UK forms a £1-billion life sciences powerhouse

Three UK investment groups have aligned to create a new company with £1 ($1.2) billion in funds to invest in life sciences, with a significant focus in oncology. The Wellcome Trust's investment arm, Syncona, joins the publicly traded investment company Battle Against Cancer Investment Trust (BACIT), and Cancer Research UK (CRUK), which is contributing assets from the £70 ($87)-million Pioneer Fund established in 2012 (*Nat. Biotechnol.* **30**, 378, 2012). The new company aims to provide the investment needed to take potential cancer drugs from the CRUK network, including the London-based Institute of Cancer Research, from discovery into phase 2. The deal, which is subject to a BACIT shareholder vote in December, would make the Wellcome Trust BACIT's largest shareholder, with a more than 30% stake in the merged entity. The firm, which will continue to operate as BACIT, expects to invest roughly £100 ($125) million per year in life sciences opportunities until its assets are fully invested in the life sciences, with at least 25% going to oncology projects and businesses. The new deal would also assure "first look" access to CRUK's pipeline even after The Pioneer Fund is fully invested. Syncona's portfolio includes Oxford-based prostate cancer imaging company Blue Earth Diagnostics; Cambridge Epigenetics in Babraham; and the T cell immunotherapy firms Autolus and Achilles Therapeutics, both in London.

"Trump is 'interested in precision medicine on that [21st Century Cures Act bill]; incoming VP [Mike Pence] is interested in the Cancer Moonshot part of it; and I'm interested in the regenerative medicine part. I want to see us finish that important new measure this year'," says Republican Senate majority leader Mitch McConnell of the prospects for the coming administration. (*Fierce Biotech*, 11 November 2016)

"Trump has been a bit of a black box on [funding for scientific research]. The good news is we don't know what it means for public funding and the bad news is we don't know what it means for public funding." Jennifer Zeitzer, director of legislative relations at the Federation of American Societies for Experimental Biology, on what lies in store under the new president. (*The Verge*, 10 November 2016)

"Trump's election does not bode well for science or most anything else of value." Neal Lane, a physicist at Rice University in Houston, and former White House science advisor under President Bill Clinton, is stunned at the outcome of the US elections. (*Science*, 9 November 2016)

predecessor. Trump will possibly discard specific Obama-administration initiatives, including recently proposed payment experiments around hospital-infused drugs. "It would be naive to believe that value, quality, transparency and price reform will be swept under the rug or go away as a result of Trump's presidency," says Marc Samuels, former healthcare advisor to President George H.W. Bush and founder and CEO of ADVI, the life sciences and healthcare services consulting firm. But any reform is likely to rely to a large extent on industry self-policing, argues Samuels. "The manner in which reform is introduced or implemented by this Congress or this president-elect will be different," he says.

The Republican solution to drug pricing has traditionally been to encourage competition, says McCaughan, which could result in shrinking regulatory hurdles to getting products to market. Any US Food and Drug Administration (FDA) reform will be designed to speed the drug approvals process—for new molecular entities, generics or both—but could exacerbate the real staffing challenges already facing the agency, he says.

"For biopharma companies, the climate at FDA has been so good, the best you can hope for is that it stays almost as good," says McCaughan. "With any transition, regardless of who the new president is, there'll be bumps." What's more, 2017 is a huge year legislatively for FDA, one that features the standard every-five-years prescription drug user fee act (PDUFA) reauthorization. The currently stalled 21st Century Cures Act, which passed the US House of Representatives in 2015 but failed to gain enough traction in the Senate, has implications for FDA and could also be revisited. The Cures Act boils down to additional funding for agencies like NIH and FDA (some of which could be earmarked for Moonshot or the Precision Medicine Initiative, for example), alongside new incentives for drug development and smoother paths to approval for industry (*Nat. Biotechnol.* **33**, 891, 2015).

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The biotech industry may also be caught up in broader policy reform and Trump administration initiatives. Trade deals, like the 12-nation Trans-Pacific Partnership (TPP), were heavily criticized by Trump during the campaign (*Nat. Biotechnol.* **33**, 1223, 2015). The TPP included a provision for five years data exclusivity on biologics, much less than the 12 years preferred by biopharma lobbyists that was made law in the US as part of the PPACA. "Various administrations pursuing trade deals have run hot and cold in protecting the intellectual property of the biopharma industry," says Spatz, and it remains to be seen "how much a Trump administration prioritizes that as it negotiates or renegotiates trade deals."

It's also unclear whether Trump would prioritize ethical issues that have motivated Republican presidents in the past. For example, federal funding for human embryonic stem cell research may also become a hot-button issue once again, but "the president-elect hasn't given an inkling" of information regarding where he stands on that issue, says Samuels.

At first glance the election results appear to be good news for drug companies. Biopharma stocks surged following the election; the NASDAQ Biotechnology Index jumped 11% on the week, a nearly unprecedented leap. On the whole, investors do not expect a Trump administration to pursue the drug pricing issue as zealously as a Clinton administration would have. Speaking for the Biotechnology Innovation Organization Kenneth Lisaius, senior vice president of communications, says, "We look forward to working with the new and returning members of the House and Senate—as well as the Trump administration—on matters and policies that promote innovative treatments and cures."

Pharma analysts say the Trump administration is likely to make it less onerous than in the past for US corporations to repatriate cash held overseas, either as a stand-alone program or as part of a broader corporate tax reform package. Currently US companies must pay a tax of 35% to repatriate their overseas cash. Any repatriation tax holiday—a previous program allowed companies to repatriate cash at a 5.25% rate in 2005—could lead to a boom in biopharmaceutical M&A. Analysts at Jefferies (New York) peg the biopharma capital influx at nearly $100 billion. Thousand Oaks, California–based Amgen alone holds $34 billion, or 91% of its total cash reserves, outside the US, according to New York–based Evercore analyst John Scotti. "If it's not an ideal M&A environment, it's at least hard to remember a better time for deal making than the first half of 2017 is shaping up to be," says Iselin, New Jersey–based Andrew Forman of Ernst & Young transaction advisory services.

Chris Morrison *Yardley, Pennsylvania*