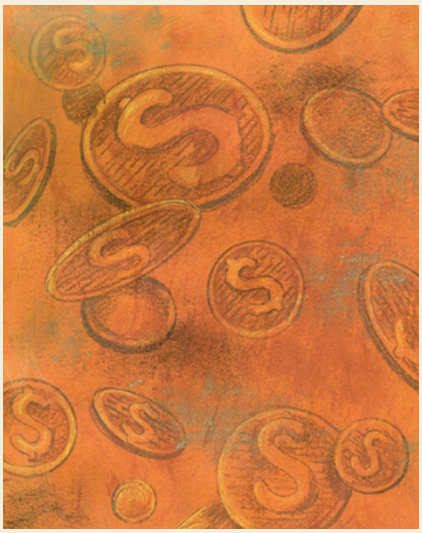
NEWS IN BRIEF

Biotech funding in Europe on the rise?



Venture capitalists are increasingly considering investing in European biotech firms over US-based firms, suggests an NVCA survey.

The lowdown: The National Venture Capital Association (NVCA) surveyed over 150 venture capital firms — which put over US$10 billion into health-care companies over the past 3 years — about their investment plans for the next 3 years. 36% of respondents plan to increase investment in life science companies in Europe, whereas only 13% plan to increase investment in the United States. Correspondingly, 31% of firms said they plan to decrease investment in life science companies in the United States, compared with 7% that plan to decrease investment in Europe. In an ongoing trend towards investing in emerging markets, 44% of respondents also said they plan to increase investment in Asia, and none said they plan to decrease investment in the region.

The survey highlighted several therapeutic areas — including cardiovascular disease, diabetes, obesity, cancer and neurological diseases — that are at a particularly high risk of decreased investment. 46% of firms expect their investment into orphan diseases to increase. Respondents cited US Food and Drug Administration (FDA) regulatory challenges as the most significant driver of investment trends, followed by reimbursement challenges.

The NVCA lamented the shifting investment strategy and its potential effects for both patients and the US economy. But Richard Bergström, Director General of the European Federation of Pharmaceutical Industries and Associations, says that as yet he sees few indications of a broad-scale shift towards increased investment in Europe. He adds that investment in Europe lags considerably behind the United States. According to an estimate by Ernst & Young, US biotech companies raised $20 billion in 2010 (from sources including venture capital firms and beyond), whereas European firms raised only $4 billion. "Regulatory reform is needed on both sides of the Atlantic to encourage increased investment," he concludes.

Cancer drug costs out of control

Reforms are needed to curb the rising costs of cancer treatment, finds a detailed review by *The Lancet Oncology* commission.

The lowdown: In an attempt to tackle the spiralling costs of cancer care, 37 members of the cancer community, including clinicians, economists, academics and patient advocates, compiled a 48-page report on the problem (*Lancet Oncol.* **12**, 933–980; 2011). They report that the total cost of care in the United States in 2010 was $124 billion, roughly 5% of the total health-care spending, in line with other surveyed countries in which it ranged from 4.1% to 9.3%. The report notes that the cost of a systemic therapy in the United Kingdom has risen from 34% of per capita gross domestic product in 1995 to 67% in 2009, and points to new agents costing over $100,000 per treatment course as evidence that costs are likely to continue to rise.

The commission concedes that high research and development (R&D) costs and limited patient populations largely explain the high costs of new drugs, though it adds that overutilization, consumer demand and futile care are also key drivers. Yet, citing the marginal efficacy of many new products, it nevertheless proposes broad strategies to bring the prices to heel. "Urgent solutions range from re-engineering of the macroeconomic basis of cancer costs (for example, value-based approaches to bend the cost curve and allow cost-saving technologies), greater education of policy makers, and an informed and transparent regulatory system."

In an associated comment article, National Institute for Health and Clinical Excellence (NICE) officials argue that drug makers can reduce clinical trial costs by up to 60% by adopting measures including electronic data capture and adaptive trial design (*Lancet Oncol.* **12**, 931–932; 2011). European Medicines Agency officials added separately that regulators and payers could work towards agreeing on pre-marketing and post-marketing evidentiary standards for relative effectiveness and could provide joint guidance on clinical development to reduce R&D costs (*Lancet Oncol.* **12**, 930–931; 2011).

New requirements for trial-result reporting are coming

The NIH is due to release new regulations on its requirements for reporting clinical trial results by the end of the year, and a call goes out to mandate the publication of more data.

The lowdown: With the enactment of the Food and Drug Administration Amendments Act of 2007, clinical trial sponsors were mandated to make a limited amount of clinical trial data publicly available for FDA-approved agents. These data are presented on ClinicalTrials.gov, although exemptions to date have meant data are not required for products that are still under development or that never achieve approval. The US National Institutes of Health (NIH) is now, however, revising its rules about reporting trial data. New regulations are due by the end of the year, at which point a public comment period will begin.

Michael Rogawski, of the University of California Davis, Sacramento, and Howard Federo, of the Georgetown University Medical Center in Washington DC, have called to broaden the reporting requirements (*Sci. Transl. Med.* **3**, 102cm29; 2011). "By reporting the results of clinical trials of abandoned products in a publicly accessible database and in the peer-reviewed journal literature, sponsors would satisfy a core ethical obligation of clinical research and enhance translational science," they write. By providing the community with data on the products that never see the light of day, they write, sponsors could help to improve the predictive validity of the screening models and prevent other investigators from unnecessarily pursuing futile treatment strategies.

A more transparent approach to trial reporting could also complement a nascent NIH drive to systematically evaluate the potential of safe but abandoned agents for development in new indications (*Nature Rev. Drug Discov.* **10**, 399–400; 2011).