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BUSINESS

about the approval process by publishing draft guidelines for tests that use multiple biomarkers. Yet to be finalized, the regulations make an important distinction: class II tests, which are merely diagnostic or prognostic, can be validated using trials on tissue-bank samples. But class III tests, which are those that also indicate which therapies should be used, must undergo a more costly trial in which patients are tracked in the future.

The shallow pockets of most diagnostic testing companies can't support the multimilliondollar costs of even the class II trials. "You need pushers and drivers to develop biomarkers," says Pat Price, a clinical researcher for Cancer Research UK at the University of Manchester, "and those are usually the drug companies." Price predicts that the drug industry will become steadily more interested in biomarkers as it comes to see its future in more segmented markets for drugs effective in particular genetic subpopulations. She says that, in general, the middle ground between biomarker discovery and the clinic is neglected by funding agencies and so is unattractive to researchers.

The EDRN is an exception — but it spends its \$28-million budget validating only diagnostic or prognostic biomarkers. According to Pass in New York, collaboration with the network has been invaluable to develop early detection biomarkers for mesothelioma. He and others are now pushing for the EDRN to develop biomarkers for therapeutic prediction to complete the continuum of treatment.

Murray Robinson, a senior vice-president at AVEO Pharmaceuticals in Cambridge, Massachusetts, says that the success of Herceptin has made parts of the pharmaceutical industry sit up and take notice.

Larger companies, such as Roche of Switzerland, are vigorously exploring the co-development of biomarkers for particular diseases and drugs to treat them. That approach may have diminished the firm's interest in stand-alone tests developed by smaller companies. René Bernards, chief scientific officer of Agendia, a cancer-diagnostics company in Amsterdam, is disappointed by the lack of interest drug companies have shown in his firm's test. MammaPrint, which predicts the likelihood of breast-cancer recurrence, is the first multigene prognostic test to be approved by the FDA.

"If it's clear that the FDA is going to regulate this space of biomarkers, and ours is the only company to clear a multigene biomarker through the FDA, you would think a few large pharmaceutical companies would want to collaborate," he says. But Bernards is still waiting for someone to bite; and patients may wait many years yet for the true dawning of the age of personalized medicine.

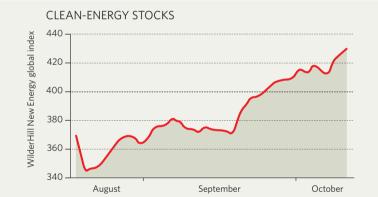
IN BRIEF

SCORING HIGH Pharmaceuticals have surpassed computing and electronics hardware as the industry sector declaring the biggest total global investment in research and development (R&D), according to an annual scoreboard published by the European Commission. The scoreboard indicates that industrial R&D by the world's top 1,000 companies — thought to account for 85% of industrial R&D between them — surged ahead last year by 10%, to €372 billion (US\$527 billion). US drugmaker Pfizer is now the biggest spender, investing €5.8 billion, whereas the largest-spending European company is DaimlerChrysler, at €5.2 billion.

DRUG PRODUCTION Ugandan president Yoweri Museveni has commissioned what his government says is the first factory in Africa that will produce full combinations of antiretroviral drugs for the treatment of AIDS. Quality Chemical Industries, a Ugandan drug importer, and Indian drug company Cipla will operate the plant, which is expected to start production early next year. The plant will also produce combinations of antimalarial drugs.

AIMING LOW Changes in UK rules on capital-gains tax could hit the emergence of London's Alternative Investment Market (AIM) as a popular global venue for listing science- and technology-based companies (see *Nature* 447, 367; 2007), some analysts say. The British finance minister, Alistair Darling, announced on 9 October that capitalgains tax would be levied at a flat rate of 18% from next April. Many investors on the AIM currently pay only 10%. But the announcement had no immediate effect on the prices of stocks listed on the AIM.

MARKET WATCH



Stocks in clean-energy companies rebounded to reach all-time highs in the past two months, after dipping with the rest of the stock market earlier in the summer.

The WilderHill New Energy Global Innovation Index (symbol NEX on the American Stock Exchange) now stands at almost twice its level at the beginning of 2006 — reflecting the new-found tendency of mainstream investors to take 'alternative energy' stocks seriously.

A closer look at the index shows a mixed pattern, says Robert Wilder, whose California-based consultancy WilderShares co-compiles the index with New Energy Finance of London.

In particular, investors have realized that biofuels based on corn (maize) will not expand as rapidly as had been hoped, given growing concerns about rising food prices and the suitability of corn as a feeder fuel.

Biofuels stocks are near to their lowest point in the past year, Wilder notes, even as the index hit a new high on growing investor confidence in wind and solar-power companies. Wilder notes that many of the solar companies, in particular, are starting to perform like regular industrial firms in a rapidly expanded market, rather than as exotic start-ups. "The 'alternative' label is dropping off," he says.

There's clearly been a flood of money into stocks in these areas but, Wilder thinks, opportunities remain in subsectors that have so far been less fashionable, such as geothermal power and companies that specialize in energy efficiency. In the stock markets, at least, "efficiency hasn't been discovered yet", he says.

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