Suffice it to say, BiovaxID is expected to be a significant driver of growth, and a catalyst for partnering and licensing opportunities for Accentia and Biovest, as we progress this product to market – a major breakthrough opportunity to save and prolong the lives of those suffering from this insidious kind of cancer.

Revimmune™

I was especially excited when we announced in 2007 that Accentia had acquired the worldwide exclusive license to Revimmune for autoimmune diseases, a technology developed at the Johns Hopkins University School of Medicine, believed to offer unprecedented benefits for the treatment of up to 80 autoimmune diseases, including multiple sclerosis (MS).

Justifying my enthusiasm, in a pre-Investigational New Drug meeting (IND), the FDA indicated its support for Accentia to submit an IND for a pivotal Phase 3 randomized, controlled, multi-center clinical trial of Revimmune, evaluating the treatment of MS.

I need to stress how important this planned trial is because it differs dramatically from the protocol of any previously conducted MS trial. All of the products currently on the market for MS were approved based on their ability to slow the progression of disability, not improve the patient's functional status. In contrast, we aim to show that Revimmune is capable of reversing the disease's effects and reducing disability.

As you can imagine, this kind of accomplishment would catapult Accentia to become a worldwide leader in the treatment of autoimmune disease, forever changing the way in which these diseases are treated – with an aim to actually improve the patient's condition and eliminate the autoimmunity.

Pending Milestones for Revimmune in 2008:

- File IND application with FDA in March / April 2008
- Commence enrollment for Phase 3 clinical trial by mid-calendar year 2008
- Cultivate relationships with potential strategic, multi-national, marketing partners

We anticipate that the Revimmune Phase 3 clinical trial protocol will include a comprehensive and proprietary risk management program to enhance patient safety by ensuring appropriate patient selection and by including specially designed supportive care, with these key aspects also enhancing the product's patent protections.

Revimmune therapy consists of an ultra-high intensity, short-course, intravenous formulation of an already approved pharmaceutical, cyclophosphamide. In previous studies, Revimmune has been shown to "reboot" a patient's immune system, thereby typically eliminating the autoimmunity. The "rebooting" process is achieved because Revimmune eliminates the cells causing the autoimmunity and spares the stem cells in the bone marrow. These surviving stem cells are then able to repopulate a restored, uncompromised immune system.

Simply said, there is no approved drug product that eliminates autoimmunity, and Revimmune would be the world's first therapy to propose the restoration of neurologic function as the primary endpoint and offer the potential for the elimination of autoimmunity.

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

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

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

Sales and Marketing

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

REVIMMUNE

Our third product candidate, Revimmune™, is being developed as a treatment for multiple sclerosis (MS). MS is an autoimmune disease that affects the central nervous system (CNS). Revimmune therapy consists of four consecutive days of in-patient or out-patient treatment with an ultra-high intensity, short-course of an intravenous formulation of cyclophosphamide, which is an approved drug for other indications. This treatment seeks to "reboot" a patient's immune system, thereby eliminating the autoimmunity which is characteristic of MS. The "rebooting" process is achieved by temporarily eliminating peripheral immune cells, including the immune cells causing the autoimmunity, while selectively sparing the stem cells in the bone marrow. The surviving stem cells are able, typically within two-three weeks, to repopulate the body with a nascent immune system which lacks misdirected immunity to self-antigens. In July 2007 the Company filed a pre-IND submission with the FDA for the commencement of a Phase 3 clinical trial and in September 2007 conducted a pre-IND meeting. We are preparing to file our IND with the FDA in the first half of calendar 2008. The Company believes that Revimmune may additionally have applications for the treatment of a variety of autoimmune diseases other than MS, including Systemic Lupus Erthematosus, Myasthenia Gravis, Aplastic Anemia and Autoimmune Hemolytic Anemia.

Multiple Sclerosis

MS is an autoimmune disease characterized by recurrent episodes of demyelination and inflammation within the central nervous system as described above. Myelin, a fatty tissue, surrounds and protects the nerve fibers of the CNS and helps those nerve fibers to conduct electrical impulses. In MS that myelin sheath is lost in different areas and results in scar tissue which is known as sclerosis. Since the myelin or the nerve fibers are damaged the nerves itself cannot conduct electrical impulses from and to the brain which results in the symptoms of MS. As a result, MS is characterized by recurrent episodes of demyelination and inflammation within the central nervous system. Although the exact cause of MS is still unknown, most researchers and clinicians believe that the myelin is damaged due to an abnormal response by the body's immune system. The immune system typically defends the body against foreign substances such as bacteria and viruses. However, in MS, the immune system fights and attacks its own tissue, specifically the myelin. There are multiple distinct clinical forms of MS, the most common of which is characterized by relapses followed by remissions (RRMS). 85% of MS patients have RRMS at disease onset, though 50% of those will ultimately convert to secondary progressive MS (SPMS).* Patients with RRMS, which is the indication Accentia intends to study, experience flare-ups (also termed as relapses or attacks) and episodes of acute worsening and exacerbations of clinical neurological symptoms. They are then typically followed by a period of recovery or remission. Several features predict the ultimate conversion to SPMS, including frequent clinical attacks, accrual of disability, and the presence of gadolinium enhancing lesions which are revealed on MRI.

Competition

Five drugs are currently approved for the treatment of RRMS: interferon ß-1b (Betaseron), interferon ß-1a (Avonex and Rebif) glatiramer acetate (Copaxone) and mitoxantrone (Novantrone). There are a number of drugs approved to treat MS, including Tysabri (natalizumab), which is the most recently approved drug for MS. We are aware of no therapy in existence for MS that has been shown to reduce disability. To our knowledge, and competitive drugs have only shown the ability to slow the progression of disability, rather than enhance or reverse the disease's effects.

* See generally "Neurology" (House Officer Series); Howard L. Weiner, Lawrence P. Levitt and Alexander D. Rae-Grant (Seventh Edition 2004)

Clinical Studies with Ultra-high Intensity Intravenous Cyclophosphamide

Phase I study at SUNY Stonybrook

Recently published data from a clinical trial in SUNY Stonybrook sought to describe the effects of high dose cyclophosphamide on severe refractory multiple sclerosis. In this study 13 patients, 54% secondary progressive MS and 46% relapsing remitting MS, were treated with high dose cyclophosphamide with mean follow-up of 15 months. Five patients showed a decrease in disability by 1.0 or more on the EDSS (an MS severity scale) with no patient showing an increase in disability by more that 1.0 on the EDSS. Following high dose cyclophosphamide treatment 2 patients had resolution of a single gadolinium-enhancing lesion, which was present on MRI at baseline. One patient showed a new enhancing lesion at baseline. Response to treatment was seen regardless of the presence or absence of gadolinium enhancing lesions at baseline. All patients reported an improvement in quality-of-life measures as well as neurologic function: gait, bladder control and visual function.

Phase I safety and tolerability study at Johns Hopkins University

Under the Revimmune for Aggressive MS clinical trial protocol at Johns Hopkins Hospital, 9 patients have been treated and followed for a mean period of 19.4 months. All 9 patients had aggressive relapsing-remitting MS, 8 of whom had failed conventional therapy and 1 was untreated. Median age at time of entry was 29 years, range of 20 to 47 years. The mean number of gadolinium enhancing lesions on baseline MRI was 6.5 (range 3-11). There was a 90% reduction in gadolinium enhancements at 6 months and subsequently a 94% reduction by 18 months following Revimmune treatment. Only one patient had an exacerbation during follow-up and was started on conventional MS therapy at 18 months. At baseline, 66% of patients had a disability score of 5.0 or more on the EDSS. This Johns Hopkins study observed a 45% reduction in disability with 4 patients having virtually no disability (EDSS score of 0-1) at an average follow-up of 20 months. This response rate in terms of reduction of disability is on a magnitude never before seen in any MS therapeutic trial.

In addition to the treatment of MS, high dose cyclophosphamide treatment has been studied in other autoimmune diseases, including the following:

Systemic Lupus:

Investigators have treated 40 severe systemic lupus erythematosus (SLE) patients in clinical studies with high dose cyclophosphamide. A significant improvement in the SLE diseases activity index was observed. There were 5 durable complete responses. Among severe, refractory cases, approximately 80% of patients treated had a complete or partial response when treated.

Myasthenia Gravis:

Using high dose cyclophosphamide, investigators have treated 11 patients with myasthenia gravis refractory to conventional immunosuppressive therapy. Nine of the subjects in the study markedly improved, and have returned to full activity.

Aplastic Anemia:

Acquired severe aplastic anemia (SAA) is a severe, life-threatening autoimmune disease wherein a patients' immune system mistakenly attacks their own stem cells in their bone marrow. Most SAA patients will die within a year of diagnosis. Investigators have treated 75 SAA patients with high dose cyclophosphamide and the majority of patients have achieved a complete remission without the need of other immunosuppressive agents.

Autoimmune Hemolytic Anemia:

Investigators have treated 10 patients with refractory autoimmune hemolytic anemia. After high dose cyclophosphamide treatment, all patients responded and became transfusion independent. There were 6 patients that achieved complete remission and 3 patients that achieved partial remission. There were no relapses at a median follow-up of 15 months and 7 of the 9 patients were able to discontinue steroids.

Development Status

The Company has filed a pre-IND submission with the FDA for the commencement of a Phase 3 clinical trial. In September 2007, we met with the FDA for a scheduled pre- IND meeting regarding the proposed design of the pivotal Phase 3 trial for Revimmune. We are preparing to file our IND with the FDA in the first half of calendar 2008. We anticipate that the trial will be a Phase 3 randomized controlled, multi-center clinical trial of Revimmune for the treatment of MS. We anticipate that the study will require approximately 200 patients to be enrolled in the clinical trial which will compare baseline disability to disability at month 12 with an option for an interim data analysis. Based on our discussion with the FDA on the design of the trial, we anticipate that the primary endpoint will be recovery of lost function based on the subjects changes in the EDSS score from baseline to 12 months. We further anticipate that our clinical trial will be conducted under a special protocol assessment (SPA). A SPA is a declaration from the Food and Drug Administration that a proposed Phase 3 trial's design, clinical endpoints, and statistical analyses are acceptable for FDA approval. We believe that the anticipated Revimmune trial design can be contrasted with the trial design for all prior approved therapeutics for MS; those previous trials primarily targeted suppression rather than elimination of autoimmunity, and used the more limited indication of a reduction in the rate of progression of disability (or loss of function) as their primary endpoint, while the trial design for Revimmune is planning to target a reduction in disability and subsequent recovery of lost function. Current immunomodulatory therapies for MS, including interferon ß, GA or mitoxantrone, do not abolish inflammation or disease progression, which we anticipate will be endpoints of a Revimmune trial. We anticipate that the Revimmune clinical trial protocol will include a risk management program to enhance patient safety by ensuring appropriate patient selection, supportive care, and tracking of outcomes data.