered into a credit facility with Laurus Master Fund, Ltd. providing for aggregate borrowing availability of up to $10 million in principal amount under which the principal and interest is evidenced by secured convertible promissory notes convertible into our common stock at an initial conversion price of $6.95 per share (but upon the completion of our initial public offering, such conversion price will be adjusted to 85% of the per share initial public offering price). In connection with this credit facility, we also issued to Laurus a warrant to purchase a number of shares of our common stock that is equal to $4.0 million divided by the initial public offering price of our common stock, and the warrant will have an initial exercise price equal to $8.17 per share (but upon completion of our initial public offering, such exercise price will be adjusted to the initial public offering price). On August 16, 2005, our credit facility with Laurus was amended by (i) increasing the loan amount (and the aggregate principal amount under the convertible promissory notes) by $5.0 million, (ii) amending and restating the previously issued warrant to increase the number of shares issuable thereunder to $8.0 million divided by the initial public offering price of our common stock, and (iii) granting to Laurus an additional warrant to purchase 277,778 shares of our common stock at an exercise price of $.001 per share.

9. During our fiscal year ended September 30, 2005, we granted stock options under our stock option plans covering an aggregate of 12,855 shares of our common stock (net of expirations and cancellations) at an exercise price of $3.16 per share. We also granted options to purchase an aggregate of 230,464 shares of our Series D preferred stock (net of expirations and cancellations) at exercise prices ranging from $1.05 to $2.11 per share. Of these, options to purchase an aggregate of 1,201 shares of our common stock have been exercised for an aggregate purchase price of $1,576.93, or a weighted exercise price of $1.31 per share, and options to purchase an aggregate of 13,279 shares of our Series D preferred stock have been exercised for an aggregate purchase price of $13,943, or $1.05 per share.

10. We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs 3, 4, 5, 6, and 8 by virtue of Section 4(2) of the Securities Act and by virtue of Rule 506 of Regulation D. Such sales and issuances did not involve any public offering, were made without general solicitation or advertising and each purchaser was an accredited investor with access to all relevant information necessary to evaluate the investment and represented to us that the shares were being acquired for investment.

11. We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs 1, 2, and 7 above by virtue of Section 4(2) of the Securities Act in that such sales and issuances did not involve a public offering. Except for the transactions described in paragraph 6 above, the recipients of securities in each of these transactions represented their intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof. Appropriate legends were affixed to the share certificates and instruments issued in all such transactions. All recipients had adequate access, through their relationships with us, to information about us.

12. We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraph 9 by virtue of Section 4(2) of the Securities Act and by virtue of Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701. Such sales and issuances did not involve any public offering, were made without general solicitation or advertising, and each purchaser represented its intention to acquire the securities for investment only and not with view to or for sale in connection with any distribution thereof, and appropriate legends were affixed to the share certificates and instruments issued in such transactions. All recipients had adequate access, through their relationships with us, to information about us.

No underwriters were employed in any of the above transactions.

Use of Proceeds

We registered shares of our common stock in connection with our initial public offering under the Securities Act of 1933, as amended. Our Registration Statement on Form S-1 (Reg. No. 333-122769) in connection with our initial public offering was declared effective by the SEC on October 27, 2005. The offering closed on November 2, 2005. The underwriters of the offering were Jefferies & Company, Inc.; Ferris, Baker Watts incorporated; Stifel, Nicolaus & Company Incorporated; and GunnAllen Financial, Inc.

All 2.4 million shares of our common stock registered in the offering were sold at the initial public offering price per share of $8.00. The aggregate gross proceeds from the offering (before underwriting discounts and commissions) were $19.2 million. The net offering proceeds to us after deducting underwriting discounts and commissions of $1.3 million and total offering expenses of $3.6 million were $14.3 million. No payments for such expenses were made directly or indirectly to (i) any of our directors, officers or their associates, (ii) any person(s) owning 10% or more of any class of our equity securities or (iii) any of our affiliates.

As of September 30, 2005, we had not completed our initial public offering and, therefore, none of the proceeds of that offering had been received or used as of the fiscal period covered by this report. Description of the use of those proceeds will be included in our quarterly report for the period ending December 31, 2005.

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, 2005, 2004 and 2003 and for the years ended September 30, 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 and 2000 and for the years ended September 30, 2001 and 2000 of our predecessor, The Analytica Group, Ltd., have been derived from our predecessor's unaudited financial statements that are not included in this prospectus.

	Years ended September 30,			From inception (April 3, 2002) through September 30,	Years ended September 30,		
					Pro forma	Predecessor	
	2005	2004	2003	2002	2002	2001	2000
	(in thousands, except per share data)						
Consolidated Statements of Operations Data:							
Net sales	$ 25,195	$ 25,936	$ 9,908	$ 2,761	$ 5,610	$2,440	$ 6,035
Cost of sales	8,234	8,814	2,936	544	1,607	972	2,290
Gross margin	16,961	17,122	6,972	2,217	4,003	1,468	3,745
Operating expenses:							
Research and development	9,589	4,210	6,112	—	—	—	—
Research and development, related party	1,319	1,309	—	—	—	—	—
Sales and marketing	15,164	12,015	4,366	—	—	—	—
General and administrative	20,657	16,729	8,868	2,027	3,140	1,304	1,560
Royalties	1,717	387	—	—	—	—	—
Impairment charges	358	360	—	—	—	—	—
Stock-based compensation	427	292	—	—	—	—	—
Other operating expense, related party	—	2,500	—	—	—	—	—
Total operating expenses	49,233	37,802	19,346	2,027	3,140	1,304	1,560
Operating income (loss)	(32,272)	(20,680)	(12,374)	190	863	164	2,185
Other income (expense):							
Interest (expense) income, net	(2,286)	(1,241)	(230)	(19)	(12)	16	83
Interest (expense) income, net, related party	(2,120)	(1,485)	(338)	—	—	—	—
Settlement expense	—	—	(1,563)	—	—	—	—
Loss on extinguishment of debt, related party	(2,362)	—	—	—	—	—	—
Other income (expense)	(56)	78	—	—	—	—	—
Net income (loss) from continuing operations before income taxes	(39,096)	(23,328)	(14,505)	171	851	180	2,268
Income tax benefit (expense)	—	—	180	(180)	(436)	—	—
Net income (loss) from continuing operations	(39,096)	(23,328)	(14,325)	(9)	415	180	2,268
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)	—	—
Absorption of prior losses against minority interest	150	—	—	—	—	—	—
Net income (loss)	(39,376)	(23,226)	(16,672)	(9,194)	(8,770)	180	2,268
Preferred stock dividends	(5,552)	(5,262)	—	—	—	—	—
Income (loss) attributable to common stockholders	$(44,928)	$(28,488)	$(16,672)	$ (9,194)	$ (8,770)	$ 180	$ 2,268
Weighted average shares outstanding, basic and diluted (1)	5,147	4,876	4,729	4,876	4,876	1,000	1,000
Per share amounts, basic and diluted (1) :							
Net Income (loss) per common share for:							
Continuing operations and minority interest	$ (8.65)	$ (5.86)	$ (3.01)	$ —	$ 0.08	$ 180	$ 2,268
Discontinued operations	(0.08)	0.02	(0.51)	(1.89)	(1.87)	—	—
Net Income (loss) attributable to common stockholders	$ (8.73)	$ (5.84)	$ (3.52)	$ (1.89)	$ (1.79)	$ 180	$ 2,268

(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, 2005, 2004, 2003, 2002 and 2001.

	September 30,				
	2005	2004[1]	2003[1]	2002	2001
			(in thousands)		
Consolidated Balance Sheet Data:					
Cash and cash equivalents	$ 2,763	$ 1,905	$ 2,937	$ 569	$ 624
Working capital	(29,644)	(31,462)	(23,104)	(88)	1,304
Total assets	35,543	28,133	23,387	6,891	1,824
Total liabilities	55,641	49,093	40,266	2,643	464
Total stockholders' equity (deficit)	(20,099)	(20,960)	(16,880)	(2,851)	1,360
Long-term obligations	11,727	9,976	7,654	—	969

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 biopharmaceutical company focused on the development and commercialization of late-stage clinical products in the therapeutic areas of respiratory disease and oncology. We have two product candidates entering or in Phase III clinical trials. One of these product candidates, SinuNase ™, has been developed at Mayo Clinic as a novel application and formulation of a known therapeutic to treat chronic rhinosinusitis, a long-term inflammatory condition of the paranasal sinuses for which there is currently no FDA approved therapy. We submitted an Investigational New Drug Application, or IND, with the FDA for SinuNase in April 2005, and the IND was accepted by the FDA in May 2005. We expect to initiate Phase III trials for the product in early 2006. 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 III clinical trial. In addition to these product candidates, we have a growing specialty pharmaceutical business through which we currently sell a portfolio of ten pharmaceutical products and we have a pipeline of additional products under development by third parties.

Our goal is to utilize our vertically integrated business structure to cost-effectively and efficiently develop and commercialize innovative therapeutics that address significant unmet medical needs. In addition to our late-stage product candidates and our specialty pharmaceutical business, we have a broad range of in-house capabilities and resources that we market to third parties and use to develop and commercialize our own products. These capabilities include analytical and consulting services relating to the biopharmaceuticals industry, such as pricing and market assessment, reimbursement strategies, clinical trial services, and outcomes research. We also produce custom biologics and cell culture systems for biopharmaceutical and biotechnology companies, medical schools, universities, hospitals, and research institutions.

Corporate History and Structure

We were organized in 2002 to provide a platform 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, 2005, the $15.0 million non-interest-bearing note was fully paid. 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 19% 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 analytical and 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, generated approximately $0.9 million, $1.1 million, and $1.3 million in net sales for the years ended September 30, 2005, 2004 and 2003, respectively. As a result of the expiration of this contract, we no longer house the NCCC. Also at the Minneapolis facility, we generated approximately $3.0 million, $2.3 million, and $4.8 million in net sales for the years ended September 30, 2005, 2004 and 2003, 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 $0.9 million, $1.0 million and $0.8 million for the years ended September 30, 2005, 2004 and 2003, 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. We are considering divesting the remaining business conducted at Minneapolis.

At our Worcester facility we currently produce vaccine 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 $0.2 million, $1.1 million and $1.4 million for the years ended September 30, 2005, 2004 and 2003, 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.

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 a portfolio of ten pharmaceutical products and have a pipeline of additional products under development through our development partners. Our currently marketed specialty pharmaceutical products include Xodol ™, a narcotic pain formulation, Respi~TANN ™, a prescription antitussive decongestant for temporary relief of cough and nasal congestion, our line of six HISTEX ™ products for the cough, cold and allergy prescription market, and two products that we co-promote. In this segment, we generated net sales of $10.7 million, $11.9 million and $3.9 million for the years ending September 30, 2005, 2004 and 2003, respectively. Our specialty pharmaceutical products under development currently include MD Turbo ™, a breath-actuated inhaler device used by patients with asthma and chronic obstructive pulmonary disease, Emezine ™, a transbuccal drug designed to control nausea and vomiting, and nine additional narcotic pain formulations for the treatment of moderate to moderately severe pain.

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 $1.4 million, $2.9 million and $0.6 million in the years ending September 30, 2005, 2004 and 2003, 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 prospectus, 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 applicable products are delivered. 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 sale of pharmaceutical products. 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, 2005, we made an additional adjustment to chargeback and return reserves of approximately 7.5 % and 8.7%, respectively, to appropriately reflect reserves for specific returns, which had the effect of reducing our net sales by $2.4 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. If we made an additional 1% adjustment to increase our accruals for both sales returns and chargebacks/rebates, the effect on net loss in the twelve months ended September 30, 2005 would be an increase of $0.2 million. Had we made the same adjustment to accruals in the fiscal years ended September 30, 2004 and 2003, net loss would have increased by $0.2 million and $0.1 million, respectively.

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 $1.2 million and $1.0 million for the years ended September 30, 2005 and 2004.

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 $0.1 million at September 30, 2005, a reduction of $0.5 million from September 30, 2004. Estimates for obsolete and unsaleable inventory are determined by management and updated quarterly. We had no reserve at 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 $0.9 million at September 30, 2005, a decrease of $0.1 million from September 30, 2004. 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 SFAS 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, 2005 and 2004 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 $2.5 million, $2.0 million, and $1.1 million in the years ended September 30, 2005, 2004 and 2003, 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 have identified several trademarks, product rights and technology rights as intangible assets with indefinite lives. These assets were valued at $1.8 million as of September 30, 2005 and 2004.

Our carrying value of other intangible assets at September 30, 2005 and 2004 was $21.2 million and $16.9 million net of accumulated amortization of $5.6 million and $3.3 million, respectively. We begin amortizing capitalized intangibles on their date of acquisition, as further described in Note 6 to our consolidated financial statements included in this form10K.

Impairment Testing

Our 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, intangible assets are 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 intangible assets with the carrying amount. If the implied fair value of intangible assets is less than the carrying amount, a write-down is recorded. Impairment would result in a write-down of the intangible asset to its estimated fair value based on the discounted future cash flows. The impairment test for the 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, 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. Goodwill is tested for impairment by comparing the carrying amount of the reporting unit to which it was assigned to the estimated fair value of the reporting unit. In accordance with SFAS 142, which relates to impairment of goodwill, impairment exists if the carrying amount of the reporting unit is less than its estimated fair value. Impairment would result in a write-down equal to the difference between the carrying amount and the estimated fair value of the reporting unit. Fair values can be determined using income, market or cost approaches.

We predominately use a discounted cash flow model derived from internal budgets in assessing fair values for our goodwill impairment testing. Factors that could change the result of our goodwill 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 $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. There was no impairment charge in the year ended September 30, 2003.

Purchased In-Process Research and Development

We account for purchased in-process research and development, or IPR&D, in accordance with pronouncements as follows:

- FASB Statement of Financial Accounting Standards No. 2, *Accounting for Research and Development;*
- FASB Interpretation No. 4, *Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method*; and
- FASB Statement of Financial Accounting Standards No. 86, *Accounting for the Costs of Computer Software to be Sold, Leased or Otherwise Marketed.*

Generally, purchased in-process research and development is distinguished from developed technology based upon whether the IPR&D projects are measurable, have substance, and are incomplete. IPR&D represents the portion of a purchase price of an acquisition related to research and development activities that have not demonstrated technological feasibility and do not have alternative future uses. IPR&D projects that have not been granted FDA approval are classified as being incomplete, and as such the associated costs are expensed as incurred. In connection with the acquisition of our Biovest subsidiary in June 2003, we incurred an immediate writedown of $5.0 million for acquired assets which were classified as purchased in-process research and development.

Stock-Based Compensation

We account for stock-based awards to employees and non-employees using the accounting provisions of Statement of Financial Accounting Standards ("SFAS") No. 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. The provisions of the revised statement are effective for financial statements issued for the first interim or annual reporting period beginning after June 15, 2005, with early adoption encouraged. We already account for options issued to employees under SFAS No. 123, so adoption of this revision is not expected to have a significant impact on our current financial position or results of operation.

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, we assumed no dividend yield, risk-free interest rates ranging from 1.62% to 4.65%, expected option terms ranging from 0.5 to 5 years, volatility factors ranging from 0% to 50%, share prices ranging from $0.02 to $5.83, and option exercise prices ranging from $1.05 to $7.62.

We recorded stock-based compensation of $0.4 million in the twelve months ended September 30, 2005, which was related to employee and non-employee stock options. We recorded stock-based compensation of $3.3 million in the year ended September 30, 2004, of which $0.3 million was related to employees, $0.4 million was related to warrants issued in connection with financing, and $2.6 million was related to warrants issued in connection with an assumption and forbearance agreement with McKesson. In the year ended September 30, 2003, we recorded stock-based compensation of $0.8 million in connection with options issued in connection with the employment terminations of two former officers. In all periods, stock-based compensation is classified in various categories in the financial statements including "interest expense" and "stock-based compensation."

Fair value determination of privately-held equity securities

In addition, during the twelve months ended September 30, 2005, we granted stock options and warrants with exercise prices ranging from $2.11 to $8.17. The fair value of the various classes of stock during this six-month period was estimated based on the incremental change from the September 30, 2004 valuation and the valuation as of December 31, 2004. The stock values as of December 31, 2004 ranged from $2.11 to $5.83. We did not change our valuation from December for this purpose. We granted stock options with exercise prices of $1.05 to $7.62 during the year ended September 30, 2004. The fair value of the various classes of stock for the various dates ranged from $1.77 to $3.87.

The values noted above were based on retrospective valuations. We did not obtain contemporaneous valuations at the time of the issuances of stock options due to limited human and monetary resources.

These grant date fair values were determined from either the retrospective valuations (such as in the case of the Series E preferred stock warrants issued with Series E preferred stock purchases) or calculations using the Black-Scholes pricing model with share price assumptions based on the retrospective valuations.

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.

The most significant changes in values from 2003 to 2004 relate to the issuance of the new Series E preferred stock, which has significant anti-dilution provisions and other preferences. While our overall enterprise value increased, the creation of this class of stock and issuance of these shares resulted in a decline in the value of our common stock at September 30, 2004.

Based on our current business plan and subsequent equity activities, further fluctuations in fair values of the various classes of stock can be anticipated. In addition, although it is reasonable to expect that the completion of our proposed initial public offering will add value to the shares because they will have increased liquidity and marketability, the amount of additional value cannot be measured with precision or certainty.

Income Taxes

We incurred net operating losses for the years ended September 30, 2005, 2004 and 2003, 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 $77.3 million as of September 30, 2005, which expires through 2025 and of which $30.0 million is subject to various Section 382 limitations.

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 this 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.

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.

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.

Results of Operations

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 $20.7 million in the year ended September 30, 2005, an increase of $3.9 million, or 23%, 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.

Stock-based Compensation. In the year ended September 30, 2005, we had stock-based compensation of $0.4 million, an increase of $0.1 million, or 33%, over the year ended September 30, 2004. This increase was primarily attributable to the changes in the value of the underlying stock at each valuation period.

Interest Expense, net. In the twelve month periods ended September 30, 2005, our net interest expense was $4.4 million, an increase of $1.7 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.

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

	Twelve months ended September 30,			
	2005		2004	
	Amount	% of Segment Net Sales	Amount	% of Segment Net Sales
Net Sales:				
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	$ 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	$ 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	$ 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	$ 1,858,789	13%	$ 1,479,461	11%
Specialty Pharmaceuticals	13,305,278	124%	10,535,583	92%
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, 2005. 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.

Year Ended September 30, 2004 Compared to the Year Ended September 30, 2003

Consolidated Results of Operations

We made one acquisition in our Biopharmaceutical Products and Services segment (*i.e.,* Biovest), and one acquisition in our Specialty Pharmaceuticals segment (*i.e.,* TEAMM) during the year ended September 30, 2003. During the year ended September 30, 2004, we acquired an additional business in the Biopharmaceutical Products and Services segment (*i.e.,* IMOR, our European subsidiary) and sold one business in the Specialty Pharmaceuticals segment (*i.e.,* AccentRx). Accordingly, the comparison of results from one year to the next considers the short period results from the dates of acquisition through the end of the fiscal period ended September 30, 2003. For the year ended September 30, 2004, a full year of results is included for all acquisitions. The results of operations for AccentRx, which we sold in December 2003, are included in discontinued operations for all periods presented.

Net sales. Our net sales for the year ended September 30, 2004 were $25.9 million compared to $9.9 million in the prior year, an increase of $16.0 million, or 162%. The increase in net sales is primarily attributable to three factors. First, we had a full year of Biovest revenues ($5.5 million) compared to only three months from the date of acquisition ($2.3 million) in the prior year. Second, we had a full year of net sales ($11.9 million) in our Specialty Pharmaceuticals segment in the year ended September 30, 2004, compared to $3.9 million in the prior year, which only included six months from the date of our acquisition of TEAMM. Lastly, the acquisition of IMOR, our European subsidiary, contributed $3.4 million in revenues in the year ended September 30, 2004, compared to no net sales in the prior year.

Cost of Sales. Our cost of sales in the year ended September 30, 2004 was $8.8 million, representing 34% of net sales, compared to $2.9 million, representing 30% of net sales, in the prior year. The increase in cost of sales was primarily attributable to a corresponding increase in net sales, primarily in our Specialty Pharmaceuticals segment. The increase in cost of sales as a percentage of net sales was due to increased discounts and rebates in our Specialty Pharmaceuticals segment as we accessed additional distribution channels to grow our sales. In addition, we experienced a higher cost of sales as a percentage of revenues in our Biovest subsidiary due to a shift in our product mix toward lower margin products.

Research and Development Expenses. Research and development expense was $5.5 million in the year ended September 30, 2004, compared to $6.1 million in the year ended September 30, 2003, a decrease of $0.6 million, or 10%. Absent the one-time charge for purchased IPR&D of $5.0 million in 2003, research and development expenses increased by $4.4 million. This $4.4 million increase was primarily attributable to increased research and development activities related to our clinical trials for BiovaxID in 2004.

Sales and Marketing Expenses. Sales and marketing expenses increased to $12.0 million in 2004 from $4.4 million in 2003, an increase of $7.6 million, or 173%. This increase was attributable to six months of activity in our Specialty Pharmaceuticals

segment in 2003 as compared to a full year in 2004 and an increase in the sales staff for our Specialty Pharmaceuticals segment in 2004.

General and Administrative Expenses. General and administrative expenses increased to $16.7 million in the year ended September 30, 2004 from $8.9 million in the year ended September 30, 2003, an increase of $7.8 million, or 88%. This increase was largely attributable to an increase in our total headcount, including sales staff increases, in our Specialty Pharmaceuticals segment to 244 at September 30, 2004 from 167 at the prior year end. The balance of the increase is attributable primarily to the timing of our acquisitions, which for the year ending September 30, 2003 did not include a full year of financial results.

Stock-based Compensation. Stock-based compensation is included in four line items in the statements of operations: stock-based compensation, gain on sale of discontinued operations, settlement expense and interest expense. The expense for 2004 consisted of $0.3 million for options issued to employees. In addition, $2.6 million, which is included within discontinued operations, was attributable to warrants issued to McKesson as part of a December 2003 assumption and forbearance agreement. An aggregate of $0.4 million is related to amortization of discounts on notes payable, which resulted from issuance of warrants in connection with financing arrangements and is reported in interest expense. Stock-based compensation in 2003 consisted solely of settlement expenses and is reported in that line item.

Interest Expense, net. Interest expense was $2.7 million in the year ended September 30, 2004 compared to $0.6 million in the year ended September 30, 2003, an increase of $2.1 million, or 350%. The increase was due to costs associated with $7.7 million of assumed debt acquired in our Biovest subsidiary purchased in June 2003, $0.4 million in amortization of discounts resulting from the issuance of stock warrants to related parties, interest on McKesson obligations of $0.7 million, and $0.7 million resulting from interest relating to mezzanine financing incurred in August 2003. However, in the year ended September 30, 2004 we used the proceeds from the sale of the assets of AccentRx to pay down long-term debt. Interest income was nominal during each of the years ended September 30, 2004 and 2003.

Settlement Expense. In the year ended September 30, 2004, we did not incur any settlement expenses. In the year ended September 30, 2003 we incurred costs of $1.6 million relating to the employment termination of two former officers. The settlement costs included legal fees, the cost of stock options granted in connection with the termination of $0.8 million, with the balance consisting of cash severance payments paid out over 16 months.

Impairment Charges. We record impairment charges when we determine that the carrying costs of intangible assets are higher at year-end than the valuation as determined in our annual review of intangible assets. In the year ended September 30, 2004, we recorded an impairment of goodwill of $0.4 million related to the acquisition of IMOR. There were no charges for impairment of goodwill or intangibles in the prior year.

Discontinued operations. We sold the assets of AccentRx in December 2003. This business was previously included in our Specialty Pharmaceuticals segment. The transaction included a cash payment of $4.2 million for various intangible assets, but did not include any fixed assets, accounts receivable, or accounts payable, nor did the buyer assume any debt. We used the net proceeds of this sale to reduce our indebtedness to McKesson Corporation. The financial statements for the year ended September 30, 2004 reflect the gain on the sale, net of income tax expense, of $1.6 million. Costs associated with this sale include the cost of warrants issued to McKesson in an assumption and forbearance agreement ($2.6 million) required in order to effect the sale. In the year ended September 30, 2004, net sales of $3.7 million from AccentRx for the period October 1, 2003 through December 9, 2003 (the date of the sale) have been netted against expenses through that period and additional costs of winding down the business through approximately May 2004. Wind-down costs related to the discontinued operations were primarily personnel and administrative costs associated with collection of accounts receivable, payables management, and information systems, and these costs are reflected in the loss from discontinued operations of $1.5 million, net of tax benefit. In the year ended September 30, 2003, net sales of approximately $20.9 million have been netted against all costs of operation of AccentRx and are included in loss from discontinued operations of $2.3 million.

Segment Operating Results

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 for the year ended September 30, 2004, representing the sale of services from the Biopharmaceutical Products and Services segment to the Specialty Pharmaceuticals segment, have been eliminated from segment sales. There were no inter-segment sales in the year ended September 30, 2003.

	Year ended September 30,			
	2004		2003	
	Amount	% of Segment Net Sales	Amount	% of Segment Net Sales
Net Sales:				
Biopharmaceutical Products and Services	$ 13,996,531		$ 5,999,136	
Specialty Pharmaceuticals	8,164,568		2,858,286	
Related party, Specialty Pharmaceuticals	3,774,521		1,050,369	
Total Net Sales	$ 25,935,620		$ 9,907,791	
Cost of Sales:				
Biopharmaceutical Products and Services	$ 6,474,220	46%	$ 2,343,193	39%
Specialty Pharmaceuticals	2,339,370	20%	592,818	15%
Total Cost of Sales	$ 8,813,590		$ 2,936,011	
Gross Margin:				
Biopharmaceutical Products and Services	$ 7,522,311	54%	$ 3,655,943	61%
Specialty Pharmaceuticals	9,599,719	80%	3,315,837	85%
Total Segment Gross Margin	$ 17,122,030		$ 6,971,780	
Research and Development Expenses:				
Biopharmaceutical Products and Services	$ 4,210,058	30%	$ 6,111,952	102%
Related party, Biopharmaceutical Products and Services	1,309,100	9%	—	0%
Specialty Pharmaceuticals	—	0%	—	0%
Total Research and Development Expenses	$ 5,519,158		$ 6,111,952	
Sales and Marketing Expenses:				
Biopharmaceutical Products and Services	$ 1,479,461	11%	$ 236,306	4%
Specialty Pharmaceuticals	10,535,583	88%	4,129,922	106%
Total Sales and Marketing Expenses	$ 12,015,044		$ 4,366,228	

Biopharmaceutical Products and Services

Net sales. Net sales in our Biopharmaceutical Products and Services segment were $14.0 million in the year ended September 30, 2004, compared to $6.0 million in the prior year, an increase of $8.0 million, or 133% over total net sales of $6.0 million in this segment in the prior year. An increase of $3.4 million in 2004 was attributable to the full year of operations in our European subsidiary. In addition, an increase of a $3.2 million in 2004 was attributable to the full year of operations in our Biovest subsidiary. The balance of the increase in 2004 was attributable to increased sales from analytical and consulting services.

Cost of Sales. Cost of sales in our Biopharmaceutical Products and Services segment for the year ended September 30, 2004 was $6.5 million, representing 46% of segment net sales, compared to $2.3 million, representing 39% of segment net sales, in the prior year. The $4.2 million increase in cost of sales, and corresponding 7% reduction in cost of sales as a percentage of net sales, was primarily attributable to a shift of our product mix toward lower margin products.

Research and Development. Research and development expenses in our Biopharmaceutical Products and Services segment for the year ended September 30, 2004 decreased to $5.5 million from $6.1 million in 2003, representing an 11% decrease. Absent the one-time charge for purchased IPR&D of $5.0 million in 2003, research and development expenses rose $4.4 million. This $4.4 million increase was attributable to a full year of operations in 2004 compared to three months in 2003, coupled with increased research and development activities for BiovaxID in 2004.

Sales and Marketing Expenses. Sales and marketing expense in our Biopharmaceutical Products and Services segment increased to $1.5 million in the year ended September 30, 2004 from $0.2 million in the year ended September 30, 2003. The increase of $1.3 million resulted from $0.5 million increased costs associated with market development activities for SinuNase and approximately $0.8 million year over year for the sales and marketing costs in Biovest. In addition, the timing of acquisitions included partial year costs in the year ended September 30, 2003.

Specialty Pharmaceuticals

Net sales. Net sales in our Specialty Pharmaceuticals segment were $11.9 million in the year ended September 30, 2004, compared to $3.9 million in the prior year, an increase of $8.0 million, or 205%. The increase of $8.0 million was attributable to a full year of operations, compared to six months of operations in 2003, as well as new product launches in 2004.

Cost of Sales. Cost of sales in our Specialty Pharmaceuticals segment for the year ended September 30, 2004 was $2.3 million, representing 20% of segment net sales, compared to $0.6 million, representing 15% of segment net sales, in the prior year. The $1.7 million increase in cost of sales and corresponding 5% reduction in cost of sales as a percentage of net sales were primarily attributable to increased discounts and rebates as we accessed additional distribution channels to grow our sales.

Research and Development. There were no research and development expenses in our Specialty Pharmaceuticals segment in the years ended September 30, 2004 and 2003.

Sales and Marketing Expenses. Sales and marketing expenses in our Specialty Pharmaceuticals segment increased to $10.5 million in the year ended September 30, 2004, compared to $4.1 million in the year ended September 30, 2003, an increase of $6.4 million, or 156%. The increase was attributed to expansion of our sales force and sales-related administrative headcount to 114 from 72 in the prior year and costs associated with new products being brought into the market in connection with license and co-promote commercialization agreements. In addition, the timing of acquisitions included partial year costs in the year ended September 30, 2003.

Discontinued operations. We sold the assets of AccentRx in December 2003. This business was previously included in our Specialty Pharmaceuticals segment. The transaction included a cash payment of $4.2 million for various intangible assets but did not include any fixed assets, accounts receivable, or accounts payable, nor did the buyer assume any debt. We used the net proceeds of this sale to reduce our indebtedness to McKesson Corporation. The financial statements for the year ended September 30, 2003, reflect the loss from operations of the business sold, net of zero tax benefit. Wind-down costs related to the discontinued operations were primarily personnel and administrative costs associated with collection of accounts receivable, payables management, and information systems, and are reflected in the loss from discontinued operations of $1.5 million in the year of the sale. In the year ended September 30, 2003, net sales of approximately $20.9 million have been netted against all costs of operation of AccentRx, and are included in loss from discontinued operations of $2.3 million. In the year ended September 30, 2002, we had net sales in the business of $17.1 million. The loss from operations of $4.5 million and the impairment loss of $4.7 million were also reflected in this year.

Liquidity and Capital Resources

Sources of Liquidity

Since our inception, we have funded our operations primarily through 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, 2005, we had cash and cash equivalents of $2.8 million compared with cash and cash equivalents of $1.9 million at September 30, 2004. On November 2, 2005, we closed our Initial Public Offering ("IPO"), with gross and net proceeds of $19.2 million and $14.1 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 II, will be sufficient to fund our operations and development activities into the third quarter of fiscal year 2006. 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. Pending completion of an anticipated Biovest financing transaction, we plan to continue to fund Biovest's operations through intercompany demand loans to the extent that advanced amounts exceed our funding commitment to Biovest under our investment agreement with Biovest. As of December 20, 2005, an aggregate of $5.5 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.

Private Placements of Capital Stock

We have received funding from private placements of our common and preferred stock and from the exercise of warrants to purchase capital stock. The table below summarizes our private placement stock issuance and warrant exercises for cash since inception:

Security	Number of Shares	Gross Proceeds
Series A preferred stock	2,794,508	$ 5,883,000
Series C preferred stock	3,562,607	7,500,000
Series E preferred stock	6,758,661	14,228,333
Common stock warrants	285,009	600,000
Series A warrant exercises	102,603	216,000
Series E warrant exercise	9,826,461	20,686,667
Total		$49,114,000

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. The warrant agreement provides that if our initial public offering had not occurred within 270 days of the date on which the credit facility was amended, then the warrant would represent the right to purchase 979,312 shares of our common stock until such time as our initial public offering occurs. The warrant has an initial exercise price of $8.169 per share, provided that from and after our initial public offering, the warrant will have an exercise price equal to our per share initial public offering price. 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 may not be exercised by Laurus until 180 days after the registration statement required to be filed by us with respect to the amended and restated secured convertible term note issued to Laurus (as described below) is declared effective or, if earlier, when the amended and restated secured convertible term note is converted or paid in full. The warrant will expire on the 5 th 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 the tangible and intangible assets of Accentia Biopharmaceuticals, Inc. and our Analytica subsidiary (including the stock of their respective subsidiaries). This security interest does not extend to any assets of our TEAMM, 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 Master Fund, LTD. ("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.

Loans from McKesson Corporation. We are also a party to secured loans with McKesson Corporation, which were assumed under a Loan Assumption Agreement with McKesson as part of our acquisition in October 2002 of the assets of APP. The debt is personally guaranteed by Dr. O'Donnell, our Chairman and Chief Executive Officer, and Dr. Ryll, our director and a limited partner in MOAB Investments, LP, a holder of our equity securities. The loans bear interest at 10.0% per annum. The loans had been in default as a consequence of covenant violations and non-payment of principal and interest at the time of acquisition. As a result of the defaults, we recorded default interest charges of $0.8 million and $0.7 million at September 30, 2005 and September 30, 2004, respectively. The outstanding balance, including principal and interest, at September 30, 2005 and September 30, 2004 was $6.1 million and $7.4 million, respectively. In February 2005, we paid the principal balance of the loans down to $6.1 million and brought all interest current. As part of the February 2005 pay-down of the debt, the loan assumption agreement was amended to provide for forbearance on principal payments through the earlier of June 30, 2005 or four days after

the completion of our initial public offering, and we subsequently received further extensions of this forbearance through September 14, 2005 in consideration of payments in the amount of $0.3 million to McKesson. On September 13, 2005, we received another extension of the forbearance through September 29, 2005 in consideration of making a $0.1 million principal payment under the loans. In November 2005, we paid $5.3 million of the principal balance of the note and extended the maturity date of the remaining $0.8 million due until July 2006.

Also as a part of the February 2005 amendment, McKesson agreed to waive its right to exercise a warrant to purchase up to 1,425,043 shares of our Series E preferred stock previously granted to McKesson.

Our loans from McKesson are secured by all of the assets of Accentia Biopharmaceuticals, Inc., including its stock in each of its subsidiaries, as well as certain publicly traded securities owned by two irrevocable trusts established by Dr. O'Donnell. In addition, prior to February 2005, the loans were secured by shares of our stock held by The Hopkins Capital Group, LLC, our shareholder and an entity in which Dr. O'Donnell is the manager, and MOAB Investments, LP. In connection with the February 2005 amendment to the McKesson credit facility, McKesson's security interest in the Accentia stock was released, although the guarantees and security interest in the publicly traded securities owned by the two trusts established by Dr. O'Donnell will remain in effect until the McKesson credit facility is paid in full and all of our obligations under our Biologics Distribution Agreement with McKesson (as described below) have been satisfied.

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. As of September 2005, a total of $4.2 million had been borrowed under this bridge loan. 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.

Other Loans and Indebtedness. In September 2004, we borrowed $0.3 million from First Commercial Bank of Tampa, which was secured by cash owned by MOAB Investments, L.P., one of our stockholders and an entity in which Dr. Ryll, one of our directors, is a limited partner. This loan was paid in full in December 2004.

As of September 30, 2005, we had a $7.0 million note payable by our TEAMM subsidiary to Harbinger Mezzanine Partners, LP, secured by receivables, equipment, inventories and intangible assets of our TEAMM subsidiary. This loan was in place at the time of our acquisition of TEAMM. We were in default of loan covenants under this loan at September 30, 2004. In March 2005, we amended the loan agreement to provide for a guarantee from Accentia Biopharmaceuticals, Inc., forbearance on covenants through September 30, 2005, and a release of the first lien against the assets of TEAMM in order to provide a first lien to Missouri State Bank, an interim provider of our revolving credit facility that was terminated prior to September 30, 2005. Concurrent with the March 2005 amendment, we also repurchased for $2.0 million from Harbinger a previously granted warrant representing the right to purchase up to 1,785,742 shares of our Series D preferred stock at an exercise price of $0.007 per share. This repurchase was effected through the cancellation of the warrant and an increase in the note balance from $5.0 to $7.0 million. Further, Harbinger agreed that it has no other right or entitlement, including but not limited to any warrant, option, conversion right, preemptive right, or other agreement to purchase any shares of our capital stock or TEAMM's capital stock

(including but not limited to shares of Series D Preferred stock and shares of common stock). In September 2005, Harbinger extended its forbearance on covenants through December 31, 2005. As of September 30, 2005 and September 30, 2004, the Harbinger note was recorded at $6.6 million and $4.2 million, respectively, reflecting a discount on long-term debt as a result of warrants issued in connection with the loan, the value of which is accreted over the term of the note. $2.0 million of the principal amount was paid in November 2005.

As of September 30, 2005, our Biovest subsidiary had convertible notes payable totaling $4.8 million in principal amount, bearing interest payable at maturity ranging from 7% to 10%. These notes were payable to former Biovest management and shareholders. As of September 30, 2005 we had accrued interest of $1.0 million under these notes, $0.7 million is shown in current maturities on long-term debt with the balance in long-term debt, less current maturities. Four notes of $0.1 million each, originally due in November 2004, September 2004, and September 2003, were renegotiated and are being paid in monthly installments. These notes consisted of bridge financing and working capital loans that were in place at the time of our acquisition of our interest in Biovest. The holders of these notes have the right to convert the principal and interest thereunder into shares of Biovest common stock, and these notes can be converted into shares of our common stock at a price equal to the then-current fair market value of our common stock (or in the case of $1.6 million in principal amount of such notes, at a price equal to 80% of such fair market value), provided that if our common stock is publicly traded at the time of conversion, then fair market value shall be deemed to be the initial public offering price of our common stock. In September 2005, Biovest and the holders of a total of $4.1 million in aggregate principal amount of these notes entered into an agreement providing that, unless the notes are earlier converted into our common stock, the notes would automatically convert into Biovest common stock on the earlier of December 1, 2005 or 30 days following the completion of this offering at conversion prices ranging from $0.40 to $1.00 per share. With the exception of four notes totaling $0.6 million all the convertible debentures issued by Biovest were converted into $3.7 million of Accentia common stock at prices ranging from $6.40 to $8 per share and $1.3 million of Biovest stock at prices ranging from $.40 to $1.00 per share. In connection with these transactions, Biovest issued an inter-company demand note to Accentia for approximately $3.7 million.

In addition to the note issued in connection with the conversion, Accentia advanced approximately $1.8 million since October 1, 2005, which is expected to be repaid in fiscal 2006, subject to successful completion of the financing transactions being pursued by Biovest. Accentia expects repayment from Biovest on the conversion note and its current year advances in fiscal 2006, as Biovest is seeking its own debt and equity financing, as separately described below. The liquidity effect of these conversions on our consolidated balance sheet was to reduce our consolidated long-term debt and increase shareholders' equity.

At September 30, 2004, we owed approximately $0.1 million in connection with the settlement of the termination of employment of two former officers. This was paid in full in January 2005.

Other Financing Transactions

In February 2004, we entered into a Biologics Distribution Agreement with McKesson Corporation that gives McKesson exclusive distribution rights for all of our biologic products (including Biovest biologic products) in the U.S., Mexico, and Canada. These distribution rights were granted to McKesson in exchange for a $3.0 million refundable deposit paid by McKesson to us. The agreement can be terminated by McKesson upon 180 days' prior written notice, upon mutual written agreement, or upon our repurchase of McKesson's distribution rights prior to FDA approval of our first biologic product. In order to repurchase the distribution rights, we must pay McKesson a cash payment equal to the greater of two times the amount of the $3.0 million refundable deposit, or $6.0 million, or 3% of the value of the shareholder's equity at the time of termination. If the agreement is otherwise terminated, then we will be required to return the $3.0 million deposit to McKesson.

In September 2004, we sold an interest in our future royalties from SinuNase to PPD for a $2.5 million cash payment. Under this agreement, we are obligated to pay PPD cumulative minimum payments equal to at least $2.5 million by the end of calendar year 2009. In the event PPD terminates the agreement for breach, including for our failure to make the minimum payments, PPD has the right to require us to repurchase the royalty interest for a purchase price equal to $2.5 million, less all royalty payments made by us to PPD. For accounting purposes, this has been accounted for as a deposit on our balance sheet at September 30, 2005 and September 30, 2004, and will be amortized into revenues as corresponding royalties are earned by PPD, at which time our corresponding deposit will be reduced. In August 2005, this agreement was amended to increase PPD's share of future royalties from SinuNase in exchange for PPD agreeing to provide certain services relating to SinuNase clinical trials and regulatory approval.

Cash Resources

At September 30, 2005, we had cash and cash equivalents of $2.8 million compared with cash and cash equivalents of $1.9 million at September 30, 2004.

On November 2, 2005, we closed our IPO, with gross and net proceeds of $19.2 million and $14.1 million, respectively.

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 $5.9 million.

Biovest Investment Agreement

Our investment agreement with Biovest provides that, within 12 months of the date of our June 2003 investment in Biovest, Biovest was required to file all necessary documents and take all necessary actions to permit the public trading of all outstanding shares of Biovest common stock that are not subject to restriction on sale or transfer under the applicable securities laws. Since August 2005, Biovest's common stock has been quoted on the OTC Bulletin Board under the symbol BVTI.OB. Although Biovest common stock was not quoted on the OTC Bulletin Board prior to August 2005, Biovest believes that, by filing all reports required to be filed by it under the Securities Exchange Act of 1934 at all times since the date of the investment agreement, it timely filed all required documents and reports and timely took all action within its control necessary to permit such stock to trade publicly during the 12-month period following our investment in Biovest. Under the Biovest investment agreement, should it be determined that Biovest should have filed additional documents or taken additional action to permit the trading of its shares within the required time period, the agreement provides that Biovest, upon 90 days' written notice with a right to cure, would be obligated to make an offer to purchase the following number of shares of its outstanding stock (other than stock held by us) as of the following dates, provided that Biovest common stock had not started trading by then: 980,000 shares at the first anniversary of the date of our investment in Biovest, 1,960,000 shares at the second anniversary, 2,940,000 shares at the third anniversary of the investment, and 3,920,000 shares at the fourth anniversary, with each such repurchase being at a price of $2.00 per share. Prior to the commencement of the quotation of Biovest's common stock on the OTC Bulletin Board, an attorney representing a group of approximately thirteen Biovest shareholders orally communicated to us that such shareholders believe that they have a claim against Biovest and/or our company as a result of the fact that Biovest common stock had not yet started trading publicly and no repurchase offer had yet been made under the investment agreement. See "BUSINESS—Legal Proceedings."

Cash Flows for the Year Ended September 30, 2005

For the year ended September 30, 2005, we used $33.0 million in cash to fund our operating activities. This consisted primarily of a net loss of $39.4 million, reduced by non-cash charges of approximately $0.7 million of depreciation, $2.5 million in amortization of intangibles, and $0.4 million of stock-based compensation. We also had non-cash charges of $2.4 million in loss on the extinguishment of debt as a result of the conversion of debt to equity. We also had $0.4 million in impairment charges due to the termination of the SRL agreement.

We used net cash in investing activities of $5.1 million in the year ended September 30, 2005, primarily consisting of payments for product rights of $4.6 million, improvements to our Worcester laboratory facility of $0.2 million, and computer equipment and office improvements of $0.3 million.

We had net cash flows from financing activities of $38.9 million in the year ended September 30, 2005, consisting of $26.3 million in proceeds from the issuance of preferred stock and common stock, $10.0 million in proceeds from convertible debentures, net funding from lines of credit of $1.7 million, $4.2 million, from the proceeds of related party debt, and proceeds from minority interest of $0.1 million. We reduced our debt by $2.3 million, paid $0.3 million in dividends, and paid deferred offering costs of $0.8 million.

Our net working capital deficit at September 30, 2005 decreased from September 30, 2004 by $1.8 million to $29.6 million, which was attributed largely to fiscal 2005 losses which were funded through debt and equity proceeds and refinancing of certain short-term debt to long-term.

The amount of our net working capital, which had a deficit of $34.9 million at September 30, 2005, will continue to be affected by our accounts receivable, and we expect that our accounts receivable will grow in connection with an anticipated growth in revenues from sales of products in our Specialty Pharmaceuticals segment. At September 30, 2005, our net accounts receivable was $4.4 million, an increase of $2.0 million from September 30, 2004.

We expect to pay, and have budgeted for payment, periodic and contractually-committed milestone payments that are quantified based on product development activities of our development partners and are not always predictable. We expect that these payments will be made from cash flow generated from our anticipated receivables growth, as well as through the proceeds from this offering. Although we expect that our net cash flows from operating activities will continue to be negative until (and if) we are able to commence sales of SinuNase and BiovaxID, we expect that increasing sales from products in our Specialty Pharmaceuticals segment will offset research and development expenses associated with SinuNase and BiovaxID.

Cash Flows for the Year Ended September 30, 2004

For the year ended September 30, 2004, we used $18.5 million in cash to fund our operating activities. This consisted primarily of a net loss from operations for the period of $23.2 million, reduced by non-cash charges approximately $0.6 million in depreciation, $2.0 million in amortization of intangibles, $2.6 million for stock- based cost related to our sale of the mail-order specialty pharmacy, and $0.7 million in stock-based compensation. We also had $0.4 million in impairment charges (recognized upon acquisition of IMOR) and other non-cash charges and incurred $0.7 million in default interest on loans. Our net working capital deficit was increased by $8.3 million from the prior year, primarily as a result of obligations associated with our product development agreements, borrowings from the secured line of credit with Missouri State Bank, and the obligation under the Biologics Distribution Agreement with McKesson. We used $3.0 million in investing activities, consisting primarily of $2.9 million acquisition of intangible assets, $0.6 million in the acquisition of IMOR, and $0.8 million purchase of laboratory equipment and leasehold improvements. We also had restricted cash of $1.3 million released in accordance with the terms of an escrow agreement for a product line acquired in the previous year. We received net cash from financing activities of $21.8 million, primarily consisting of proceeds from the issuance of $15.8 million in preferred stock, $6.2 million in line of credit and stockholder loan proceeds, and $5.5 million in proceeds from deposits and the sale of royalty rights. We reduced debt by $6.1 million and paid $0.1 million in dividends.

Our business has changed significantly since its inception, primarily as a result of our acquisition and the sale of the assets of AccentRx. Our accounts receivable balance in AccentRx (which was sold in December 2003) was $1.4 million at September 30, 2003 and was substantially collected during the ensuing year with the exception of a nominal balance for which there was a reserve. Our Biovest subsidiary had receivables of $1.0 million at September 30, 2003, and only $0.1 million a year later, reflecting the increasing focus on our BiovaxID project and away from the historical cell culture products business of Biovest. At the same time, receivables in our Specialty Pharmaceuticals segment reflected an increase to $1.3 million, from a year earlier balance of $0.7 million. Our Analytica subsidiary, with its acquisition of IMOR effective in October 2003, had accounts receivable at September 30, 2004 of $1.8 million, compared to $0.9 million the year before.

Our accrued expenses at September 30, 2004 decreased by approximately $3.5 million compared to September 30, 2003. The decrease was due primarily to a reduction of accrued expenses for our Specialty Pharmaceuticals segment relating to $4.3 million due to McKesson for returned product. This amount was converted to Series E preferred stock during fiscal 2004. In addition, the provision for returned goods for the Histex product line decreased from $1.7 million at September 30, 2003 to $0.1 million at September 30, 2004 as Histex product was returned during fiscal 2004. Those decreases were partially offset by increases in accruals for compensation, rebates, chargebacks, and royalties.

Accounts payable changed primarily as a result of increased sales in the year ended September 30, 2004 over the prior year. Accounts payable decreased $1.3 million primarily due to the reduction in accounts payable for our discontinued operations of $4.8 million. This reduction was offset by an increase of $1.7 million for vaccine development related payables in Biopharmaceutical Products and Services and $1.8 million in Specialty Pharmaceuticals primarily relating to manufactured product and marketing expenses, including sample expenses.

If sales in our Specialty Pharmaceuticals segment increase based on the timeline of existing products under development, we expect that accounts receivable and related accounts payable will increase as we bring products to market. If we experience growth in our accounts receivable, we anticipate that asset-based financing arrangements may be used to fund associated cash flow requirements.

Cash Flows for the Year Ended September 30, 2003

For the year ended September 30, 2003, we used $5.7 million in operating activities. This consisted of a net loss from operations for the year of $16.7 million, reduced by $0.3 million of depreciation, $1.1 million in amortization of intangibles and accretion of discount on long-term debt, and $0.8 million in stock-based compensation. In addition, we expensed $5.0 million of IPR&D costs acquired in our Biovest acquisition and incurred $0.6 million in default interest on loans. We received net cash flow from investing activities in the year ended September 30, 2003 of $2.5 million, which consisted of cash received as part of our acquisition of TEAMM of $2.5 million and restricted cash of $0.7 million which was released as part of an escrow agreement related to a product acquisition. This was offset by approximately $0.7 million in intangible assets as part of our acquisition, as well as fixed assets acquired. We had net cash flows from financing activities in the year ended September 30, 2003 of $4.3 million. This consisted of net proceeds from stockholder notes and long-term debt of $3.1 million and issuance of preferred stock for cash received of $1.3 million.

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 segment, including regulatory approvals of SinuNase and BiovaxID, as well as the

commercial launches of various products in our Specialty Pharmaceuticals segment pipeline. 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 pipeline products into 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, 2005. The long- and short-term debt, fixed milestone obligations and license fees are reflected as liabilities on our balance sheet as of September 30, 2005. Operating leases are accrued and paid on a monthly basis.

The amounts listed for product distribution and license agreements represent our fixed obligations payable to distribution partners for licensed products. The amounts listed for minimum royalty payments do not include those royalties on net sales of our products that may be in excess or not subject to minimum royalty obligations.

The amount listed under "technology purchase agreement" represents those payments due SRL Technologies for the purchase of a sustained release technology.

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] [b]	$ 18,749	$ 11,034	$ —	$ —	$ 29,783
Technology purchase agreement	—	—	—	—	—
Product distribution agreements	83	—	—	—	83
License agreements	—	—	—	—	—
Minimum royalty payments	900	800	—	—	1,700
Product manufacturing and supply agreements	269	423	—	—	692
Cooperative research and development agreement	580	290	—	—	870
Employment agreements	2,345	4,439	2,354	—	9,138
Operating lease obligations	3,723	2,140	607	—	6,470
	$ 26,649	$ 19,126	$ 2,961	$ —	$ 48,736

(a) Includes interest on long-term debt.
(b) Excludes $5.0 million in debt subsequently converted to equity.

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 $2.0 million and $4.6 million in fiscal years 2005 and 2006, 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 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 $1.8 million in additional funds subsequent to that date.

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

Related-Party Transactions

For a description of our related-party transactions, see "RELATIONSHIPS AND RELATED TRANSACTIONS."

Recent Accounting Pronouncements

In November 2004, the FASB issued SFAS No. 151, "Inventory Costs." The statement amends Accounting Research Bulletin ("ARB") No. 43, "Inventory Pricing," to clarify the accounting for abnormal amounts of idle facility expense, freight, handling costs, and wasted material. ARB No. 43 previously stated that these costs must be "so abnormal as to require treatment as current-period charges." SFAS No. 151 requires that those items be recognized as current-period charges regardless of whether they meet the criterion of "so abnormal." In addition, this statement requires that allocation of fixed production overhead to the costs of conversion be based on the normal capacity of the production facilities. The statement is effective for inventory costs incurred during fiscal years beginning after June 15, 2005, with earlier application permitted for fiscal years beginning after the issue date of the statement. The adoption of SFAS No. 151 is not expected to have any significant impact on our financial position or results of operations.

In December 2004, the FASB issued SFAS No. 153, "Exchanges of Nonmonetary Assets—An Amendment of APB Opinion No. 29." APB Opinion No. 29, "Accounting for Nonmonetary Transactions," is based on the opinion that exchanges of

nonmonetary assets should be measured based on the fair value of the assets exchanged. SFAS No. 153 amends Opinion No. 29 to eliminate the exception for nonmonetary exchanges of similar productive assets and replaces it with a general exception for exchanges of nonmonetary assets whose results are not expected to significantly change the future cash flows of the entity. The adoption of SFAS No. 153 is not expected to have any impact on our financial position or results of operations.

In December 2004, the FASB revised its SFAS No. 123 ("SFAS No. 123R"), "Accounting for Stock Based Compensation." 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 to be recognized over the period during which the employee is required to provide service in exchange for the award. The provisions of the revised statement are effective for financial statements issued for the first interim or annual reporting period beginning after June 15, 2005, with early adoption encouraged. We account for options issued to employees under SFAS No. 123 so adoption of this revision is not expected to have a significant impact on our financial position or results of operations.

This statement applies to all awards granted after the required effective date and to awards modified, repurchased, or cancelled after that date. The cumulative effect of initially applying this statement, if any, is recognized as of the required effective date. As of the required effective date, all public entities and those nonpublic entities that used the fair-value-based method for either recognition or disclosure under Statement 123 will apply this statement using a modified version of prospective application. Under that transition method, compensation cost is recognized on or after the required effective date for the portion of outstanding awards for which the requisite service has not yet been rendered, based on the grant-date fair value of those awards calculated under Statement 123 for either recognition or pro forma disclosures.

In March 2005, the FASB issued Interpretation No. 47, "Accounting for Conditional Asset Retirement Obligations, an interpretation of FASB Statement No. 143" ("FIN 47"), which requires an entity to recognize a liability for the fair value of a conditional asset retirement obligation when incurred if the liability's fair value can be reasonably estimated. FIN 47 is effective for fiscal years ending after December 15, 2005. The Company is currently evaluating the effect that the adoption of FIN 47 will have on its consolidated results of operations and financial condition but does not expect it to have a material impact.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections" ("SFAS 154"), which replaces Accounting Principles Board Opinion No. 20 "Accounting Changes" and SFAS No. 3, "Reporting Accounting Changes in Interim Financial Statements—An Amendment of APB Opinion No. 28." SFAS 154 provides guidance on accounting for and reporting of accounting changes and error corrections. It establishes retrospective application, or the latest practicable date, as the required method for reporting a change in accounting principle and the reporting of a correction of an error. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005, and is required to be adopted by the Company in the first quarter of fiscal 2006. The Company is currently evaluating the effect that the adoption of SFAS 154 will have on its consolidated results of operations and financial condition, but does not expect it to have a material impact.

Qualitative and Quantitative Disclosures 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 cash and cash-equivalent assets 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 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 beginning on F-1 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 caption Directors and Executive Officers 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 the Company's 2006 Annual Meeting of Shareholders (the "Proxy Statement").

We have adopted a Code of Business Conduct and Ethics that applies to our directors and employees (including our principal executive officer, principal financial officer, principal accounting officer and controller), and have posted the text of the policy on our website (www.accentia.net) in connection with "Investor Relations" materials. We intend to satisfy the disclosure requirement under Item 10 of Form 8-K regarding an amendment to, or waiver from, a provision of this Code by posting such information on our website, at the address and location specified above. In addition, we intend to promptly disclose (1) the nature of any amendment to our Code that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions and (2) the nature of any waiver, including an implicit waiver, from a provision of our Code that is granted to one of these specified officers, the name of such person who is granted the waiver and the

date of the waiver on our website in the future. You may also request a copy of the Code by contacting our investor relations department at investors@accentia.net.

ITEM 11. EXECUTIVE COMPENSATION

The information in response to this item is hereby incorporated by reference to the information under the caption "Compensation of Executive Officers" presented in the Company's Proxy Statement. Information appearing in the Proxy Statement under the headings "Report on Executive Compensation by the Compensation Committee and Board of Directors", "Common Stock Performance" and "Report of Audit Committee" is not incorporated herein and should not be deemed to be included in this document for any purposes.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The information in response to this item is hereby incorporated by reference to the information under the caption "Security Ownership of Certain Beneficial Owners and Management" presented in the Company's 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 Company's Proxy Statement.

ITEM 14. PRINCIPAL ACCOUNTANTS FEES AND SERVICES

The information required by this item is incorporated by reference to the section entitled "Principal Accountants Fees and Services" in the Company's Proxy Statement.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES AND REPORTS ON FORM 8-K

(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
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).

Number		Description of Document
4.3	—	Agreement of Merger and Plan of Reorganization, dated January 8, 2003, between Registrant, 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 Registrant, 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 Registrant 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 Registrant 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 Registrant 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 Registrant 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 Registrant 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 Registrant 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 Registrant 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 Registrant 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).

Number	Description of Document
10.1 —	License Agreement, dated April 12, 2004, between Registrant 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 Registrant and Mayo Foundation for Medical Education and Research, 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 Registrant 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 Registrant and Biovest International, Inc., 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 June 15, 2004, between Registrant and Argent Development Group, LLC, as amended (filed as Exhibit 10.5 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).
10.6[b] —	Distribution Agreement, dated March 12, 2004, between Registrant 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).
10.7 —	Biologics Distribution Agreement, dated February 27, 2004, between Registrant 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).
10.8[b] —	Distribution Agreement, dated May 28, 2003, between Registrant and Acheron Development Group, LLC (filed as Exhibit 10.8 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[b] —	Distribution Agreement, dated May 23, 2003, between Registrant and Ryan Pharmaceuticals, Inc, as amended (filed as Exhibit 10.9 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).
10.10[b] —	Amended and Restated Distribution and Supply Agreement, dated August 12, 2005, between Registrant 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).
10.11[b] —	Product Development Agreement, dated January 24, 2003, between Registrant 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).
10.12 —	Cooperative Research and Development Agreement, dated May 27, 1999, between Registrant 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).
10.13[b] —	Manufacturing and Supply Agreement, dated June 6, 2003, between Registrant and Mikart, Inc. (filed as Exhibit 10.13 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).
10.14[b] —	Supply Agreement, dated December 1, 2004, between Registrant 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).

Number	Description of Document
10.15 —	First Amended and Restated Royalty Stream Purchase Agreement, dated August 11, 2005, between Registrant 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).
10.16 —	Office Lease, dated May 1, 2004, between Registrant, 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).
10.17 —	Standard Form of Lease, dated April 1, 2004, between Registrant, 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).
10.18 —	Agreement of Lease, dated December 1998, between Registrant, 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).
10.19 —	Agreement of Lease, dated February 26, 2002, between Registrant, 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).
10.20 —	Lease, dated March 22, 2005, between 460 Park Associates, as Landlord, and Registrant, 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).
10.21 —	Space Lease, dated October 26, 1995, between Registrant, as Tenant, and Worchester 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).
10.22 —	Lease Agreement dated December 2003, between Registrant 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).
10.23[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).
10.24[a] —	Employment Agreement, dated January 1, 2005, between Registrant 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).
10.25[a] —	Employment Agreement, dated April 3, 2002, between Registrant 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). .
10.26[a] —	Second Amended and Restated Executive Employment Agreement, dated December 31, 2004, between Registrant 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).
10.27[a] —	Employment Agreement, dated January 1, 2005, between Registrant 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).
10.28[a] —	Employment Agreement, dated January 1, 2005, between Registrant 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).
10.29 —	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).

Number	Description of Document
10.30 —	Form of Warrant for Purchase of Shares of Series E Convertible Preferred Stock granted by Registrant to Series E Holder (filed as Exhibit 10.30 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).
10.31 —	Form of Warrant for Purchase of Shares of Series D Convertible Preferred Stock granted by Registrant to Series D Holder (filed as Exhibit 10.31 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).
10.32 —	Form of Warrant for Purchase of Common Stock granted by Registrant 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).
10.33[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).
10.34[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).
10.35[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).
10.36 —	Revolving Credit Agreement, dated March 30, 2004, between Missouri State Bank and Trust Company and Registrant, 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).
10.37 —	Bridge Loan Promissory Note, dated October 15, 2003, of Registrant payable to Alan MacInnis (filed as Exhibit 10.37 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).
10.38 —	Loan Agreement, dated August 9, 2003, between Registrant and Harbinger Mezzanine Partners, L.P., together with Secured Promissory Note, Stock Purchase Warrant and Security Agreement, as amended (filed as Exhibit 10.38 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).
10.39 —	Accentia Assumption of Debt and Security Agreement, dated December 31, 2003, between Registrant 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).
10.40 —	Forbearance Agreement, dated December 9, 2003, between Registrant, Accent Rx, Inc. and McKesson Corporation (filed as Exhibit 10.40 to the Registration Statement on Form S-1 filed on February 11, 2005 2005 (Registration No. 333-122769) and incorporated herein by reference).
10.41 —	Warrant Purchase Agreement, dated December 1, 1998, between Registrant 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).
10.42 —	Credit Agreement, dated November 30, 1998, between Registrant 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).
10.43 —	Security Agreement, dated November 30, 1998, between Registrant 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).
10.44 —	Amended Secured Promissory Note, dated August 31, 2001, of Registrant payable to Peter J. Pappas, Sr., as amended (filed as Exhibit 10.44 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).
10.45 —	Amended Secured Promissory Note, dated October 11, 2001, of Registrant payable to Dr. Anaka Prakash, as amended (filed as Exhibit 10.45 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).

Number		Description of Document
10.46	—	Amended Secured Promissory Note, dated October 11, 2001, of Registrant payable to Frank and Gwyndolyn Korahais, as amended (filed as Exhibit 10.46 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).
10.47	—	Amended Secured Promissory Note, dated October 11, 2001, of Registrant payable to Constantine and Mary Soras, as amended (filed as Exhibit 10.47 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 Secured Promissory Note, dated October 16, 2001, of Registrant payable to Christos Soras, as amended (filed as Exhibit 10.48 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).
10.49	—	Amended Secured Promissory Note, dated October 25, 2001, of Registrant payable to Andreas Konstantinidis, as amended (filed as Exhibit 10.49 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).
10.50	—	Amended Secured Promissory Note, dated November 6, 2001, of Registrant payable to John M. and Maria S. Lignos, as amended (filed as Exhibit 10.50 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).
10.51	—	Amended Secured Promissory Note, dated November 7, 2001, of Registrant payable to Fay W. and Helen M. Logan, as amended (filed as Exhibit 10.51 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).
10.52	—	Amended Secured Promissory Note, dated December 3, 2001, of Registrant payable to Robert Dillon, as amended (filed as Exhibit 10.52 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).
10.53	—	Amended Secured Promissory Note, dated December 12, 2001, of Registrant payable to Robert Dillon, as amended (filed as Exhibit 10.53 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).
10.54	—	Amended Secured Promissory Note, dated January 10, 2002, of Registrant payable to Kit Ching Wong, as amended (filed as Exhibit 10.54 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).
10.55	—	Amended Secured Promissory Note, dated January 22, 2002, of Registrant payable to Robert Dillon, as amended (filed as Exhibit 10.55 to the Registration Statement on Form S-1 (Amendment No. 8) filed on October 3, (Registration No. 333-122769) and incorporated herein by reference).
10.56	—	Amended Secured Promissory Note, dated January 31, 2002, of Registrant payable to Laury Pensa, as amended (filed as Exhibit 10.56 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).
10.57	—	Amended Secured Promissory Note, dated December 3, 2002, of Registrant payable to John M. and Maria S. Lignos, as amended (filed as Exhibit 10.57 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).
10.58	—	Amended Secured Promissory Note, dated December 13, 2002, of Registrant payable to Fay W. and Helen M. Logan, as amended (filed as Exhibit 10.58 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).
10.59	—	Secured Promissory Note, dated June 10, 2003, of Registrant payable to Othon Mourkakos, as amended (filed as Exhibit 10.59 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).
10.60	—	Secured Promissory Note, dated June 10, 2003, of Registrant payable to Dr. Christopher Kyrikides, as amended (filed as Exhibit 10.60 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).
10.61	—	Convertible Secured Promissory Note and Security Agreement, dated June 12, 2003, between Registrant and Morrison Cohen Singer & Weinstein, LLP (filed as Exhibit 10.61 to the Registration Statement on Form S-1 filed on February 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).

Number		Description of Document
10.62	—	Secured Promissory Note, dated June 16, 2003, of Registrant payable to Peter J. Pappas Sr, as amended (filed as Exhibit 10.62 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).
10.63	—	Secured Promissory Note, dated June 16, 2003, of Registrant payable to Angelo Tsakopoulos, as amended (filed as Exhibit 10.63 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).
10.64	—	Lease Agreement, dated November 2004, between Registrant 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).
10.65	—	Post Residential Rental Agreement, dated April 15, 2005, between Registrant 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).
10.66[(b)]	—	Manufacturing and Supply Agreement, dated August 23, 2002, between Registrant 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).
10.67	—	Securities Purchase Agreement, dated April 29, 2005, between Registrant and Laurus Master Fund, Ltd. (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).
10.68	—	Security Agreement and Master Security Agreement, dated April 29, 2005, between Registrant and Laurus Master Fund, Ltd. (filed as Exhibit 10.68 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).
10.69	—	Amended and Restated Secured Convertible Term Note, dated August 16, 2005, of Registrant payable to Laurus Master Fund, Ltd. (filed as Exhibit 10.69 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).
10.70	—	Amended and Restated Secured Convertible Minimum Borrowing Note, dated August 16, 2005, of Registrant payable to Laurus Master Fund, Ltd., as amended (filed as Exhibit 10.70 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).
10.71	—	Secured Revolving Note, dated April 29, 2005, of Registrant payable to Laurus Master Fund, Ltd. (filed as Exhibit 10.71 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).
10.72	—	Stock Pledge Agreement and InterCompany Note Pledge Agreement, dated April 29, 2005, between Registrant and Laurus Master Fund, Ltd. (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).
10.73	—	Amended and Restated Common Stock Purchase Warrant, dated August 16, 2005, granted by Registrant to Laurus Master Fund, Ltd. (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).
10.74	—	Subsidiary Guaranty, dated April 29, 2005, between Registrant and Laurus Master Fund, Ltd. (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).
10.75	—	Registration Rights Agreement, dated April 29, 2005, between Registrant and Laurus Master Fund, Ltd., 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).
10.76	—	Promissory Note, dated September 1, 2001, of Registrant payable to Dr. David DeFouw, as modified on February 28, 2005. (filed as Exhibit 10.76 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).

Number		Description of Document
10.77	—	Promissory Note, dated September 1, 2001, of Registrant payable to Ioannis Kordistos, 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).
10.78	—	Promissory Note, dated September 1, 2001, of Registrant payable to Dr. Robert Evans, as modified on February 28, 2005 (filed as Exhibit 10.78 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).
10.79	—	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. 6) filed on July 11, 2005 (Registration No. 333-122769) and incorporated herein by reference).
10.80	—	Omnibus Amendment and Consent, dated August 16, 2005, between Registrant and Laurus Master Fund, Ltd. (filed as Exhibit 10.80 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).
10.81	—	Common Stock Purchase Warrant, dated August 16, 2005, between Registrant and Laurus Master Fund, Ltd. (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).
10.82	—	Bridge Loan Agreement, dated August 16, 2005, between Registrant 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).
10.83	—	Option Agreement, dated December 6, 2005, between Registrant and Mayo Foundation for Medical Education and Research (See Note B)
10.84	—	Licensing and Distribution Agreement, dated November 22, 2005, between Registrant and Collegium Pharmaceuticals, Inc. (see Note B)
10.85	—	Promissory Note Dated September 30, 2005
14.1	—	Code of Conduct
14.2	—	Director Indemnity Agreements
21	—	Subsidiaries of the Registrant (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.

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, 2005 and 2004 and the related consolidated statements of operations, stockholders' deficit, and cash flows for the years ended September 30, 2005, 2004 and 2003. 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, 2005 and 2004 and the consolidated results of their operations and their cash flows for the years ended September 30, 2005, 2004 and 2003 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 $79.3 million during the three years ended September 30, 2005, $20.8 million of which was attributable to its 81% owned subsidiary, and, as of that date, had a working capital deficiency of approximately $29.6 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, P ISER & COMPANY, P.A.

Tampa, Florida
December 1, 2005, except for Note 2, for which the date is December 29, 2005

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

	September 30,		
	2005	2004	Pro Forma 2005 (Unaudited)
ASSETS			
Current assets:			
Cash and cash equivalents	$ 2,763,452	$ 1,904,938	$ 16,869,452
Accounts receivable:			
Trade, net of allowance for doubtful accounts of $345,458 and $150,000 at September 2005 and 2004, respectively	3,715,488	2,394,453	3,715,488
Stockholder	676,752	784,082	676,752
Inventories	1,013,896	1,337,757	1,013,896
Inventory deposits	844,740	—	844,740
Unbilled receivables	690,886	783,973	690,886
Prepaid expenses and other current assets	385,241	450,369	385,241
Total current assets	10,090,455	7,655,572	24,196,455
Goodwill	1,193,437	1,193,437	1,193,437
Other intangible assets:			
Product rights	21,216,334	14,603,640	21,216,334
Non-compete agreements	2,104,000	2,104,000	2,104,000
Trademarks	1,631,474	1,629,433	1,631,474
Purchased customer relationships	1,268,950	1,268,950	1,268,950
Other intangible assets	648,040	645,029	648,040
Accumulated amortization	(5,631,122)	(3,324,275)	(5,631,122)
Total other intangible assets	21,237,676	16,926,777	21,237,676
Furniture, equipment and leasehold improvements, net	1,775,819	2,007,986	1,775,819
Inventories	—	289,000	—
Deferred offering costs	821,573	—	—
Other assets	423,644	59,862	423,644
	$ 35,542,604	$ 28,132,634	$ 48,827,031

(Continued)

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(CONTINUED)

	September 30,		
	2005	2004	Pro Forma 2005 (Unaudited)
LIABILITIES AND STOCKHOLDERS' DEFICIT			
Current liabilities:			
Current maturities of long-term debt:			
Related party	$ 7,414,742	$ 12,361,909	$ 7,414,742
Other	9,998,372	26,893	9,998,372
Lines of credit	3,767,221	3,272,587	3,767,221
Accounts payable (including related party of $346,423 at September 30, 2005)	5,519,626	6,650,103	5,519,626
Accrued expenses (including related party accrued interest of $147,983 and $376,481 at September 2005 and 2004, respectively)	6,899,882	6,143,283	6,899,882
Unearned revenues	863,096	1,291,151	863,096
Product development obligations (including $200,000 and $1,000,000 due to related party at September 30, 2005 and 2004, respectively)	500,000	4,391,750	500,000
Dividends payable	575,447	288,662	575,447
Due to employees	17,839	113,981	17,839
Stockholder advances and notes	350,000	750,000	350,000
Customer deposits	828,050	826,855	828,050
Deposits, related party	3,000,000	3,000,000	3,000,000
Total current liabilities	39,734,275	39,117,174	39,734,275
Long-term debt, net of current maturities:			
Related party	3,661,917	—	3,661,917
Other	5,490,252	5,280,944	5,490,252
Notes payable, stockholders	—	2,194,693	—
Line of credit, related party	4,180,000	—	4,180,000
Other liabilities, related party	2,574,865	2,500,000	2,574,865
Total liabilities	55,641,309	49,092,811	55,641,309

(Continued)

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED BALANCE SHEETS

(CONTINUED)

	September 30,		
	2005	2004	Pro Forma 2005 (Unaudited)
Commitments and contingencies (Notes 10, 16 and 17)	—	—	—
Stockholders' deficit:			
Common stock, $0.001 par value; 300,000,000 shares authorized; 5,170,421 and 4,876,328 shares issued and outstanding at September 30, 2005, and 2004, respectively. 28,481,329 Pro Forma outstanding shares at September 30, 2005	5,170	10,265	28,481
Preferred stock, Series A, $1.00 par value; 10,000,000 shares authorized; 2,937,013 and 1,939,483 shares issued and outstanding at September 30, 2005, and 2004, respectively. No Pro Forma outstanding shares at September 30, 2005	6,183,000	4,083,000	—
Preferred stock, Series B, $1.00 par value; 30,000,000 shares authorized; 3,895,888 and 3,835,390 shares issued and outstanding at September 30, 2005, and 2004, respectively. No Pro Forma outstanding shares at September 30, 2005	239,919	80,742	—
Preferred stock, Series C, $1.00 par value; 10,000,000 shares authorized; 3,562,607 shares issued and outstanding at September 30, 2005, and 2004, respectively. No Pro Forma outstanding shares at September 30, 2005	7,500,000	7,500,000	—
Preferred stock, Series D, $1.00 par value; 15,000,000 shares authorized; 4,672,482 and 4,616,451 shares issued and outstanding at September 30, 2005 and 2004, respectively. No Pro Forma outstanding shares at September 30, 2005	219,769	105,411	—
Preferred stock, Series E, $1.00 par value; 60,000,000 shares authorized; 20,506,178 and 6,858,731 shares issued and outstanding at September 30, 2005 and 2004, respectively. No Pro Forma outstanding shares at September 30, 2005	49,789,554	14,439,000	—
Additional paid-in capital	28,744,833	20,674,003	105,938,191
Accumulated deficit	(112,780,950)	(67,852,598)	(112,780,950)
Total stockholders' deficit	(20,098,705)	(20,960,177)	(6,814,278)
	$ 35,542,604	$ 28,132,634	$ 48,827,031

See notes to consolidated financial statements.

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ending September 30,		
	2005	2004	2003
Net Sales			
Products	$ 10,882,685	$ 10,528,756	$ 4,160,374
Services	10,460,011	11,632,343	4,697,048
Related party, products	3,766,586	3,774,521	1,050,369
Related party, services	85,500	—	—
Total net sales	25,194,782	25,935,620	9,907,791
Cost of sales:			
Products	4,479,395	3,852,880	1,332,478
Services	3,753,930	4,960,710	1,603,533
Total cost of sales (exclusive of amortization of acquired product rights)	8,233,325	8,813,590	2,936,011
Gross margin	16,961,457	17,122,030	6,971,780
Operating expenses:			
Research and development	9,588,677	4,210,058	6,111,952
Research and development, related party	1,319,185	1,309,100	—
Sales and marketing	15,164,067	12,015,044	4,366,228
General and administrative	20,658,808	16,728,873	8,868,076
Royalties	1,717,291	387,130	—
Impairment charges	357,931	359,445	—
Stock-based compensation, general and administrative	427,380	292,346	—
Other operating expense, related party	—	2,500,000	—
Total operating expenses	49,233,339	37,801,996	19,346,256
Operating loss	(32,271,882)	(20,679,966)	(12,374,476)
Other income (expense):			
Interest expense, net	(2,286,333)	(1,240,906)	(230,205)
Interest expense, net, related party	(2,119,621)	(1,485,616)	(337,500)
Settlement expense	—	—	(1,562,850)
Loss on extinguishment of debt, related party	(2,361,894)	—	—
Other income (expense)	(56,384)	78,164	—
Loss from continuing operations before income taxes	(39,096,114)	(23,328,324)	(14,505,031)
Income tax benefit	—	—	180,000
Net loss from continuing operations	(39,096,114)	(23,328,324)	(14,325,031)
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)	(2,346,912)
Absorption of prior losses against minority interest	150,000	—	—
Net loss	(39,376,224)	(23,225,941)	(16,671,943)
Constructive preferred stock dividend	(4,949,031)	(4,906,612)	—
Preferred stock dividends, other	(603,097)	(355,367)	—
Loss attributable to common stockholders	$ (44,928,352)	$ (28,487,920)	$ (16,671,943)
Weighted average shares outstanding, basic and diluted	5,147,222	4,875,683	4,728,718
Per share amounts, basic and diluted:			
Loss attributable to common stockholders per common share for:			
Continuing operations and minority interest	$ (8.65)	$ (5.86)	$ (3.01)
Discontinued operations	(0.08)	0.02	(0.51)
Loss attributable to common stockholders	$ (8.73)	$ (5.84)	$ (3.52)

See notes to consolidated financial statements.

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
YEARS ENDED SEPTEMBER 30, 2005, 2004 AND 2003

	Common Stock		Preferred Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount	Shares	Amount			
Balances, October 1, 2002	4,875,641	$ 10,264	8,086,768	$ 9,030,742	$ 10,800,745	$ (22,692,425)	$ (2,850,674)
Issuance of preferred stock for acquisition of TEAMM Pharmaceuticals, Inc.	—	—	4,612,504	97,102	—	—	97,102
Issuance of preferred stock for cash	—	—	609,443	1,283,000	—	—	1,283,000
Stock-based compensation	—	—	—	—	1,262,948		1,262,948
Net loss for the year	—	—	—	—	—	(16,671,943)	(16,671,943)
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)
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 period	—	—	—	—	—	(39,376,224)	(39,376,224)
Beneficial conversion feature and warrants related to convertible debentures	—	—	—	—	3,964,240	—	3,964,240
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	$ 28,744,833	$ (112,780,950)	$ (20,098,705)

(Continued)

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF STOCKHOLDERS' DEFICIT
YEARS ENDED SEPTEMBER 30, 2005, 2004 AND 2003

(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, October 1, 2002	688,771	$ 1,450,000	3,835,390	$ 80,742	3,562,607	$ 7,500,000	—	$ —	—	$ —	$ 9,030,742
Issuance of preferred stock for acquisition of TEAMM Pharmaceuticals, Inc.	—	—	—	—	—	—	4,612,504	97,102	—	—	97,102
Issuance of preferred stock for cash	609,443	1,283,000	—	—	—	—	—	—	—	—	1,283,000
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, September 30, 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, September 30, 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

See notes to consolidated financial statements.

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended September 30,		
	2005	2004	2003
Cash flows from operating activities:			
Net income (loss)	$(39,376,224)	$(23,225,941)	$(16,671,943)
Adjustments to reconcile net loss to net cash flows from operating activities:			
Depreciation	705,959	593,256	310,800
Amortization	2,448,916	1,969,779	1,074,246
Stock-based cost of disposal of business	—	2,581,600	—
Stock-based compensation	434,583	683,236	781,650
Accretion of debt discounts	1,771,321	—	20,054
Other non-cash charges	(69,600)	95,350	(8,375)
Loss on extinguishment of debt, related party	2,361,894	—	—
In-process research and development costs acquired	—	—	5,040,853
Impairment charges	357,931	359,445	—
Default interest charged	—	748,149	558,040
Increase (decrease) in cash resulting from changes in:			
Accounts receivable	(1,153,984)	1,625,247	1,522,324
Inventories	265,159	293,356	455,183
Inventory deposits	(844,740)	—	—
Unbilled receivables	(46,405)	(474,891)	231,010
Prepaid expenses and other current assets	33,059	270,880	(196,848)
Other assets	(268,567)	(13,078)	40,194
Accounts payable	(1,147,670)	(1,650,915)	5,221,387
Accrued expenses	1,996,248	(3,546,190)	(3,053,756)
Unearned revenues	(428,055)	405,497	(498,214)
Due to affiliate	—	113,981	(355,896)
Customer deposits	(32,048)	633,317	(187,462)
Net cash flows from operating activities	(32,992,223)	(18,537,922)	(5,716,753)
Cash flows from investing activities:			
Cash paid in business acquisition	—	(600,874)	—
Cash received in business acquisition	—	—	2,464,796
Proceeds from restricted cash	—	1,270,823	736,283
Acquisition of furniture, equipment, and leasehold improvements	(478,743)	(784,524)	(161,542)
Cash paid for acquisition of product rights and other intangibles	(4,600,593)	(2,940,345)	(575,099)
Net cash flows from investing activities	(5,079,336)	(3,054,920)	2,464,438
Cash flows from financing activities:			
Deferred offering costs	(821,573)	—	—
Payments on notes payable and long-term debt	(2,268,616)	(5,250,004)	(1,654,715)
Proceeds from deposits and other liabilities	—	5,500,000	—
Proceeds from issuance of common stock	618,178	1	—
Proceeds from issuance of preferred stock	25,654,178	15,793,874	1,283,000
Payment of Series E preferred stock dividends	(316,311)	(67,015)	—
Proceeds from related party borrowings	4,180,000	2,943,299	600,000
Proceeds from convertible debentures	10,000,000	—	—
Proceeds from long-term debt	—	524,531	4,120,794
Repayment of amounts due to stockholders	—	(885,418)	—
Proceeds from line of credit, net	1,734,217	3,272,587	—
Proceeds from minority interest investment	150,000	—	—
Net cash flows from financing activities	38,930,073	21,831,855	4,349,079
Net change in cash and cash equivalents	858,514	239,013	1,096,764
Cash and cash equivalents at beginning of period	1,904,938	1,665,925	569,161
Cash and cash equivalents at end of period	$ 2,763,452	$ 1,904,938	$ 1,665,925
Supplemental cash flow information:			
Cash paid for:			
Interest	$ 3,424,730	$ 1,258,149	$ 110,349
Income taxes	—	—	—

ACCENTIA BIOPHARMACEUTICALS, INC. AND SUBSIDIARIES

CONSOLIDATED STATEMENTS OF CASH FLOWS

(CONTINUED)

Supplemental Disclosure of Non-cash Investing and Financing Activities:

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 German subsidiary.

* In connection with the acquisition of product rights of $4.4 million, the Company entered into short-term financing arrangements with the sellers 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.

2003:

* The Company issued 4,612,504 shares of Series D preferred stock with a fair value of $0.1 million pursuant to the acquisition of TEAMM Pharmaceuticals, Inc.

* The Company issued 230,583 warrants to purchase Series D preferred stock with a fair value of $481,298 pursuant to the Harbinger Mezzanine long-term debt agreement.

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 a biopharmaceutical company 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 III 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 III clinical trial. In addition to these product candidates, the Company has a growing specialty pharmaceutical business with a portfolio of ten currently marketed products and a pipeline of products under development by third parties.

As discussed in Note 3, effective October 1, 2002, the Company acquired the assets of AccentRx, an entity operated under the common control of the stockholders of the Company and 91.6% owned by such stockholders through the exchange of common equity. The reorganization was accounted for in a manner similar to a pooling of interests, where the assets and liabilities of Accentia and AccentRx were combined at historical costs, and the operations are presented as if combined for all periods presented. During fiscal 2004, this business was discontinued. See Note 3.

The TEAMM and Biovest acquisitions were completed on April 1, 2003 and June 30, 2003, respectively. The 2003 statements of operations and cash flows reflect activity of twelve months for Accentia, AccentRx and Analytica, six months for TEAMM commencing April 1, 2003 and three months for Biovest commencing July 1, 2003. See Note 3 for additional information on these acquisitions. All entities either had an original fiscal year end of September 30 or converted to a September 30 fiscal year at the time of acquisition.

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. In this segment, the Company generated revenues of $14.5 million, $14.0 million and $6.0 million during the years ended September 30, 2005, 2004 and 2003, respectively.

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 Xodol ™, a narcotic pain formulation, Respi~TANN ®, a prescription antitussive decongestant for temporary relief of cough and nasal congestion, our line of six HISTEX ™ products for the cough, cold and allergy prescription market, and two products which we co-promote. In this segment the Company generated revenues of $10.7 million, $11.9 million and $3.9 million for the years ending September 30, 2005, 2004 and 2003, respectively. Specialty pharmaceutical products under development currently include MD Turbo ™, a breath-actuated inhaler device used by patients with asthma and chronic obstructive pulmonary disease, Emezine ™, a transbuccal drug designed to control nausea and vomiting, and nine additional narcotic pain formulations for the treatment of moderate to moderately severe pain.

1. Description of business and summary of significant accounting policies (continued)

Principles of consolidation

The accompanying consolidated financial statements include the accounts of Accentia and its three wholly-owned subsidiaries, and its 81% owned subsidiary. All intercompany accounts and transactions have been eliminated. The Company does not currently recognize a minority interest in its 81% 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.

Variable interest entity

As discussed in Note 3, in connection with the Company's acquisition of Biovest, Biovest qualified as a variable interest entity in that, while Accentia owned the majority interest in the Company (the stock had been issued), they lacked voting control as a result of a voting proxy provision, but qualified as the primary beneficiary pursuant to Financial Accounting Standards Board Interpretation 46, *Consolidation of Variable Interest Entities*. As such, Accentia was required to consolidate Biovest on the date of acquisition. Effective October 16, 2003, the voting control was transferred to Accentia and Accentia then continued to consolidate Biovest, but under standard consolidation rules pursuant to Statement of Financial Accounting Standards No. 141, *Business Combinations*.

Unaudited pro forma financial information

The accompanying unaudited proforma balance sheet gives effect to the proceeds of $14.1 million in net proceeds from the initial public offering, which was completed on November 2, 2005, and the costs associated therewith, as well as the conversion of all preferred stock to common stock effective upon completion of the offering.

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 $0.3 and $0.2 million at September 30, 2005 and 2004, respectively, which management considers adequate; however actual write-offs may exceed the allowance.

One customer 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 accounts receivable balance as of September 30, 2005.

1. Description of business and summary of significant accounting policies (continued)

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%

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. One of these three customers (McKesson) accounted for approximately 15% of the Company's trade accounts receivable balance as of September 30, 2004. They are as follows:

	Sales
Customer 1	15%
Customer 2 (McKesson)	15%
Customer 3	10%
	40%

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%

Two customers in the Specialty Pharmaceuticals segment accounted for 25% of consolidated net sales for the year ended September 30, 2003.

	Sales
Customer 1	14%
Customer 2 (McKesson)	11%
	25%

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

1. Description of business and summary of significant accounting policies (continued)

might be impaired. The Company has identified certain trademarks, product rights and technology rights 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:

	Estimated Useful Lives
Noncompete agreements	2 to 4 years
Customer relationships	10 years
Software	3 years
Patents	3 years
Product rights	4.5 to 20.5 years

Advertising expense

The Company expenses the costs of advertising, which includes promotional expenses, as incurred. For the years ended September 30, 2005, 2004, and 2003, 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.

Fair value of financial instruments

The carrying amounts of current assets and current liabilities such as cash, accounts receivable, accounts payable, customer deposits and accrued liabilities approximate fair value because of the short maturity of these items. The fair value of the Company's borrowings, including deposits and other liabilities, if recalculated based on current interest rates (9.75% current borrowing rate) would be approximately $34.6 million or $2.9 million lower than the recorded amounts.

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 at September 30, 2005 amounted to $1.8 million (See Note 6). In accordance with Statement of Financial Accounting Standards No. 142, Goodwill and Other Intangible Assets ("SFAS 142"), indefinite lived assets resulting from the purchases are not amortized into operations. Rather, such amounts are tested for impairment at least annually. The impairment test is calculated at the reporting unit level. This 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, intangible assets are 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 intangible assets with the carrying amount. If the implied fair value of intangible assets are less than the carrying amount, an impairment charge is recorded. 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 $0.4 million, $0.4 million and $-0- during the years ended September 30, 2005, 2004 and 2003, respectively. See Note 15 for further discussion.

1. Description of business and summary of significant accounting policies (continued)

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.

1. Description of business and summary of significant accounting policies (continued)

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 applicable products are delivered. 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 $ 0.2 million, $1.7 million, $1.5 million as of September 30, 2005, 2004 and 2003.

1. Description of business and summary of significant accounting policies (continued)

During 2004, the Company entered into an agreement with Pharmaceutical Product Development, Inc. ("PPD"), a preferred 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. The $2.5 million funds received are presented as "other liabilities, related party" in the accompanying consolidated balance sheet as of September 30, 2004. As of September 30, 2005, the balance of this liability is $2.4 million, reflecting royalties payable to PPD accrued as of the date.

Cost of sales

Cost of sales excludes amortization of acquired product rights of $1.5 million, $0.4 million, $0.1 million in 2005, 2004, and 2003, 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. In addition to the purchased in-process research and development costs discussed in Note 3, 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 $10.9 million in the year ended September 30, 2005, $5.5 million in the year ended September 30, 2004 and $6.1 million in the year ended September 30, 2003.

Stock-based compensation

The Company has adopted the accounting provisions of Statement of Financial Accounting Standards No. 123—Accounting for Stock-Based Compensation ("FAS 123"), 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:

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

2003:	Range of values	Weighted Avg.
Dividend yield	$ 0	$ 0
Expected volatility	0% to 55.486%	6.37%
Risk free interest rate	1.62 – 3.37%	2.36%
Expected life	2.2 to 5 years	3.9 years

1. Description of business and summary of significant accounting policies (continued)

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,		
	2005	2004	2003
Numerator:			
Net loss applicable to common stockholders	$ (44,928,352)	$ (28,487,920)	$ (16,671,943)
Denominator:			
For basic loss per share—weighted average shares	5,147,222	4,875,683	4,728,718
Effect of dilutive securities	—	—	—
Weighted average shares for dilutive loss per share	5,147,222	4,875,683	4,728,718
Net loss per share applicable to common stockholders, basic and dilutive	$ (8.73)	$ (5.84)	$ (3.52)
EPS effect of preferred dividends	$ (1.08)	$ (2.16)	$ —

The effect of common stock equivalents are not considered in the calculation of diluted loss per share because the effect would be anti-dilutive. They are as follows:

	2005	2004	2003
Options and warrants to purchase common stock	3,027,933	1,933,158	793,192
Preferred stock convertible to common stock	35,574,154	20,812,662	13,308,715
Preferred stock options and warrants convertible to preferred which is then convertible to common	1,211,502	15,307,015	2,273,165

Note: Share and per share information throughout these financial statements has been retroactively adjusted to effect the 2005 1-for-2.1052 reverse stock split discussed in Note 12.

Reclassification:

Certain amounts in the 2004 and 2003 financial statements have been reclassified to conform with the 2005 presentation.

Deferred offering costs:

Deferred offering costs represent legal, accounting and other costs associated with the initial public offering that will be charged to additional paid-in capital offering in fiscal 2006 upon completion of the initial public offering.

Recent accounting pronouncements

In December 2004, the FASB revised its SFAS No. 123 ("SFAS No. 123R"), "Accounting for Stock Based Compensation." 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. The provisions of the revised statement are effective for financial statements issued for the first interim or annual reporting period beginning after June 15, 2005, with early adoption encouraged. The Company accounts for options issued to employees under SFAS No. 123; accordingly adoption of this revision is not expected to have a significant impact on the Company's current financial condition or results of operation.

1. Description of business and summary of significant accounting policies (continued)

This Statement applies to all awards granted after the required effective date and to awards modified, repurchased, or cancelled after that date. The cumulative effect of initially applying this Statement, if any, is recognized as of the required effective date. As of the required effective date, all public entities and those nonpublic entities that used the fair-value-based method for either recognition or disclosure under Statement 123 will apply this Statement using a modified version of prospective application. Under that transition method, compensation cost is recognized on or after the required effective date for the portion of outstanding awards for which the requisite service has not yet been rendered, based on the grant-date fair value of those awards calculated under Statement 123 for either recognition or pro forma disclosures.

In March 2005, the FASB issued Interpretation No. 47, "Accounting for Conditional Asset Retirement Obligations, an interpretation of FASB Statement No. 143" ("FIN 47"), which requires an entity to recognize a liability for the fair value of a conditional asset retirement obligation when incurred if the liability's fair value can be reasonably estimated. FIN 47 is effective for fiscal years ending after December 15, 2005. The Company is currently evaluating the effect that the adoption of FIN 47 will have on its consolidated results of operations and financial condition but does not expect it to have a material impact.

In May 2005, the FASB issued SFAS No. 154, "Accounting Changes and Error Corrections" ("SFAS 154"), which replaces Accounting Principles Board Opinion No. 20 "Accounting Changes" and SFAS No. 3, "Reporting Accounting Changes in Interim Financial Statements—An Amendment of APB Opinion No. 28." SFAS 154 provides guidance on accounting for and reporting of accounting changes and error corrections. It establishes retrospective application, or the latest practicable date, as the required method for reporting a change in accounting principle and the reporting of a correction of an error. SFAS 154 is effective for accounting changes and corrections of errors made in fiscal years beginning after December 15, 2005, and is required to be adopted by the Company in the first quarter of fiscal 2006. The Company is currently evaluating the effect that the adoption of SFAS 154 will have on its consolidated results of operations and financial condition, but does not expect it to have a material impact.

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 $79.3 million and used cash from operations of $57.2 million during the three years ended September 30, 2005, and has a working capital deficit of $29.6 million at September 30, 2005. The Company projects operating deficits for fiscal 2006 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)		
	2005	2004	2003
Accentia	$ 27.9	$ 14.2	$16.4
Biovest	$ 11.5	$ 9.0	$ 0.3
Consolidated	$ 39.4	$ 23.2	$16.7

Since the Company's inception, operations have been funded primarily through private placements of capital stock, debt financing, conversions of debt to equity, and financing transactions with strategic partners. These transactions are described throughout the footnotes. In addition, on November 2, 2005, the Company closed its Initial Public Offering ("IPO"), with gross and net proceeds of $19.2 million and $14.3 million, respectively. The Use of Proceeds section refers to the consummation of several commitments described in the Form S-1 filing.

The Company is projecting that operating cash flow deficits for the early part of fiscal 2006 will be offset by net cash inflows from financing activities, as well as from proceeds from the initial public offering, completed within the first quarter of fiscal 2006, repayment of advances to our subsidiary Biovest, the placement of private equity, the exercise of warrants, and bank financing offset by debt repayments.

2. Liquidity and management's plans (continued)

Subsequent to September 30, 2005, convertible debentures issued by Biovest having principal and accrued interest in the amount of $1.3 million were converted by their holders into shares of Biovest common stock at a conversion price ranging from $.40 to $1.00 per share. Following this conversion, Accentia exercised its First Right of Refusal to maintain its ownership percentage and accordingly received 7,119,000 shares of Biovest stock in exchange for the issuance of a promissory note bearing interest at prime rate and payable in December 2010. In addition, $3.7 million of principal and accrued interest under convertible debentures issued by Biovest were converted into Accentia stock at prices ranging from $6.40 to $8 per share. In connection with these transactions, Biovest issued an inter-company demand note to Accentia for approximately $3.7 million. Accentia has advanced approximately $1.8 million since October 1, 2005, which is expected to be repaid in fiscal 2006. Accentia expects repayment from Biovest on the conversion note and its current year advances in fiscal 2006, as Biovest is seeking its own debt and equity financing, as separately described below. The liquidity effect of these conversions on the consolidated balance sheet was to reduce our consolidated current and long-term debt and increase shareholders' equity by $5.0 million.

Additionally, in November 2005, following the IPO, the Company paid $2.8 million to Laurus Master Funds which was applied to its line of credit.

On December 29, 2005, Laurus Master Fund, LTD. ("Laurus") agreed to make a loan to the Company 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, the Company granted Laurus a warrant to purchase up to 51,000 shares of common stock at an exercise price of $0.01 per share.

Following the IPO, as part of the plan to secure additional financing, the Company paid $2.0 million to Harbinger, which reduced its note to $5.0 million.

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 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, coporate 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. If none of the foregoing funding sources are available during the next six months, management believes that the Company can reduce or eliminate expenses in a relatively short period to enable us to continue business activities, on a reduced basis, into the 2007 fiscal year.

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. Pending completion of an anticipated Biovest financing transaction, the Company plans to continue to fund Biovest's operations through intercompany demand loans to the extent that advanced amounts exceed the funding commitment to Biovest under the investment agreement with Biovest. As of December 1, 2005, an aggregate of $5.5 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. After the completion of a funding transaction by Biovest, if any, Management does not anticipate that Accentia will continue to finance Biovest's operations. In addition, upon the completion of such 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

Acquisitions

Effective October 1, 2002, the Company through a wholly owned subsidiary, Accent RX, Inc., acquired all of the assets and assumed substantially all of the liabilities of American Prescription Providers, Inc. ("APP"), a company under substantially common ownership and control with that of the Company, through issuance of 4,875,166 shares of Accentia common stock and payment of $0.2 million in cash. The assets acquired and liabilities assumed were recorded at APP's historical cost basis, and the results of operations of AccentRx are included in the accompanying consolidated financial statements for the years ended September 30, 2003 and 2002 in accordance with SFAS 141 Appendix D (substantially equivalent to a pooling of interests). Disposition of this segment of business is discussed below. AccentRx conducted a pharmacy business with sales of specialty pharmaceuticals.

Effective April 1, 2003, the Company acquired 100% of the outstanding capital stock of TEAMM, a Delaware corporation, through issuance of 4,612,504 shares of Accentia Series D convertible preferred stock. Also, pursuant to the merger agreement, the Company 1) converted options to purchase 362,232 shares of TEAMM common stock to options to purchase 362,232 shares of Accentia Series D preferred stock which are subject to the same vesting periods and terms of the TEAMM options, except the exercise price was changed to $0.50 per share; 2) converted outstanding TEAMM warrants to acquire 988,145 shares of Accentia Series D preferred stock; and 3) issued options to acquire 598,247 shares of Accentia common stock to TEAMM management and sales representatives. Intangible assets acquired consisted of $0.5 million in non-compete agreements which have an estimated life of 2 years, $0.1 million of trademarks which have estimated lives of 4.5 to 10 years, $6.7 million of product rights which have estimated lives of 4.5 to 11.5 years and $0.6 million in trademarks and customer relationships with indefinite lives. The Company's consolidated financial statements include TEAMM's results of operations from the date of acquisition. TEAMM markets and sells pharmaceutical products that are developed primarily through third party development partners.

On June 16, 2003, the Company acquired 81% of the outstanding voting shares of Biovest (27,891,037 shares of common stock and 8,021,886 shares of preferred stock , all of which were newly issued by Biovest). No amounts were payable to the minority stockholders. Consideration for the purchase of the shares was $2.5 million in cash (paid to Biovest) and a $17.5 million note payable (due to Biovest) . While the consideration for the shares was the note, the note was not collateralized or secured by the stock. All shares were issued, legally voting, fully-paid and non-assessable. These shares were immediately placed on the stock register of Biovest with the Company listed as the record owner thereof; however, for the period from acquisition to October 16, 2003, Biovest qualified as a variable interest entity due to the existence of a voting trust. The Company also met the criteria for the primary beneficiary in accordance with FIN 46. As such, Biovest was consolidated with the Company from the date of acquisition and the Company's consolidated financial statements include Biovest's results of operations from July 1, 2003 forward. On October 16, 2003, the voting trust that created the variable interest was terminated, and Biovest satisfied all criteria for consolidation pursuant to FAS 141.

Accounting for the acquisition of Biovest in accordance with generally accepted accounting principles (pursuant to ARB 51) requires that intercompany balances and transactions be eliminated. This includes intercompany open account balances, security holdings, sales and purchases, interest, and dividends, as consolidated statements are based on the assumption that they represent the financial position and operating results of a single business enterprise. As a result, the entire $20.0 million investment in Biovest is eliminated in consolidation since all of the consideration was paid to Biovest. The purchase price post-consolidation represents Biovest's deficit in stockholders' equity on the date of the acquisition of $2.9 million. Cumulative payments to date on the $17.5 million note aggregated $16.8 million at September 30, 2005, leaving a remaining internal commitment (and unpaid balance) of $0.7 million.

The purchase price for purposes of generally accepted accounting principles ($2.9 million as described above) has been allocated to the assets acquired and liabilities assumed based on their estimated fair values. In ascertaining fair value, the gross purchase price was used and then reduced pro rata to amounts determined post-consolidation. The gross purchase price of $20.0 million plus liabilities assumed less identifiable tangible assets leave an intangible value to be allocated of $24.9 million. That intangible value was allocated, and then reduced pro rata to the $2.9 million post-consolidation purchase price plus pre-existing intangibles of $2.7 million, as follows:

3. Acquisitions and dispositions (continued)

	Intangible value	Pro rata amount
	(in thousands)	
Trademarks	$ 117	$ 26
Customer relationships	607	137
In-process research and development	22,312	5,042
Software	1,409	318
Patents	457	103
Total	$ 24,902	$ 5,626

The Company accounted for the Analytica, TEAMM and Biovest acquisitions using purchase accounting standards established in FAS No. 141, *Business Combinations* , and FAS No. 142, *Goodwill and Other Intangible Assets*. Accordingly, the acquisition purchase prices were allocated to the assets acquired and liabilities assumed based on their estimated fair values.

The fair values of assets acquired and liabilities assumed in connection with the acquisitions accounted for as purchases are as follows:

	Biovest at 100%	TEAMM
Assets acquired:		
Cash acquired	$ —	$ 1,859,769
Current assets	2,807,000	1,964,269
Restricted cash	—	2,007,106
Furniture, equipment and leasehold improvements	956,000	103,865
Other intangible assets	2,767,000	7,848,000
Other assets	127,000	—
Total assets acquired	6,657,000	13,783,009
Current liabilities	4,968,000	8,685,907
Long-term debt	4,548,000	5,000,000
Total liabilities assumed	9,516,000	13,685,907
	$ (2,859,000)	$ 97,102

Purchased in-process research and development

In connection with the acquisition of Biovest, the Company has determined that $5.0 million of the fair value of the acquisition price qualifies as in-process research and development, and as such, this amount was expensed as research and development expense on the acquisition date. Details relating to this technology acquisition are as follows:

The in-process research and development acquired was related to an injectable autologous (patient-specific) vaccine for the treatment of follicular non-Hodgkin's lymphoma. Follicular non-Hodgkin's lymphoma 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. The technology is referred to as "the BiovaxID project."

Significant appraisal assumptions used at acquisition were as follows:

- Material cash inflows from the BiovaxID project were, at the time of acquisition, anticipated to commence in fiscal 2004 (notwithstanding that such cash inflows did not ultimately commence in fiscal 2004).
- Material anticipated changes from historical pricing and margins were not considered as there was no history. There were projected material increases in the expenditures associated with the project over the historical levels in order to advance the project through the clinical trial stage.
- The risk adjusted discount rate applied to the estimated future cash flows was 55%.
- The total fair value of assets and intangibles to be allocated exceeded the invested capital and purchase price and therefore a pro rata write down was required to reduce the fair values to the actual amounts paid, so the fair value of in-process research and development of $22.3 million was reduced to $5.0 million, which was expensed at the acquisition date.

3. Acquisitions and dispositions (continued)

The BiovaxID project is in the Phase III trial stage and there are substantial regulatory approvals remaining before the product can be launched, and as such is incomplete for purposes of ascertaining in-process research and development status. Through its Cooperative Research and Development Agreement with NIH, Biovest has corporate sponsorship rights to technology, which gives Biovest the right to develop the vaccine and, if successful, to market it. The technology is unique in that the vaccine is autologous, that is, derived from a patient's own cancer cells. It is designed to utilize the power of the patient's immune system to recognize and destroy cancerous lymphoma cells while sparing normal cells.

The Phase III clinical trial requires approximately 450 patients to be enrolled. Costs incurred with development of this technology since the date of acquisition are included in research and development in the accompanying statements of operations. Estimated costs to complete the project, which include instrument development, vaccine procession and clinical trials are estimated at $24.6 million as of September 30, 2005. Although Management currently anticipates completion of enrollment for Phase III clinical trial in calendar year 2007, the time it takes to reach the clinical endpoint following the completion of enrollment may be several years, and 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. Risks associated with completing development relate to achieving the necessary patient enrollment and the ability to adequately scale-up the vaccine manufacturing and production process through commercially acceptable and FDA approved instrumentation that will allow for the vaccines to be manufactured in a large-scale facility to meet anticipated market demand. At September 30, 2005, 187 patients have been enrolled of the total 450 needed. Delays in completing recruitment of patients further delays FDA approval and commercial launch of the product. In addition, the Company cannot be certain of when enrollment will be complete or if the vaccine will demonstrate sufficient efficacy and safety to gain FDA approval. Even if approved, the Company cannot be certain if sufficient demand exists for the product or if the vaccine can be produced profitably on a commercial scale.

Other 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 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 and allocated in a manner similar to the previous acquisition of a similar business, Analytica. 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.

Dispositions

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.

3. Acquisitions and dispositions (continued)

Revenues and pre-tax income (loss) reported as discontinued operations are as follows:

	2005	2004	2003
Revenues	$ —	$ 3,745,688	$ 20,849,904
Pre-tax loss	$ (430,110)	$ (1,516,017)	$ (2,346,912)

Continuing cash flows in 2005 from discontinued operations result from the resolution of lease matters.

4. Inventories

Inventories consist of the following:

	September 30,	
	2005	2004
Pharmaceutical products held for sale	$ 814,862	$ 579,751
Finished goods, other, net of $0.3 million allowance for obsolescence	35,787	536,006
Work-in-process	120,977	61,000
Raw materials	42,270	450,000
	1,013,896	1,626,757
Less: long-term inventories	—	(289,000)
	$ 1,013,896	$ 1,337,757

During 2003, the Company recorded a $0.3 million inventory allowance for obsolete inventory, which is included in cost of sales in the accompanying 2003 statement of operations. The $0.3 million allowance was eliminated in the three months ended December 31, 2004 in connection with the write-off of inventory.

5. Unbilled receivables and unearned revenues

Unbilled receivables and unearned revenues are as follows:

	September 30,	
	2005	2004
Costs incurred on uncompleted service contracts	$ 7,020,113	$ 5,828,796
Estimated earnings	7,286,296	5,271,685
	14,306,409	11,100,481
Less billings to date	(14,478,620)	(11,607,659)
	$ (172,210)	$ (507,178)

These amounts are presented in the accompanying balance sheets under the following captions:

	September 30,	
	2005	2004
Unbilled receivables	$ 690,886	$ 783,973
Unearned revenues	(863,096)	(1,291,151)
	$ (172,210)	$ (507,178)

6. Other intangible assets

Intangible assets, other than goodwill, consist of the following:

	September 30, 2005	September 30, 2004	Weighted Average Amortization Period
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	149,624	146,613	3.5 years
Purchased customer relationships	1,043,813	1,043,813	9.5 years
Product rights	21,216,334	14,603,640	14.3 years
Software	498,416	498,416	3.5 years
Trademarks	106,041	104,000	7.5 years
	25,118,228	18,500,482	
Less accumulated amortization	(5,631,122)	(3,324,275)	
	19,487,106	15,176,207	
Other intangible assets	$ 21,237,676	$ 16,926,777	

	Activity Year Ended Sep. 30, 2003					
	Acquired in Teamm Bus Acq	Acquired in Biovest Bus Acq	Purchased in 2003	In process R&D Expensed in 2003	2003 Amortization	Balance at Sep. 30, 2003
Indefinite-life intangibles:						
Trademarks	$ 349,000	$ 26,433				$ 1,525,433
Goodwill						893,000
Purchased customer relationships	225,137					225,137
						2,643,570
Amortizable intangible assets:						
Noncompete agreements	524,000					2,104,000
Patents		103,248	—			103,248
Purchased customer relationships		137,000	36,463			803,463
Software		318,329	—			438,329
Trademarks	104,000					104,000
Product rights	6,743,000		553,829			7,296,829
Purchased in-process R&D		5,040,853				5,040,853
Purchased in-process R&D expense				$ (5,040,853)		(5,040,853)
Accumulated amortization					$ (1,074,246)	(1,354,496)
	$ 7,945,137	$ 5,625,863	$ 590,292			9,495,373
Total						$ 12,138,943

6. Other intangible assets (continued)

	Acquired in Imor Bus Acq.	Purchased in 2004	2004 Amortization	Balances Sep. 30, 2004
Indefinite-life intangibles:				
Trademarks	—	—		$ 1,525,433
Goodwill	300,437	—		1,193,437
Purchased customer relationships	—	—		225,137
				2,944,007
Amortizable intangible assets:				
Noncompete agreements	—	—		2,104,000
Patents	—	43,365		146,613
Purchased customer relationships	240,350	—		1,043,813
Software	60,087	—		498,416
Trademarks	—	—		104,000
Product rights	—	7,306,811		14,603,640
Accumulated amortization			$ (1,969,779)	(3,324,275)
	$ 600,874	$ 7,350,176		15,176,207
Total				$ 18,120,214

	Balances Sep. 30, 2004	Acquired in 2005	2005 Amortization	2005 Elimination	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)		(2,448,916)	$ 142,069	(5,631,122)
	15,176,207	$ 8,087,746	$ (3,918,916)	$ 142,069	19,487,106
Total	$ 18,120,214				$ 22,431,113

6. Other intangible assets (continued)

Product rights by product are as follows:

Product Rights:	Licensor		Developer if product under development at Sept 2005	Acquired in Teamm Bus Acq	Purchased Fiscal Year 2003	2003 Amortization	Balance 30-Sep-03	Purchased Fiscal Year 2004	2004 Amortization	Balance 30-Sep-04	Product obligation 30-Sep-04
Chronic rhinosinusitis ...	Mayo	(i)	Accentia	$ —	$ —	$ —	$ —	$ 2,155,000	$ (48,000)	$ 2,155,000	$ 1,005,000
Histex	Andrx		Product in market	999,000	—	(111,000)	999,000	—	(222,000)	999,000	—
Respitan			Product in market	607,000	—	(30,000)	607,000	—	(61,000)	607,000	—
Alcotin/Novacort .	Primus		Product in market	—	—	—	—	250,000	(42,000)	250,000	—
Sustained release ..	SRL	(a)	N/A technology	—	—	—	—	1,470,000	(50,690)	1,470,000	1,360,000
Asthma	Mayo	(b)(i)	Mayo & Accentia	—	—	—	—	—	—	—	—
CRS Worldwide ...	Mayo	(c)(i)	Accentia	—	—	—	—	—	—	—	—
Emezine	Arius	(d)	Arius	—	—	—	—	1,300,000	(31,707)	1,300,000	1,000,000
Xodol	Ryan	(e)	Product in market	1,392,000	300,000	(73,565)	1,692,000	500,000	(172,130)	2,192,000	270,000
Pain	Argent	(f)	Mikart	—	—	—	—	814,148	(30,154)	814,148	756,750
Pain	Acheron	(g)	Mikart	1,783,000	100,000	(65,831)	1,883,000	—	(131,662)	1,883,000	—
MD Turbo	Respirics	(h)	Respirics	1,962,000	150,000	(51,512)	2,112,000	700,000	(120,973)	2,812,000	—
Other				—	3,829	—	3,829	117,663	(27,000)	121,492	—
				$ 6,743,000	$ 553,829		7,296,829	$ 7,306,811		14,603,640	$ 4,391,750
Less accumulated amortization						$ (331,908)	(331,908)		$ (937,316)	(1,269,224)	
							$ 6,964,921			$ 13,334,416	

Continued

6. Other intangible assets (continued)

	Licensor		Developer if product under development at Sept 2005	Balance 30-Sep-04	Impairment Fiscal Year	Purchased Fiscal Year 2005	2005 Amortization	Balance 30-Sep-05	Product obligation 30-Sep-05
Product Rights:									
Chronic rhinosinusitis ...	Mayo	(i)	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	(a)	N/A technology	1,470,000	(1,470,000)	—	(101,379)	—	—
Asthma	Mayo	(b)(i)	Mayo & Accentia	—	—	—	—	—	—
CRS Worldwide	Mayo	(c)(i)	Accentia	—	—	—	—	—	—
Emezine	Arius	(d)	Arius	1,300,000	—	300,000	(68,902)	1,600,000	200,000
Xodol	Ryan	(e)	Product in market	2,192,000	—	—	(368,688)	2,192,000	300,000
Pain	Argent	(f)	Mikart	814,148	—	643,792	(70,649)	1,457,940	—
Pain	Acheron	(g)	Mikart	1,883,000	—	—	(131,661)	1,883,000	—
MD Turbo	Respirics	(h)	Respirics	2,812,000	—	120,000	(142,168)	2,932,000	—
AllerNase	Collegium	(j)		—	—	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	

6. Other intangible assets (continued)

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, which is being developed under predicate device FDA guidelines. Development and approval paths are expected to average approximately 24 months. The Company's cash flow projections for all products and technologies support recoverability for capitalized intangibles, and as such, no impairment charges were deemed appropriate.

(a) Represents the licensing rights for a patent-pending drug-delivery technology being developed by a third party. This technology will be applied to a variety of chemical compounds that would potentially result in commercialized products.

(b) Represents the right under a license agreement to commercialize an asthma therapy using low-dose antifungals under patents held by Mayo Foundation.

(c) Represents exclusive worldwide rights licensed from Mayo Foundation for commercialization of therapy for chronic rhinosinusitus, still in the FDA-approval process as of March 31, 2005.

(d) Represents exclusive U.S. rights for distribution of anti-emetic therapy for treatment of nausea and vomiting acquired from a third party. 505(b)(2) application submitted to FDA in April 2005 by development partner, and FDA approval currently expected in 2006.

(e) 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.

(f) Represents exclusive U.S. distribution rights acquired from third-party under a distribution agreement for nine products, of which two product submissions have been filed with FDA, with approval expected early 2006. Four product submissions to FDA are expected in July 2005, with expected approval mid-2006. The remaining two product submissions are expected in first quarter 2006, with expected approval in first quarter 2007.

(g) Represents exclusive U.S. distribution rights acquired from a third party under a distribution agreement for one product, with expected submission to FDA in first quarter 2006 and expected approval early in 2007.

(h) Represents distribution rights acquired from a third party for a medical device that can be used in the administration of multiple products. FDA submission was in February 2005, with expected clearance in mid-2005.

(i) The Mayo Clinic has approved patents supporting these products.

(j) 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 2006 and expected approval in the third quarter of 2006.

See Notes 10, 17 and 19 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,	
2006	$ 1,940,266
2007	1,595,168
2008	1,412,768
2009	1,300,788
2010	1,299,461
Thereafter	11,938,655
	$ 19,487,106

Goodwill expected to be deductible for income tax reporting purposes aggregated $0.3 million, $0.3 million and $0 at September 30, 2005, 2004 and 2003, respectively.

7. Furniture, equipment and leasehold improvements

Furniture, equipment and leasehold improvements consist of the following:

	September 30, 2005	September 30, 2004
Furniture	$ 253,130	$ 378,389
Office and laboratory equipment	2,737,291	2,629,882
Leasehold improvements	791,687	551,085
	3,782,108	3,559,356
Less: accumulated depreciation and amortization	(2,006,289)	(1,551,370)
	$ 1,775,819	$ 2,007,986

8. Lines of credit

Lines of credit consists of the following:

	September 30, 2005	September 30, 2004
Promissory note, interest at 3%; matured November 2004; secured by stockholder certificate of deposit	$ —	$ 250,000
Revolving credit agreement, interest at prime plus 1% (5.5% at September 30, 2004); repaid 2005; secured by Company's accounts receivable; personal guaranty of major stockholder	—	2,999,500
Convertible secured revolving note due to Laurus Master Fund, Ltd., interest at prime plus 2% (8.75% at September 30, 2005); matures April 2008; principal and accrued interest convertible at fixed conversion price of $6.95 per share (See Note 9)	3,767,221	—
Bridge note, interest at 4.25%, unsecured matures August 2007 or completion of a debt or equity financing resulting in more than $35.0 million in net proceeds (a)	4,180,000	
Other	—	23,087
	$ 7,947,221	$ 3,272,587
Less current maturities	3,767,221	3,272,587
	$ 4,180,000	$ 0

(a) The Company 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. This 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 an initial public offering by the Company (imputed interest was nominal). 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 to the Company.

On August 16, 2005, the Company 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. 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 but unpaid interest) will become due upon the earlier of August 16, 2007 or the completion by the 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). The Company 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 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.

8. Lines of credit (continued)

Under the August 2005 bridge loan agreement with Hopkins II, the Company has the unconditional right to borrow up to $5.0 million in the aggregate upon ten days' prior written notice to Hopkins II, provided that the Company's right to borrow any amounts in excess of $5.0 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, 2005, a total of $4.2 million had been borrowed under this bridge loan. 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.

Weighted average interest on all short-term borrowings aggregated 6.42% and 5.30% at September 30, 2005 and 2004, respectively. At September 30, 2005, the Company has an aggregate of $4.4 million available under its lines of credit.

9. Long-term debt

Long-term debt consists of the following:

	September 30, 2005	September 30, 2004
Related party:		
Convertible term loan due to McKesson, a holder of shares of preferred stock and major supplier, payable at 10% contract rate plus 5% default rate; due upon closing of IPO(a)(e)	$ 3,900,000	$ 3,900,000
Revolving line of credit, due to McKesson, interest payable monthly at 10% contract rate plus 5% default rate (e)	2,095,414	2,190,703
Interest on McKesson loans	—	1,306,189
Notes payable, former Biovest management, interest at 7%; due in June 2006; working capital loans due in fiscal 2006; bridge financing due in fiscal year 2006; and other notes due in installments through 2006(c)	4,439,328	4,538,000
Long-term accrued interest (c)	641,917	427,017
	11,076,659	12,361,909
Less current maturities	(7,414,742)	(12,361,909)
	$ 3,661,917	$ —
Other:		
Convertible term note due to Laurus Master Fund, LTD., interest payable monthly at prime rate plus 4%; due April 2008(f)	$ 8,193,238	$ —
Note payable, Harbinger Mezzanine Partners, LP, (a holder of shares of our preferred stock), net of discount; secured by receivables, equipment, inventories and intangible assets of TEAMM; interest payable monthly at 13.5%; $7.0 million principal balance matures June 2006. The loan agreement contains covenants including fixed charge coverage and minimum EBITDA; compliance with the covenants has been waived until December 31, 2005(b)(g)	6,589,854	4,169,945
Legal settlement obligation. Repaid in 2005	—	146,985
Notes payable, Biovest bridge financing, due in 2006	100,000	100,000
Notes payable, Biovest 2000 bridge financing, interest at 10%, due in 2006(d)	175,469	300,000
Note payable, bank. Repaid in 2005.	—	253,947
Other	119,050	138,150
Long term accrued interest(c)	311,013	198,810
	15,488,624	5,307,837
Less current maturities	(9,998,372)	(26,893)
	$ 5,490,252	$ 5,280,944

Footnotes to long-term debt

(a) The terms of this note, among other things, restrict additional borrowings by the Company and require the Company to maintain certain minimum current ratios and funded debt to earnings before interest, taxes, depreciation and amortization ("EBITDA") and funded debt to capital levels, as defined.

9. Long-term debt (continued)

(b) 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.

(c) No payment of interest due until maturity (2006-2007). 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. $5.0 million was subsequently converted to equity.

(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) Subsequent to September 30, 2005, loan paid down to $0.8 million, which is due July 2006.

(f) Note is convertible into shares of common stock at $6.95 per share, exercisable through April 2008; however, conversion of the term loan is contingent upon completion of an effective Registration Statement. See Laurus Master Funds, Ltd section below per discussion of terms.

(g) On March 25, 2005 the loan agreement was amended to provide for a guarantee from the parent, Accentia Biopharmaceuticals, Inc. and a release of the first lien against the assets of TEAMM in order to provide a first lien to Missouri State Bank, the provider of our revolving credit facility in addition to certain other concessions. Concurrent with the March 2005 amendment, the Company also purchased the Stock Purchase Warrant from Harbinger for $2.0 million through an increase in the note balance from $5.0 to $7.0 million. Subsequent to September 30, 2005, the loan was paid down by $2.0 million.

Future maturities of long-term debt are as follows as of September 30, 2005:

Years ending September 30,	
2006	$ 9,998,372
2007	3,301,931
2008	2,188,321
	$ 15,488,624

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, 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 ($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.

9. Long-term debt (continued)

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.

In connection with the company's Laurus financing transactions, the Company applied the tenets of Emerging Issues Task Force Consensus No. EITF 98-5, Accounting for Convertible Securities with Beneficial Conversion Features or Contingently Adjustable Conversion Features. The Company also considered the guidance of Accounting Principles Board Opinion Number 14, Accounting for Convertible Debt and Debt Issued with Stock Purchase Warrants and EITF 00-27, Application of Issue No. 98-5 to Certain Convertible Instruments. It is Management's opinion that these standards apply to the accounting for these agreements.

The allocation of proceeds between the convertible debt and warrants was made based upon the relative fair value of the instruments. The Black-Scholes Model was used to determine the fair value of the warrants using the following assumptions:

Share price	$ 8.00
Exercise prices	$.001-$8.00
Expected lives	270-365 days
Interest rate	3.54%
Expected volatility	50%

The beneficial conversion feature was calculated using that effective conversion rate, following the initial allocation described above. The effective conversion rate is calculated by dividing the amount allocated to the debt by the number of common shares into which the debt is convertible. A beneficial conversion feature is present when the effective conversion rate is lower than the value of the underlying common stock.

Application of these accounting standards resulted in the following:

Total proceeds	$15,000,000
Discount associated with warrants, amortized using the effective interest method over the life of the debt	$ 1,268,069
Beneficial conversion feature associated with line of credit, amortized using the effective interest method over the life of the debt	$ 1,267,820
Penny warrants, amortized using the effective interest method over the life of the debt	$ 1,398,350
Beneficial conversion feature associated with Contingently Convertible Term Loan, to be recorded upon completion of initial public offering/registration statement effectiveness	$ 2,664,802

10. 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, 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 at September 30, 2004 consists of amounts due from McKesson, a holder of preferred stock. These amounts are due in accordance with customary trade terms in the Specialty Pharmaceuticals segment.

10. Related party transactions (continued)

Net sales, services

Net sales from services reflect $0.1 million in revenues earned in our Biopharmaceutical Products and Services segment for consulting work performed for PPD.

Due to employees

Due to employees as of September 30, 2005 and 2004 consists of an amount due to current employees (prior owners) of IMOR pursuant to the purchase agreement.

Notes payable, stockholders

Notes payable, stockholders at September 30, 2004 are unsecured 6% convertible notes in an aggregate amount of $3.0 million. Discounts on these notes aggregated $0.06 million at September 30, 2004. These discounts result from the issuance of 760,023 warrants to purchase Series A preferred stock associated with the extensions of maturity dates and are accreted over the life of the debt. At September 30, 2004, $0.8 million was currently due and the balance was due December 2005. In 2005, $2.8 million of this debt was converted to equity, resulting in a loss of $2.4 million on extinguishment of debt at September 30, 2005.

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, 2005 and September 30, 2004.

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

10. Related party transactions (continued)

products that do not require FDA approval and 14% of licensed products, which is expected to occur within 18 months to two years. 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 preferred 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, 2005 and 2004. 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 2005 and 2004 consolidated statement of operations for the year ended September 30, 2004. 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), $0.2 million and $1.0 million of which is accrued and included in "product development obligations" in the accompanying 2005 and 2004 consolidated balance sheet 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 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, 2005 and 2004, 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

10. Related party transactions (continued)

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 2005 and 2004.

Other related party transactions

See Note 8 and 9 for other related party debt.

The Company has entered into certain transactions with entities and individuals who own stock in the Company. The following is a summary of the other significant related party transactions not discussed elsewhere for the years ended September 30, 2005, 2004 and 2003.

	September 30,		
	2005	2004	2003
Clinical trials costs—vaccine [a]	$ 1,309,052	$ 1,309,100	$ —
Drug purchases [b]	—	15,710,723	18,854,081
Business travel—aircraft expense [c]	331,052	173,000	44,000
Related party accrued interest [d]	147,983	376,481	210,396
Security interest in note payable [e]	—	250,000	—
Fair value of warrants issued for loan guarantee [f]	—	62,040	—

See footnotes on following page.

(a) On September 30, 2004 we entered into a Master Services Agreement and Project Addendum agreement with PPD Development LP (hereinafter "PPD"). PPD, a Contract Research Organization and principal stockholder of Accentia, will perform a side range of services in the conduct and data management of the ongoing Phase III clinical trial of BiovaxID, Biovest's personalized therapeutic vaccine for indolent follicular non-Hodgkin's lymphoma. This pivotal Phase III clinical trial has been ongoing since 2000. The services to be performed by PPD include identification, recruitment and qualification of additional clinical trail sites to accelerate the pace of the patient enrollment into the trial, facilitation of patient enrollment, coordination of data and information management services, and regulatory compliance function, among others. The agreement with PPD may be terminated by Biovest at any time upon 30 days notice. Expenses in this regard approximated $1.5 million and $1.1 million for the years ended September 30, 2005 and 2004 respectively.

(b) McKesson is a major supplier and preferred stockholder of the Company. Purchases were made during 2003 and 2004 as indicated in the table above.

(c) The Company pays travel costs for its executives for usage of an airplane partially-owned by the Company's Chief Executive Officer. Cost incurred and paid includes direct out-of-pocket costs, including per diem pilot costs and fuel. Total costs incurred in the fiscal years ended September 30, 2005, 2004 and 2003 were $.03 million, $0.2 million and $0.04 million, respectively.

(d) These amounts represent accrued interest on shareholder notes and one month's interest due to Harbinger at each of the periods presented in this table, and are included in accrued expenses in the accompanying balance sheets.

(e) This amount represents the face value of the certificate of deposit pledged by a stockholder on the $0.3 million promissory note discussed in Note 8. During the twelve months ended September 30, 2005, this promissory note was paid in full.

(f) The Company issued warrants to purchase 285,009 shares of common stock at $2.11 per share in consideration of a guarantee and pledge of securities by a principal stockholder during the fiscal year ended September 30, 2004.

11. Income taxes

The Company's deferred tax assets and liabilities consist of the following:

	September 30, 2005	September 30, 2004
Deferred tax assets:		
Accrued expenses deductible in future	$ 2,991,000	$ 3,799,000
Allowance for doubtful accounts	45,000	58,000
Basis difference in assets	359,000	117,000
Inventory valuation allowance	318,000	117,000
Stock based compensation	755,000	590,000
Intangibles	1,628,000	1,628,000
Net operating loss carryforward	31,849,000	18,033,000
Valuation allowance	(35,668,000)	(21,500,000)
	2,277,000	2,842,000
Deferred tax liabilities:		
Intangibles	(2,277,000)	(2,842,000)
	$ —	$ —

Income tax (expense) benefit consists of the following:

	Year ended September 30, 2005	2004	2003
Current	$ —	$ —	$ 180,000
Deferred	352,000	218,000	(3,627,000)
Benefit of net operating loss carryover	(13,816,000)	(8,253,000)	(6,325,000)
Increase in valuation allowance	14,168,000	8,035,000	9,952,000
	$ —	$ —	$ 180,000
Allocation between continuing and discontinued operations:			
Continuing operations	$ —	$ —	$ 180,000
Discontinued operations	—	—	—
	$ —	$ —	$ 180,000

The expected income tax benefit at the statutory tax rate differed from income taxes in the accompanying statements of operations as follows:

	2005	2004	2003
Statutory tax rate	34%	34%	34%
State taxes	4%	4%	4%
Acquisition adjustments	—	—	(136)
Other	(2%)	—	—
Change in valuation allowance	(36)	(38)	98
Effective tax rate in accompanying statement of operations	0%	0%	0%

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.

11. Income taxes (continued)

The Company has a federal net operating loss carryover of approximately $83.9 million as of September 30, 2005, which expires through 2025, and of which $30.0 million is subject to various Section 382 limitations. 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.

Further, during the year ended September 30, 2003, Biovest, the Company's 81%-owned subsidiary, waived approximately $29.0 million in net operating loss carryforwards. These losses were waived effective with the acquisition of Biovest by the Company on July 1, 2003. The deferred tax asset and associated valuation allowance of $11.0 million were reduced accordingly.

12. Stockholders' equity

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
Total shares issued during the year ended September 30, 2005	15,055,600

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 expire upon closing of the initial public offering. The Company has recorded a constructive dividend of $4.9 million attributable to the fair value of warrants issued in connection therewith. As noted below, the fair value of the Series E preferred stock at September 30, 2004 was determined to be $3.87 per share based on a valuation performed. The constructive dividend was ascertained through a relative fair value determination.

12. Stockholders' equity (continued)

The holders of the outstanding shares of Series E preferred stock as a class shall have the right to a cumulative quarterly dividend of an amount equal to the greater of: a) 5% of TEAMM net revenue resulting from all current or future products owned, controlled or in which any commercialization rights are held or, b) 5% of Biovest net revenue from the sale in the United States market of all current and future products owned, controlled or in which any commercialization rights are held. At September 30, 2005, preferred dividends declared but unpaid aggregated $0.6 million.

Other

In addition, the Company amended its Articles of Incorporation to provide for additional shares of Series E preferred stock and to provide that any shares issuable to Laurus in connection with the Laurus transaction will not increase the amount of shares into which the Company's Series E preferred stock is convertible under the antidilution protections afforded the Series E preferred stock under the Company's Articles of Incorporation

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 uses the income and market approaches to estimate the value of the enterprise at each date on which securities are 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 are 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 are 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.

As disclosed more fully below, the Company granted stock options with exercise prices of $1.05 to $7.62 during the 12 months ended September 30, 2004. The fair value of the various classes of stock for the various dates based on the valuations are as follows:

Date	Common	Series A	Series B	Series C	Series D	Series E
April 2002	$ 0	$ 0	$ 0.02	$ 1.68	N/A	N/A
Sept. 2002	$ 0	$ 0	$ 0.02	$ 1.68	N/A	N/A
April 2003	$ 0	$ 0.02	$ 0.02	$ 1.89	$ 0	N/A
Sept. 2003	$ 2.13	$ 2.11	$ 2.36	$ 2.11	$ 2.11	N/A
Sept. 2004	$ 1.77	$ 2.11	$ 2.53	$ 2.11	$ 2.11	$ 3.87
December 2004	$ 3.73	$ 2.11	$ 2.59	$ 2.11	$ 2.11	$ 5.83

The values noted above were based on retrospective valuations performed. The Company did not obtain contemporaneous valuations by an unrelated valuation specialist at the time of the issuances of stock options as management's efforts were focused on research and development activities for the non-Hodgkin's lymphoma vaccine in the Biopharmaceutical segment as well as new product development and product launches in the Specialty Pharmaceuticals segment.

In addition, due to the magnitude of the 2003 acquisitions, management's focus was integration of the new businesses into the Company's then existing business activities, including establishing operating policies, procedures and internal controls. Further, financial resources were limited due to the significant operating and cash flow deficits associated with these acquired businesses.

12. Stockholders' equity (continued)

As noted in an analysis that follows, during the year ended September 30, 2004, the Company granted options and warrants with grant date fair values ranging from $0.13 to $1.68. During the year ended September 30, 2005, the Company granted options and warrants with grant date fair values ranging from $1.05 to $1.64. These grant date fair values were determined from either the valuations (Series E preferred stock warrants issued with Series E preferred stock purchases) or calculations using the Black-Scholes pricing model with share price assumptions based on the valuations.

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.

The most significant changes in values from 2003 to 2004 relate to the issuance of the new Series E preferred stock which has significant antidilution provisions and other preferences. While the overall enterprise value of the Company increased, the creation of this class of stock and issuance of these shares resulted in a decline in common value at September 30, 2004. The increase in the value of common stock at September 30, 2005 resulted from an overall increase in the Company's enterprise value.

Based on the Company's current business plan and subsequent equity activities, further fluctuations in fair values of the various classes of stock can be anticipated. In addition, although it is reasonable to expect that the completion of the Company's proposed initial public offering will add value to the shares because they will have increased liquidity and marketability, the amount of additional value can be measured with neither precision nor certainty.

Stock options and warrants

Stock options and warrants issued, redeemed and outstanding during the year ended September 30, 2005, 2004 and 2003 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 issued and outstanding October 1, 2002	9,500	—	—	—	—	—	1.05
Warrants issued	95,003	—	—	—	1,218,728	—	0.17
Options issued	689,401	—	—	712,521	—	—	1.14
Options issued as part of TEAMM acquisition	—	—	—	—	355,629	—	1.05
Options terminated/forfeited	(712)	—	—	—	(13,714)	—	1.05
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	
Options and warrants outstanding September 30, 2004	1,933,158	760,023	950,029	712,521	1,816,610	11,067,832	1.89

12. Stockholders' equity (continued)

	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	
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

As noted above, securities were issued on dates other than the dates on which retrospective valuations were performed. With regard to option and warrant issuances in the quarter ended December 31, 2003, management believes that the value determined for the underlying securities at September 30, 2003 approximates the December 2003 value. With regard to option and warrant issuances in the three quarters ended September 30, 2004, management believes that the value determined for the underlying securities at September 30, 2004 approximates the values at those interim dates. With regard to option and warrant issuances during the year ended September 30, 2005, management believes that the incremental change of the underlying stock from the September 30, 2004 valuation is allocable on a pro rata basis.

The weighted average grant date fair values of stock options and warrants granted during the years ended September 30, 2005, 2004, and 2003 were as follows:

	Weighted Average Grant Date Fair Value	
	Options	Warrants
Year ended September 30, 2005	$ 1.05	$ 2.69
Year ended September 30, 2004	$ 0.13	$ 1.68
Year ended September 30, 2003	$ 0.44	$ 1.47

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	

12. Stockholders' equity (continued)

The following table summarizes information for options and warrants outstanding and exercisable at September 30, 2004:

Options and Warrants Outstanding				Exercisable	
Range of Exercise Prices	Number	Weighted average remaining life	Weighted average exercise price	Number	Weighted average exercise price
$ 0.02-1.05	3,105,352	7.62 years	$ 0.57	2,876,534	$ 0.53
$ 1.06-2.11	12,845,730	2.77 years	2.11	12,253,063	2.11
$ 2.12-2.63	1,151,337	9.24 years	2.63	19,417	2.63
$ 2.64-7.62	137,754	9.73 years	6.93	116,378	7.62
	17,240,173	4.13 years	$ 1.89	15,265,392	$ 1.85

Stock-based compensation is included in the following line items in the accompanying financial statements:

	September 30, 2005	2004	2003
Statement of operations:			
Stock-based compensation	$ 434,583	$ 683,236	$ —
Settlement expense	—	—	781,650
Gain on sale of discontinued operations	—	2,581,600	—
Interest expense	1,771,321	—	20,054
Balance sheet:			
Product rights	200,000	18,179	—
Discount on notes payable (balance to be amortized into interest expense)	3,183,404	830,054	461,244

13. 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 $0.04 million, $0.09 million, and $0.05 million, to the plan for the years ended September 30, 2005, 2004, 2003, respectively. Participants are always 100% vested in their contributions and earnings. Employer contributions are fully vested after three years of service.

On February 1, 2005, the Company's board of directors terminated the Company's 2003 Stock Option Plan and adopted the Accentia Biopharmaceuticals, Inc. 2005 Equity Incentive Plan, under which an additional 3,000,000 shares of common stock are reserved for issuance.

14. 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 $1.6 million and $0.3 million for the years ended September 30, 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. There were no inter-segment sales in the year ended September 30, 2003.

14. Segment information (continued)

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	22,493,935	13,048,669	35,542,604
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

14. Segment information (continued)

Segment information for the year ended September 30, 2003 is as follows:

	Biopharmaceutical Products and Services	Specialty Pharmaceuticals	Total
Net sales:			
Products	$ 1,302,088	$ 3,908,655	$ 5,210,743
Services	4,697,048	—	4,697,048
Total net sales	5,999,136	3,908,655	9,907,791
Cost of sales:			
Products	739,660	592,818	1,332,478
Services	1,603,533	—	1,603,533
Total cost of sales	2,343,193	592,818	2,936,011
Gross margin	3,655,943	3,315,837	6,971,780
Sales and marketing	236,306	4,129,922	4,336,228
Research and development	6,111,952	—	6,111,952
Total assets	12,699,714	10,687,049	23,386,763
Goodwill	893,000	—	893,000

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 16% 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, 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

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)	(39,834,970)	458,746	(39,376,224)
Total Assets	33,039,912	2,502,692	35,542,604
Goodwill	893,000	300,437	1,193,437

15. Impairment charges

In 2004, the Company recorded an impairment of goodwill of $0.4 million related to the acquisition of IMOR. The Company identified an error in the recording of the net assets acquired from IMOR subsequent to the date of acquisition and was unable to obtain a purchase price adjustment.

In 2005, the Company recorded an impairment of acquired product rights of $0.4 million related to the termination of the SRL agreement

16. 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. The agreements also provide for the payment of royalties based on sales of products and in certain cases, minimum royalties.

Parties to these agreements are as follows:

- Mayo Foundation for Medical Education and Research ("Mayo")
- SRL Technologies, Inc. ("SRL")
- Arius Pharmaceuticals, Inc. ("Arius")
- Argent Development Group, LLC ("Argent")
- Ryan Pharmaceuticals, Inc. ("Ryan")
- Andrx Laboratories, Inc. ("Andrx")
- Respirics, Inc. ("Respirics")
- Acheron Development Group, LLC ("Acheron")
- Mikart, Inc. ("Mikart")

In connection with these agreements, the Company has recorded an aggregate obligation of $0.5 million as of September 30, 2005.

Future minimum payments under these agreements (recorded obligations and commitments for future minimum annual royalties, but exclusive of those dependent upon the third party milestones) are as follows:

Year ending September 30,	
2006	$ 1,399,996
2007	399,996
2008	399,996
2009	99,999
	$ 2,299,987

b) Stanford

In September 2004, the Company entered into an agreement with Stanford University 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.

16. Product rights and obligations (continued)

c) Product manufacturing and supply agreements

In connection with the Ryan Agreement and Acheron Agreement, the Company has entered into Manufacturing and Supply Agreements with Mikart ("Mikart Agreements") providing for Mikart to be the exclusive manufacturer and supplier of Xodol and an additional pain product. The Mikart Agreements are for five years each commencing on the day that Mikart is authorized to begin manufacturing Xodol and after FDA approval of the pain product, with automatic one year renewal terms. The Mikart Agreements may be cancelled by either party after the initial five year term by six months notice of intent to do so. The Mikart Agreements call for minimum purchase requirements of Xodol and the pain product by the Company.

As of September 30, 2005, the Company has a minimum purchase commitment for Xodol effective as of June 2004, the date of FDA approval. The Company does not yet have a minimum purchase requirement for the other pain products since the product has not been approved by the FDA.

Under the Ryan Agreement, which the Company entered into in May 2003 and amended in October 2004, Ryan granted the Company exclusive U.S. distribution rights to Xodol. The agreement provides for a running royalty to Ryan based on the Company's net sales of Xodol, subject to annual minimum royalties. Ryan was also granted a warrant to purchase 59,377 shares of the Company's common stock at an exercise price of $5.33 per share. The term of this agreement is perpetual, provided that either party can terminate it if the other party becomes insolvent, enters bankruptcy or receivership, or materially breaches the agreement and fails to cure the breach within 30 days of notice of breach.

d) Product development agreement

On January 24, 2003, TEAMM entered into a Product Development Agreement ("Respirics Development Agreement") with Respirics, Inc. ("Respirics") for TEAMM to fund further development of the MD Turbo ™ inhale drug device ("MD Turbo") in order to enable its approval by the U.S. Food and Drug Administration ("FDA"). In exchange for this funding, Respirics entered into an exclusive distribution arrangement ("Respirics Distribution Agreement") with TEAMM for sales of MD Turbo in the United States, which shall only become effective and binding upon Respiric's successful completion of the 5 phase development program.

e) Formulation agreement

On January 20, 2005, the Company executed an agreement with Emerson Pharma Services, Inc. for $0.3 million to develop formulation, and to provide data to determine physical and chemical stability of a drug delivery system, and to produce a prototype and final formulation for stability studies.

g) Master service agreement

On February 21, 2005, the Company executed a Master Services Agreement with Fulcrum Pharma Developments, Inc. to manage activities related to the chemistry, manufacturing and controls involved in the development of certain products. The agreement was amended on February 28, 2005 to include services related to an IND application. The aggregate total of fees under the agreements, to be paid in monthly amounts through February 28, 2006 is approximately $0.1 million, plus certain pass-through costs.

17. Commitments and contingencies

a) Operating leases

The Company has operating leases for various facilities, automobiles, machinery, and equipment, which expire at various times through 2009. The annual aggregate rental commitments under non-cancelable leases are as follows:

Year ending September 30,	
2006	$ 3,723,344
2007	2,140,177
2008	1,488,941
2009	1,393,910
2010	607,905
	$ 9,354,277

The annual aggregate future rental income from sub-leases is as follows:

Year ending September 30,	
2006	$69,466

Rent expense for all operating leases was approximately $2.5 million, $1.9 million, and $1.2 million for the years ended September 30, 2005, 2004, and 2003 respectively. Rental income from subleases aggregated $0.4 million in each of the years ended September 30, 2005, 2004 and 2003, 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 III 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 III clinical trials through commercialization will commit Biovest to several years of significant expenditures before revenues will be realized, if ever. The agreement expires in September 2009, but may be unilaterally terminated by either party by giving thirty days written notice.

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.

17. Commitments and contingencies (continued)

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

In 2003, the Company entered into a settlement agreement with two former officers whereby the Company was obligated to pay an aggregate of $0.8 million. In addition, the Company issued 712,521 options to acquire Accentia Series C preferred stock (valued at $0.8 million pursuant to the Black-Scholes formula) for total settlement costs of $1.6 million, all of which have been satisfied at September 30, 2005. There is a pending matter relating to the interpretation of certain terms of the settlement with regard to expiration of the options granted at the date on which a registration statement is filed for an initial public offering and expiration on that date of a put option for two hundred thousand shares, which currently is not effective until September 2006. The Company believes the terms of the settlement are not ambiguous and that the options and put requirement expire upon filing of a registration statement. The Company is vigorously defending this action.

In 2004, the landlord of APP filed an action, which alleged a fraudulent transfer in connection with Accentia's acquisition of this now discontinued operation, AccentRx. The plaintiff is seeking to annul the dissolution of APP, compel specific performance of the lease and to provide for an escrow of sufficient funds to provide for satisfaction of underlying lease liability. The Company is vigorously disputing this claim and continues to make monthly lease payments as they come due and will seek to enter into a replacement sublease upon expiration of the existing sublease. The Company has received a settlement offer of $0.9 million payable upon expiration of the sublease. The net present value of all expected future lease payments has been accrued pursuant to the exit and discontinuance of the AccentRx activities.

In addition, in January 2005, a former employee of Biovest filed a claim alleging past compensation due and non-payment of one hundred twenty thousand options as well as on an obligation to re-purchase 168,836 shares of Biovest stock at $2.00 per share based on an alleged third-party beneficial arrangement under the Accentia/Biovest Investment agreement. The Company, through its Biovest subsidiary, intends to defend this claim and has recorded all obligations that it considers to be due at September 30, 2005.

In October 2002, the Company's subsidiary, Accent RX, Inc., acquired the assets and certain liabilities of American Prescription Providers, Inc. and American Prescription Providers of New York, Inc., collectively referred to as APP, which at the time of purchase operated a mail-order specialty pharmacy focused on filling prescriptions for AIDS patients and organ transplants. Following the purchase of APP's assets, Accent RX operated the mail-order business until it sold the assets of this business in December 2003 to a third-party in an arm's length transaction. After the sale of the APP assets, Accent RX ceased to engage in business. APP learned in 2002 that the U.S. Department of Justice was conducting an industry-wide investigation under anti-kickback laws and other laws and regulations relating to purchases and sales of Serostim, an AIDS-wasting drug manufactured by Serono, Inc., from 1997 through 2000. As part of this investigation, in May 2002, APP received a subpoena from the U.S. Attorney's Office for the District of Massachusetts, and in March 2004, it received a federal grand jury subpoena seeking records related to Serostim prescriptions dispensed by APP, reimbursement claims submitted to Medicaid for Serostim, and APP's relationships with Serono. The Company is not aware of any investigation into the acts of Accent RX or the Company with regard to the conduct of the mail-order pharmacy business following Accent RX's purchase of APP's assets.

In May 2005, the U.S. Attorney's Office notified APP that it believes that APP has significant potential liability as a result of allegedly unlawful rebates and discounts paid to them by Serono between 1997 and 2000. In August 2005, the U.S. Attorney's Office orally and informally indicated to our legal counsel that, as a result of these allegedly unlawful rebates and discounts, it was considering instituting a civil action against Accent RX, our company, APP (which has since dissolved and been liquidated),

17. Commitments and contingencies (continued)

and shareholders of APP who received APP assets as a part of the liquidation of APP. However, it is not possible to predict the outcome of this investigation and whether the government will formally commence any action challenging any of APP's prior programs and practices or APP's liability or exposure as a result thereof. In the event of litigation, the Company believes that APP will have defenses that will be vigorously asserted. However, the Company cannot predict whether Accent RX could be held liable for the prior acts of APP as a result of Accent RX's purchase of APP's assets or whether the government will commence any actions against Accent RX. The Company believes that, because the Company has always been operated as a distinct legal entity from Accent RX, it is unlikely that the Company will have material financial exposure in the event that Accent RX or APP incurs a material penalty in connection with this matter. Similarly, the Company does not believe that any adverse legal or regulatory determinations regarding APP or Accent RX or any persons associated with APP or Accent RX would have any material effect on the ability of the Company and its subsidiaries to conduct their current or expected business operations.

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,	
2006	$ 2,345,000
2007	2,150,000
2008	2,289,000
2009	2,130,000
2010	224,000
	$ 9,138,000

g) Biovest Investment Agreement

The Company's Investment Agreement with Biovest requires that Biovest file all necessary documents and take all necessary actions to permit its outstanding shares that are not subject to restriction on sale or transfer under the applicable securities laws to trade publicly. The Company believes this agreement gives Biovest broad discretion in determining how to satisfy this requirement. The agreement does not place any obligation or responsibility on us with regard to this requirement. Biovest believes that it has filed all required documents and reports with the Securities and Exchange Commission and that most of its outstanding stock, other than the Biovest shares held by us, can be freely traded without further action by Biovest. Should it be determined that Biovest should have filed additional documents or taken additional action to permit such trading in its outstanding stock, Biovest would be required under the Investment Agreement to make an offer to purchase shares of its outstanding stock as follows: 980,000 shares of Biovest common stock on the first anniversary of the investment, 1,960,000 shares at the second anniversary of the investment, 2,940,000 shares at the third anniversary of the investment, and 3,920,000 shares at the fourth anniversary of the investment, with each such repurchase being at a price of $2.00 per share. We do not believe that we are under any obligation to fund or otherwise participate in any tender offer required of Biovest.

19. Quarterly financial data

	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 income (loss)	(11,032,146)	(7,649,767)	(10,378,776)	(10,315,535)
Net loss per share available to common stockholders	($3.12)	($1.53)	($2.04)	($2.04)

SCHEDULE OF VALUATION AND QUALIFYING ACCOUNTS

Selected balance sheet accounts include the following:

	Balance, Beginning of Period	Additions Charged to Expense	Deductions	Balance, End of Period
Allowance for doubtful accounts:				
2005	$ 150,000	$ 227,187	$ 31,729	$ 345,458
2004	450,000	279,497	579,497	150,000
2003	1,184,356	52,687	787,043	450,000
Amortization of intangibles:				
2005	$ 3,324,275	$ 2,448,916	$ 142,069	$ 5,631,122
2004	1,354,496	1,969,779	—	3,324,275
2003	280,250	1,074,246	—	1,354,496
Accumulated depreciation:				
2005	$ 1,551,370	$ 705,959	$ 125,894	$ 2,131,435
2004	1,171,065	593,256	212,951	1,551,370
2003	1,262,236	310,800	401,971	1,171,065
Allowance for obsolescence:				
2005	$ 300,000	$ —	$ —	$ 300,000
2004	300,000	—	—	300,000
2003	—	300,000	—	300,000

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, 2005

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 of the Board; Director (Principal Executive Officer)	December 29, 2005
By: /s/ Alan M. Pearce Alan M. Pearce	Chief Financial Officer; Director (Principal Financial Officer and Principal Accounting Officer)	December 29, 2005
By: /s/ Steven R. Arikian, M.D. Steven R. Arikian, M.D.	Director; President and Chief Operating Officer, Biopharmaceutical Products and Services	December 29, 2005
By: /s/ Martin G. Baum Martin G. Baum	Director; President and Chief Operating Officer, Specialty Pharmaceuticals	December 29, 2005
By: /s/ Dennis L. Ryll Dennis L. Ryll	Director	December 29, 2005
By: /s/ David M. Schubert David M. Schubert	Director	December 29, 2005
By: /s/ John P. Dubinsky John P. Dubinsky	Director	December 29, 2005
By: /s/ Steven J. Stogel Steven J. Stogel	Director	December 29, 2005

Registrar and Transfer Agent

American Stock Transfer & Trust Company
59 Maiden Lane
New York, New York 10038
(800) 937-5449

Stock Trading Symbol

Accentia's shares trade on the The Nasdaq Stock Market® under the symbol "ABPI"

Annual Meeting

Accentia's 2006 Annual Meeting of Shareholders will be held on April 6, 2006, at 10:00 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

Corporate Headquarters

324 South Hyde Park Ave., Suite 350
Tampa, Florida 33606
(813) 864-2554
www.accentia.net

Investor Relations Firm

The Investor Relations Group
11 Stone St., 3rd Floor
New York, New York 10004
(212) 825-3210

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 with the Securities and Exchange Commission. All forward looking statements are qualified in their entirety by this cautionary statement, and Accentia undertakes no obligation to revise or update this Annual Report to reflect events or circumstances after the date hereof.

Corporate Headquarters

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