

IN brief

Deal validates DARPins

Zurich-based biotech Molecular Partners expanded an existing alliance with specialty pharma Allergan of Bridgewater, New Jersey, to develop ocular products to compete in the \$4-billion eye market. Ankyrin repeat proteins (DARPins), designed by Molecular Partners, are a type of protein therapeutic to bind almost any target. “In size it is more like a nanobody or single-chain antibody fragment,” says Arne Skerra, at Germany’s Munich Technical University. Another advantage is lower cost of goods. “As DARPins are manufactured in *Escherichia coli*, they are much cheaper than proteins made in mammalian cells,” observes Alain Beck, at the Centre d’Immunologie Pierre Fabre, Geneva. He rates the DARPins platform as one of the most advanced and interesting of several non-IgG-based protein scaffold platforms now emerging. The agreement includes taking Molecular Partners’ MP0260, a molecule targeting both vascular-derived endothelial growth factor (VEGF) and platelet-derived growth factor to a human proof of concept, as drugs for age-related macular degeneration to compete in the same indication as Lucentis (ranibizumab) and Avastin (bevacizumab). The companies are also working on MP0112, a VEGF-targeting protein in phase 2b for retinal disease. Molecular Partners has DARPins in development in inflammation, oncology and other diseases. “To our knowledge, there is no one but Molecular Partners, and our licensed partners, working commercially on DARPins,” says CEO Christian Zahnd.

Susan Aldridge

Biosurveillance plan unveiled

President Barack Obama issued the first-ever National Strategy for Biosurveillance, a comprehensive plan for coordinating human, animal and plant disease surveillance efforts. Without calling for new programs, this plan, released in July, combines strategies already in place for “gathering, integrating, interpreting and communicating” information related to biological threats, diseases and natural disasters. The aim is “to achieve early detection and warning,” taking into account the overall situational awareness of an incident to enable better decision making. A schedule for implementing this plan is expected soon. Meanwhile, several bills before Congress, if passed, would undergird the biosurveillance strategy with legislative authority and would also authorize funding for several closely allied federal programs. They include the WMD (weapons of mass destruction) Prevention and Preparedness Act (H.R. 2356), for bioterrorism defense. Another bill, the Pandemic and All-Hazards Preparedness Reauthorization Act (H.R. 2405), includes provisions for vaccines in the event of an influenza pandemic as well as for analyzing clinical specimens during outbreaks that might involve bioterrorism. Finally, the Foodborne Illness Reduction Act (S. 1529) would bolster the authority of the US Department of Agriculture to set forth and enforce food-safety provisions. With Congress recessed, these bills have nowhere to go unless and until a lame-duck session is convened after the November elections.

Jeffrey L Fox

wearable sensor that continuously detects basic blood chemistry using microneedles. By tracking changes in various chemical indicators, including various ions and metabolites, imbalances can be caught before they become problems. “Physicians use a number of different data points to make diagnoses about patients, but about 70% of the data they use to make an accurate diagnosis comes from a set of 20–25 basic blood chemistry tests,” says Pushpala. By tracking these parameters in real-time, their device could potentially warn patients of physical problems that they can remedy themselves, such as dehydration, or that will require prompt medical attention, such as kidney dysfunction. “If you give people passive feedback in an actionable manner, they are much more likely to change their behavior,” says Pushpala. The company has already built prototypes, with an eye toward testing their patch with early users in the near future.

In every respect, wearable sensors are a triumph over daunting technical challenges. For a patient lying in a hospital bed, performing an ECG reading is straightforward, but as soon as the patient begins running around outside a controlled environment, the signal gets marred with artifacts that make interpretation difficult. The devices need enough battery life to continuously generate and wirelessly broadcast data over extended periods of time. “Our current generation ECG patch uses 1 milliwatt of power to stream data via wireless connection to a smart phone,” says IMEC’s Penders, “and it can operate from three or four days, up to a month, depending on what you do with it.” This can also be balanced by using a lower sampling rate; for example, Dexcom CGM sensors transmit glucose data every five minutes even though higher frequencies are possible, enabling the transmitter to operate continuously from six months to a year (although the blood sensor component must be replaced after seven days). IMEC and others are also exploring alternative modes of energy harvesting, such as from body heat or movement, which could power wearable sensors indefinitely without an external battery, although considerable improvements in device energy efficiency—particularly with regard to data transmission—are still needed.

Other critical issues remain. For example, in liberating patient data from the exclusive control of doctors and hospitals, sensor manufacturers have to ensure that these data stay secure and that users can control access to their personal health information. Also, as medical data begin to pour into

everybody’s laptops and smart phones, first as a trickle then as a torrent, companies will need to design interfaces and applications that enable patients and doctors to understand and interpret what they are reading. “Physicians are going to be getting massive amounts of data, and how is that going to be analyzed and translated?” asks Palin. “And how do we get patients to take responsibility for maximizing their health, and what tools will help somebody who is really motivated to manage their chronic disease really well?”

As for software design, an ‘open’ philosophy embracing contributions from app-builders seems ideal for these sensors. Some of the best applications are likely to emerge from ‘mash-ups’ of different sensor feeds, and although most companies working in this area aim to ramp up the number of tests that can be conducted by a single device, there is a clear recognition that different platforms will ultimately need to play well together.

Finally, unlike other medical devices which can be relatively clunky as long as they perform their intended function reliably, these consumer-facing systems must be comfortable and unobtrusive—pairing the medical technology expertise of established industry leaders like Medtronic with the user-friendly design instincts of the start-ups. “Anybody who uses the words ‘adherence’ or ‘compliance’ should understand that these are not user problems—they’re product problems,” says Gandhi. “We want to see more devices that really understand the user and how they go about their lives.”

The challenges ahead are huge but the payoffs could be enormous. Already two separate X-Prize challenges are underway to reward breakthroughs relevant to wireless medical sensor development: the \$10-million Qualcomm ‘Tricorder’ X Prize and the \$2.25-million Nokia Sensing X Challenge. Public health services and insurers could save big by minimizing hospitalizations and preventing repeat visits for the same ailment by helping patients to stay on top of their health.

Finally, given the ever-falling cost of semiconductor chip manufacture, the combination of cheap wearable sensors and mobile-enabled doctor consultation could soon benefit even relatively remote communities in the developing world. “One of the first things anyone wants is healthcare for their family, and yet there’s a shortage of physicians and basic infrastructure in the developing world that we would take for granted in the West,” says Savage. “But there is mobile telephone signal everywhere.”

Michael Eisenstein Philadelphia