

## IN brief

## Oslo's cancer leap

Norway aims to cement its status as a world player in cancer research with the creation of a \$200 million Cancer Innovation Park based in Oslo. The park, announced in November and due to be completed in 2012, will include pharma giants London-based GlaxoSmithKline and AstraZeneca, 25 biotech companies working on developing cancer treatments, the University of Oslo's Radium Hospital and a specialist science high school. The Norwegian Cancer Registry, which holds data on all Norwegian cancer cases since the 1950s, will also be on site. By encouraging organizations to pool their expertise, the creators—the Oslo Cancer Cluster (OCC) in partnership with the Oslo City Council—hope to speed the delivery of drugs from basic research to the market. The Institute of Cancer Research at the Radium Hospital will run phase 1 clinical trials. Organizations will also be obliged to take on interns from the high school, which the OCC hopes will turn out a new generation of scientists. One company setting up shop at the park is Oslo-based siRNAsense, which develops RNAi therapeutics for melanoma and breast cancer. "It's a great advantage being in an environment with other innovative companies and academic groups," says CEO, Hanne Mette Kristensen. "Also, being able to support a school where it's easier for students to see why science is important is definitely very positive and we would like to be able to contribute to that." —Hayley Birch

## Cell/gene potency guides

The US Food and Drug Administration (FDA) has issued a draft guidance for testing the potency of cellular and gene therapy (CGT) products. The guidance clarifies the potency information needed to support an Investigational New Drug Application or a Biologics License Application for products reviewed by the FDA's Office of Cellular, Tissue and Gene Therapies. There was "an urgent need for this document," says the FDA's Denise Gavin, as many CGTs have been held up going into phase 3 trials owing to difficulties establishing appropriate potency tests. The document outlines three potency measurement categories—biological assays, nonbiological assays and matrix assays—used individually or in combination. The guidance does not cover the selection of an assay, however, because the inherent variability of CGT products requires appropriate potency measurements for an individual product. Companies are responsible for devising their own potency assays, and the FDA evaluates their adequacy on a case-by-case basis. The guidance recommends that companies start determining which product attributes are related to potency even at the preclinical stage. "The main thing is don't delay your product characterization," says Gavin. He encourages companies to discuss their plans with the FDA but acknowledges that potency tests "may change significantly" as products are developed. The draft is open for comment until 7 January 2009. —Asher Mullard

Obama's 'change' mantra is likely to hold sway—during his election campaign, he expressed his support for continued subsidies of corn-based, first-generation biofuels and, if anything, an acceleration of the migration toward second-generation biofuels.

In Europe, however, inertia still prevails. Biofuels along with other forms of renewable energy are currently the subject of a year-long, three-way political horse-trading process, involving the European Commission (EC), the European Parliament and European Union member states, operating through the Council of Ministers. These are due to agree this month on new legislation—in the form of a renewable energy directive—that will define the landscape for Europe's biofuels suppliers. "Industry is really waiting until December for the outcome," says Dirk Carrez, public policy director at the Brussels-based industry lobby EuropaBio. "What they want is certainty."

At issue are the consumption targets and the sustainability criteria that will, presumably, frame Europe's biofuels policy for the next decade or more. Energy security has been the main driver of US biofuels policy, whereas in Europe, reducing greenhouse gas emissions has received more focus. The various institutions involved in the debate have proposed different thresholds for achieving reductions in greenhouse gas emissions. The European Commission recommends that all biofuels attain a minimum 35% reduction in carbon emissions compared with fossil fuel usage. In September, the European Parliament proposed a 45% threshold, rising

to 60% by 2015. Such a regime would favor innovative technologies, but EuropaBio fears that it could hamper the development of a market for first-generation biofuels before their second-generation successors can emerge. It is already clear that Europe will not reach a target set in an earlier piece of legislation, the biofuels directive 2003/30/EC, which called on member states to ensure that biofuels accounted for 5.75% of their total transport fuel consumption by the end of 2010. "We're now at 2.5% or something like that," says Carrez. Moreover, the European Parliament is also proposing a policy review in 2014, which could, theoretically, overturn a long-term target of a 10% share by 2020.

The silver lining to the current cloud of uncertainty is that Europe's focus on sustainability could turn out to be a strength in the long run. "My own belief is that it prepares Europe well for the future, because it's an issue that needs to be addressed," says Jonathan Johns, head of Ernst & Young's UK renewable energy group. "I just think the food-versus-fuel issue isn't going to go away." Achieving a smooth transition to sustainable supplies of biofuels will be crucial. "My worry is you could spoil the distribution of biofuels," he says. "[If] the market gets spoiled, this becomes known as the technology that didn't work."

So far, there has been little linkage between Europe's failed agricultural biotech policy and its emerging biofuels policy, but the two will, inevitably, collide at some point. "It has implications. We cannot hide from it," says former EuropaBio director general Johan Vanhemelrijck, a veteran

## SELECTED research collaboration

Partner 1	Partner 2
AFFIRIS (Vienna)	GlaxoSmithKline (London)
Lpath (San Diego)	Merck Serono (Geneva)
ImmunoGen (Waltham, Massachusetts)	Bayer (Leverkusen, Germany)
Cellartis (Gothenburg, Sweden)	Novo Nordisk (Bagsvaerd, Denmark)/Lund University (Sweden)

\* Financial details not disclosed.