# More gene therapy mergers

Two of the more established gene therapy companies have found independence too expensive. In mid-January, Somatix (Alameda, CA) was acquired by Cell Genesys (CG, Foster City, CA) in a tax-free, stock-for-stock "merger," while Novartis (Basel, Switzerland) bought the remaining 27% of SyStemix (Palo Alto, CA) that it did not yet own, for $76 million.

Somatix was one of the oldest gene therapy companies (founded in 1988 on work from the laboratory of Richard Mulligan at Massachusettes Institute of Technology). Through development and acquisition—of cell therapies from Hana Laboratories in 1990, retroviral vectors from Genesis in 1991, and adenoviral and adeno-associated viral vectors from Merlin Pharmaceuticals in 1995—Somatix had become technology-rich. But it needed a new partner to fund the costly phase III trials of its only clinical product, the GVAX melanoma vaccine, and Somatix had only $9.7 million in the bank and a $21 million burn rate per year. Its earlier partner, Bristol-Myers Squibb (Syracuse, NY), concerned that GVAX therapy for advanced melanoma might not be cost effective and might in any case be superseded by Somatix's own allogeneic approach, had not renewed its collaboration agreement.

Enter capital-rich CG, a company with $85 million in the bank, an oncology program with two products headed for the clinic and two ex vivo gene therapy treatments for AIDS in phase II testing, funded by a $150 million deal with Hoechst Marion Roussel (HMR, Kansas City, MO) struck in late 1995. Before the January merger, CG's gene therapy portfolio was spare, consisting of a number of proprietary genes, a few vectors, a gene activation technology that is the subject of a second deal with HMR, stem cell technology, and a T-cell therapy platform. In 1996, it decided to focus on gene therapy, according to Tom Smart, former director of business development at CG, and now at GenVec. To that end, it spun out its monoclonal antibody program into a new company, Abgenix, and curtailed its protein and cell therapy programs.

The acquisition of Somatix will add adenoviral, AAV, and retroviral technologies and cell therapy technologies to CG's portfolio. CG's CFO Kathy Glaub says that the company will consolidate the two companies' stem cell programs, file an investigational new drug application in the second quarter of 1997 for its own cancer program, and change the GVAX vaccine's target from melanoma to lung or prostate cancer, using an adenoviral vector. Switching target and vector should reduce transfection time, thereby cutting costs and rendering the vaccine more "economically attractive" to potential partners, Glaub adds. The new GVAX vaccine should begin trials this year. Somatix, however, will lose half of its 85 employees and the rest will move to Foster City.

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Novartis' acquisition of SyStemix is the final completion of a takeover by degrees. In October 1996, SyStemix' board and shareholders had rejected an earlier bid of $17 per share as too low. The offer they accepted in January was worth $19.5 million.

"The price of these two deals is an indicator of a broad and continuing interest in gene therapy," says Rick Waldron, CFO of GeneMedicine (The Woodlands, TX), a company that has remained independent. When a gene therapy company teams up with just one large pharmaceutical company, "it is most likely to end up as an acquisition," he observed, "which is why we, and other gene therapy companies like us, have a number of partnerships." Corange (Bermuda), the parent company of Boehringer Mannheim (Mannheim, Germany) spend $4 million to increase its shareholding in GeneMedicine, to 10% of the company's shares.

*Vicki Brower*

# Human xenotransplants banned in UK

There will be no clinical trials of transplanting pig organs in humans in the United Kingdom, at least for the time being. That was the conclusion of a report published in mid-January from the UK's Advisory Group on the Ethics of Xenotransplantation. Meanwhile, the talking continues. The government reaction to the "unanswered questions" posed in the report was to form a Xenotransplantation Interim Regulatory Authority, and to appoint Lord Habgood of Calverton—formerly the Archbishhop of York—to head it. The interim body will regulate development until primary legislation is introduced. Stephen Dorrell, secretary of state for health, said "It is essential that the risks associated with xenotransplantation are better understood before the technique is used in humans."

The UK's leading xenotransplantation company has welcomed the move. "We've been beating on the door of government for a couple of years," says David White, formerly of Imutran, a company now owned by Novartis (Basel, Switzerland). According to David Shapiro of the Nuffield Council on Bioethics, a privately funded body that produced a report on the ethics of xenotransplantation in March 1996, it was the prospect that Imutran might try to enter the clinic in 1996 with a pig-to-human heart transplant that prompted the government to appoint Ian Kennedy, Professor of Medical Law and Ethics at Kings College, London, to head the advisory commission that has just filed its report.

Dorrell is taking most of the Kennedy commission's advice, placing great emphasis on protecting the public from the emergence of zoonotic diseases. Recent incidents involving the apparent transmission of bovine spongiform encephalopathy from cows to cause Creutzfeldt-Jakob disease in humans, has made British policy-makers particularly sensitive to zoonoses. The panel called for more research into the risk to humans of pig pathogens, particularly endogenous porcine retroviruses. The disease risk has long been anticipated by companies raising transgenic pig herds, "We always planned for the preclinical studies to assess risk," says Imutran's White.

The UK's proposed regulation, which involves a centralized authority, contrasts in part with US regulations. which has already permitted some cellular transplant protocols to go forward. Although the US Food and Drug Administration (Rockville, MD) does require that any clinical studies involving xenogenic cell, tissues, and organs be performed under an investigational new drug application, the initial responsibility for developing protocols rests with the clinics' own safety and ethics committees (such as those dealing with biosafety or experimental animals).

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*The UK Department of Health is inviting comment on the Government Response to the Kennedy Report until April 17, 1997.*