internal memorandum requesting blue-sky wish lists of devices and tools from Merck's drug discovery and development personnel. Zohar and Turner decided at the outset that the new enterprise should be kept both entrepreneurial and truly independent with no pharma partner sitting on the board. The concept would work, they believed, because pharmas would be throwing in ideas and specific inputs from the ground up. They theorized that the process would yield ready-for-use, post-beta devices and technologies based on customers' wish lists and would not have to be reconfigured dozens of times before use. "It's actually a huge benefit if you think about it," says David Steinberg, founding CEO of Enlight and senior principal at PureTech. "As of now Enlight has its three biggest customers around the table from the very beginning, and they have a vested interest in seeing the technology successfully commercialized."

One major incentive for the pharmas to come together was the proviso that any new technologies created would be 'precompetitive', meaning that their functions and purposes would be general in nature. This would ensure that no single company would risk giving away pre-development secrets to their partners, who also happen to be competitors. The fact that none of the pharmas is on the board ensures confidentiality and no unfair competitive advantage for one partner over another.

The first company spun out of Enlight is Boston-based Endra, which is developing molecular imaging techniques to scan and visualize drug targets and tissues *in vivo*. The device is slated for use in a broad spectrum of diseases, including cancers and cardiovascular disorders. PureTech looks at more than 800 academic projects and technology platforms each year, and ~25% fall into the enabling technology category. "We recognize that a lot of venture firms are not funding those types of technologies, but rather are more interested in investing in clinical-stage or close-to-clinical-stage therapeutic programs. That's the kind of environment we're in," says Zohar. "However, we are, in fact, seeing some really transformational technologies in some cases—things that could create a shift in the industry if developed and applied." And she believes there's a way to make it pay. "With Endra, we expect something around two years from funding to commercialization," says Zohar, a far cry from the usual 10- to 12-year development cycle for a drug.

The crux of PureTech's value proposition is in the economy of shorter development time frames. Even with much lower revenue and margin potential than a blockbuster drug, many enabling technologies could be created from start to finish with less risk and much less capital during the time it takes to develop a single drug. Certainly, the single greatest factor favoring Enlight's success is its symbiotic relationship with its pharma partners, who are making specific product requests. "The reason Merck was interested in Endra was that it would fill a gap within the spectrum of imaging technologies that we would like to apply to pre-clinical and clinical research," says Reid Leonard, executive director for external research and licensing at Merck Research Laboratories in Boston. "These technologies need to be developed," he says. "However, it wouldn't fit our strategy to try to develop them on our own. Enlight will fill in the missing pieces to turn fundamental technology into products."

PureTech won't talk about the financial arrangements or splits in profits among partners and itself. Quite naturally the pharma partners won't turn down opportunities to enjoy profits if new products are commercialized, but the main benefit they seek is in the use of new instruments and assist technologies. Most big pharmas and large public biotech companies have corporate VC (CVC) arms (**Table 1**) that seek strategic benefits in the form of new drugs from small companies that have already received a few rounds of venture funding. The idea is to acquire the company or its molecules or its entire technology platform. That differs from the enabling technology model of Enlight, which will start projects and companies *de novo*. Indeed, the CVC divisions probably won't be involved closely with Enlight, which will deal mostly with scientists in pharma's R&D divisions who need the tools.

In the meantime, it seems unlikely that Enlight and its funding model will spur the creation of many similar ventures. "There are a limited number of large pharmaceutical companies," says Mark Heesen, president of the National Venture Capital Association. "And it's going to be a long time before we actually know if there's going to be any success here. I think venture capitalists are willing to sit back and wait and see what happens." But PureTech is making plans. David Steinberg intends to add one or two more big pharmas to the Enlight project, and he also says there has been some serious talk about similar ventures outside the US. "We would potentially consider European and Asian pharmas—Japanese in particular."

George S Mack *Columbia, South Carolina*

IN brief

EU clone green light

An EU preliminary report has found that food from clones is probably safe but highlighted animals' ill health as a cause for concern. On 24 July, an expert committee of the Parma, Italy–based European Food Safety Authority (EFSA) called it "highly unlikely" that milk or meat derived from cloned cattle, pigs or, more importantly, their offspring, will harm food safety. However, the panel said that young clones and their surrogate mothers experience "significant animal health and welfare issues," and that "uncertainties" remain because fewer than 4,000 such cattle and 500 such pigs were alive worldwide in 2007. The European Commission is not expected to decide on a ban of cloning-derived products until outcomes of a large public opinion poll and an extensive stakeholder consultation have been published. The US Food and Drug Administration (FDA) declared food from clones and their progeny safe in January 2008. FDA assessments cannot include animal welfare, and neither the FDA nor the EFSA can weigh ethical questions. Eurogroup for Animals, a Brussels-based animal welfare group, responded by calling for an immediate EU ban on cloning for food, but European animal breeders argue such a ban would be premature and unenforceable. "We should not deprive breeders of a technique that could one day offer significant opportunities for precision animal breeding," says Anne-Marie Neeteson, of the European Forum of Farm Animal Breeders, an industry group based in Oosterbeek, The Netherlands. *–Peter Vermij*

Return to sender

Officials at the US Food and Drug Administration (FDA) in July announced a key change in the way they notify companies when their therapeutic product applications fall short. Instead of merely saying a product is 'not approvable', the FDA Center for Drug Evaluation and Research (CDER) will issue 'complete response' letters to product sponsors describing specific deficiencies and, when possible, recommending actions to address those deficiencies. Beyond bringing the practice for therapeutic products into line with current notification procedures for biologics, this new procedure also provides CDER with a "neutral way of conveying information to a company when we cannot approve a drug application in its present form," says CDER director Janet Woodcock. Thus, this change is not expected to have much impact on biotech companies because the policy had been implemented earlier, according to a spokesperson for the Biotechnology Industry Organization in Washington. But some analysts predict these changes will add uncertainty to the drug review process, and may have a negative impact on stock values if it remains up to individual drugmakers to decide how much information from such letters to disclose. *–Jeffrey L Fox*