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Market Research Shows Spherix's Naturlose® Readily Accepted by Diabetes Patients Meets MD's Treatment Need

BETHESDA, MD. Spherix Incorporated (NASDAQ/SPEX) reported that Naturlose, a natural sugar approved as a food ingredient in the U.S. and abroad, has been found to reduce the spikes of serum glucose that follow consumption of food (1). In a Phase 3 human clinical trial, Spherix is currently studying the efficacy and safety of Naturlose for the treatment of diabetes. While the Phase 3 trial is ongoing, Spherix has engaged market research companies to seek feedback as to the likelihood of Naturlose market acceptance assuming successful completion of the Phase 3 trials and ultimate FDA approval.

Focus group testing with diabetes patients and physicians who treat diabetes has identified a clear role for Naturlose in the management of diabetes. A series of focus group meetings were held in two U.S. cities. The testing included demographically diverse groups of both general practitioners and endocrinologists, as well as patients ranging from the age of 30 to 70.

Patients, many of whom suffer side effects from current oral diabetes medications, valued the safety of a natural product already approved for use in food. Patients expressed a preference for the soft chewable formulation, with the fast-dissolving oral and powdered forms ranking second and third, respectively. The convenience of meal-time dosing was also mentioned by patients. Patients expressed a clear need for more information about diabetes. Many feared the long-term consequences of poor long-term control of blood glucose and were eager to have practical advice on improving their health.

Physicians, who treat diabetes with multiple drugs, each acting at a different biochemical point to control blood sugar, were intrigued by Naturlose's novel mechanism of action. For physicians, drug choice was a complex algorithm involving level of glucose control, tolerance to side effects, cost, and patient compliance. The consensus of the physicians was that with three of four of the most widely prescribed drugs to treat type 2 diabetes, patient toleration of side effects limited their ability to achieve the glycemic control that they seek for their patients. Physicians expressed significant frustration with the ability of current medications to control patients' blood sugar to guideline-based goals, and saw value in being able to add a safe new therapeutic approach to their arsenal.

Both patients and physicians expressed interest in the safety and efficacy data currently being developed for Naturlose in the Phase 3 trial. Because Naturlose is approved as a food ingredient and the food-grade sugar is available, both patients and physicians had the opportunity to taste Naturlose during the focus group meetings. The sweet flavor had great appeal. After tasting Naturlose one general practitioner remarked, "We are all going to start taking it."

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Data from the national prescription audit of the diabetes category for 2007 revealed 167,019,000 total prescriptions, with 58,015,000 new prescriptions. The diabetes category remained very active in 2007. Price level and positioning on insurer and managed care formularies are important issues that manufacturers continuously address. Regardless of product launch date, the share of new prescriptions remains around 30%. More recent brand product launches with the largest marketing budgets show a higher share of new prescriptions. However, generics with recent launches are also showing year-to-year prescription growth. As a result, significant opportunities exist for Spherix over the next several years.

1. Yongming Lu, Gilbert Levin, Thomas Donner. Tagatose, a New Anti-Diabetic and Obesity-Control Drug. *Diabetes, Obesity and Metabolism*. 10, 2008, 109–134.

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Spherix’s mission is to create value and increase shareholder wealth through innovations that benefit our clients and the human condition. Spherix offers innovations in biotechnology, and provides technical and regulatory consulting services to biotechnology and pharmaceutical companies.

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