Protalix BioTherapeutics Announces Completion of Enrollment for its Pivotal Phase III Clinical Trial of Gaucher Disease

December 2, 2008

CARMIEL, Israel, December 2, 2008 -- Protalix BioTherapeutics, Inc. (Amex: PLX), announced today that it has completed enrollment in the Company's pivotal phase III clinical trial of prGCD, a proprietary plant cell expressed recombinant form of human glucocerebrosidase (GCD) for the treatment of Gaucher disease. Gaucher disease is a rare and serious lysosomal storage disorder in humans.

"The completion of enrollment signifies that we are one important step closer to our goal of commercializing prGCD," said Dr. David Aviezer, President and Chief Executive Officer of Protalix BioTherapeutics. "We expect to analyze the results of this key study and to report the results in the second half of 2009. We anticipate submitting a New Drug Application to the FDA and other comparable regulatory agencies in the fourth quarter of 2009."

The Company's phase III clinical trial of prGCD is designed as a multi-center, randomized, double-blind, parallel group, dose-ranging trial to assess the safety and efficacy of prGCD in naive patients suffering from Gaucher disease. In the trial, patients are selected randomly for one of two dosing arms and receive IV infusions every two weeks for nine months. The primary endpoint of the study is the change, calculated in percentages, in spleen volume from baseline, as measured by MRI.

"I am very encouraged by the progress of the study and the patient responses demonstrated to date" said Professor Ari Zimran, Director of the Gaucher Clinic at Shaare Zedek Medical Center in Jerusalem and a Principal Investigator of the Company's pivotal Phase III trial of prGCD. Dr. Rene Heitner, a Pediatrician at the Morningside clinic in South Africa and a Principal Investigator of the phase III clinical trial of prGCD said "At our clinical site, patients appear to be tolerating and progressing very well on the bi-weekly infusions of prGCD."

The Company's pivotal phase III clinical trial of prGCD is being conducted under a Special Protocol Assessment (SPA) agreement with the U.S. Food and Drug Administration (FDA). An SPA is a procedure by which sponsors and the FDA reach agreement on the design and size of clinical trials intended to form the primary basis to support approval of a New Drug Application. There have been no Serious Adverse Events reported in connection with the phase III clinical trial.

About Protalix BioTherapeutics

Protalix is a biopharmaceutical company. Its goal is to become a fully integrated biopharmaceutical company focused on the development and commercialization of proprietary recombinant therapeutic proteins to be expressed through its proprietary plant cell based expression system. Protalix's ProCellEx(TM) presents a proprietary method for the expression of recombinant proteins that Protalix believes will allow for the cost-effective, industrial-scale production of recombinant therapeutic proteins. Protalix is treating patients in its pivotal phase III clinical trial in Europe, the United States, Israel, and other locations for its lead product candidate, prGCD, for its enzyme replacement therapy for Gaucher disease, a lysosomal storage disorder in humans, and has reached an agreement with the United States Food and Drug Administration on the final design of the pivotal phase III clinical trial through the FDA's Special Protocol Assessment (SPA) process. Protalix is also advancing additional recombinant biopharmaceutical drug development programs. For more information, please visit our website at www.Protalix.com.

Safe Harbor Statement:

To the extent that statements in this press release are not strictly historical, all such statements are forward-looking, and are made pursuant to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. These statements are based on our current beliefs and expectations as to such future outcomes. Drug discovery and development involve a high degree of risk. Factors that might cause such a material difference include, among others, uncertainties related to: the ability to attract and retain partners for our technologies and products under development; the identification of lead compounds; the successful preclinical development of our products; our preparation and filing of applications for regulatory approval; the approval or potential rejection of any applications we file with the FDA, or other regulatory authorities; the completion of clinical trials; and other factors described in our filings with the Securities and Exchange Commission. The statements are valid only as of the date hereof and we disclaim any obligation to update this information.

Contact:
Marcy Strickler
The Trout Group, LLC
Telephone: 646-378-2927
Email: mstrickler@troutgroup.com