Personalized reimbursement

Revenue for pharmacogenomic testing is expected to grow ~25% a year from 2004 to 2011, according to the report "US Genetic Diagnostics Market" released in October by consultancy Frost and Sullivan of San Antonio, Texas. Current reimbursement policies, however, are discouraging the development of tests that help match patients to therapies, according to panelists at the Burrill and BIO Personalized Medicine Meeting on October 18 in San Francisco. Whereas drugs are reimbursed according to their clinical value, diagnostic tests are typically reimbursed according to how they are manufactured. That means that tests can still be reimbursed at very low rates even if expensive clinical trials show huge medical benefits. Frost and Sullivan analyst Martin Nejat says the problem is significant. "Clinicians, patients, testing laboratories and test manufacturers are likely to stay away from tests that are not reimbursed to a high degree." But the Centers of Medicare and Medicaid Services (CMS) of the US Department of Health and Human Services is still unsure what kinds of evidence it wants to see [from manufacturers] when making coverage decisions. CMS head Mark McClellan said at the meeting he is very interested in supporting targeted treatments, but that relevant studies are still being done. Biotech investor Steve Burrill also said CMS, whose policies are generally adopted by private insurance companies, will do more to shape personalized medicine than FDA will, perhaps allowing non-US markets to adopt personalized medicine further. "The reimbursement arena is the gatekeeper," he remarked, so an effective test without the right codes won't get reimbursed. *MB*

China OKs oncolytic adenovirus

The State Food and Drug Administration of China in Beijing approved a new drug license for H101, an oncolytic adenovirus treatment, on November 4. The combination of H101 and chemotherapy was reported to be effective in 78.8% of tested patients with head-and-neck squamous-cell carcinoma. Developed by Shanghai-based Sunway Biotech, this first second generation gene therapy treatment uses a recombinant oncolytic adenovirus type 5 that is defective in the expression of the *E1B-55K* gene and destroys cancer cells deficient in the tumor suppressor gene *TP53* in which it can replicate, but not normal cells that have a functional *TP53* pathway. H101 is the same tumor-specific, replication-competent adenovirus as that previously developed by Onyx Pharmaceuticals (ONYX-015), clinical development of which was discontinued in 2003, ostensibly due to lack of funds. In January, Onyx received $1 million from Sunway to license ONYX-015, with additional payments likely for achieving clinical benchmarks and royalties on net sales. H101 joins Shenzhen-based SiBiono GenTech's Gendicine, an adenoviral gene therapy already marketed in China for head-and-neck cancer that delivers *TP53* to tumors, inducing apoptosis and death (*Nat. Biotechnol.* **22**, 3–4, 2004). According to Fang Hu, president of Sunway, the new treatment has a clear targeting mechanism and kills cancer cells caused by mutations of genes in addition to *TP53* . The new drug is expected to become commercially available in the first quarter of 2006. *HJ*

News in Brief written by Monya Baker, Hepeng Jia, Hanna Meerveld, Peter Mitchell, Peter Vermij & Emily Waltz

First biofuel-powered train unveiled in Sweden

Kalle Rimling

On October 24, 2005 SvenskBiogas, a wholly-owned subsidiary of the Swedish public utility company Tekniska Verken i Linköping, Sweden's largest producer of gas from biomass for use in transport, launched the country's first biogas-fueled train to service stations between Linköping and Västervik. The new train, refitted with engines capable of combusting a 97% methane mixture, will run once daily, covering the 80 kilometers between the coastal towns. Its fuel will be produced in Linköping, where, this year, anaerobic digestion tanks converted roughly 27 metric tons of slaughterhouse by-products, 13 tons of redundant plant material and 10 tons of human waste into 5 tons of vehicle fuel and 45 tons of fertilizer, according to Carl Lilliehöök, managing director of SvenskBiogas. Animal waste, the fuel's main component, was composed of unused organs and fat from about 700 cows. He adds that the SvenskBiogas plant has proven sufficiently efficient and reliable to fuel a growing fleet of vehicles, including local city buses and taxis. In November, SvenskBiogas commenced construction of a second, corn-digesting plant, in Norrköping, Sweden. "Having received visitors from California, Canada, Argentina, Ireland, the UK and Uganda, we hope to be ready to start exporting the technology within a year," says Lilliehöök. *PV*

French government tech fund

The French government launched another investment initiative in October to fund the country's biotech startups. But this time, companies at all stages of development are eligible for the money. The 150 ($175) million fund, called the Technology Fund of Funds (FFT), will support 9–12 venture capitalists (VCs) who will each invest in 10–12 startups. The two funding initiatives in the past instructed VCs to invest 60% of their money in companies that were less than seven years old. But this time the rules have been relaxed and VCs can invest in companies in later stages of development. "The French market has matured," says Pascal Lagarde, managing director of Caisse des Depots, a government-supported financial institution that is partially funding the initiative. Funding should reflect the changes, he says. "It's a good step," says Phillippe Pouletty, president of France Biotech, the French biotech association and lobbying group. "But by itself, it's not going to improve the position of private equity in Europe. There are other pieces to the puzzle." Those pieces, he says, include a proposed 6 ($7) billion funding of a private equity fund, typically funded by venture capitalists and built on money from pension fund companies, stock market equity, tax incentives and better allocation of academic funding. Money for the FFT project comes from Caisse des Depots, the European Investment Bank and the French government. The two previous funds, the Public Venture Capital Fund in 1998 and the Venture Capital Promotion Fund in 2000, have financed 492 companies to date, according to Lagarde. *EW*

UK tropical disease drug unit

Scotland's Dundee University has set up an in-house drug discovery unit to bring drug candidates against tropical diseases through to the clinical stage. The project, which has received £12 ($21) million in charitable funding, including a £9 ($14)-million grant from the Wellcome Foundation, is believed to be the first of its kind. It will recruit experts from industry in all the major disciplines of drug discovery, paying industry-level salaries. David Glover, former medical director of biotech company Cambridge Antibody Technology, says the initiative is addressing a "vital but largely neglected area of drug research." The attrition rate for anti-infective drugs in development is significantly less than other major therapeutic areas. "Once in the clinic they could have better than average prospects of getting eventual approval," Glover adds. If Dundee succeeds in its preclinical work, it will try to get the product into clinical research through a public-private partnership, working with an institution like the Institute of One World Health or the Gates Foundation. The university will keep any intellectual property from the research but will have to consult Wellcome on licensing decisions. Wellcome expects the Dundee group to attract extra charitable funding during the project's expected five-year lifetime, and does not exclude refinancing the project. *PM*

Chiron acquired by Novartis

Novartis entered the vaccine market with its takeover of US vaccine maker Chiron of Emeryville, California, on October 31. With a $5.1-billion bid, Swiss giant Novartis of Basel bought the 58% of Chiron shares it didn't already own. Novartis could have either left Chiron alone or decided to protect its 42% share investment by acquiring Chiron in the belief that it could bring value to Novartis. "Novartis isn't acquiring Chiron for their biopharmaceutical business," comments Aaron Geist, a senior research analyst at Robert W. Baird and Co. in Milwaukee, Wisconsin. "They're acquiring them for their vaccine and blood screening business." Now that "the government is taking flu and infectious diseases much more seriously than they have in the past," adds Geist, "it mitigates the risk." The deal came just two weeks after the US Food and Drug Administration announced it would allow Chiron's flu vaccine, Fluvirin, back on the US market. Chiron's license to distribute the vaccine in the US had been suspended since October 2004, when regulators discovered the company's Fluvirin manufacturing plant in Liverpool, UK, had been contaminated (*Nat. Biotechnol.* **23**, 1191, 2005). The blow forced Chiron to miss out on revenues from last year's flu season. *EW*

Bioprospecting below zero

Marbank, a new biobank focusing on cold-adapted marine organisms, funded by the Norwegian Ministry of Fisheries and Coastal Affairs, was launched at the University of Tromsø in Norway, late October. An associated high-throughput screening facility, called Marbio, was set up to screen samples from the icy waters north of Spitsbergen, ~80° north latitude, for biologically active compounds. Marbio is funded by the Norwegian Research Council, the University of Tromsø and industry as part of an eight-year-long research program. Local biotechs including immuno-modulator firm Biotec Pharmacon, anti-infective play Lytix Biopharma and nutraceutical company Probio have pooled their efforts with Madrid-based Pharmamar, which specializes in marine-derived drugs, in funding 25% of the €15–24 ($17–28) million effort. In return, these companies get exclusive access to the Marbank compounds for defined periods, first rights of refusal on any compounds within their area of interest and the possibility of having those compounds characterized. Researchers also hope to find new tools for molecular biology to follow. "These molecules are user friendly. When a molecule has done its job and you want to get rid of it—just increase the temperature," says professor Trond Jørgensen of the Institute for Marine Biotechnology in Tromsø. *HM*

Selected research collaborations

Partner 1	Partner 2	$(million)	Details
OncoTherapy Science (Tokyo)	BioWa (Princeton, NJ), a subsidiary of Kyowa Hakko Kogyo (Tokyo)	*	A partnership to identify and develop monoclonal antibodies (mAbs) to treat cancer. OncoTherapy will identify cancer antigens and generate mAbs against them. BioWa will apply its technology that enhances antibody-dependent cellular cytotoxicity, to the mAbs to harness the human immune system in the fight against cancer cells. The partners will share profits from future antibody products on a 50-50% basis.
Alcon Laboratories (Fort Worth, Texas)	Dharmacon (Lafayette, CO), a subsidiary of Fisher Scientific International (Hampton, New Hampshire)	*	A partnership to develop a new class of RNAi therapeutics for ophthalmic diseases. Alcon and Dharmacon will select gene targets to pursue. Dharmacon will use its small interfering RNA technologies to develop compounds as drug candidates. Dharmacon is eligible for milestones and royalties.
Agensys (Santa Monica, California)	Sanofi Pasteur (Lyons, France), the vaccines subsidiary of Sanofi-Aventis Group (Paris)	*	A collaboration to develop vaccines directed at colorectal and prostate cancers. Agensys will select and characterize the cancer targets from its portfolio, and Sanofi will validate these targets and develop vaccine products. Sanofi retains an option to exclusively license worldwide rights for up to six targets.

*Financial details not disclosed *EW*