



European Biotechnology

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Interview

Mark Fahy, the
London Stock
Exchange Head
of UK Small and
Mid-Cap team, on
why we're seeing
IPOs again



FREE EXCERPT

ANTIBIOTIC CRISIS

A matter of life and death

Digital Health

A bright future: How long until
E-health delivers on its promise?

Bioeconomy

Industry rediscovers wood as
a versatile high-tech material

Cancer

Oncologists evaluate clinical
benefits in novel therapies

CROs & CMOs

Generalists and specialists in
the growing outsourcing market



MORE PREDICTIVE

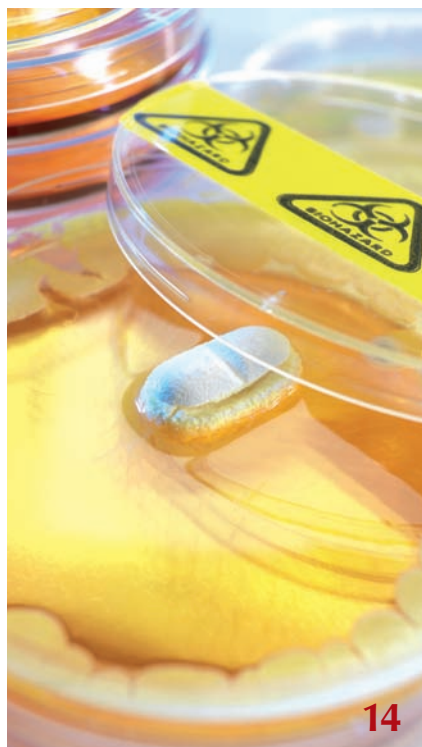
MORE HUMAN

SETTING THE STANDARD IN
GENETICALLY ENGINEERED
& PRECISION RESEARCH
RODENT MODELS

Genetically Engineered Models & Services
Precision Research Models
Integrated Custom Model Generation & Breeding

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COVER STORY



14

Antibiotic crisis: five minutes to midnight

Seventy years after Alexander Fleming discovered penicillin and 15 after Big Pharma got out of antibiotics R&D, multi-resistant bugs are now found across the globe. Worried governments have set up emergency plans to limit overuse of anti-bacterial medicines in clinics and farms, while the WHO has launched a global action plan that was adopted by G7 leaders in June. Attempts to coax Big Pharma back into the less than lucrative area haven't been very successful so far – but biotech SMEs are rising to the challenge.

INSIGHT EUROPE

- 6 ESMO experts rank clinical benefit of novel cancer therapies
- 8 European Commission and Bio-pharma associations to measure uptake of biosimilars across the EU; IVD regulation set to ruin SMEs; EU-funded researchers establish liver-cell-based tox testing
- 10 European Commission confirms ban on products from Indian CRO; Heard in Brussels
- 12 Bio-Based Industries launch €200m call; European Commission to decide soon on regulatory path for new plant breeding technologies

ECONOMY

- 22 Study gives EU IPO biotech update in H1/2015
- 24 Interview: Why the LSE is tempting US companies away from NASDAQ; Mark Fahy, Chris Mayo, London Stock Exchange
- 27 Update on clinical trials
- 30 EMA News
- 32 IP Flash
- 34 Analyst commentary
- 35 Euro Biotech Stocks
- 38 Start-up stories: Eligo Bioscience, Paris, France

REGIONAL NEWS

- 46 Northern Europe: Sweden, Denmark, Finland, and Norway
- 48 Western Europe: France, Belgium, The Netherlands and the UK
- 50 Central Europe: Austria, Germany and Switzerland
- 54 Southern Europe: Italy, Spain, Portugal, Croatia and Slovenia
- 56 Eastern Europe: Poland, Hungary, Romania, Bulgaria and the Czech Republic

SCIENCE & TECHNOLOGY

- 64 Liquid biopsy tests allow early detection of pancreatic cancer
- 66 Protein switch triggers brain regeneration; A biotech label for freshness
- 68 Chase away tumour-promoting macrophages; How *H. pylori* attaches to the stomach

SERVICE

- 96 Biopeople
- 97 News from partner associations: SBA; BIO Deutschland; DIA, EAPB
- 104 Events
- 105 Company index
- 106 Encore

BIOECONOMY

Uprooting old ideas in a venerable industry

The European forest industry is being forced to redefine business models that focus on paper and planks. Following a G7 decision to foster the transition to a bioeconomy, many experts view wood as the most promising sustainable source biofuel and biochemicals. But the industry has even more up its sleeve.



E-HEALTH



The evolution of mobile health

The future looks bright for digital health solutions, and analysts anticipate that the market will grow rapidly in the near future. At the same time, new players are likely to enter the arena and challenge Big Pharma's current dominant role in the healthcare system.

EDITORIAL

Morphing markets

Panic-mongering has grown common in news reporting, especially when it comes to global problems like climate change or antibiotic resistance. Particularly in Europe, most reports generally focus more on the unsolved problems and less on the new opportunities.

For this issue, we've decided to take a different approach. While there's no denying that resistance to current antibiotics is a growing problem, we decided to address the topic by mapping the landscape of ambitious EU innovators coming up with fresh approaches aimed at coping with the danger posed by resistant pathogens (see p. 14).

While G7 Heads laid the groundwork for the end of fossil-based (energy) production in June, bio-based alternatives still struggle with economic viability. Our reporter Martin Laqua talked in-depth with players from the forest-based industries about how they plan to address the bioeconomy challenge (see p. 40).

Instead of backing the upcoming EU data-protection reform, European consumers appear to be more interested in the latest smartphone technology. Bernd Kaltwaßer has investigated the implications for the future digital health market (see p. 58). We found the novel technologies are nothing to panic about – they'll just help provide better medicine.



Thomas
Gabrielczyk
Editor-in-Chief

SPECIAL

CMOs/CROs

- 71 Intro: outsourcing set to increase
- 72 Complete registration of novel antibody formats
- 74 Advanced cell line development
- 76 Pichia – competitive through diversity
- 80 Plasmid DNA: a raw material adjuvant
- 82 Outsourcing process development
- 85 Accelerating clinical studies
- 86 Value-adding perfusion-based biomanufacturing
- 89 EDC efficiency and eCRF design
- 92 In vitro testing of biosimilars

3P Biopharmaceuticals S.L. (ES)	84, 93	Hospira One 2 One Global Pharmaceutical (USA)	CP4	Radium Hospital Research Found. (N)	46
AbbVie Inc. (USA)	28, 29	ibacon (GER)	78	Ranbaxy Laboratories Ltd. (IND)	10
Abivax AB (F)	22	IBM Corp. (USA)	62	Regeneron Pharmaceuticals Inc. (USA)	29
Ablynx BV (B)	28	IES (CH)	79	ReiThera Srl (IT)	68
Accelera Srl (IT)	78	Immunocore Ltd. (UK)	48	Rentschler Biotechnologie GmbH (GER)	86, 95
Actelion Pharma AG (CH)	18, 51	Imperial Innovations Group plc (UK)	27	Richter-Helm BioTec GmbH & Co. KG (GER)	70
Affibody AB (SE)	51	IMS Health (UK)	6, 8	RightsDirect (GER)	52, 53
Albany Molecular Research Inc. (AL)	54	IncBio (PT)	54	Rigontec GmbH (GER)	96
Alexion Europe SAS (F)	30	Innate Pharma SAS (F)	49	Roche AG (CH)	18, 27, 29, 48, 50, 56, 72
Amarna Therapeutics (NL)	50	Intrexon Corp. (USA)	49	Roche Diagnostics GmbH (GER)	65
AnaPath GmbH (CH)	78, 87	Janssen Pharmaceutica N.V. (B)	28	RTW Investments (USA)	48
Apeiron Biologics AG (AT)	49, 50	Jumisc (ES)	78	Safety Alliance (CH)	78, 79, 87
Apitope International NV (B)	28	Karolinska Development AB (SE)	47	Samsung (KR)	60
Aprea AB (SE)	96	KBI Biopharma, Inc. (USA)	81	Sandoz AG (CH)	32, 57
arGEN-X BV (NL/B)	49	Kempen & Co (NL)	34	Sanofi SA (F)	18, 29, 30, 34, 49, 50
Arthur D. Little (UK)	59	KPMG (GER)	59	Santhera Pharmaceuticals (CH)	29, 32
AstraZeneca AB (SE/UK)	18, 48, 68	Labco (F)	51	SAP AG (GER)	62
Audentes Therapeutics Inc. (USA)	30	Labena d.o.o. (SL)	55	Sarepta Therapeutics Inc.	32
Axxam SpA (IT)	55	Laboratorios del Dr. Esteve, S.A. (ES)	30	Sartorius Stedim Biotech GmbH (GER)	33, 88, 94
BASF (GER)	54	Life Science Austria LISA (AT)	17	Scancell Holding plc. (UK)	27
Basilea Pharmaceutica (CH)	18, 30	Lokon Pharma AB (SE)	30	Sekab E-Technology AB (SE)	42
Bavarian Nordic A/S (DK)	28	M+W Process Industries GmbH (GER)	75	Selcia Ltd (UK)	79
Bayer AG (GER)	18, 55, 59, 62	Malin Corp. plc (IRL)	48	Selvita S.A. (PL)	57
BD Biosciences (USA)	21	MB2 LLC (USA)	47	Shield Therapeutics plc (UK)	22
Berlin Partner für Wirtschaft und Technologie (GER)	31	MediGene AG (GER)	48	Smurfit Kappa plc (IRL)	42
BIA Separations d.o.o. (SL)	55	Medimmune Ltd (UK)	48	Sotio a.s. (CZ)	57
BIOCOM AG (GER)	57, 61, 101	Merck KGaA (GER)	28, 34	Spinifex Pharma Pty Ltd (AUS)	51
Biogen Idec (USA)	29, 51	Merck Sharp & Dohme Ltd (USA)	30	St1 Biofuels Oy (FI)	46
Bioiberica S.A. (ES)	55	Metabolic Explorer (UK)	42	Sterne, Kessler, Goldstein & Fox (USA)	11, 32
BioMarin Europe Ltd. (UK)	32	MetSä Group Coop. (FI)	41, 42	Stora Enso Ventures Oy (FI)	41, 42
Biomax AG (GER)	51	Microsynth AG (CH)	89	Summit Therapeutics plc (IRL)	34
Biophytis SAS (F)	22	MLM Medical Labs GmbH (GER)	23	Sun Pharmaceuticals Ltd (IND)	10
Biotech AG (GER)	51	Molecular Partners AG (CH)	50	Svenska Cellulosa AB (SE)	42
BioVersys AG (CH)	15, 18	Monsanto (USA)	12, 54	Swiss Biotech Association (CH)	101
Boehringer Ingelheim (GER)	29	MotifBio (USA)	24	Synexus Clinical Research Ltd (UK)	56
Bone Therapeutics (B)	30	Mundipharma EDO GmbH (CH)	27	synlab GmbH (GER)	51
Borregaard ASA (N)	42	Nanobiotix S.A. (F)	29	Taconic Biosciences (GER)	CP2
Braster SA (PL)	56	Neurimmune AG (CH)	29	Targovax AS (N)	46
Bristol Myers Squibb (USA)	30, 48	Norske Skog ASA (N)	42	Thermo Fisher Scientific (USA)	CP-Tip-on, 7, 13
BSL Bioservice GmbH (GER)	78	nova-Institut GmbH (GER)	43	TiGenix N.V. (B)	49
Calibrium LLC (USA)	47	Novartis AG (CH)	18, 46, 51, 57	UBM EMEA Amsterdam – CPHI (NL)	103
CANDOR Bioscience GmbH (GER)	26	Novo Nordisk A/S (DK)	47, 94	uniQure BV (NL)	48
Cassiopea SPA (IT)	22	Oncos Therapeutics Oy (FI)	46	UPM-Kymmene (FI)	41
CELONIC AG (CH)	73, 74	One Way Liver Genomics S.L. (ES)	55	Vaccibody AS (N)	46
Cempra Inc (USA)	18	OPIS s.r.l. (IT)	27, 89	Valmet Oyj (FI)	42
CEVEC Pharmaceuticals GmbH (GER)	63	Oxitec Ltd. (UK)	49	Vaxxilon (CH)	51
Cinven Ltd (UK)	51	PDS Life Sciences (CH)	79	Verseon (USA)	24
Coretherapix (ES)	49, 54	Pfizer (USA)	12	Vetter Pharma International GmbH (GER)	29, 82, 83
Cosmo Pharmaceuticals (IT)	18, 22	Pfizer (USA)	12	VGXI Inc (USA)	27
Crucell N.V. (NL)	28	Pfizer (USA)	12	Viomedo UG (GER)	62
CSL Behring GmbH (GER)	30	Plexcera Therapeutics EU Ltd (IRL)	30	Vitae Pharmaceuticals Inc. (USA)	29
CTC North GmbH & Co. KG (GER)	71, 85	Pliva Croatia Ltd. (HR)	55	Vitameter Inc. (CDN)	62
Cytomet GmbH & Co. KG (GER)	30	Polaris (FI/NO)	46	Vivotecnica Research S.L. (ES)	79
Da Volterra (F)	15, 18	Polpharma S.A. (PL)	56	VTU Technology GmbH (AT)	76, 85
Dentons Europe LLP (GER)	25	ProBioGen AG (GER)	91, 92	Wacker Chemie AG (GER)	67
DIA Europe (CH)	9	ProMetic BioTherapeutics Ltd (UK)	30	Wilex AG (GER)	50
Dicerna EU Ltd (UK)	30	Prosensa BV (NL)	32	Woodford Investment Management LLP (UK)	48
Dr. Knoell Consult GmbH (GER)	79	PureTech (USA)	24	ZAB Brandenburg Economic Development Board (GER)	CP3
EBD Group (CH)	39	Puretech Health plc (USA)	22	Zeltia Group (ES)	28
Effimune SAS (F)	27	Quintiles Ltd (UK)	68	ZHAW – Zurich University of Applied Sciences (CH)	45
Eli Lilly (USA)	48				
Eligo Biosciences (F)	38				
Eppendorf AG – Bioprocess Center Europe (GER)	35				
Evotec AG (GER)	49, 50				
Fab'entech (F)	30				
Faron Pharmaceuticals Ltd. (FI)	22, 47				
Fate Therapeutics Inc. (USA)	30				
FGK Clinical Research GmbH (GER)	83				
Fidelity Management & Research Company (USA)	48				
Flamel Technologies (F)	34				
Fujifilm Diosynth Biotechnologies (UK)	77				
Gadea Pharmaceutical Group (ES)	54				
Galapagos NV (B)	28				
Galmed Pharmaceuticals (IL)	55				
Garmendia (ES)	54				
GE Healthcare (UK)	94				
Gedeon Richter Ltd. (HUN)	57				
Generali Deutschland Holding AG	59				
Genetrix Group (ES)	49, 54				
Genmab A/S (DK)	34, 46, 47				
GlaxoSmithKline Biologicals (B)	30				
GVK Biosciences (IND)	10				
Hack my Hormones Inc. (USA)	62				
HealthCap (SE)	46				
Heidelberg Pharma AG (GER)	50				
High-Tech Gründerfonds Management GmbH (GER)	19				
Holmen AB (SE)	42				

INNOVATION, GROWTH AND SUSTAINABLE DEVELOPMENT

GLOBAL BIOECONOMY SUMMIT 2015



Driving a Global Bioeconomy

GLOBAL BIOECONOMY SUMMIT Bioeconomy has gained momentum as a strategy to foster sustainable development and green growth. More than 30 industrialised and emerging economies have developed political strategies. However, the differences are huge. The German Bioeconomy Council is therefore organising the first Global Bioeconomy Summit on 25–26 November in Berlin. Participants from more than 40 countries worldwide have registered to pioneer an agenda driving a global and sustainable bioeconomy. More information: www.gbs2015.com

POTSDAM DAYS ON BIOANALYSIS 2015

Nov 4 - 5, 2015 | POTSDAM | GERMANY

November 4

International Technology Forum on *In vitro*-Diagnostics and Regenerative Medicine

November 5

Potsdam Colloquium on Bioanalysis

The symposium will include an international scientific lecture program with sessions on immunotherapy, transplantation medicine, development of non-clinical-assays for ATMP, biophotonics, point-of-care-testing – infectious diseases as well as m-health & diagnostics.

Participating companies

Autoimmun Diagnostika, Bayer HealthCare,
Beckman Coulter, co.don, Curetis, Exploris, Ibidi,
Illumina, Novartis, NovoNordisk, Qiagen, R-Biopharm,
Sanofi, Siemens Corporate Technology, Xintela AB

Key speakers

Till Bachmann | Edinburgh, UK

Frank Emmrich | Leipzig, Germany

Max Fleischer | Munich, Germany

Matthias von Herrath | Seattle, USA

Evy Lundgren-Åkerlund | Lund, Sweden

Joerg Neukammer | Berlin, Germany



The accompanying program includes partnering, poster and industry exhibition.
Call for posters: Deadline for abstract submission: October 15.

Participation in the symposium is free of charge. Registration is requested.

www.b2match.eu/potsdamdays-bioanalysis2015



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NEWS

EC okays megamerger

🇪🇺 In mid-August, the European Commission approved the takeover of Lake Forest-headquartered contract manufacturer Hospira by Pfizer for about €15.3bn (\$17bn) under EU merger regulations. Under the deal, the US pharma giant will become a leader in the emerging market for biosimilars. The approval is conditional to Pfizer divesting in infliximab biosimilar drugs and sterile injectable drugs, mostly chemotherapeutics.

Focus on Alzheimer's

🇪🇺 The Innovative Medicines Initiative (IMI) has launched a €95m call for proposals focused on six research areas, four of which involve Alzheimer's disease. The other areas focus on diabetes and on how to best gain patients' input on the risk-benefit assessment of new medicines. The Alzheimer's projects include evaluation of the diagnostic value of amyloid imaging in drug development, identification of new targets in patients carrying the inflammatory risk markers TREM2 and CD33, and apolipoprotein-E biology. An additional project seeks to identify people who are in early stages of the disease. Just in March this year, IMI launched a joint Alzheimer's Research Platform with a budget of €138m.

Self-regulation

🇪🇺 🇬🇧 In mid-August, EU food watchdog EFSA (Parma) rejected concerns from nine NGOs that the Agency's risk assessment of Monsanto's genetically modified oilseed rape MON88302 was inadequate and flawed. The GMO is tolerant to the company's herbicide glyphosate.

Bioeconomy booster

BIOECONOMY The Bio-Based Industries Joint Undertaking (BBI JU) launched a €200m EU call for bioeconomy and signed its first ten grant agreements worth €120m at its Brussels Info Day. Seven of the projects are Research and Innovation Actions aimed at replacing fossil-based materials with biobased materials:

- US4GREENCHEM – pre-treatment of lignocellulosic feedstock
- PROVIDES – new sustainable pulping technologies
- SmartLi and Greenlight – fibres and polymers from lignin
- CARBOSURF – fermentation processes to produce biosurfactants and specialty carbohydrates
- PROMINENT – extracting protein products from plant residues

- NewFert – nutrient recovery from waste streams and residues

The other three are demonstration and platform technology projects:

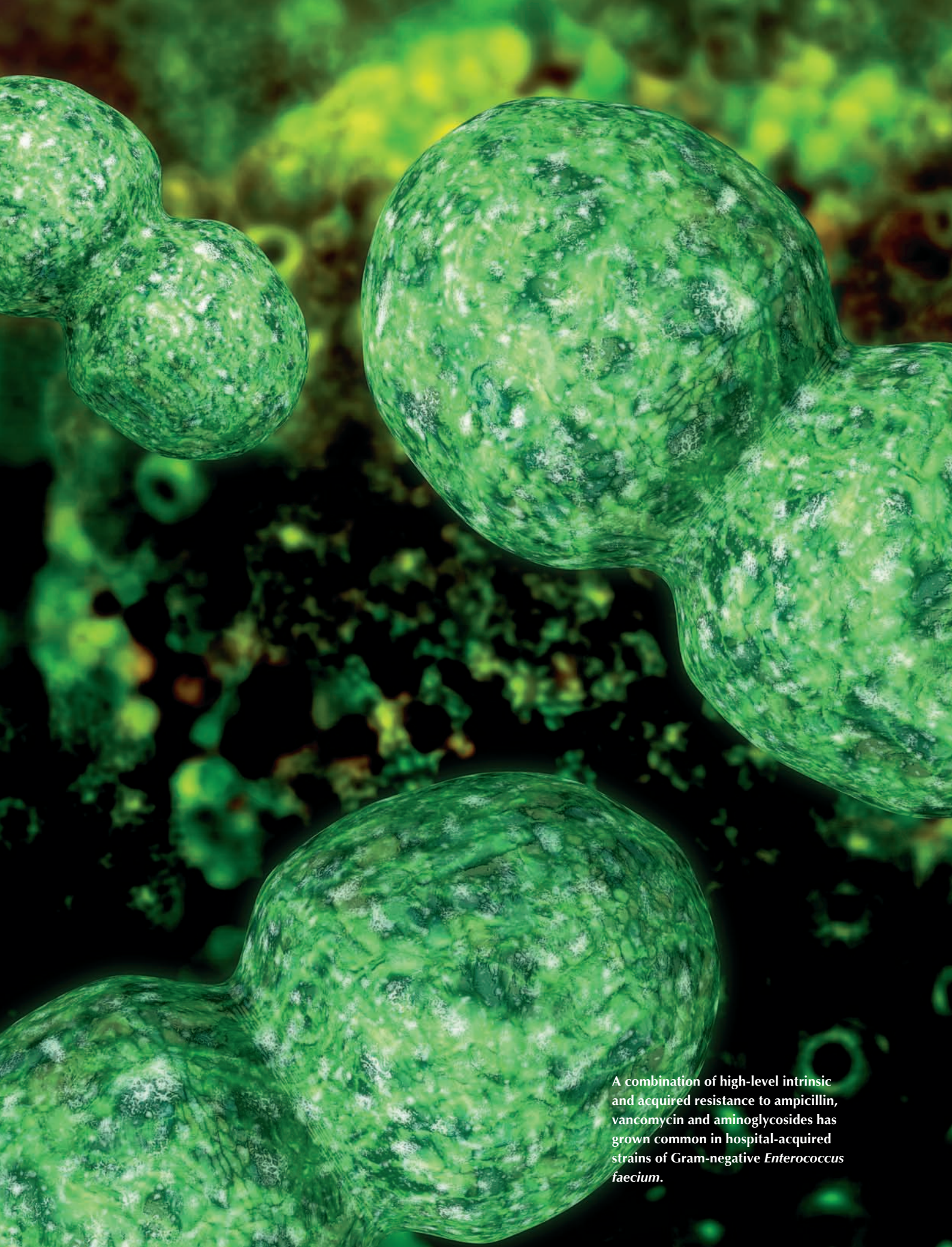
- PULP2VALUE – a biorefinery for sugar beet pulp
- ValChem – techno-economic validation of the manufacture of chemicals from wood (see page 40)
- FIRST2RUN – exploiting underutilised oil crops to extract vegetable oils

While the EU's bioeconomy annual turnover has been estimated at about €2 trillion, the industrial biotech sector is significantly smaller. At the end of June, the BIO-TIC consortium, another EU-funded project, presented a roadmap designed to establish a €50bn industrial biotechnology sector in Europe by 2030. ■



The next regulatory hot potato

AGRICULTURE Results of a legal analysis on "New plant breeding technologies", such as targeted mutation by CRISPR/CAS9 or ODM, will be announced by the European Commission at the end of September. German GMO Authority BVL told EUROBIOTECH that the Commission asked it not to push forward field trials with Cibus Europe's herbicide-tolerant oilseed rape "SU Canola" until the end of the year. In contrast to the US, where in mid-July, the White House initiated a review of ag-biotech rules, the BVL as well as a study by EU researchers commissioned by the EC, have already greenlighted Cibus' ODM technology as "not GMO". ■



A combination of high-level intrinsic and acquired resistance to ampicillin, vancomycin and aminoglycosides has grown common in hospital-acquired strains of Gram-negative *Enterococcus faecium*.

Time is running out

ANTIBIOTIC CRISIS Big Pharma deserted the antibiotics market around the turn of the millennium. Since then, bacterial resistance to the around 80 available broad-spectrum antibiotics has only grown. Experts now say that's due to substance overuse and bacterial adaptation. Even though most patients with bacterial infections can still be treated, statistics show that multidrug-resistant (MDR) strains in ICUs and infections with multiresistant microbes are on the rise. Governments all over the world are now trying to coax companies back into the field.

When Alexander Fleming discovered penicillin back in 1928, he was aware that widespread use of his live-saving antibiotic could eventually create resistant microbe survivors. A bacteria's inherent ability to adapt through mutation and transfer resistance by mobile genetic elements is at the heart of an important and unavoidable fact. Every antibiotic is little more than a stopgap. Over the last several decades, the broad, non-targeted and inappropriate application of broad-spectrum antibiotics in both livestock farming and medicine have accelerated the development of MDR superstrains. What's worse is that since the late 1990s, drug development has begun to lag behind the evolution of dangerous pathogens, as Big Pharma companies exited the field to focus on medical areas of high medical need that promise better returns on investment.

The consequences are beyond serious. According to the leading US-based health institute (CDC), 23,000 Americans die every year when standard antibiotics fail to stop resistant bacteria. Figures from the European Centre for Disease Control and Asian authorities indicate 25,000 annual deaths in the EU (2009), 38,000 deaths in Thailand and 58,000 deaths in India. There are no official fatality figures from China, which consumes roughly half of the global antibiotics supply of 162,000 tonnes per year. 48% of those medications are used to prevent infections in livestock or breeding, while just over half are employed in human medi-

cine (ENVIRON SCI TECH, doi: 10.1012/acs.est.5b00729). Statistics are also missing for most other countries.

So far, attributable deaths have mostly involved vulnerable patients in hospital ICUs or babies living under unsanitary conditions. But as antibiotic concentrations in wastewater rise due to overuse in medicine and animal husbandry alongside bacterial resistance attributed to

gene transfer in soil, the situation is deteriorating. "It's important to prevent panic-mongering, but at the same time to understand the gravity of the situation," says Marc Gitzinger, CEO of Swiss antibiotics developer Bioversys. "We currently only have a few medicines against which bacterial pathogens haven't developed resistance. It's also true that pathogens like methicillin-resistant *Staphylococcus aureus* (MRSA) initially occurred in ICUs, but subsequently spread to the general population," he adds.

Governments and health bodies are particularly concerned that with a shortage in the supply of novel antibiotics, things could soon take a dramatic turn for the worse. Fears that last-resort antibiotics could stop working are being fueled by a worst-case scenario published last December by ex-Goldman Sachs head Jim O'Neill on behalf of UK Prime Minister David Cameron. His ominous 'Review on Antimicrobial Resistance' (AMR) says the economic cost of resistance to antibiotics, HIV and malaria meds could by 2050 amount to the incredible figure of US\$100 trillion if the number of deaths they cause rises by 10 million per year. Although that mortality figure is purely speculative, it certainly caught global attention among policymakers.

More founded figures from the World Health Organisation (WHO) were published in the first AMR surveillance report last December. In its survey on the global spread of MDR strains in 114 nations, the ...



FLORENCE SÉJOURNÉ
CEO, Da Volterra SA, Paris

? Why have SMEs formed the BEAM Alliance?

! Current EU industry initiatives to tackle the antimicrobial resistance challenge are mostly pharma-based. With the BEAM Alliance, we wanted to be able to speak with one voice to European stakeholders ... today, EU funding could definitely be reinforced towards the antimicrobial innovative pipeline developed by SMEs, as that's where most of the innovation is coming from in this therapeutic area.

» Read the full story in the printed issue.

A missing ingredient

STOCK MARKETS There has been a long drought for biotechs seeking money on European stock markets. But now, going public on the London Stock Exchange is having a renaissance. Head of small and mid-cap companies Mark Fahy and his colleague Chris Mayo explain what European stock exchanges have to offer for Life Sciences companies, and why London is even tempting US companies away from NASDAQ.

EuroBiotech Next to Paris, London is one of the most successful stock market locations in Europe at the moment. Why?

Mayo London Stock Exchange is doing very well, yes. 2014 was the best year for Life Sciences capital raising in London in the last ten years. We had the largest biotech IPO globally by proceeds with Circassia, which was around £210m. The best performing IPO in London last year, 4D Pharma, was a biotech offering. And yet, 2015 will be the best year ever. We are already approaching US\$3bn raised. We have shown this year that Life Sciences companies are able to raise capital from both UK and US investors through a London listing. And a very interesting fact: at one point, we had more Life Sciences companies from the US listed in London than from the UK. There are now three US companies listed here: Puretech Health PLC, Verseon Corporation and Motifbio PLC.

EuroBiotech So what can London offer that New York cannot?

Fahy First of all, there is the scale. What London Stock Exchange does very well is offer access for smaller companies. In markets like NASDAQ, companies of less than a US\$250m valuation tend to struggle to get any kind of investor or analyst coverage. And it shows: the performance of biotechs in that cap range that went public there last year flatlined across the year. New York does not really have a good market offering for smaller companies, whereas London does. Another point concerns investors and peer group. We are starting to see significant investor



MARK FAHY is head of the UK Small & Mid-Cap team at the London Stock Exchange (LSE). Fahy studied economics in Lancashire, UK. He worked as a Fund Manager for Pilkington Pension Services Ltd, a UK pension fund, for almost eight years before switching to the LSE in 2004. He is also an Associate of the Society of Investment Professionals. At LSE, Fahy advises companies that are considering a flotation.



CHRIS MAYO is a consultant for Primary Markets at the London Stock Exchange Group. In this role, he advises and supports companies and their investors in assessing their IPO strategy.

appetite in the biotech sector across the UK and Europe. Take, for example, tech transfer: there is a growing mass of businesses based or listed in the UK, which is acting as a pull for companies in from all around the world of a similar type that look to list in London to be alongside that peer group, and also act as investors who understand that sector perhaps better than they do in the US or other parts of the world.

Mayo For instance, the best performing main market IPO last year was a company called Allied Minds PLC. Allied Minds is a tech transfer company that turns scientific discoveries from dozens of US universities and research institutions into commercial products. Their London listing was probably one of the main reasons why Puretech decided to list here as well, having seen how well Allied Minds did just one year before. London has almost formed its own kind of specialism in tech transfer companies. And that was one of the key attractions for Puretech: there were already three companies listed in London with a similar business model. In the US, on the other hand, there were no such businesses listed.

EuroBiotech Some say that NASDAQ offers better comparability for most biotechs. Is a peer group the key factor for selecting a suitable market?

Mayo I think healthcare is one of those sectors of which one has to take a global view. And investors increasingly do that

» Read the full interview in the printed issue.



Paving the way for an arboreal comeback

FOREST-BASED INDUSTRIES Demand for paper and natural building materials is low, and both revenues and employee numbers are falling at firms involved in wood-based industries. But the sector is adapting. Business models are growing more complex as companies reach out for cross-sectoral collaborations. A central point in the agenda that's in line with the overarching bioeconomy concept is the ongoing search for sustainable and profitable uses for wood and its components. EUROBIOTECH takes a look at the Big Players and what they have to offer so far.

>> Read the full story in the printed issue.



On the road to Digital Health

E-HEALTH Although predicting the future is a tricky business, biotech experts worth their salt agree that the coming years will see tremendous growth in the digital health market. Along with start-ups, established pharma and biotech firms, a number of companies from outside the Life Sciences sphere – eager to explore the new possibilities – are hurriedly entering the market. But despite the bright forecasts, digital health has yet to deliver on its promise. Meanwhile, politicians and regulators are fighting to keep pace with developments in technology.

>> Read the full story in the printed issue.