

## **Cato BioVentures Seeks Strategic Marketing Partner for FDA-Approved NutreStore™**

**DURHAM, NORTH CAROLINA, DECEMBER 6, 2005** — Cato BioVentures, the venture capital affiliate of Cato Research Ltd., a leading contract research organization, announced today its plan to seek a strategic marketing partner in the United States for NutreStore™ (L-glutamine powder for oral solution). NutreStore™ was approved by the U.S. Food and Drug Administration (FDA) in 2004 for use, in combination with Zorbtive™ (somatropin (rDNA origin) for injection), for the treatment of patients with Short-bowel Syndrome (SBS), a potentially life-threatening condition resulting from a resected bowel or a disease of the gastrointestinal tract.

NutreStore™ therapy for SBS represents a new treatment option for patients in the United States struggling daily with SBS. “The treatment of SBS using NutreStore™ and Zorbtive™ has the potential to enable those dependent on costly and inconvenient intravenous nutrition to take necessary nutrients orally,” said Lynda Sutton, co-founder of Cato BioVentures and Cato Research.

NutreStore™ is taken orally, in combination with Zorbtive™, to increase the absorption of nutrients into the body. NutreStore™ allows patients to consume a specialized high-carbohydrate, low-fat diet, adjusted for individual patient requirements and preferences. With NutreStore™ and Zorbtive™, the nutritional needs of SBS patients can often be met more through oral means than intravenous supplementation.

Cato BioVentures, in a strategic collaboration with Cato Research, partnered with Douglas Wilmore, M.D., Professor of Surgery at Brigham and Women's Hospital and founder of Nutritional Restart Clinic of Boston, Massachusetts, to form Nutritional Restart Pharmaceutical (NRP) in 1996. Cato Research conducted NRP's drug development activities, which included designing and performing NRP's clinical programs and navigating the complex regulatory pathways with the FDA.

The NutreStore™ and Zorbtive™ clinical program culminated with a randomized, controlled, double-blind, parallel-group Phase 3 clinical study which evaluated the efficacy and safety of NutreStore™ in combination with Zorbtive™ in subjects with SBS who were dependent on intravenous nutritional support. This clinical study demonstrated that total volume, caloric content and frequency of intravenous nutritional support were all reduced in subjects receiving NutreStore™ and Zorbtive™ when compared with subjects receiving either NutreStore™ or Zorbtive™ alone. Importantly, the reduction in weekly volume, caloric content, and frequency of intravenous nutritional support is maintained for at least 16 weeks. By helping reduce patients' need for intravenous nutritional support, NutreStore™ in combination with Zorbtive™ holds great promise for those suffering from this devastating disorder.

“We are pleased to have helped NRP obtain one of only approximately 30 new molecular entity approvals by the FDA last year,” said Allen Cato, M.D., Ph.D., co-founder Cato BioVentures and Cato Research. “The data supporting NRP's approved New Drug Application are robust, with the primary and all secondary efficacy endpoints achieving a highly statistically significant

“p-value” of <0.001 (or p<0.001). To my knowledge, NutreStore™ is the first amino acid to be approved by the FDA as a new drug.”

### **About Cato BioVentures**

Cato BioVentures is the venture capital affiliate of Cato Research, a leading contract research organization (CRO). Cato BioVentures invests its CRO Service Capital™ through strategic development partnerships with management teams focused on developing innovative therapeutics, medical devices and diagnostics for cardiovascular disease, CNS disorders, metabolic syndrome and oncology. Cato BioVentures invests in great people building great life science companies that will make a difference in healthcare for decades to come. Cato BioVentures has offices in Silicon Valley and near Research Triangle Park. To learn more, visit Cato BioVentures’ website at [www.catobioventures.com](http://www.catobioventures.com).

### **About Cato Research Ltd.**

Founded in 1988 by Dr. Allen Cato and Lynda Sutton and headquartered near Research Triangle Park, Cato Research is a full-service contract research and development organization providing strategic and tactical support for clients in the pharmaceutical, biotechnology, and medical device industries. Services range from design and management of preclinical and clinical studies to submission of regulatory documents required for marketing approval. With a staff of 300 and offices located in the United States, Europe, Canada, Israel, and South Africa, the Cato Research team consistently demonstrates an unsurpassed level of responsiveness, flexibility, attention to detail, and passion for bringing their clients’ products to market rapidly and cost-effectively. For more information, visit Cato Research’s website at [www.cato.com](http://www.cato.com).

### **About Short-bowel Syndrome (SBS)**

Short-bowel syndrome is a result of the surgical removal of part of the small intestine due to trauma or disease. Post-surgery, the small intestine’s ability to absorb the nutrition a person needs from food is severely impaired, requiring costly and inconvenient supplemental nutritional support. Before the development of NutreStore™ in combination with Zorbitive™, many SBS patients received their nutrition from a nutrient-rich fluid administered intravenously for several hours at a time and multiple times per week. Complications associated with SBS include malnutrition and dehydration, which can lead to weakness, fatigue, depression, weight loss, bacterial infections, and food sensitivities.

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