



European Biotechnology

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Interview

Serial founder
Andreas Bergmann
explains how his
companies will
extend personalised
medicine beyond
oncology.



High Potential

FREE EXCERPT



Ruling under fire

Scientists press EU Commission to modernise GMO legislation

Artificial Intelligence

How the new paradigm of AI is disrupting drug development

Bioeconomy/COP24

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More money needed to drive the bioeconomy



MICHAEL NETTERSHEIM joined BASF Venture Capital in 2011 from High-Tech Gruenderfonds, Germany. Prior to this, he was responsible for corporate finance and IR at a publicly listed biotech company in Munich. Within the Bio-based Industries, he is currently serving on the Boards of Directors of Advanced BioNutrition Corp., P2 Science Inc., and Renmatix Inc. (all US). Nettersheim studied chemistry at the University of Bonn, where he was awarded a doctorate in biochemistry. He holds a MBA from the Kellogg-WHU Executive MBA Program.

Bioeconomy comprises the Bio-Based Industries (BBIs) and the Blue Economy of the sea. Investments into the Bioeconomy help reduce Europe's dependence on non-renewable natural resources, transform the production of food and manufacturing of biomaterials, and promote sustainable and resource-efficient production. This sounds like a very attractive field for investors. However, an analysis of the European Investment Bank (EIB) revealed that funding of BBI projects is not as high as it should be. Companies suffering from this lack of funding are mainly those with successfully tested products and where small-scale pilot production had been demonstrated. Further up-scaling and market development require much more capital, often well above available funding levels.

For demonstration plants, typical investment volumes range from €10m to €100m; for commercial scale plants these figures are much higher. The capital demand varies depending on technology and product type. Investors favour projects with lower capital needs in order to limit a too high exposure to single investments, but also to minimise financing risks of individual investments. Those BBI companies that manage to receive funding still face significant challenges, such as technological risks when up-scaling, regulatory uncertainties, as well as business risks arising from volatility of market demand and input factors. Investing in this field therefore requires specific knowledge about technologies and markets. As a result, only a handful of specialised financial investors and a few corporate venture capitalists are investing in BBIs. This is in line with EIB's finding that 77% of bioeconomy projects in Europe are facing issues in raising investments when scaling up technologies to demonstration or even to industrial scale. To address the funding gap, the EIB has just recently announced the launch of a Circular Bioeconomy Investment Platform (CBIP). An initial €100m will be made available from EIB on very favorable terms, clearly with the intention to mobilise additional public and private capital. The vehicle itself is conceived as a specialist fund which should help to crowd in more investors by removing barriers resulting from limited understanding of the sector. For BBI projects seeking funding this would be a great step forward.

Specialist Investors have learned to manage technological, up-scaling and market development risks. This, however, is different for regulations affecting individual investment cases, sometimes literally overnight. The most prominent example is the recent classification of CRISPR-Cas9 technology as genetic engineering by the European Court of Justice. For investors those kinds of risks are hardly assessable and manageable, thereby creating a significant investment barrier for specialist and generalist investors alike. In addition to launching the CBIP, reliable and efficient frameworks are important drivers to increase investor commitment to the European Bioeconomy. These frameworks should cover innovation and technology utilisation, labeling, and classification of products as well as environmental, sustainability, and societal aspects.

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COVER STORY



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Cannabis and the great green rush

Marijuana is the most cultivated, trafficked and abused illicit drug worldwide. But the list of European countries that see clear medical benefits from the plant and want to legalise cannabis for medical purposes has grown long. Canadian manufacturers in particular have been signing export deals with European governments to get a foot in the door in the billion dollar business. Gold fever is growing in the industry, but doctors urge caution on the path to improving care for patients.

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ARTIFICIAL INTELLIGENCE

Drug discovery and AI

The time it takes to bring a drug to market hasn't improved significantly for 40 years now, and productivity in terms of return on investment is even dropping in the pharmaceutical industry. Will powerful new algorithms help usher in a new age of drug development? We talked with CEOs from companies confident that AI is going to make all the difference. But will it really?



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BIOECONOMY



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Need for incentives

Six years ago the European Commission launched its Bioeconomy Strategy, but since then investment in biotech has actually dropped. Faced with climate change and other global threats, the EC now wants to go green through funding. Industry leaders and experts recommend ramping up innovation – and paying for it with taxes on CO₂.

EDITORIAL

The tightrope

For regulators, CRISPR-Cas9 genome editing is a tough topic to legislate. It can bring huge benefits, or wreak irreversible damage on humankind and the environment. The claimed birth in China of genome-edited HIV-resistant twins in November rightly provoked an international outcry, as it both violated Chinese law and crossed accepted ethical and moral lines. Control of research is crucial to prevent the misuse of this powerful technology by renegade researchers. At the same time, plant researchers in Europe are suffering under over-regulation in the field of genome editing (see p. 6), which blocks them from commercialising crops that can be adapted within a generation to withstand the impacts of climate change. All because the plants have been declared GMOs.

Meanwhile, killing mosquitos with gene traps as they head to the Northern hemisphere carrying malaria and dengue might morph into an uncontrolled field release experiment. What to do with the many different applications of one technique?

Interest and advisory groups have called for a staggered approach to regulation and control of genome editing that looks at the very different risks and potentials posed by CRISPR-Cas9 technology in various applications. In light of the global challenges, it's high time regulators forget dogmas and do more to balance science with ethics.



Thomas
Gabrielczyk
Editor-in-Chief



SPECIAL

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The great green rush

CANNABIS It's the most commonly cultivated, trafficked and abused illicit drug worldwide, and there's still a lot of social stigma attached to the recreational use of pot. But it's slowly dawning on regulators in countries from Canada to the US to South Africa that by ignoring the clear medical benefits of marijuana, they may have thrown the baby out with the bathwater. Countries across Europe are now also opening their minds, laws and wallets to cannabis.

When every other method fails to control a patient's pain, a low-dose cannabinoid treatment can be a highly effective approach, says Dr. Marc Seibolt. He works at the Munich-based Algesiologikum MVZ GmbH, one of Germany's largest pain therapy clinics. Since 2013, Seibolt has been prescribing medical cannabis as an additional therapy if various other treatment methods prove ineffective or are simply not providing sufficient relief. "Cannabis-based drugs have huge potential for patients with chronic – especially neuropathic – pain, spasticity in multiple sclerosis, and loss of appetite, nausea and vomiting," the pain expert says. The German government now also recognises that potential, and legalised the medical use of the *Cannabis sativa* plant in March 2017.

Around 147 million people – or nearly 2.5% of the global population – consume cannabis regularly. The World Health Organisation (WHO) says that makes marijuana and the family of other products derived from the plant the most commonly cultivated, trafficked, and abused illicit drug worldwide. But more and more, its bad reputation is improving. Cannabis no longer provides just a way for people to get high, but is increasingly recognised for its proven pharmaceutical benefits in fields like pain management. "The newly enacted cannabis legislation has led to a much wider acceptance of cannabinoids as a drug in the population than was previously the case," says Prof. Dr. Sven Gottschling,



PROF. DR. SVEN GOTTSCHLING
Chief Physician, Center for Palliative Medicine and Child Pain Therapy, Saarland University Hospital

? When do you prescribe cannabis as a therapy?

! *Cannabinoid-based drugs are not a first-line therapy. They're usually an additional therapy if various other treatment methods have not been effective or not sufficiently effective. I see a wide range of indications here – from chronic pain and nerve pain to lack of appetite, nausea relief, treatment of refractory seizures in children, and severe restlessness in the palliative situation.*

Chief Physician at the Center for Palliative Medicine and Child Pain Therapy at Saarland University Hospital. He began working with cannabis products as a pediatric oncologist, where he treated children with cannabinoids who had massive appetite disorders and weight loss. Before long, it gained acceptance

in cancer therapy as a good way to stimulate appetite and at the same time relieve nausea. "In the past, I had to convince and persuade sceptical patients. But today, many patients approach us proactively with the desire for a cannabinoid therapy. In particular, the demand for flowers has certainly risen".

Health insurance companies hesitant about paying for it

Before the law was liberalised in Germany, patients who suffered from diseases like multiple sclerosis, chronic pain or cancer could only use cannabis if they had applied for a specific exemption at the country's Federal Institute for Drugs and Medical Devices (BfArM). As regulations were extremely strict, that effectively meant only a few hundred patients with specific indications were granted permission to use the plant for medicinal purposes. But numbers are now rising steadily. Figures from market research institute IQvia reveal that there were around 3,500 prescriptions issued directly in March last year. By October, that number had more than doubled to around 7,300 prescriptions.

Overall, physicians in Germany like Seibolt and Gottschling are now able to treat significantly more patients with cannabinoids because the legalisation has made it possible for patients to apply via an application procedure without any indication restrictions [...]

» Read the full story in the printed issue.

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Can machines learn to discover drugs?

ARTIFICIAL INTELLIGENCE Take the right dataset, add an ingenious algorithm or two – and voilà! Your billion-euro blockbuster molecule is ready! AI-driven drug development is exciting investor interest, while Big Pharma is also asking what forms of artificial intelligence can be slotted in at what stages in the process. AI-powered drug repurposing has seen some candidates enter clinical stage testing, but it's still unclear whether the technology is already powerful enough for *de novo* molecule discovery.

» Read the full story in the printed issue.

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Race against time

BIOECONOMY After a quick start out the gates in 2012, the European Commission proceeded to carry out a lengthy review of its bioeconomy strategy – slamming the brakes on investor interest in EU biotechs developing solutions for the move to a low-carbon, zero-waste economy. Following several reports that suggested the bloc will miss internationally agreed sustainability targets, the EC now wants to speed up the switch to biobased production. Industry stakeholders presented a huge range of promising technologies at the EFIB, but are still awaiting the go-ahead.

» Read the full story in the printed issue.

HORIZON EUROPE

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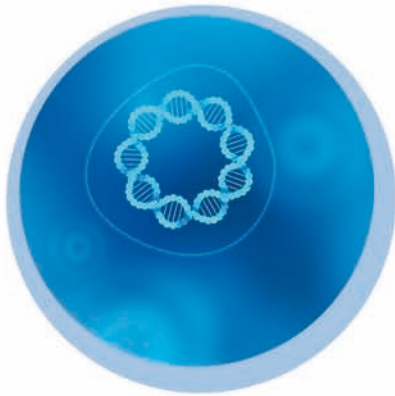
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