



**For Immediate Release**

**Xcellerex, Pfenex Inc and Collaborators Complete Successful Test:  
Rapid Production of Swine Flu H1 Hemagglutinin**

**Marlboro, MA and San Diego, CA– May 17, 2010** – Xcellerex, Inc. and Pfenex Inc. announced today that the companies, along with deltaDOT Ltd. and BioPharm Services have successfully demonstrated the production of purified swine flu H1 hemagglutinin (California strain) in 42 days starting from the amino acid sequence of the protein. During that period, the gene was cloned and expressed, fermentation and purification processes developed, and the quality product shown to be fully within the specifications set out by the Defense Threat Reduction Agency (DTRA) under its Accelerated Manufacturing of Pharmaceuticals contract.

The test followed completion of 24-month, \$19 million Phase 1 and Phase 2 contracts funded by both the Defense Advanced Research Projects Agency (DARPA) and the Defense Threat Reduction Agency's Transformational Medical Technologies Initiative (TMTI). The contracts are part of a government effort to support development of advanced manufacturing technology to address pandemic or biosecurity threats. The test results exceeded the goal for rate of production by at least 10 fold and exceeded all product quality specifications.

Xcellerex, the prime contractor, joined with Pfenex, Inc, BioPharm Services, and deltaDOT. The team combined Pfenex's *Pseudomonas fluorescens*-based rapid strain engineering platform, Pfenex Expression Technology™, with Xcellerex's microbial PDMax™ high speed process development and FlexFactory® single-use manufacturing technologies and deltaDOT's Peregrine® label free CE-based analytical technology. The team was guided by BioPharm Services systems integration, data management/process economics, and discrete event modeling technology.

"We are very pleased with the results of the test, which demonstrated the performance of rapid, flexible, and portable biomanufacturing," said Parrish Galliher, Xcellerex's founder and Chief Technology Officer. "The results exceeded our expectations and we thank Pfenex, deltaDOT and BioPharm Services for their teamwork to achieve these outstanding results."

The test demonstrated the speed and capability of the platform in producing a real-world vaccine, in this case swine flu H1 within 12 weeks of receipt of an unknown target amino acid sequence. The team succeeded in developing a strain and bioprocess, and fully characterizing the purified product in less than six weeks and at a cost, that (scaled to manufacturing) would be less than \$0.50/dose. The previous two phases of the contract were aimed at developing the high efficiency bacterial expression system using Pfenex's Pfenex Expression Technology in conjunction with Xcellerex's single-use FlexFactory platform to grow microbial production strains to high cell densities and to purify model vaccine and antibody molecules. Analytical capability was supplied by deltaDOT, and project systems integration and process economic analyses were provided by BioPharm Services.

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"The successful execution of the test brings to conclusion an extraordinary multi-year effort put forth by all the participants on the team," added Charles Squires, VP Discovery and External Partnerships at Pfenex Inc. "The team was able to bring together cutting edge protein expression, production and analytical technologies with state of the art process modeling software to deliver a vaccine antigen with unprecedented speed, quality and cost."

"Any program can look good in the simulation; making this a reality took some truly innovative technology and dedicated people both at the companies and our government sponsors," said Peter Latham, President of BioPharm Services, US. "The results of this program will provide valuable tools for biodefense and pandemic response."

Stuart Hassard, Chief Scientific Officer of deltaDOT Ltd, commented, "deltaDOT is delighted that our label free capillary electrophoresis technology was able to contribute to the successful outcome of this far-sighted program. The potential impact of the AMP enterprise on the rapid delivery of pharmaceuticals in cutting edge technology platforms, such as the one developed by this consortium, cannot be underestimated and will prove its worth over the coming years."

#### **About DTRA and TMTI**

DTRA is the intellectual, technical and operational leader for the Department of Defense (DoD) and the U.S. Strategic Command in the national effort to combat the weapons of mass destruction (WMD) threat. The ultimate goal of TMTI is to develop a long-term, sustained capability to rapidly respond to a novel biological threat by integrating all aspects of response, from identification through the development and manufacturing of new medical countermeasures.

#### **About Xcellerex, Inc.**

Xcellerex is revolutionizing the way biomolecules are developed, manufactured, and commercialized. The company's unique single-use component technology platform transforms biomanufacturing economics, enabling the development of biotherapeutics and vaccines, and dramatically improving the ability of Xcellerex and its partners to deploy manufacturing capacity. Xcellerex leverages its technology and services platform by: 1) commercializing its FlexFactory® biomanufacturing platform (complete, turnkey, modular production trains) and XDR (unique, single-use component bioreactor systems); 2) building a portfolio of proprietary biotherapeutics and vaccines through creative alliances and in licensing; and 3) creatively structuring transactions around FlexFactories, XDRs and its pipeline. Based in Marlborough, Massachusetts, Xcellerex is backed by an experienced management team and top-tier venture investors including Kleiner Perkins Caufield & Byers, VantagePoint Venture Partners, and SCG Capital. For more information, please visit the company's website at <http://www.xcellerex.com>.

#### **About Pfenex Inc.**

Pfenex Inc. is a protein production company leveraging the unique and powerful Pfenex Expression Technology™ platform based on the micro-organism, *Pseudomonas fluorescens*, for the production of research proteins, reagent proteins, biosimilars and innovator biopharmaceuticals. For more information please visit [www.pfenex.com](http://www.pfenex.com)

#### **About BioPharm Services**

BioPharm Services is a technical consultancy dedicated to helping clients in the biopharmaceutical manufacturing sector to reduce costs, understand their markets, improve productivity and reduce their time to market. The company offers a range of specialist services including program management and business development services from the US office and economic analysis with their BioSolve package and custom cost models, process simulation (BioSim), facility design and design for disposables from the UK operation. See [www.biopharmservices.com](http://www.biopharmservices.com).

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**About deltaDOT Ltd**

deltaDOT is a biotechnology company that is developing and commercializing highly innovative enabling technologies and products in the bioscience arena. The company was founded in 2000 and is a spin-out from Imperial College London, UK. It is focused on the harnessing of cutting-edge particle physics technology and its application to the needs of biomolecular separation, including proteins, DNA and RNA analysis. The company has a strong proprietary position and extensive expertise in instrumentation, micro-fluidics, automation, computing and analysis which will contribute to improvements in knowledge, profitability and process time throughout drug discovery and general life sciences research. Find out more about deltaDOT Ltd at [www.deltadot.com](http://www.deltadot.com)

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