



**FOR IMMEDIATE RELEASE**

February 16, 2005

**BIOLEX AND OCTOPLUS ANNOUNCE JOINT DEVELOPMENT OF LOCTERON™:  
A NOVEL, CONTROLLED RELEASE FORMULATION OF ALFA INTERFERON**

***Clinical Trials to Commence in 2005***

**PITTSBORO, NC, USA / LEIDEN, THE NETHERLANDS, FEBRUARY 16, 2005.** Biolex, Inc., a protein therapeutics company, and the drug delivery and development company OctoPlus announced today that they have entered into collaboration for co-development of a controlled release formulation of recombinant human alfa interferon. The product, named Locteron™, combines OctoPlus' proprietary biodegradable PolyActive™ drug delivery technology with Biolex' BLX-883, a recombinant alfa interferon produced in its proprietary LEX System™. Locteron is designed to be more convenient for patients than the current pegylated alfa interferon products on the market as it is expected to be administered every two weeks. Alfa interferon is a protein used to treat infectious diseases, such as Hepatitis C and B, and certain cancers. World-wide sales for alfa interferon in 2004 exceeded US \$3 billion.

Under the terms of the agreement, OctoPlus and Biolex will co-develop Locteron, including the establishment of manufacturing capabilities to support clinical development and commercialization. Initial focus will be on the treatment of Hepatitis C. The companies expect Locteron to enter clinical trials in mid-2005. Financial terms of the collaboration have not been disclosed.

In preclinical studies, Biolex has shown that BLX-883 is comparable to commercially available alfa interferon and that it can be produced cost-effectively using Biolex' proprietary LEX System in the company's cGMP manufacturing facilities. Biolex recently announced the filing of an Investigational New Drug Application (IND) with the U.S. Food and Drug Administration and the European equivalent, a Clinical Trial Application (CTA), for the initiation of clinical trials of BLX-883, an immediate release formulation of Locteron. Dosing in the initial clinical study commenced this month.

OctoPlus has shown in preclinical studies that, when formulated with PolyActive, sustained alfa interferon levels in plasma can be achieved, for a period up to two weeks and longer, with a single injection. In contrast, all pegylated alfa interferon products currently on the market require weekly injections. OctoPlus has also demonstrated in these preclinical studies that alfa interferon, when formulated with PolyActive, is gradually released after injection, thus avoiding both high peak and low trough plasma levels. This key feature may result in an improved clinical profile for the drug candidate with possibly fewer side-effects.

“We are very pleased to enter into this agreement with Biolex. Their innovative, cost-effective manufacturing platform allows for global commercialization of Locteron. Also, we are very impressed with their skills and expertise in the area of recombinant protein development,” stated Joost Holthuis, Ph.D., Chief Executive Officer of OctoPlus. “This partnership exemplifies our





increased focus on investing in the development of products based on our drug delivery technologies to an advanced clinical stage.”

“We looked at a number of drug delivery technologies and were impressed with the many benefits of PolyActive and the development capabilities of OctoPlus. Combining these benefits with the manufacturing advantages provided by the LEX System may result in a far superior and more cost-effective version of alfa interferon than what is currently commercially available,” said Jan Turek, President and CEO of Biolex. “This collaboration builds on our business strategy to develop a pipeline of proprietary Biolex proteins. We are delighted to be working with OctoPlus to develop this product, and look forward to having Locteron, our second drug candidate, enter the clinic later this year.”

### **About OctoPlus**

OctoPlus is a product-oriented drug delivery company that focuses on the development of innovative drug delivery systems to build a pipeline of product candidates. OctoPlus is also an internationally established provider of pharmaceutical development services and GMP manufacturing for pharmaceutical and biotechnology companies. The company is located in Leiden, The Netherlands.

### **About Biolex**

Biolex, Inc. is a private, venture capital-backed biopharmaceutical company. Biolex is developing recombinant human therapeutic proteins that, until now, have been impossible or very expensive to develop in existing expression systems. Biolex' proprietary LEX System has demonstrated speed, regulatory and economic benefits with hard-to-make proteins and monoclonal antibodies. Biolex has a pipeline of proprietary products in development and its lead candidate, BLX-883, is currently in a Phase 1 clinical trial. Biolex also is partnering with pharmaceutical and biotechnology companies seeking the protein development and production benefits the LEX System offers. Biolex has entered into corporate partnerships with Centocor, Inc., Medarex, Inc., and other pharmaceutical/biotechnology companies. The Company's headquarters, research laboratories and clinical manufacturing facilities are based in Pittsboro, North Carolina. Visit the Company's web site at [www.biolex.com](http://www.biolex.com).

Locteron and BLX-883 are investigational drug candidates and have not been approved by the U.S. Food and Drug Administration or any other regulatory agency.

For further information please contact:

#### **OctoPlus:**

Joost Holthuis, Ph.D., Chief Executive Officer

Tel+ 31 (0) 71 5244044

Email: [holthuis@octoplus.nl](mailto:holthuis@octoplus.nl)

Website: [www.octoplus.nl](http://www.octoplus.nl)

#### **Biolex:**

John Irick, SVP and Chief Business Officer

Tel : 919-542-9901

or: Michelle Linn, Linnden Communications

Tel : 508-869-0138 ; [michlinn@charter.net](mailto:michlinn@charter.net)

