

Life Sciences and Industry Magazine

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Interview Roche pRED head John Reed explains his strategy to boost success in early pharma development.



Capital Market

An analysis of Europe's biotech stock market landscape

Human Brain Project

Clash between experimental neuroscientists and IT fans

Confidentiality

EMA tables rules for publication of clinical study reports

EuroBiofairsCompass

Your guide to the top life science events in early 2015

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COVER STORY



Can biotech halt the plastic flood?

Every year, 20 million tonnes of plastic waste that will persist in the environment for over five centuries end up in the oceans. Biotechnologists and chemists are now testing pioneering concepts aimed at using the litter as a resource to generate products with added value. Other researchers are trying to design plastics that have a limited shelf-life without changing the product characteristics that make the material so popular. Their efforts are being backed up by a new EU policy priority aimed at changing our attitude towards plastics.

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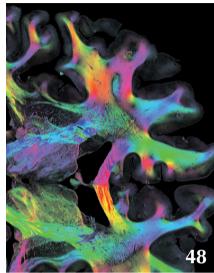
CAPITAL MARKET

European upswing ends biotech dry spell

Will 2014 be remembered as the long-awaited end to the financial drought in Europe's biotech industry? A new analysis reports a significant upswing in European stock markets for the sector. Private capital investment also looked to be recovering, with a high number of new funds launched this autumn.



NEUROTECHNOLOGIES



Brain rush – mining, mapping & models

The controversial Human Brain Project is one of several mega-efforts worldwide aimed at coming to grips with this most complex of organs. What impact will the Big Data approach have on neuroscience and personalised medicine?



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EDITORIAL

Sustainability blues

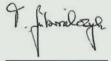
Sustainability has become a buzzword for everything and nothing. When we received your positive feedback on the relaunch of our magazine, we also wondered if that will prove a sustainable phenomenon.

Biotech companies that want to go public continue to wonder whether an IPO in the US or in Europe will secure sustainable financing for their projects. To answer that question, our editor Sandra Wirsching dove deep into the finance scene at BIO-Europe and a study presented by BIOCOM AG in late November on the 15 most important stock exchanges in Europe (p. 34).

When top-notch European neuroscientists team up to send the European Commission a furious protest letter about the €1.2bn Human Brain Project, something somewhere must have gone wrong. Correspondent Philipp Graf looks at whether it's sustainable to replace experimental neuroscience with a search for new computing architectures (p. 48).

And there's no question the five tonnes of litter every EU citizen generates annually is not sustainable. 10% of it is plastic that persists for centuries and pollutes our oceans. Biotechnologists are working on solutions to the global problem (p.14).

So this holiday season, don't forget to wrap those gifts in reusable packaging! Here's to a sustainable Merry Christmas and a Happy New Year!







Copycat check

BIOSIMILARS An update of the European Medicines Agency's general biosimilars guideline is set to make the global development of biosimilars easier and more cost-effective. The revision of the Agency's 2005 overarching guidelines, which will take effect on 30 April 2015, allows biosimilar developers for the first time to use a comparator not authorised in the European Economic Area (EEA) to demonstrate biosimilarity in clinical and preclinical in-vivo studies. Up to now, companies that used for example FDA-approved comparators to file for market authorisation in Europe had to repeat clinical studies with an EEA-approved reference product, raising development costs.

According to the EMA, the comparator will need to be authorised by a regulato-



Celltrion and Hospira are co-marketing the first EU-approved Remicade biosimilar.

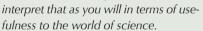
ry authority with similar scientific standards, such as ICH countries. However, companies will be required to demonstrate that the comparator is representative of the reference product authorised in the EEA.

The guideline update additionally includes some deviations from the original rules. Based on data that demonstrate comparability with the originator product, companies will be allowed to extrapolate use of the biosimilar medicine to all indications the originator has been approved for. Both extrapolation of indications and the globally harmonised rules for the use of comparators are expected to support the adoption of biosimilars, as they make development more cost-effective.

Heard in Brussels

Dear Carlos ...

BRUSSELS We have a new set of European Commissioners, and I thought that in this issue, it would be very nice to have a look at one of them through the lens of biotechnology. Commissioner for Research, Science and Innovation Carlos Moedas is our man, and a quick look at his bio shows that he combines origins in engineering with a career in banking and real estate. You may



I was going to give a detailed analysis of Jean-Claude's invitation letter to Carlos, but to be honest, it was so full of titles like 'Commissioner in charge of Better Regulation, Inter-institutional Relations, the Rule of Law and the Charter of Fundamental Rights' (yes, my friends that is a job) – that I thought we would just write our own letter of appointment to Mr. Moedas so that he knows what he needs to do. Here goes ...

Dear Carlos,

You're becoming a Commissioner in the new EC at a particularly challenging time for the European Union. As well as doing all the standard stuff – such as liking Europe, looking smart on the television and not fiddling expenses – we, the scientific community, would very much like you to prioritise the following activities in your portfolio:

1. Linking together research and infrastructure planning and funding at the European, national and regional levels, so that the next scientific breakthrough can be developed quickly to market/field or patient, rather than floating about until somebody from the US or China decides



CLAIRE SKENTELBERYSecretary General of the European Biotechnology Network

they will do it instead and the European taxpayer subsidises profits somewhere else and then has to buy the final product.

- 2. Making the best use of Europe's brains by opening up the often clogged scientific pipeline between school, university and the wide world of biotech, and ensuring that talents are not lost for any reason throughout careers.
- 3. Empowering SMEs

further to drive innovation into commercial reality, plus recognising where the skills and financial gaps are and plugging them.

- 4. Stop asking nicely for private investment in science and incentivise it to be an integral part of investment portfolios.
- 5. Ensure that when you spend public money on science, you spend wisely, spend big and spend consistently big words and small money do not deliver crops, medicine or energy.
- 6. Join it all up. In a complex and fastchanging world, the bottlenecks often have little to do with the science and everything to do with a lack of money, regulatory barriers, access to downstream partners and getting the right skills at the right time.

To help you fulfil your responsibilities, the whole scientific community in Europe will guide you on your way. You are just about to find out what a passionate sector you serve. We look forward to working with you on the next step needed by Europe's scientific community.

Yours sincerely All of Us Well, that should do it.



Holding back the tide in a sea of plastic

POISIONED PLANET Plastics are a growing threat to the environment, wildlife and human health. In 2012, just 3% of the 280 million tonnes of plastic produced globally were recycled. 20 million tonnes of that end up in the oceans every year. What's the best way to address this global threat? And how can biotech contribute to a solution?

panish conservation biologist Renaud de Stephanis describes the tip of an iceberg that is made up of human-generated waste: "It was as if it had a rock inside its intestines. Nothing could get through. There was so much plastic that it finally exploded." The sperm whale he found in March 2012 on a beach south of the city of Granada was one isolated victim of the mismanaged plastic waste being blown by the wind from landfills into the sea. According to the researcher at the Estacion Biologica de Donana, "the sea is full of rubbish." Over a period of decades, items made of nearly indestructible plastics are weakened by UV and ground up into tiny microplastic beads that have so far been found in the digestive tracts of 663 marine species. "And that is what we end up eating," says de Stephanis succinctly.

Recent studies show that harmful chemicals like DDT or polychlorinated biphenyls (PCBs) accumulate in non-degradable microplastics at levels over a million times higher than those in sea water. And these toxins are regularly taken up by fish, turtles, shellfish and seabirds. About 80% of the constantly growing problem comes from plastic waste disposed of on land. Every year, an estimated 20 million tonnes of non-recycled plastic waste joins the 140 million tonnes of plastic garbage that have accumulated at the flat-water centres of five gigantic ocean gyres (see map, p. 18).

Dubbed the Great Pacific Garbage Patch, the largest of these – which lies between Hawaii and California – is over twice the size of Germany. Though it can't be seen by satellite, the diffuse soup of microplastics poses a huge danger to the maritime environment. According to figures released by the US Environmental Protection Agency (EPA), ingested plastics kill a million seabirds and 100,000 sea mammals each year. Most of it originally comes from the partially-degraded packaging materials and plastic bags that make up a little over a third of annual global plastics production.

The global challenge

Called "a major environmental issue the world must address" at the UN's 2012 Rio+20 conference, the problem is mainly due to the six polymers that make up 80% of the US\$ 400bn plastics market: polyethylene (PE, 29%), polypropylene (PP, 19%), polyvinyl chloride (PVC, 11%), polystyrene (PS, 7.5%), polyethylene terephthalate (PET, 6.5%), and polyurethane (PU, 7%). Mostly made from petroleum – but also from biobased PE, PP, or PET versions whose building blocks come from renewable resources – these plastics persist for at least 500 years in the environment.

After Rio+20 stakeholders urged action to "significantly reduce the amount of marine littering by 2025", an action plan was set up. Additionally, 60 plas-

tics industry organisations kick-started 180 projects.

Although not every country is able to end landfilling as a first-aid measure, some have come close to perfecting plastics management infrastructures. In Germany, for example, all plastic waste must be incinerated to provide energy before it can go to landfills. "The plastics utilisation rate is nearly 99%. What more can be expected?" says Michael Herrmann from PlasticsEurope, the European plastic industry's voice. Many developing countries, on the other hand, are drowning in seas of their own waste because they don't have the industrial composters to cope with biodegradable plastics like polylactide (PLA), starch blends, polyhydroxyalkanoates (PHA) or polybutylene succinate (PBS) (see table, p. 16), nor do they have recycling capacities for durable fossil and biobased polymers. "Marine waste - especially in developing countries – is coming from the lack of capacity to manage waste," stresses Erin Simon, the Manager for Packaging and Material Science at the World Wide Fund for Nature (WWF). So where can these countries turn for help?

Biotech masterminds

At the current stage, only a few pioneers are thinking about how they can turn the problem into an opportunity. A team of ...

>> Read the full story in the printed issue.



Biotech momentum on financial markets

CAPITAL MARKET UPSWING Will 2014 be remembered as the long-awaited end of the financial dry spell for Europe's biotech industry? The results from a new analysis of European biotech stocks has the sector holding its collective breath in hope. Biotech IPOs in Europe and capital increases via stock markets has risen significantly in 2014, while sources of private capital are also picking up speed, with seven new funds set to pour in substantial amounts of fresh cash. So is this nothing more than a flash in the pan, or is it the beginning of a renaissance in the field?

Orphan boost

Scottish government has awarded health boards £40m in funding to give patients better access to modern therapies against rare diseases (orphan drugs). The New Medicines Fund will replace the Rare Conditions Medicines Fund set up in March last year, which sponsored the cost of 45 different medicines for orphan diseases. It doubles the amount of funding available for orphan drugs that – due to a bad cost-utility analysis – have been rejected by the Scottish Medicines Consortium (SMC) for reimbursement in NHS Scotland.

In contrast to EU countries such as Germany or the Netherlands, orphan drugs in Scotland have to go through the same pharmacoeconomic evaluation process as regular drugs, which results in a significantly lower reimbursement rate. Following recommendations from the Scottish Parliament, however, changes to the way medicines are assessed by the SMC were put in place in May 2014. The new funding is "long-overdue recognition", says Alastair Kent OBE, Director of Genetic Alliance UK. "There is a postcode lottery in Scotland on who qualifies for the drugs. There needs to be a clear framework on obtaining the drugs and what the money is spent on. It should not be left to local healthcare boards," he explained. "The money cannot disappear on other health budgets." According to Kent, the new fund is a good start, although "we won't know how successful it is until it has reached the patients and delivers exactly what it intended to."

Purchase Down Under

IMMUNOTHERAPY French biopharma firm Immutep SA finalised a takeover deal in November with Prima BioMed Ltd. The Melbourne-based biotech company is a developer of personalised immunocellular therapeutics for the treatment of cancer. "We have been talking to Prima since January," said Immutep CEO John B. Hawken. Under the agreement, Prima is set to pay Immutep around US\$28m via a combination of cash, shares and warrants. The deal is subject to the fulfillment of fixed performance milestones. To fund the acquisition, Prima secured an investment agreement with New Yorkbased private equity firm Bergen Asset Management for up to US\$ 37.4m.

Immutep specialises in developing immunotherapeutics in oncology. Target-

ing Lymphocyte Activation Gene 3 (LAG-3), its lead product (IMP321) is expected to boost T cell responses to tumours. The compound has completed a Phase II trial in combination with chemotherapy to treat metastatic breast cancer. "This has vindicated the belief of our founder, Frederic Triebel, who thought that the immune system could be re-activated to attack metastatic cancer (ever) since he participated in the first IL-2 trials in metastic renal cell carcinoma 30 years ago," said Hawken. In addition, the Orsay-based company has successfully out-licensed two other products based on the LAG-3 technology to pharma giants GSK and Novartis, which acquired licensee CoStim. Prima has been listed on the Frankfurt Stock Exchange since mid-2012.

Tour d'Europe

FUNDING In mid-October, 8,000 European scientists gathered in Paris, Madrid and Rome for a continent-wide protest against austerity, short-termism and a lack of adequate career structures. Triggered by a French initiative, the researchers took to the streets to fight for higher budgets. "Sciences en Marche" was formed after the country's National Committee of Scientific Research (CoNRS) released a crushing report showing that funds for R&D and permanent jobs in France are falling in comparison to other countries. "We realised we needed to bring together the whole scientific community - labs, universities, all disciplines, and all categories of staff," said the initiative's president, biologist Patrick Lemaire.



A joint effort

OSTEOARTHRITIS Innovate UK has awarded a £2.4m grant to Londonbased drug developer Calchan Holdings Ltd and Belgian biotech Galapagos NV for their research on pain caused by degenerative joint disease. The Biomedical Catalyst Early Stage Round 2 funding from the UK's innovation agency will be used for the further development of compounds aimed at a novel target in osteoarthritic pain. The two companies will collaborate on identifying preclinical candidates. "Pain in osteoarthritis remains a major unmet medical need," says CEO of Galapagos Onno van de Stolpe. He hopes the collaboration will bring a new class of treatments to the clinic. The WHO estimates that 9.6% of men and 18% of all women over the age of 60 are affected by the degenerative joint disease.

A specialist in state-dependent calcium ion channel blockers, Calchan acquried its assets (two Phase II first-inclass painkillers) in 2011 as part of a restructuring at mother company Convergence Pharmaceutical Ltd.

Winning the bid for Botox

TAKEOVER It's not every day that a company enters the top ten in its sector, but that day has come for Actavis. Christmas arrived early for the generics giant after it won a seven-month takeover battle to acquire Botox maker Allergan for US\$66bn (€53bn) or US\$219 (€175) per share. It's a happy ending for the California-based pharma, which thereby avoided a hostile takeover by Canadian pharmaceutical Valeant. Allergan shareholders are now set to receive a combination of US\$129.22 in cash and 0.3683 Actavis shares for each share of Allergan stock. For Actavis, the merger is a major coup. "This acquisition makes us one of the world's Top 10 pharma companies," says Actavis CEO and President Brent Saunders, who will head the combined company. He hopes for revenues of US\$23bn over the next year from Allergan's ophthalmology, neurosciences and dermatology business together with Actavis' gastroenterology and women's



health franchises. In the same week as the announcement of the Actavis-Allergan deal, the Dublin-based pharma also finalised the acquisition of Durata Therapeutics, which will enhance its Infectious Disease portfolio with a novel antibiotic for acute bacterial skin infections in adults (Dalvance). Actavis' share price rose by over 10% between 14–18 November on the news.

Faulty gene-fixing on Horizon

GENOMICS The CRISPR (Clustered Regularly Interspaced Short Palindromic Repeats)-Cas9 system has the biotech industry buzzing with excitement as research in the area of gene editing picks up speed. UK biotech firm Horizon Discovery is one of several companies claiming a piece of the action. After successfully securing £68m (€86m) with an IPO in March, the Cambridgebased firm has since acquired US Sage Labs Inc. for US\$48m (€39m), strengthening an IP portfolio in CRISPR technology. The aim of Horizon's Genesis platform is to promote the use of the gene-editing technology and to expand its portfolio of knock-out cell lines as disease models and compound screening tools. Horizon hopes the deal will establish the company as a leader in genomics and gene editing. "With the addition of Sage, we have expanded the range of services we can make to researchers, starting from the first stages

of discovery in cellular models through to late preclinical animal studies," says Horizon CTO Eric Rhodes.

Because it makes gene editing fast, easy and cost-effective, the CRISPR-Cas9 system has been lauded as a vital new tool for precise genome modification in organisms, including human cell lines. One of the scientists instrumental to the discovery back in 2012 is Breakthrough Prize winner Emmanuelle Charpentier, a department head at the Helmholtz Centre for Infection Research (HZI, Germany), who has been a member of Horizon's scientific advisory board since August.

Pharma kingpin Novartis has also jumped on the CRISPR bandwagon. Together with Atlas Venture in November, it decided to invest US\$15m in the launch of Intellia Therapeutics Inc – a potential rival for Horizon. The Swiss giant wants to use the system for developing CAR-T cancer therapies.

NEWS

Luck of the Irish

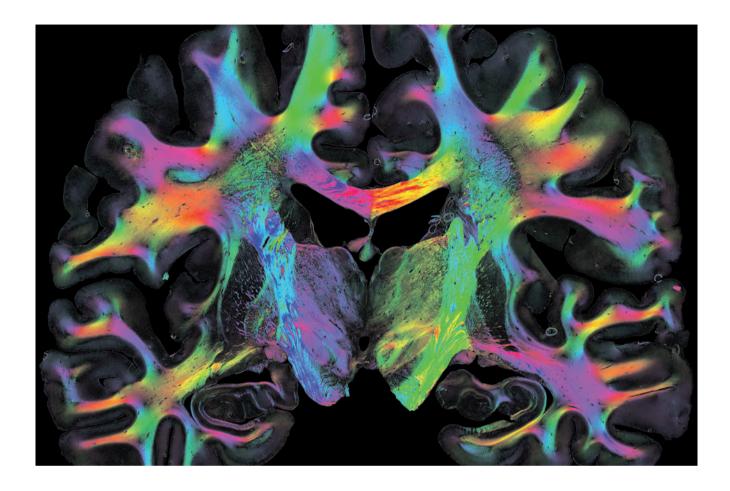
There's been some good news for Ireland's job market. Bristol-Myers Squibb has announced plans to build a €720m plant in Dublin that will create 400 permanent positions and a further 1,000 temporary jobs in the country. In total, BMS says it will invest nearly US\$ 1bn (€802m), and will use the plant to manufacture a range of biological drugs currently under development. To be built on a site where BMS currently has a bulk manufacturing plant, the 30,000m² facility should be operational by 2019.

Bioamber breakout

Reverdia, a joint venture between Royal DSM and Roquette Frères, has announced that it is preparing to license its Biosuccinium – a biobased succinic acid – which is produced at its Italian plant in Cassano Spinola. Competitor Succinity, a joint venture between Corbion Purac and BASF, also produces commercial quantities of bio-based succinic acid for the global market at its site in Montmeló (Spain).

Biobank security

The Integrated Biobank of Luxembourg (IBBL) announced in October that it is to receive funding from the country's Ministry of Research. The state renewed its contract with the organisation, awarding €30.8m in funding for its research programmes to be paid out by 2017. It will also support a series of objections, and help the IBBL assume its role of service provider in Luxembourg's biotech sector.



Brain rush – mining, mapping & models

NEUROTECHNOLOGIES The European Commission's ambitious €1.2bn Human Brain Project (HBP) is one of several major collaborative research programmes aimed at tackling the complexities of our grey matter. Now home to HBP headquarters and a new Wyss Center, Geneva is emerging as Europe's neurotech hub. What impact is the massive push for knowledge having on neuro-drug development and personalised medicine?

Research strategy: Balancing Roche pRED's pipeline

STRATEGY Since taking over Roche Pharma Research and Early Development (pRED) just over a year ago, John Reed has carried out a pipeline review, reorganised development focus, and reached out to academic and biotech partners. EuroBiot spoke with the cell biologist about his organisation's strategy and goals.

EuroBiotech_John, in April of 2013 you took the helm at Roche pRED after 21 years at San Diego's Sanford-Burnham Institute. How is carrying out translational research at an academic institution different than working for a pharma company?

Reed_I think some parts of the pharma job are similar, but in the academic context, the remit really was focused on basic science that led to target discovery/ target validation and early steps in drug discovery, although we stopped short of advanced lead optimisation and moving into the clinic. When we had reached that point, we typically tried to spin candidates out into a biotech company, moving them out of the non-profit academic environment to one aimed at profit - one where you can raise the funds necessary to reach the lead optimisation phase and eventually early development. So I think that the biggest difference is the span and the culture here in pharma, and I view it as my job to bring candidates from target through to Phase II in man. That's a broader scope, and also a different focus in terms of the amount of what I call 'applied vs. basic' research. I would say that having spent years in basic research provides a great reference point for a job in pharma, because it teaches you what you need to know about good critical thinking and good scientific methods. It also helps you acquire a good appreciation of how to analyse data, and makes you look very vigorously at the evidence surrounding a target and the drug discovery programmes that you devise.



DR. JOHN REED has been Head of Roche Pharma Research & Early Development (pRED) since April 2013. The world's most-cited cell biologist from 1995-2005 and a holder of more than 90 patents, Reed spent over 20 years at San Diego's Sanford-Burnham Medical Research Institute, and was its CEO for over a decade. The apoptosis expert has also been a board member at numerous biotech companies, among them Clovis and Isis Pharmaceuticals.

EuroBiotech_Some reports suggest gRED performed better than pRED. What was your starting point when you joined Roche, and where do you see potential for improvement?

Reed Here at Roche we have a first-inclass agenda that is always focused on innovation in areas of high unmet medical need. Whenever you innovate, you have to be prepared to take risks. pRED has traditionally shouldered a lot of challenging therapeutic areas with a lower probability of success, but we have revisited our strategy to make sure that we continue bringing innovative medicines to patients in the future, as we have done recently with Gazyva. Our colleagues at gRED have been very successful and productive. We're delighted that we're all part of Roche.

EuroBiotech_Could you describe the consequences of your pRED pipeline review - both in terms of strategy and prioritisation of compounds and plat-

Reed_We came up with a review process that took about nine months from the time I arrived. It's a four-pillar plan. The first pillar was to take a careful look at the investments we make in very different therapeutic areas: to evaluate the allocations across the different therapeutic areas, and then to rebalance that so we would then have a good mix of lower and higher 'pts' (probability of therapeutic success) indications and a good mix in terms of the risk value that you look at when you're managing a portfolio. That led to a few adjustments. We decided to exit cardiovascular and metabolic ...

Plan of action

SWEDEN Three associations – Swedish Medtech, SwedenBIO and the trade association for the research-based pharma industry Läkemedelsindustriföreningen (LIF) - presented a joint action plan for the life sciences at the end of October. Aimed at strengthening the Nordic country's competitiveness, the 25 measures include the prioritisation of early biomedical research, the facilitation of access to venture capital and other forms of financing, and the intensification of a national e-health strategy. The organisations said that although "there have been several major initiatives to strengthen the sector, and many of these are good and will produce results in the long term," they want to address the fact "that there is still no coherent strategy that includes all the important aspects."

A united front

UNITED KINDOM Life science organisations in the UK are pooling resources in the newly-formed United Life Sciences strategic partnership. With the Biolndustry Association (BIA) leading the way, the organisations Bionow, BioPartner and One Nucleus have published a 'Life Sciences Manifesto' outlining key issues for the sector and making policy recommendations to the British government.

Among other issues, the associations are lobbying for the continuation of funding programmes such as the Biomedical Catalyst and tax relief policies like the Patent Box, which reduces corporate tax on profits earned from patented inventions and other innovations. Additionally, they are calling for flexible new routes in the areas of licensing, evaluation and reimbursement – in particular an 'Early Access to Medicines' scheme and the full utilisation of the European Medicine Agency's 'Adaptive Licensing' pilot. With the partnership, the BIA's CEO Steve Bates says the organisations are aiming to provide "a united front and critically, one voice, to the government."



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Winners & losers

SHOOTING STAR

French scientist Emmanuelle Charpentier was among this year's winners



at the star-studded Breakthrough Prize Awards in California. She was instrumental in discovering the CRISPR-Cas9 geneediting system in 2012.

BYE-BYE BAGS The plastic bag industry could be on its way out. By 2025, the



EU aims to reduce the number of bags by 80% through introducing mandatory pricing on them or

limiting the number of bags used annually to just 40 units per person. Currently, 100 billion plastic bags are produced yearly in the EU.

What fascinates you most about your job? ...



BEN CHAFFEY Clinical Operations & Business Development Manager, Biosignatures, UK

"... the realisation that effective management can be a scientific topic as much as biology is. Working at the interface of the two disciplines is very stimulating!"

Boozy fruit flies

FOOD SCIENCE After leaving two different types of yeast out on a lab bench over the weekend, Belgian biologist Kevin Verstrepen



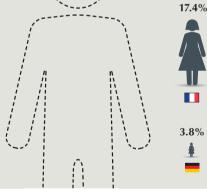
returned to find a colony of escaped fruit flies residing on the fruity-smelling wild-type strain of yeast, whilst ignoring the yeast with the mutant gene ATF1. The *S. cerevisiae* ATF1 gene controls the production of volatile acetate esters. After some more experiments (doi: 10.1016/j. celrep.2014.09.009) Verstrepen reasoned that common brewer's yeast may have evolved aromas to attract fruit flies, which help disperse the yeast cells. The distinct fruity flavours present in some types of beers today, he concludes, could be down to a co-evolutionary process.

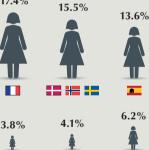
It's a man's world

UK recruitment service Liftstream has published a downloadable report on gender diversity in European biotech companies. It examined 1,491 companies and shows there is significant male dominance in biotech boardrooms.



11.2% Ø







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#BandAid30 #Viehbacher

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Sanofi CEO #Chris Viehbacher fired after a 60-hour board tussle. http://bloom.bg/11aLg6G @BloombergNews

IP Special

NEXT ISSUE In the upcoming spring edition of European Biotechnology, we'll feature our Intellectual Property Special. The issue will be published on 5 March 2015. If you'd like to place an advertisement, please contact us by 13 February. Your editorial contact is Thomas Gabrielczyk (+49-30-264921-50). Questions regarding advertising can be directed to Oliver Schnell (+49-30-264921-45), Andreas Macht (+49-30-264921-54) or Christian Böhm (+49-30-264921-49).

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