# MEDICAL DEVICE DAILY™

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*As Congress headed for home . . .*

## Radiology scanning fails to win roll-back of payment reductions

**By MARK McCARTY**
***Medical Device Daily* Washington Editor**

WASHINGTON — As the 109th Congress drew its last breaths — or some might say, gasps — it cobbled together various measures designed to deal with some of the healthcare funding dilemmas that dotted the legislative calendar all year long, some in connection with the Deficit Reduction Act (DRA) of 2005.

Makers of scanning equipment will head home for the holidays with coal in their stockings. Congress did not roll back the impending cuts to payments for imaging services that the DRA imposed on the **Centers for Medicare & Medicaid Services**. H.R. 5704, introduced by Rep. Joe Pitts (R-Pennsylvania), would have suspended the cuts for two years (*Medical Device Daily*, July 7, 2006), but despite substantial support in the House, the bill never flew.

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*Financings roundup*

## Artes Medical seeking $51.8M via IPO of 4.6 million shares

**By HOLLAND JOHNSON**
***Medical Device Daily Associate* Managing Editor**

**Artes Medical** (San Diego), a developer of products used by dermatologists and cosmetic surgeons, reported filing for a 4.6 million share initial public offering.

The company, which makes the ArteFill micro-injectable product that combines bovine collagen and synthetic microspheres to treat nasolabial folds (that is, smile lines) estimated the net offering proceeds from this offering will be about $51.8 million — or $60.2 million if the underwriters exercise their over-allotment option in full. The figure is based on an assumed share offering price of $13, the mid-point of the stated share price range.

Artes said it intends to use the net proceeds from this offering to build its sales and marketing organization and implement promotional and advertising campaigns related

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*Report from Europe*

## EU grant supports IDIBAPS project to develop DNA chip

**A *Medical Device Daily* Staff Report**

The European Union, through the Sixth Framework Program, has approved a project led by **IDIBAPS-Hospital Clinic**, with the aim to validate the IBDchip (Inflammatory Bowel Disease DNA Chip) within the European Community

It is said to be the world's first diagnostic DNA chip, and has the main object to predict prognosis and response to therapy of patients suffering from inflammatory bowel disease. The program has a EUR 2.5 million budget for the next three years for conducting several studies, including a total of 3,000 to 4,000 patients in seven European countries.

A consortium that includes seven European centers in inflammatory diseases and genetics; an enterprise with the technology for manufacturing the chip; and an enterprise in laser technology, in charge of optimizing the reading of the chips, has been created for conducting this project.

The consortium is coordinated by Dr. Miquel Sans,

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*Back-stopping new drugs*

## Singulex developing troponin test for earlier detection of AMI

**By KAREN YOUNG**
***Medical Device Daily* Staff Writer**

Earlier this month, **Pfizer** (New York) reaped a large number of negative headlines when it reported that it had to stop its Phase III ILLUMINATE trial of a new drug that it had expected to raise good cholesterol, the halt due to an increased rate of death in those receiving only the investigational drug torceptrapib.

**Singulex** (Hayward, California), a small biotechnology company, is working on a troponin assay that a new paper demonstrates has promise in detecting the well-known biomarker for heart damage in normal patients. The company plans ultimately to offer the assay both to pharmaceutical companies for clinical trial monitoring of adverse heart events and therefore to avoid disappointments, such as those by Pfizer, at a late stage in drug development — within two to three years — for clinical diagnostics.

Additionally, pharmas are increasingly calling for such

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## Singulex

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assays for testing of patients to determine potential adverse reactions to an approved drug — a development their liability attorneys probably are actively urging.

Current assays, can typically detect a heart attack four hours or more following a heart attack.

The paper on this assay, the Erenna Bioassay System, just published in *Clinical Chemistry*, features research by Alan Wu, PhD, professor of laboratory medicine at **University of California, San Francisco**. Singulex evaluated Erenna's performance in specimens from healthy individuals and patients with chest pain.

Study findings showed the presence of cTnI in the blood of healthy individuals, established normal baseline concentrations of cTnI, and demonstrated that Singulex's Erenna assay platform was able to detect small changes in concentration levels of cTnI, which could be an early indicator of AMI that is below the current and standard detectable limit of 350ng/L.

Restated, the assay is designed "to incorporate direct, single-molecule detection technology with customized clinical assays that are capable of quantitatively detecting 'therapeutically significant' biomarkers at sub-picogram concentration levels," the company said.

Singulex plans to offer the troponin assay along with an "assay menu" to pharma companies in Q107 via its Erenna platform, Philippe Goix, president/CEO of the company, told *Medical Device Daily*.

"We need to continue to expand on the . . . clinical value of troponin," Goix said, saying that the company's strategy will be to enter into a collaboration with a "top medical institution" to further investigate the biomarker.

Singulex also hopes to develop its troponin assay for clinical diagnostic use, and it will "definitely be available for collaboration tied to the diagnostic focus," Goix said.

The company already has developed more than 75 assays for protein and metabolite biomarkers. Singulex also has developed customized assays for pharma companies. All of these assays are available now to pharma companies and universities through the companies Early Technology Access Program, or eTAP.

The Erenna Bioassay System, to be launched next year, will feature a menu of assays derived from these.

The research conducted by Wu and his colleagues "offers preliminary clinical results for the use of Singulex' customized Erenna assays in the early detection" of heart attack, or acute myocardial infarction (AMI) and demonstrates diagnostic capabilities that meet recently redefined criteria for AMI diagnosis as outlined and recommended by the **European Society of Cardiology** (Sophia Antipolis, France) and the **American College of Cardiology** (ACC; Bethesda, Maryland).

According to Wu, results of this preliminary clinical study show that with the use of a high-sensitivity assay, there are detectable troponin concentrations in the sera of health individuals in a "Gaussian distribution" (essentially a normal bell-curve distribution somehow associated with German mathematician Carl Friedrich Gauss).

He also noted that the data suggest that a high-sensitivity assay can detect the presence of AMI earlier than with a conventional cTnI assays. It may also identify more subjects at risk for future adverse events, particularly important not only in a clinical setting but in the clinical trial procedures of pharma companies.

"During this collaboration, I was very excited . . . that we were able to measure troponin I in normal [people]. And no one has been doing that before — no one,"Goix told *MDD*.

Still, he acknowledges that Singulex does not have all the answers yet, but he said the company wants to continue to expand on this academic study and demonstrate results in a larger trial.

Goix said he was "intrigued and excited" by the potential of the company's technology to "add the clinical utility in a diagnostic setting."

In a nod to the many and much-discussed efforts characterized as personalized medicine, Goix said, "The reason why we want to bring this capability . . . is that if you develop a diagnostic along with a drug," there would be a clinical action "tied to the diagnostic, so we feel that would be even more powerful." ■

## Europe

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Partnering with the ALS Association are **Galapagos** (Mechelen, Belgium) and **Stem Cell Innovations** (SCI; Leiden, the Netherlands/Houston). Funding is contingent on the companies' success at specific points in the project.

"The unique ability provided by SCI to screen human motor neurons at large scale, and Galapagos' target discovery engine, will open new approaches to developing medicines that may stop ALS," said Lucie Bruijn, science director and vice president of the ALS Association. "We see this alliance as an important initiative within The ALS Association's mission to find a cure for and improve living with ALS."

Stem Cell Innovations has a human stem cell technology based on cells that are exempt from the presidential ban in the U.S. These pluripotent stem cells are able to produce motor neurons that can grow robustly in the lab.

"The human motor neuron cultures derived from our PluriCells will form the basis of this exciting alliance," said SCI's CEO, James Kelly.

Galapagos has a technology that brings in or removes, in turn, large numbers of genes to lab-grown cells that reflect aspects of a disease of interest. This identifies which genes might serve as drug targets in the disease. The Galapagos technology will be applied to the SCI motor neuron cells. ■