

# BioWorld Today

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## *EuroBio 2008*

### France Missing the Boat as Biotech Moves Downstream

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PARIS - The action is moving downstream in biotechnology with an estimated €10 billion (US\$13.5 billion) being spent worldwide over the next few years for facilities to mass-produce a wave of bio-based medications expected to be approved for release by 2012.

The spending is nearly evenly split among North America, Europe and Asia-Pacific, according to a French industry report presented ahead of the annual congress **EuroBio** that opens here today.

Seven projects are scheduled for Europe, according to the French Pharmaceutical Manufacturing Association (LEEM; Les Entreprises du Médicaments), which commissioned the study jointly with the high technology research cluster south of Paris, Genopole. Four bioproduction facilities are being built in Ireland alone with Eli Lilly and Co. opening this year; both Centocor Inc. and Merck & Co., coming online in 2011; and Amgen Inc. heading for an opening in 2012.

The other three European projects on the boards include a Pfizer Inc. building in Sweden, a Biogen Inc. facility in Denmark and Lilly building a second facility in Italy scheduled for 2009.

"The missing man in this picture is France," said Christian Lajoux, president of LEEM during the presentation at the International Symposium for Bioproduction held at Genopole, an affiliated pre-event for **EuroBio 2008**.

"Not a single mass production facility is planned for France between now and 2011," he said, adding that while France today may claim to be the fourth-ranked producer of pharmaceuticals, that standing is at high risk in the evolving world of biopharmaceuticals.

According to the study, biomedications will grow 12 percent from €80 billion this year to €127 billion in 2012, with the FDA approving 127 such therapies in 2007 and with 231 approvals expected in 2012.

Meanwhile, traditional pharmaceuticals are expected to grow just 4 percent during the same period from €680 billion to €710 billion.

There were 369 biotherapies in Phase I trials during 2007, another 259 in Phase II and 126 advancing to Phase III, he reported. Biopharmaceuticals make up a growing segment of new therapies, claiming a 30 percent share for the past four years, according to the French-language executive summary of the LEEM-Genopole study released Monday.

Three-fourths of those therapies have made it to the market, according to the report, and close to 60 percent are American in origin.

Where pharmaceutical companies show a steady 17 percent revenue growth in medications based on biotechnology, the industry saw a setback in 2007 to a slim 6.1 percent growth overall, underlining the fact that today "the industry is principally supported by the market for biopharmaceuticals," according to the report.

The upstream pressure for market-scale production is running toward a bottleneck in downstream capacities for filtration and polishing of bio-batches, which was a central theme of the presentations during the day-long Genopole symposium.

Currently, capacity for processing bio-derived pharmaceuticals around the world is built to support batches going to clinical trials and not the large-scale production necessary to fulfill market demand for medications when they are approved.

Between **2008** and 2011, 1 million liters of bioproduction capacity will be added to the current 3 million liter capacity at a cost that LEEM estimated to be \$13.5 billion. In North America, 40 percent of the €3.8 billion to be spent will be for new facilities, while 60 percent will be invested in the expansion of existing facilities.

By contrast, 80 percent of the €3.2 billion to be spent in Asia will be for new capacity, mostly in Singapore, according to Lajoux.

In Europe, the €3 billion to be invested in bioproduction facilities will be split 60 percent for new plants and 40 percent for expanding existing production.

A map of Europe pinpointing the locations of biopharmaceutical laboratories and contract manufacturing organizations (CMOs) shows a thick swath of dots sweeping from Ireland through England and arcing deep into Germany, but clearly bypassing France.

The three CMOs in France have a combined capacity of just 500 liters, said Lajoux, who noted the new bioreactors at Genopole alone would double that capacity.

The inauguration of the Genopole bioproduction facility, designed to support the start-ups in the cluster through Phase III, was set for the opening of **EuroBio**. But the head of the project, Alain Metayer, told *BioWorld Today* the opening was delayed until late November when the schedules of key French ministers and regional politicians can be aligned.

After the cascade of hard facts describing a miserable condition for French capacity, the recommendations from the study partners for enhancing the country's competitive status in the shifting landscape of pharmaceutical production sounded not only soft but purely aspirational.

The recommendation to focus first on boosting clinical batch capacity was less a statement of strategy as a concession describing real-world challenges faced by French biotechs.

Currently, French companies are forced to not only outsource production but to send it out of the country as well. France can claim to be the fourth-ranked country worldwide for biotechnology, Lajoux said, adding that it is a "very modest fourth place" with 175 biotechnology companies compared to 300 in the UK and the same number in Germany, while America is home to some 1,300 biotech businesses.

The French government, he noted, has assigned a priority to biotechnology, having earmarked 25 percent of its research and development budget to the sector.

"The objective having been stated, all that's left is to give the means to achieve this objective," he said referring to the long history of the French government for loudly announcing its intentions but quietly failing to authorize budget credits to support the programs.

The presentation, which concluded with a call to keep molecules in France by boosting capacity, creating a more bio-business friendly climate and pushing education and training, met with polite applause but failed to come to a convincing point.

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