



company profile

Revolutionizing the way biomolecules are developed, manufactured and commercialized

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.

The Opportunity

The biotherapeutic and vaccine markets are undergoing enormous growth and change. More than 500 products, including therapeutic proteins, monoclonal antibodies, and vaccines are in clinical development and approximately 100 are on the market today.

The vaccine industry is undergoing a renaissance driven by scientific advances, the commercial success of new products, and an urgent need for new products to meet the twin threats of pandemic influenza and bioterrorism. In addition the industry is undergoing a shift from egg-based to cell-based fermentation.

In this environment, biomanufacturing and the ability to deploy it rapidly and cost-effectively is becoming a strategic capability that is enabling to new biomolecule development and commercialization.

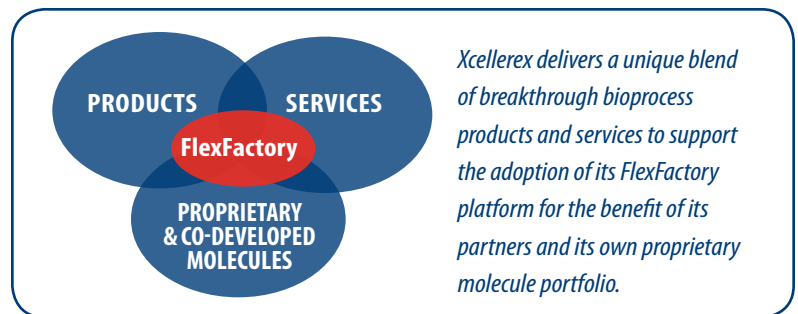
Increasingly, traditional biomanufacturing models — fixed, dedicated facilities and outsourced, contract manufacturing (CMO) — have become development and commercial barriers. For the growing number of biomolecules aimed at specific subpopulations within a disease class, traditional manufacturing economics will not yield acceptable returns-on-investment. In addition, for many companies that have not pursued biomolecules to date, manufacturing expertise represents a major barrier to entry. Outsourcing is not an option due to the lack of CMO capacity and capability and “limited control of destiny.”

A traditional commercial manufacturing facility for a single product requires an investment of \$100-\$300 million and three to five years for construction and validation of its systems. Much of the cost is due to the infrastructure to maintain sterile conditions in reaction vessels and large scale environmental controls to maintain air quality in manufacturing suites.

In addition, the long lead time required to build a new facility increases development risk because manufacturing capacity decisions must be made early, well before it is known whether a product will succeed in the clinic and reach the marketplace. The CMO model presents significant challenges in efficiency, scalability, timing and control.

The Xcellerex Solution

Xcellerex is commercializing a highly innovative manufacturing technology platform based on proprietary, single-use component technology that drastically improves the overall economics of biomolecule development. The platform is built around the FlexFactory™, the first, complete turnkey, modular production train and fully-integrated XDR single-use bioreactor systems with demonstrated performance that is comparable to traditional stainless systems. FlexFactory combines the sophisticated control and process capability of traditional manufacturing with the simplicity of Xcellerex's novel disposable platform and capability.



The technology platform allows manufacturing capacity to be deployed with greater speed and flexibility, and at significantly reduced costs compared with conventional technology. For example, fully integrated manufacturing capacity can be established within one year vs. three-to-five years at a capital reduction of 50% to 75% compared with traditional facilities.

The FlexFactory technology increases manufacturing productivity, allowing rapid changeover for the manufacture of multiple products at the same facility, and the ability to make process changes rapidly and to transfer the entire facility for local manufacturing. The technology is scalable to 5,000L working volume, sufficient for commercializing most products.

Because the FlexFactory is modular, it allows manufacturing capacity to be adjusted rapidly and efficiently to match demand.

The company has demonstrated the potential of its unique platform through successful campaigns for GMP production of therapeutic proteins, including monoclonal antibodies and vaccines. The FlexFactory can produce biomolecules in all widely used cell lines, including mammalian, insect, fungal, e. coli, and yeast. Xcellerex has established global acceptance with a customer base that includes top-tier pharmaceutical and biotechnology companies in the Americas, Europe and Asia.

MANAGEMENT

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President & Chief Executive Officer
(Reliant COO, Lilly VP)

PARRISH GALLIHER

Founder & Chief Technology Officer
(Millennium, LeukoSite, Biogen,
Alpha-Beta Technology)

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Xcellerex, Inc.

170 Locke Drive
Marlborough, MA 01752
508-480-9235
866-XCELLEREX
(866-923-5537)

www.xcellerex.com

Commercial Strategy

Xcellerex's strategy is to capitalize on its technology and services platform by:

- X Commercializing FlexFactories and XDR bioreactors with pharmaceutical and biotechnology companies
- X Developing a pipeline of proprietary biomolecules, including biotherapeutics and vaccines
- X Entering creative corporate alliances to build its pipeline as well as commercialize FlexFactories and XDR bioreactors

The company's approach is based on the unique ability to combine the platform and the product for internal development or for delivering to a partner a FlexFactory complete with a developed product.

Management and Organization

Xcellerex has built a management team with world class expertise in biologics manufacturing and outstanding track records in growing life science organizations. Joe Zakrzewski, CEO, brings a wide range of commercial, corporate and business development experience from a 20-year career at Eli Lilly and Reliant Pharmaceuticals. Parrish Galliher, Chief Technology Officer, founded Xcellerex in 2002 after an extensive career that included positions as head of manufacturing at Biogen and Millennium Pharmaceuticals.

Xcellerex has developed an international team of technical sales professionals to serve customer demand in all major global markets. The company maintains 60,000 square feet of laboratory and manufacturing space at its headquarters location in Marlborough, Massachusetts, USA.

The company has raised over \$55 million to date from investors including VantagePoint Venture Partners, Kleiner Perkins Caufield & Byers, and SCG Capital.

Recent Milestones & Developments

▶ Xcellerex was awarded an \$11 million Phase 2 contract by the U.S. Defense Threat Reduction Agency (DTRA), to develop technology for accelerated monoclonal antibody and vaccine manufacturing.

▶ Xcellerex is launching its expanded line of bioreactors designed to **grow bacteria and other high density, high productivity cell lines**. Testing to date has yielded unparalleled results that have not been approached by other single-use bioreactor systems.

Current data demonstrates performance equivalent to stainless steel systems for:

- Pseudomonas OD (optical density) 260
- Yeast OD of 170
- e. Coli OD of 140
- Neurospora cell mass of 40 g/l dry cell weight.

Additional data for additional cell lines, including picchia and blue-green algae will be published soon.

▶ The biopharmaceutical division of a major pharma organization presented detailed results of a **head-to-head comparison between the Xcellerex XDR single-use bioreactor and an existing stainless steel bioreactor system**. Several evaluation runs were conducted in both batch refeed and fed-batch modes.

At the 500 liter scale, the Xcellerex system demonstrated comparable performance for cell density, viability and metabolic profiles. The titer was found to be comparable, and product quality was found to be equivalent to internal reference materials.

▶ Xcellerex is scheduled to file an **IND on its first proprietary molecule** in 2009.

▶ Xcellerex launched the **world's first 2,000 liter single-use bioreactor** to complement its 50, 200, 500 and 1000 liter models.

▶ Xcellerex will deliver a validated **FlexFactory for clinical trials to a client in Europe in seven months**, which includes a GMP run performed by a newly trained customer team at the Xcellerex facility.