

PROTALIX

Biotherapeutics

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September 15, 2011

Dear Shareholders:

The last year was both challenging and exciting. In August 2011, we announced that the U.S. Food and Drug Administration, or the FDA, had accepted for review the resubmission of the new drug application (NDA) we submitted for the taliglucerase alfa, our proprietary plant cell expressed form of human Glucocerebrosidase (GCD), which is being developed for the treatment of Gaucher disease. The FDA has granted a February 1, 2012 action date under the Prescription Drug User Fee Act (PDUFA), the date by which the FDA is expected to respond to the NDA. This announcement represents a promising milestone for our company.

As you know, we first submitted an NDA for taliglucerase alfa in April 2010, and in February 2011, we received a Complete Response Letter, or CRL, from the FDA with respect to the NDA. A CRL is issued by the FDA when its review of a file is complete and questions remain that preclude the FDA's approval of the NDA in its then current form. While we were of course disappointed by this development, we were encouraged by the nature of the questions in the CRL. Notably, the FDA did not request additional clinical studies. Rather, the CRL also requested data regarding our taliglucerase alfa switchover trial and our long-term extension trial, data that was not available when we first submitted the NDA. The FDA also presented questions in the CRL that were intended to clarify issues relating to chemistry, manufacturing and controls (CMC). Final top line results from the adult patients participating in the switchover trial were released in July 2011 and the requested data was included in our resubmission. The resubmission also included requested clinical data from our long-term extension trial.

We are pleased with the results of the switchover trial. Twenty six adult patients were enrolled in the switchover trial in which they were switched from Cerezyme to an equivalent dose of taliglucerase alfa. Cerezyme was the standard of care when we initiated the switchover trial. The data supports the efficacy and safety data package and shows that patients can be switched from Cerezyme to taliglucerase alfa. The long-term extension trial studied patients that completed our phase III clinical trial of taliglucerase alfa and were subsequently treated with taliglucerase alfa for a total of at least 24 months. These patients continued to show a mean improvement in efficacy and the drug was well tolerated. We intend to release complete results from the switchover trial and the long-term extension trial at various medical conferences over the next year.

An encouraging side note to our experience with the CRL response is the experience we have had with Pfizer Inc., our commercial partner for taliglucerase alfa. We have found Pfizer to be a true partner and a valuable regulatory and analytical resource as we worked together to prepare our response to the FDA.

As we wait for the FDA to respond to the resubmitted NDA, we are excited about our company's future. We believe that we have adequately addressed the requests outlined by the FDA in the CRL, and we plan to work closely with the FDA as it moves forward with its review of the NDA. The anticipated FDA marketing approval of taliglucerase alfa will not only present us with our first commercial product, we believe that it will serve as a proof of concept of our ground-breaking plant cell based protein expression technology, and will mark a new era in therapeutic protein biotechnology.

While we have focused significant efforts on the FDA approval of taliglucerase alfa, we have also been focused on other important regulatory approvals. We have applied for marketing approval of taliglucerase alfa in Israel and Pfizer, with our assistance, has submitted applications for marketing approval of taliglucerase alfa in the European Union, Brazil and Australia. Since the applications were submitted, our manufacturing facility in Carmiel, Israel has been found acceptable in audits by the FDA and the comparable authorities of Israel and Brazil.

Although not yet approved for commercial use, hundreds of patients have been treated to date with taliglucerase alfa under several regulatory settings which has allowed us to collect a robust global clinical database regarding taliglucerase alfa. In addition to our clinical trials, we have provided taliglucerase alfa for patients in the United States, the European Union, Israel, South Africa, Brazil and other countries through compassionate use and similar programs. We do not generate revenues in connection with most of those programs. However, Pfizer has sold taliglucerase alfa to the Brazilian government for gross proceeds of approximately \$30 million in connection with a short-term supply agreement and is selling the drug to the French government under a Temporary Authorization for Use (ATU).

Our efforts have not been limited to taliglucerase alfa. In December 2010, we conducted a pre-Investigational New Drug (IND) meeting with the FDA regarding PRX-102, our product candidate under development for the treatment of Fabry disease. We expect to file an IND with the FDA before the end of this year and to commence a phase I/II clinical trial of PRX-102, our modified alpha Galactosidase enzyme shortly thereafter. Subjects in the first trial will be patients of Fabry disease. We are continuing development efforts for PRX-105, our plant cell expressed pegylated recombinant acetylcholinesterase product candidate for biodefense indications, and are in discussions with defense authorities and other government bodies around the world. We have completed a phase I clinical trial of PRX-105. In addition, we are promoting the use of this product candidate for other important clinical indications. We expect to hold meetings with regulatory authorities in the near future in connection with PRX-106, or pr-antiTNF, our plant cell expressed fusion protein that we are developing for the treatment of certain immune diseases, such as rheumatoid arthritis. We are continuing our development of an orally-administered glucocerebrosidase enzyme for the treatment of Gaucher disease. In addition to these candidates, we have additional undisclosed proteins that are currently the subject of animal studies.

In March 2011, we raised approximately \$22 million in a public offering of our common stock underwritten by Citigroup Global Markets and Barclays Capital. We believe that these resources, together with revenues from taliglucerase alfa sold in Brazil and France, have provided, and will continue to provide, the capital necessary to fund our on-going and planned clinical trials, and to as enhance our research and development activities and manufacturing capacity.

Last year, the chairman of our Board of Directors, Mr. Eli Hurvitz, unfortunately had to resign from his position. On behalf of our company, I would like to thank Eli for his leadership and to wish success to Mr. Zeev Bronfeld who stepped up to the position of interim chairman.

We believe we have addressed many of the challenges of the last year and we are looking forward to continuing our efforts in the upcoming year. We thank our shareholders, employees and partners for their continued support.



Dr. David Aviezer
President and Chief Executive Officer