

research-driven company with fewer than 500 employees and the credit would equal half of their investment.

Second, BIO is proposing to reform the eligibility for reduced capital gains rate under Section 1202 of the Internal Revenue Code. Under current law, only investments in businesses with \$50 million or less in gross assets qualify. But the cost of drug development requires successive rounds of financing that render small companies ineligible because they appear to be asset-rich when, over the long term they end up losing money. BIO proposes to increase this cap to \$150 million. Bruce Booth, a partner at Atlas Ventures, Cambridge, Massachusetts, thinks such changes could help, adding “if you’re going to invest, much like we do at Atlas, with the expectation of being with the company for 7–10 years, the tax structure should be different from that if you’re investing over days or over 1–2 years, like many hedge funds.”

Third, BIO is requesting legislators to take a look at refunds on net operating losses. Under current tax law, net operating losses on a company’s balance sheet cannot be refunded if that company has undergone an ownership change. As such changes are frequent in biotech, BIO is intent on removing these restrictions.

A fourth idea is to emulate tax breaks that other countries have set up for commercial entities actively involved in patenting. These so-called patent boxes, launched in the UK and France, give favorable tax rates for income generated from patents issued locally.

And BIO also wants to reform the law to reward capital repatriation. The proposal is to create tax holidays for large multinational companies with earnings held abroad that invest in small innovative companies in the US. “Repatriation has been talked about for 7–8 years, but it’s been hard to get through,” says Booth. “It seems obvious to bring some of that money from off-shore entities and encourage large pharma companies, as a condition to bringing it back, to support early-stage innovation.”

Overall, however, there is some skepticism as to whether these changes to the tax regime would result in more innovation in the industry. Conko, for example, argues tax breaks would likely only encourage companies to shift their strategies so they qualify, rather than induce them to innovate. “We’ve learned over time that when companies or industries try to negotiate targeted subsidies, the end result will be that more money will flow into those businesses, but not in a way that is productive or innovative.” Corey Goodman, biotech veteran and former president of New York-based Pfizer’s Biotherapeutics and Bioinnovation Center agrees: “What I see is an industry in which the three legs of the stool—academia, biotech and

pharma—are in much worse shape than anyone is saying. My question is whether these proposals will be enough. We have to find other ways to get the private sector to fund innovative research, as in the end, many of the industry’s problems can only be solved that way.” Felix Frueh, head of the personalized medicine section at Medco Research Institute, thinks BIO needs to build on these proposals by thinking more expansively: “[We should] look at the strength of the [The National Institutes of Health] NIH, or any other agency, take that strength and enable the environment to get the work done and done better [in the private sector]. It gets back to putting the focus on the patient. If the biotech industry is thinking about remaking the paradigm of how their products can impact healthcare, they have to think about the environment in which they are delivering care and think beyond just the products themselves.”

Teri Melese, head of the University of California, San Francisco’s Office for Research Technologies and Alliances, also thinks BIO missed an opportunity to address the interface between industry and the public sector. For example, aspects of the Sunshine Act (requiring disclosure of conflicts of interest), which was ultimately rolled into the 2010 Patient Protection and Affordable Care Act, are creating hurdles to productive collaborations between the public and private sectors. “It will take some creativity to work out a legal framework for defining how companies and academics can work together—what is precompetitive versus competitive.” In what situations do ties with commercial entities become an encumbrance to academic investigators? This is becoming especially important as the number of new startups launched by institutions slows to a trickle and the emphasis on fostering direct industry–academia interactions increases.

Keeping innovation on American soil may also prove a Sisyphean task. BIO states that in 2009, 35% of pharma companies outsourced to Asia, primarily China and India, and almost a third of small US biotech firms have been tapped to move their R&D operations abroad. BIO is proposing a clutch of strategies to stem this drain. “The reality is, both in Europe and the United States, a lot of the innovation is moving to Southeast Asia” because of lower manufacturing and labor costs, OECD attorney Cohrssen says. “US companies are moving over there, they’re building factories, they’re partnering in these countries.”

To stimulate the biofuels industry, BIO is pushing for the Biomass Crop Assistance Program to be reauthorized to 2017. This would encourage farmers to grow new crops for advanced biofuels. The industry association also proposes to create a crop insurance program for those producers trying out new crops, establishing a grant program

to fund demonstration projects and expanding the definition of renewable chemicals. BIO is again suggesting tax incentives, such as a tax credit for renewable chemicals and tax codes reform as ways to bring commercial volumes of affordable biofuels to market.

Similar to changes in the healthcare sector, changes to regulatory oversight of plant products could foster the generation of more innovative agricultural biotech varieties with improved yield or salt or drought tolerance to address climate change, says Martina Newell-McGloughlin, director of University of California System-wide Biotechnology Research and Education Program at UC Davis. “There’s all this potential here, but there’s a real unwillingness to [develop the products] because the regulatory environment is so inhibitory,” she says. Still Newell-McGloughlin remains upbeat about BIO’s proposals—she says that even if only some of the recommendations make it through into policy, this will be progress.

Karen Carey York, Pennsylvania, with additional reporting by **Laura DeFrancesco**

IN brief

13,000-biomarker deal

A Hyderabad-based firm entered an agreement in June to make its 13,000-biomarker database available to US researchers. Indian contract research organization GVK Biosciences signed a deal in June with Indianapolis-based Indiana Clinical and Translational Sciences Institute (CTSI), and a similar pact was signed with the Biomarker Qualification Group of the US Food and Drug Administration (FDA) in April. The GVK Clinical Biomarker Database called GOBIOM “is probably the first comprehensive biomarker-oriented database,” says Lang Li, head of bioinformatics at CTSI. It is a repository of biochemical, genomic, imaging, metabolite, cellular, physiological and clinical scoring-scale information gathered from clinical trial reports, scientific conferences and public literature. The data include preclinical, exploratory and clinically evaluated compounds—but not validated biomarkers—for 16 different therapeutic areas across 528 indications. GVK Biosciences said its collaborations with the genomics group of the FDA “helped us in developing a tetrahedral data model linking the biomarker to the disease, drug and target,” as a discovery tool for basic scientists developing new compounds, as well as clinicians designing phase 0, 1 or 2 trials, he said. GOBIOM is available to CTSI investigators, and scientists at Indiana, Purdue and Notre Dame Universities and affiliated organizations. “We have plans to develop a series of clinically relevant biomarkers for personalized medicine as well as conducting new discoveries,” says Anantha Shekhar, director of the Indiana CTSI. Financial details of the deal were not disclosed. *Killugudi Jayaraman*