

IN brief

New EU states ranked

The biotech industry in most of the EU's new member states lags behind that of their Western European neighbors, despite many declaring biotech a national priority. The 14 allbio report produced by EuropaBio and Zurich-based Venture Valuation is the first to gather data on the state of the biotech industry in the 12 new member states and 2 candidate countries. The report identifies 260 biotech companies—70% are in the service sector—operating in these countries and at least 18 therapeutic products in development. Hungary, Poland, the Czech Republic and Estonia lead the group, although the report found no correlation between a country's gross domestic product and the strength of its biotech sector. According to Patrik Frei of Venture Valuation who authored the report, despite a highly educated workforce, these countries lack support structures for small and medium-sized enterprises and funding for intellectual property and technology transfer. "It is essential to get these fundamentals right because private equity and venture capital will not invest without them," Frei notes. Erno Duda, who heads the Hungarian Biotechnology Association, notes that the Hungarian biotech sector has grown from 10 to 110 companies in only a few years. "Hungary has a strong science base, especially in medicinal chemistry," he says. "The biggest obstacle now is lack of management knowledge. But we are beginning to have the critical mass of companies to make a cluster."

Susan Aldridge

15 states sue Amgen

New York and 14 other states have filed a lawsuit alleging that Amgen offered doctors illegal kickbacks to increase sales of its blockbuster anemia drug. The multi-state case charges Thousand Oaks, California-based Amgen of overfilling vials of erythropoietin-stimulating agent Aranesp (darbepoetin alfa) by 16–19% to provide medical practices with free product for which they could then bill insurers. An ex-employee turned whistleblower, who first filed a complaint in 2006, alleges that Amgen's sales force promoted the overfill and the revenue it would bring from third-party payers such as Medicaid. Drug wholesaler ASD Healthcare and drug-purchasing International Nephrology Network, both based in Frisco, Texas, are also named in the suit. The plaintiffs are requesting treble damages, which could amount to several billions of dollars; the defendants deny the charges. Wells Wilkinson, director of the Boston-based consumer watchdog Prescription Access Litigation, calls the scheme a creative variation on a widespread marketing tactic of inducing doctors to inflate drug prices on reimbursement. "Recent lawsuits have been seeking increasingly larger fines from drug companies," he notes. "These are encouraging signs that the federal government is going to take a stronger stand against prescription drug fraud." Until the penalties are sufficiently severe, companies will continue to use these types of "egregious" marketing ploys, he predicts.

Asher Mullard

There is also brightening news regarding employment. After a staggering 52 companies reduced their workforce in the first quarter, restructuring and downsizing activity tapered off significantly (Table 2); indeed, 2009 could end up resembling 2008 in totality—a victory of sorts. In this regard, M&A activity has hampered job growth, Wasden says, as merging companies create redundancies, and thus pink slips, and it usually takes months before those people find their way to new jobs or start-ups.

Even if the crisis is passing, opinions vary on what sort of rebound biotech will see. When the economy retracts as strongly as it did in 2008, history suggests a recovery of similar slant—a 'V-shaped' recovery, as opposed to a 'W' shape, wherein the economy would surge and fall again. Wasden thinks the recovery will fall somewhere in between.

Table 2 Company restructurings

2006	35
2007	57
2008	114
2009 (first three quarters)	98

Source: BioCentury.

"The general view is that the worst is behind us," he says. "And I'm actually more optimistic than a lot of people. I see it as more of a 'U' recovery."

This means slower, gradual growth, which might not give much comfort to those firms treading water or in danger of slipping beneath the waves. But given the way 2009 began, any signs of recovery are fueling optimism.

Brady Huggett, Business Editor

The biotech Stradivarius

Thanks to a 'biotech' intervention, the modern fiddle in the picture fooled more than 100 listeners in a blind test. Professor Francis Schwarze of the Swiss Federal Laboratory for Materials Testing and Research treated Norwegian spruce and sycamore with two fungi to recreate the effects of cold climate thought to cause the superior quality of the wood used by Antonio Stradivari in the 17th century. Schwarze commissioned violin craftsman Michael Rhoneimer of Baden, Switzerland to build an instrument which was tested alongside untreated fiddles and a \$2 million Stradivarius. Listeners were asked to identify the Strad, and while 113 picked the biotech fiddle, only 39 correctly identified the Strad.



Michael Rhoneimer

IN their words

"It's not credible for him not to be considered a lobbyist," Craig Holman, of consumer advocacy group Public Citizen, argues that BIO's Jim Greenwood should officially declare himself a lobbyist. (*Pharmalot*, December 7, 2009)

"I do believe the sections relating to the creation of a market for biosimilar products is one area of the bill that strikes the appropriate balance in providing lower cost options." Rep. Lynn Jenkins (R. Kansas), one of dozens of lawmakers who, during the health-care debate in the House, parroted language verbatim from text provided by Genentech (S. San Francisco, California). (*New York Times*, November 14, 2009)

"The Iceland-based subsidiary [Islensk Erfdagreining] that performs all of deCODE's human genetics work—manages its population resources, conducts its research and services, offers and processes its tests and genome scans, and whose scientists and laboratories are licensed to undertake this work—is not in bankruptcy." DeCODE genetics CEO Kari Stefansson clarifies that his company's bankruptcy will not affect the Icelandic database that holds the medical and genetic records of the island's population. (*Nature News*, November 23, 2009)

"We're excited about the potential of this. It can be a fundamental game-changer." John Maraganore, of Cambridge, Massachusetts-based Alnylam, on the company's internal small-interfering RNA program against transthyretin amyloidosis. (*Xconomy*, December 12, 2009)

New product approvals

Kalbitor (ecallantide)	Dyax (Cambridge, Massachusetts)	The US Food and Drug Administration approved Kalbitor for acute attacks of hereditary angioedema (HAE) in patients 16 years and older. The first subcutaneous HAE treatment, the drug is a reversible plasma kallikrein inhibitor.
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