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Interview

Aleks Engel from
Novo Holdings
on a new fund
that will mobilise
SMEs in the fight
against antibiotic
resistance.



Antibiotic Resistance



FREE EXCERPT

The phage's are back

Genome editing

EU Court's Advocate General
disappoints GM opponents

Immunology

How fast food corrupts your
immune system permanently

Big Bioindustry

Attracting investment to scale
up bio-based production

GMP bioproduction

Which CDMOs will seize the
lead in an expanding market?

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We need creative investment to tackle AMR



CHRISTOPH SPENNEMANN

oversees the Intellectual Property (IP) Unit at the United Nations Conference on Trade and Development (UNCTAD). Christoph will organise a session on fostering investment in the development of new antibacterial prevention technologies at UNCTAD's 2018 World Investment Forum. He holds a master's degree in international economic law and European law from the University of Lausanne and practised law in Berlin.

Each year, 700,000 people worldwide die of resistant infections; estimates say this figure will rise to 10 million victims a year by 2050 unless effective action is taken to tackle antimicrobial resistance (AMR).¹ From an investment perspective, the main problem is a lack of incentives for the private sector to engage in AMR-related R&D. The need to use antimicrobials rationally to avoid the development of resistance seriously limits a developer's expected return on investment (ROI). Antimicrobial R&D is mainly carried out by biotech-oriented small and medium-sized enterprises (SMEs), which face difficulties in attracting the needed investment. One of the reasons for this is national pricing schemes that do not take account of the public health value of new antimicrobials, such as reduced times for treatment and hospitalisation, and the economic value of preventing infections in the first place.

What can be done to address this situation? Action at two levels is needed. First, it is important to identify investors to assist SMEs in their R&D. We should inter alia be looking out for non-traditional investors, such as health insurers and hospital owners, who have an economic interest in reducing resistances. Second, there needs to be a global debate on how to reconcile the industry's need for ROI with the need to make new antimicrobials accessible to patients, especially in developing countries where currently more people suffer from lack of access to antibiotic treatments than from resistance. Due to global mobility, bacteria in developing countries directly affect European societies. European governments should take the lead in the design of innovative incentive schemes beyond ad hoc projects, i.e. on a more permanent basis.

The United Nations Conference on Trade and Development (UNCTAD) through its World Investment Forum (WIF) on 22–25 October 2018 in Geneva provides a platform for both approaches.² One of its events ("Fostering investment in the development of new antibacterial prevention", 24 October) will enable partnerships between developers of novel AMR treatments and interested funders, thereby providing investors with a global platform to publicise their contribution to public health. The WIF will also feature a policy dialogue between the industry, investors, payers, and governments to clarify the essential "ground rules" governing investment in AMR. ■

FREE EXCERPT

COVER STORY



Antibiotic resistance: Phages to the rescue?

The crisis caused by antimicrobial resistance is growing worse, and in the search for solutions, it makes sense to take a closer look at an alternative that's already out there – bacteriophages. They've been used in Eastern Europe for decades. Now pressure is mounting on global health authorities to see whether bacteria-killing viruses or products based on them could provide a viable option to antibiotics. But guidelines are lacking in Western countries, and many doctors remain cautious about the idea of treating infections with viruses.

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IMMUNOLOGY



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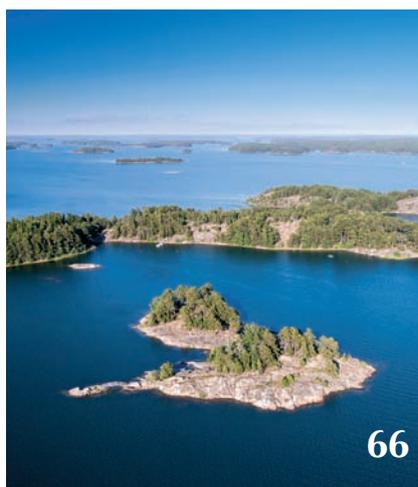
Fast food epigenetics

Everyone knows that too much fast food is unhealthy, but now researchers have discovered that a few burgers early on can actually double the risk of later contracting chronic diseases like diabetes, atherosclerosis, or stroke. And immunologists now say even returning to a healthy diet later in life might not help, because fast food reprogrammes activity in the innate immune system.

FINANCING

Cash for going green

Despite several promising biorefinery projects, the finance industry remains largely sceptical about developing businesses that involve bio-based products and power generation. Now the European Investment Bank is pushing financiers to take a bigger stake in the success of the bioeconomy. The newest instrument is dubbed the Circular Bioeconomy Thematic Investment Platform.



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EDITORIAL

Battling infections

After most of the low-hanging fruit was harvested until the 1970s, antibiotics have become a niche market. Big Pharma long ago turned to areas that offer a better return on investment (see Editorial, p. 3). However, after the WHO, G20 and other bodies kicked off initiatives to tackle emerging antibiotic resistance, development activity has revived, particularly in the biotech SME scene.

A novel investment fund commissioned by the Novo Nordisk Foundation is aiming to make up for the 30-year pause in antibiotic development by investing in biotechs that have new concepts and modalities (see Interview, p. 22).

The Chair of the fund's Scientific Advisory Committee believes most new compounds will come from biological sources, including sea organisms and bacteriophages.

The bacteria-specific killers have been used in Eastern Europe and Russia for decades – long before Big Pharma invented the term “targeted therapies”. Phages are now being re-evaluated by Western biopharma alliances (see Cover Story, p 14).

However, since old scaling models (“sell as much you can”) won't apply to novel anti-infectives, new ways have to be found to make profit for developers. And regulators will have to sign off as well.



Thomas Gabrielczyk
Editor-in-Chief

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Fighting AMR: turning the p(h)age

PHAGE THERAPY The rapid development of antibiotic resistance has become a major public health issue that could soon kill 10 million people annually. One promising alternative to ineffective antibiotics has been around for almost a century – bacteriophages. The microbe-killing viruses are used in medicine in Georgia, Poland and Russia, but have been neglected by western doctors. Now pressure is mounting on global health authorities to put the option back on the table.

When the 33-year-old Ukrainian soldier Dimitry F. badly injured his right knee during a mission, he had to be given a prosthesis. Before long, the area grew infected with a pan-resistant *Pseudomonas* strain – a potentially fatal diagnosis, because the bacteria was resistant to all currently available antibiotics. Only an old therapy from Georgia that was never really adopted by Western medicine could save his leg. Bacteriophages, also known as phages, are viruses that target specific strains of bacteria and reproduce in them. In the process, they destroy their host so effectively they appear to have eaten it, which explains the Greek origin of the name (phagein = devour). After latching on to a bacteria's outer surface, phages inject their own nucleic acid and hijack their host's genetic machinery, effectively turning them into phage factories. Those factories eventually produce so many copies of the phage that they burst. If this process happens inside the human body, the phages produced eventually decay and disappear after lysing all of the target bacteria, while their components are metabolised. The viruses have been widely used for medical purposes in Russia, Georgia and Poland, but for a variety of reasons never took off elsewhere in the world

Phages – an antibiotic alternative?

The Head of Septic Surgery and Infectious Disease Research at Charité University Hospital in Berlin has however built up a library of phages that specifically target the bacteria which produce biofilms. Last year, Andrej Trampuz founded the startup Phagomed Biopharma GmbH. "Our vision is to develop phage therapy for indications where current antibiotic therapy is limited," says Alexander Belcredi, co-founder and CEO of Phagomed. "The fact that we had so much knowledge about the experimental and last-resort treatments right from the start is a real asset." One indication Phagomed is working on is

for periprosthetic joint infections like that contracted by Dimitry F. Bacterial infections of hip or knee prostheses are often associated with biofilms. According to Belcredi, the antibiotic dosages needed to eliminate that boundary and effectively destroy the bacteria are typically toxic for humans. Specific phage cocktails, however, could solve the problem. "We've already demonstrated strong phage activity against *S. aureus* biofilms," Belcredi says. "That allows us to eradicate a mature MRSA biofilm more effectively than with antibiotics, and at doses feasible in humans." The



ALEXANDER BELCREDI
CEO of Phagomed Biopharma GmbH

? What fascinates you most about phage therapy?

! The paradox that exists between the biological principle – that phages infect and lyse bacteria – and the complete lack of human pharmaceutical applications in Western medicine.

results of that study will be published this year. Phagomed was incorporated in November 2017, and is currently completing a seed financing round.

The problem of ineffective antibiotics in biofilm-associated infection is one aspect of a much wider problem – that antimicrobial resistance (AMR) as a whole is taking on frightening dimensions. Recently the World Health Organization published a comprehensive report based on data from 500,000 patients in 22 countries on the worldwide status of AMR. The numbers are alarm-

ing. Around 50,000 people are currently being killed by antibiotic-resistant infections every year in the EU and the US alone. The WHO estimates that annual costs generated by the problem top €7bn (\$8.3bn) in Europe and \$6.5bn (€5.5 bn) in the United States. New approaches for tackling the AMR crisis are therefore urgently needed. But do those approaches have to involve traditional antibiotic treatments? Phage therapy proponents say it makes sense to take a closer look at what's already out there.

The first mass medical application of phages took place during the Winter War (1939–1940) between Finland and the former Soviet Union. During the three months of the conflict, around 6,000 soldiers were treated with bacteriophages. Big pharmaceutical companies like Eli Lilly (US) and Behring-Werke (Germany) also focused on the production of phage preparations in large scales at the time. But with the subsequent development of antibiotics, which can be used to treat a broad range of bacteria, phage therapy was soon ignored by pharmaceutical companies on the western side of the Cold War.

A long-forgotten history

The therapeutic advantages of phage therapy were first uncovered in 1917, when Felix d'Herelle was working as a research assistant at the Pasteur Institute in Paris. Although the researcher didn't know what type of microorganism was killing the bacteria in his experiments, his findings opened a new chapter on tackling the infections they cause. In 1936, together with his friend microbiologist George Eliava, d'Herelle would lay the foundations for the George Eliava Institute of Bacteriophage, Microbiology and Virology (EIBMV) in the Georgian capital Tbilisi. The institute still exists today, and has been a last-ditch destination for patients with chronic infections since Western companies stopped phage programmes in favour of antibiotics [...]

» Read the full story in the printed issue.



How fast food hijacks young genes

TRAINED IMMUNITY Americans and Europeans love fast food, even though doctors are now more certain than ever that the highly processed meals that go hand-in-hand with a hectic Western lifestyle are not a smart health choice. The latest findings suggest that fa(s)t food imprint key genes in the innate immune system, possibly causing the permanent immunological hypersensitivity that is at the root of diabetes, atherosclerosis and other common diseases of civilisation.

Eicke Latz is concerned. Especially when the renowned expert for innate immunology from the University of Bonn in Germany speaks of the first worldwide statistics on obesity in children and adolescents. "It's crucial to educate children on healthy diets," he stresses. "They can't be subject to manipulation through food industry advertising. They should be enabled to make informed choices when it comes to nutrition."

According to the very first global meta-analysis of Body Mass Index (BMI) development from 1975-2016 across the globe, which was published in the December issue of *LANCET* (doi: 10.1016/S0140-6763(17)32129-3), obesity is definitely on the rise. Funded by AstraZeneca, the NCD risk factor collaboration reports that 124 million youngsters between 5-19 years of age have a BMI over 30. Many of those young people live in Europe, high-wage English-speaking countries, or emerging countries (for boys see map p. 54). 60% of the obese youngsters will remain obese in adulthood as well, doubling their risk of developing chronic diseases. In the mid-term, that will have already cash-strapped healthcare budgets on the ropes. In Europe, treating the young obese already makes up 6% of all healthcare costs.

The future cost of diabetes alone is ruinous, even for wealthy countries like export world champion Germany. According to Michael Laxy, the head of a study

group at IGM Munich that analysed diabetes costs from 2012-2015, co-morbidities such as retinopathy drive annual per patient costs of around €2,800. The growth of diabetic incidence and treatment costs like those associated with blindness (€12,000), diabetic ulcers (€5,200), foot amputation (€52,000), renal insufficiency (€92,000) and cardiovascular complications (€10,800-80,000) are expected to contribute dramatically to future healthcare expenses.



EICKE LATZ Director of the Institute of Innate Immunology at the University of Bonn, Germany

? What must be done to prevent a disease-prone Generation XXL?

! We can achieve a lot through prevention. We should establish health education in schools to immunise the next generation against food industry temptation.

For over 10 years, researchers have known that fast food consumption correlates with obesity and impaired metabolism (*LANCET*, 2005; 365: 36-42). According to a 15-year study conducted by US and Norwegian researchers, people who visited fast food restaurants more than twice a week weighed roughly 4-5 kg more than those who visited them less than once a week. Insulin resistance was also twice as likely in the former.

"Fast food has a lifelong impact on health."

What concerns Latz most about the fast food-obesity correlation is his own recent findings. Previous research has linked the consumption of Western-style diets to chronic subsymptomatic inflammation, which is believed to trigger diseases such as type 2 diabetes, obesity, atherosclerosis, cardiovascular disease, Alzheimer's disease and cancer. That's why "it's of fundamental importance to understand the mechanisms that link consumption of calorie-rich diets to increased inflammation," Latz explains.

In mid-January, his group reported in *CELL* (doi: 10.1016/j.cell.2017.12.013) that even transient fast food consumption [...]

» Read the full story in the printed issue.

FREE EXCERPT



Finland's Archipelago Sea will be the focus of the first Environmental Impact Bond.

Follow the money – from niche to norm

BIOECONOMY Despite seemingly insurmountable environmental challenges ahead and the many 'successes' flaunted by big biorefinery projects, the wider business community remains stubbornly sceptical about developing business within the bio-based paradigm. Now policy-makers are pushing financiers to take a bigger stake in its success. New efforts are underway to drive private investment in bioeconomy ventures.

>> Read the full story in the printed issue.

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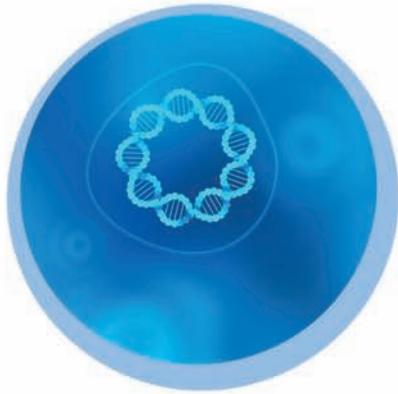
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