IN brief

Industry gains on money-back schemes

Risk-sharing agreements that assess innovative drugs based on long-term cost effectiveness may not be helping governments save money, a new study suggests. "In the short term, it's been to [industry's] advantage," says lead investigator Mike Boggild, a neurologist at The Walton Centre in Liverpool. In 2002, the UK government entered a 'risk-sharing' agreement over five multiple sclerosis drugs that the UK's National Institute for Health and Clinical Excellence (NICE) had deemed too expensive. NICE reversed its decision after drug makers dropped their prices and agreed to reimburse government if the drugs did not prove cost effective in the long term. The study results based on two-years' data suggest that the drugs are not cost effective, although Boggild warns it is too early to draw firm conclusions. "The cost effectiveness of the drugs can go in either direction, depending on which assumptions we use," he says. This type of scheme is inherently difficult to run, adds Jon Nicholl, director of the Medical Care Research Unit at Sheffield University, UK, because stakeholders have conflicting interests: the state wants to reduce costs, whereas industry wants to maximize profits. A different approach, in which firms refund treatment costs for nonresponsive patients, may be a better way to improve cost effectiveness, he says. *Asher Mullard*

$2 million rice verdict against Bayer

A St. Louis district court has ordered Bayer CropScience to pay over $2 million in compensatory damages to two Misssouri-based rice farmers whose crops cross-bred with the company's genetically modified (GM) LibertyLink during field testing. When the unwanted presence of transgenic rice was discovered in 2006, several countries halted US rice imports, which led to farmers' economic loss and prompted more than 1,000 similar lawsuits against Bayer CropScience, whose US operations are based in The Research Triangle Park, North Carolina. This first trial, whose verdict was issued last December, has been called a bellwether case. "We are studying the court's award of monetary damages in detail and are considering our options," says Richard Breum, corporate spokesperson for Bayer CropScience in Monheim, Germany. "Since each case is different, we evaluate each separately. Last year the court ruled against the plaintiffs in their efforts to obtain class action status in the litigation, noting overall differences in individual plaintiff's situations and claims." In 2007 the US Department of Agriculture (USDA) decided against pursuing enforcement action against the company. It noted that investigators within the Animal and Plant Health Inspection Service (APHIS) at USDA were "unable to make any definitive determinations" about the inadvertent release, during field trials, of two varieties of LibertyLink rice that then mixed with commercial rice crops in Missouri and several neighboring states. *Jeffrey L Fox*

Biorefineries' stimulus win

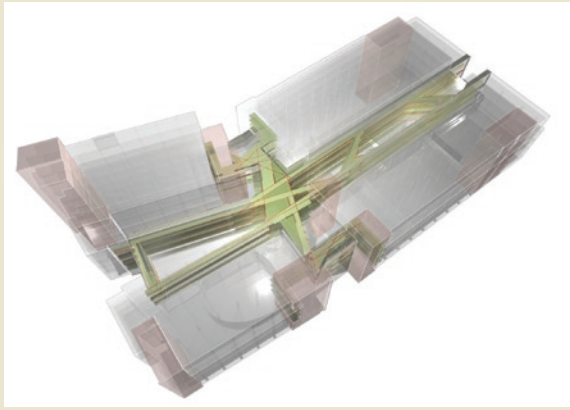
Nineteen start-ups have landed the bulk of federal stimulus funding earmarked for industrial biofuel and biomass programs. The US Department of Energy (DOE) in December announced $564 million in funding towards the building and operating of facilities that convert next-generation feedstocks such as switchgrass and wood chips into fuels and products. Grants range from $2.5 million to $81.1 million each (**Table 1**), which dwarf funds allocated to related areas such as plant genomics research. Small-scale or pilot facilities will receive up to $25 million, demonstration scale $50 million, and one company, Bluefire Ethanol in Irvine, California, more than $81.1 million to build a commercial plant. Amyris Biotechnologies, for example, will add its $25 million to the $165 million investment money it has accrued over the last 7 years. The Emeryville, California–based company will use the stimulus grant to expand its pilot facility, explore feedstocks for making renewable hydrocarbons and scale-up production of both fuel and biobased chemicals, says Kinkead Reiling, cofounder. But the money is not intended to cover all biorefinery building costs—the DOE expects grant winners collectively to match prize funds with at least $700 million in nonfederal investment. "[The grants] can boost investor confidence in those projects and allow companies to attract the full amount of the funding needed to get the project done," says Paul Winters, a spokesperson for the Biotechnology Industry Organization in Washington, DC. Adds Reiling, "It's an excellent shot in the arm for the industry, but compared to the size of the problem [energy crisis], it's small." The stimulus bill, known as the American Recovery and Reinvestment Act, was passed in February 2009. *Emily Waltz*

Table 1 Selected biofuel companies receiving US stimulus funds

Company /location	Grant ($ million)	Project description
Bluefire[a]/California	81.1	To construct a facility that produces ethanol fuel from woody biomass, mill residue and sorted municipal solid waste. The facility will have the capacity to produce 19 million gallons of ethanol per year and will be in Fulton, Mississippi.
BioEnergy International[b]/ Lake Providence, Louisiana	50.0	To produce succinic acid from sorghum. The biological process being developed displaces petroleum-based feedstocks and uses less energy per ton of succinic acid produced than its petroleum counterpart.
Enerkem[b]/ Pontotoc, Mississippi	50.0	Located at an existing landfill, this project will use feedstocks such as woody biomass and biomass removed from municipal solid waste to produce ethanol and other green chemicals through gasification and catalytic processes.
INEOS New Planet BioEnergy[b]/ Vero Beach, Florida	50.0	This project will cultivate algae in ponds that will ultimately be converted into green fuels, such as jet fuel and diesel, using the Dynamic Fuels refining process.
Sapphire Energy[b]/ Columbus, New Mexico	50.0	To cultivate algae in ponds that will ultimately be converted into green fuels, such as jet fuel and diesel, using the Dynamic Fuels refining process.
Algenol Biofuels[c]/ Freeport, Texas	25.0	To produce ethanol directly from carbon dioxide and seawater using algae. The facility will have the capacity to produce 100,000 gallons of fuel-grade ethanol per year.
UOP[c]/ Kapolei, Hawaii	25.0	To integrate existing technology from Wilmington, Delaware–based biofuels firm Ensyn and UOP to produce green gasoline, diesel and jet fuel from agricultural residue, woody biomass, dedicated energy crops and algae.
ZeaChem[c]/ Boardman, Oregon	25.0	To use purpose-grown hybrid poplar trees to produce fuel-grade ethanol using hybrid technology. Additional feedstocks such as agricultural residues and energy crops will also be evaluated in the pilot plant.
HALDOR TOPSOE[c] /Des Plaines, Illinois	25.0	To convert wood to green gasoline by fully integrating and optimizing a multi-step gasification process. The pilot plant will have the capacity to process 21 metric tons of feedstock per day.
ICM[c]/ St. Joseph, Montana	25.0	To modify an existing corn-ethanol facility to produce cellulosic ethanol from switchgrass and energy sorghum using biochemical conversion processes.
Amyris Biotechnologies[c]	25.0	To produce a diesel substitute through the fermentation of sweet sorghum. The pilot plant will also have the capacity to coproduce lubricants, polymers and other petrochemical substitutes.

[a]Increased funding to existing biorefinery projects. [b]Demonstration scale. [c]Pilot scale. Source: US Department of Energy

Purpose-built chromosome



"It's functional, and also a very good metaphor for what the center is trying to achieve." Larry Malcic, one of the architects of London's UK Centre for Medical Research and Innovation (UKCMRI), says scientists exclaimed, "that's a chromosome," when he presented the building designs without knowing its symbolic significance. The new $978 million UKCMRI is being built in central London as a partnership between University College London, Cancer Research UK, the Medical Research Council and the Wellcome Trust. It will house four leading science organizations to conduct biomedical research on genetics, stem cells and common diseases, and is expected to open in 2015. (*Times*, December 8, 2009)

IN their words

"They just wait until WHO [World Health Organization] says 'pandemic' and activate the contracts." Wolfgang Wodarg, a member of the German Social Democratic Party and chair of PACE health committee, conveniently shifts blame for Germany's surplus H1N1 vaccine stocks on to the companies that redirected resources and expertise to make a product available in just a few months. (*Pharma Times*, January 4, 2010)

"These sweetheart deals are being done on the backs of consumers. From the perspective of the Federal Trade Commission, [they] are one of the worst abuses across the board in healthcare and should be stopped." Federal Trade Commission (New York) chairman Jon Leibowitz will press for a provision in the healthcare reform bill to end deals in which brand-name drugmakers pay generic producers to delay copycat versions of best-selling meds. (*New York Times,* January 12, 2010)

"The pharmaceutical industry has destroyed so much institutional knowledge over the last decade that it makes the Taliban, blowing up temples, look like high school pranksters." Anonymous blogger. (*In the Pipeline*, January 12, 2010)

"Cannibalism is rife within the biotech industry!" Barry Canton, a cofounder of Ginkgo Bioworks (Boston), on how his and other companies are acquiring equipment castoffs from universities and other companies from online auctioneers. (*The Boston Globe*, January 4, 2010)

IN brief

FDA balks on MedImmune's cell-grown flu vaccine

The shift towards new cell culture–based flu vaccine production has been dealt a blow as MedImmune of Gaithersburg, Maryland, puts its manufacturing efforts on hold. The AstraZeneca subsidiary took this step after the US Food and Drug Administration (FDA) requested follow-on studies that would substantially increase the cost and time to market beyond what the company expected. In its contract with the Department of Health and Human Services (HHS), MedImmune proposed an efficacy study comparing immune responses in volunteers receiving cell-produced with those receiving egg-produced vaccines, considering them genetically identical, followed by a large safety trial. But the FDA termed cell-grown vaccine a new product, requesting Medimmune conduct a clinical trial during an influenza season, as well as demonstrate efficacy in adults before vaccinating children. The plan "became cumbersome and complicated and did not address significant scientific and medical issues we thought we needed to address to advance this vaccine," says George Kemble, vice president of vaccine R&D at MedImmune. "I don't think there is any deliberate delay," says Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases, noting the move is due to safety and efficacy data gathering. Jose Romero, member of the FDA vaccine advisory committee, comments in an unofficial capacity, "General FDA concerns include exposing humans to adventitious agents that might be lurking in cell lines or the remote possibility of transmitting an oncogene that could create cancer in a human host." Elsewhere, last November, Novartis of Basel inaugurated a $1 billion cell culture flu vaccine manufacturing facility in partnership with the HHS. The plant in Holly Springs, North Carolina, is the first large-scale cell culture flu vaccine and adjuvant production facility in the US. *Wendy Wolfson*

SELECTED research collaborations

Partner 1	Partner 2	$ (millions)	Details
Alopexx Pharmaceuticals (Cambridge, Massachusetts)	Sanofi-Aventis (Paris)	375	Sanofi-Aventis will pay Alopexx for rights to codevelop a monoclonal antibody (mAb) for treating *Escherichia coli*, *Staphylococcus aureus* and other infections. Alopexx receives an upfront payment, research funding and is eligible for milestone payments that could reach $375 million in total, plus royalties. Sanofi will have the option to license the product, which will be in phase 1 trials in 2010.
Seattle Genetics (Bothell, Washington)	Millennium/ Takeda (Osaka, Japan)	290	Millennium will pay $60 million upfront, plus milestones that could exceed $230 million, to codevelop Seattle Genetics' brentuximab vedotin (SGN-35). The antibody drug conjugate composed of an anti-CD30 mAb and monomethyl auristatin E is currently in a pivotal phase 2 trial to treat relapsed and refractory Hodgkin's lymphoma. Under the agreement, the Takeda Group keeps commercial rights to the drug outside the US and Canada where Seattle Genetics retains full rights.
Athersys (Cleveland)	Pfizer (New York)	111	Pfizer will pay Athersys $6 million initially and up to $105 million in the future for rights to develop Athersys's stem cells to treat ulcerative colitis and Crohn's disease. The product, MultiStem, consists of multipotent adult progenitor cell, and is in early clinical trials for heart attacks and in cancer patients receiving bone marrow transplants.
Syngenta (Basel)	CSR Sugar (Melbourne, Australia)	*	Syngenta has acquired exclusive global rights, excluding Australia, to CSR Sugar's SugarBooster, a transgenic technology to develop cane plants with high sugar content. The license agreement includes milestone payments and royalties on product sales to CSR Sugar. The terms of the deal were not disclosed.

*Financial details not disclosed.