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Interview

Novartis CEO Vasant Narasimhan reveals why he bets on one-time curative treatments and digital tools

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Haemophilia A

Fixing the leak

Nanobots
Microscopic drug delivery systems – the next big thing

Agrochemistry
Bayer-Monsanto to bet on genome editing in crop design

Bioeconomy
Global policy leaders lay out agenda to push biologisation

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Single-use plastics: New EU rules to reduce marine litter

MICHAEL CARUS The founder and Managing Director of the nova-Institute studied physics and mathematics at the University of Cologne. Carus became a lecturer at the University of Tübingen, on the topics of ecology, nuclear energy, and radioactivity. He worked as a science journalist and scientist at the KATALYSE Environmental Institute with a focus on energy, ecology, and renewable resources, and two years in the solar industry. In 1994, he founded the nova-Institute for Ecology and Innovation.

Plastics are magical materials, and they will be even more important in the future than they are today. But they lead to microplastics in the environment, especially noticeable as "marine littering." The European Commission is now proposing, among other things, a ban on certain single-use plastic products, including "plastic cotton buds, cutlery, plates, straws, drink stirrers, and sticks for balloons, which will all have to be made exclusively from more sustainable materials instead." The Commission's legislative proposal must then be negotiated with the member states and the European Parliament. And here substantial changes should still be made – because so far industry and politics continued to fail in this area.

Microplastics have been in the public eye for at least ten years. The plastics industry has waited until the public pressure became too high to ignore. Then their argument was, what can our plastics do if people do not handle our products properly and politicians do not organise better recycling programmes? But in fact, the plastics industry can do something about it. For years, there has been another solution for plastic products that are practically impossible to recycle or whose preparation is far too costly: biodegradable plastics.

The European Commission has spent several million Euros over the last ten years to develop and certify such plastics. Plastics that are biodegradable in water, soil, home compost or industrial composting and do not leave any microparticles behind. And today there are many producers of biodegradable plastics; there are certifications and labels. But these new plastics are still a little too expensive to become sure-fire success. And now they don't even get a chance in the new European plastics strategy!

Seize the opportunity for innovation and sustainability now. We prohibit single-use products if they are not biodegradable. But let us give biodegradable plastics, which have been successfully developed for years, their chance on the market! We also need alternatives to plastic products that, even when used properly, end up in the environment and are difficult or impossible to recycle. A few examples would be mulch films, tree protection covers, plant clips, binding yarns, strings for lawn trimmers, carrier polymers for fertilizers and pesticides, and even plastic baits at sea. Let us take a step forward in all of Europe. Because now is the time when the rules for the coming decades are being made.

Further reading: http://bio-based.eu/policy/#innprobiofacts

Picture: Nova Institute, Cologne

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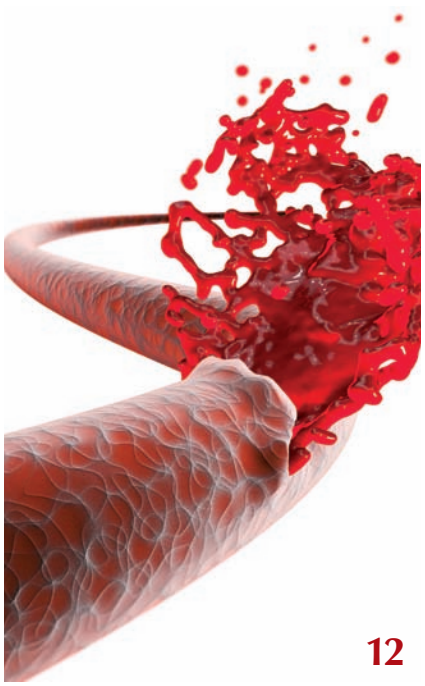
COVER STORY



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Stopping the bleed

Since factor VIII replacement therapies hit the market, life expectancy for haemophilia patients has risen to normal levels. But around 25% of those who suffer from haemophilia A still have no therapeutic options, because their immune systems form antibodies against clotting products that can stop bleeding. Researchers and companies in the growing US$15bn haemophilia medications market are feverishly exploring new ways to identify patients at risk and offer them alternative treatments, while a series of mergers and acquisitions have changed the playing field for established markets and players.

INSIGHT EUROPE

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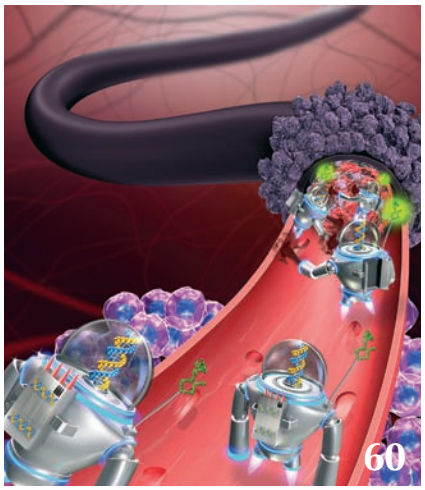
DRUG DELIVERY



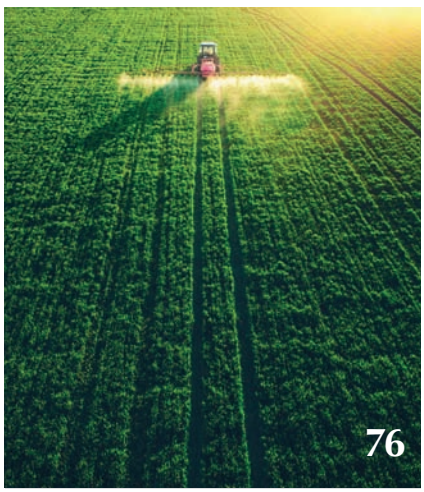
Nanobot healthcare

They're small, fast – and could be the future of medicine. Nanobots have already been used in animal trials to attack tumours, and have proven effective. But there are still a few problems to overcome before doctors begin injecting millions of tiny machines into humans. Not least that researchers still have to figure out how to get rid of the microscopic helpers once they've done their job.

AGRI-BIOTECH

Consolidation up top

They co-created Agent Orange. Now agri-biotech giants Bayer and Monsanto are about to merge into a single mega-entity for pushing genetic engineering technologies in the crop design market. EUROPEAN BIOTECHNOLOGY takes a look at what consumers and farmers can expect, and how new products will be regulated in the age of the 'Big Four'.



Pictures: iordani/fotolia.com (top), loneroc/shutterstock.com (middle), ABLinc. (bottom)

SPECIAL

Event compass

EDITORIAL

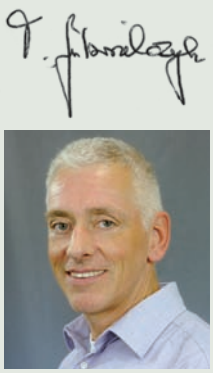
Global discharge

At the recent Global Bioeconomy Summit (see. p. 30), US researcher John Schramski had an interesting message. He sees our planet as an accumulator that's been charged up by hundreds of millions of years of photosynthesis. Until now, he said, Earth has been able to effortlessly top up reserves. But as energy consumption by humans exploded over the past century, its currency of biomass and fossil fuel has been almost fully depleted. "We have to slow down," Schramski warns – because without our natural resources we won't survive.

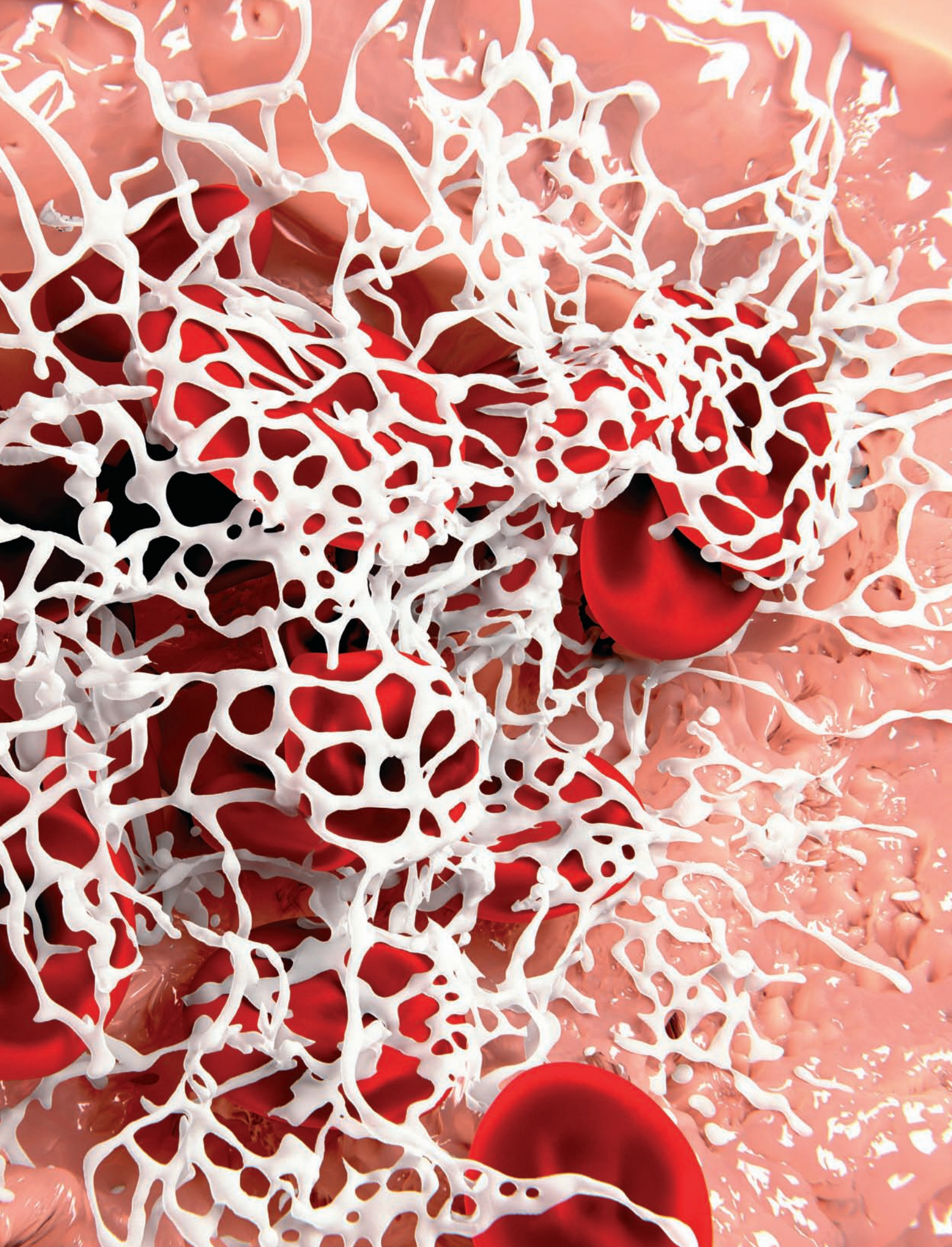
An interesting aspect of the international meeting was that two major lobbies were apparent. There were those who pushed the idea that we all need to focus on sustainability, because no one knows how much longer we can go on exploiting our planet (see p. 32). On the other side were those who primarily see the economic opportunities attached to green technology (see p. 28).

Maybe biologisation of the industry is about both. Making money, but with the right biotechnologies for rebalancing economic, social and ecological imbalances.

The challenge now is to separate those who tout old technology to make money under green labels from those offering the right solutions.



Thomas Gabrielczyk
Editor-in-Chief



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Closing the gap in haemophilia therapy

FACTOR VIII INHIBITORS About 25% of the people who suffer from haemophilia A have no therapeutic options, because their immune system forms antibodies against clotting products that can stop bleeding. Researchers and companies in the growing US$15.8bn haemophilia market are feverishly exploring new ways to identify patients at risk and offer them alternative treatments. A series of mergers and acquisitions have changed the playing field for established markets and players.

Every time Michael fell when he was a child, his parents had to rush him to the hospital. "Between the ages of one and six, we were there pretty much every day," his mother remembers. Her son is one of 320,000 people worldwide with haemophilia A, the more common form of the genetic condition. People living with the hereditary disease either don't produce enough of a clotting protein called factor VIII, or they lack it completely. Because their blood doesn't clot properly, it can lead to uncontrolled bleeding. The disease is called 'mild' when FVIII levels are 5%-40% of normal levels, 'moderate' when between 1%-5%, and 'severe' when they're under 1%. Michael has the severe form. Injections with factor VIII, the current standard of care, can prevent and treat bleeding episodes. "I try to do what I can, and not spend too much time thinking about what I can't do," says Michael, now a young man. "For me, that's a kind of motto in life." Starting in the 1950s, prophylactic factor VIII infusions were derived to treat haemophiliacs with plasma-derived factor VIII products from donors. In the 1990s, complementary treatments with recombinant factor VIII proteins hit the scene. Prophylactic factor VIII replacement therapy has now cut the average number of bleeds from more than 40 a year to under two. Today, a child born with severe haemophilia can expect to have a normal lifespan. But besides annual treatment costs of US$150,000-$300,000 per patient, other serious hurdles remain. Prophylactic therapy patients continue to need drugs that will decrease their need for immunosuppressants. The half-life of the active factor VIII protein is also short, and needs to be extended. And most importantly, a significant number of patients simply don't respond to treatment. Almost one in three people with severe haemophilia A also develops inhibitors – antibodies that identify the recombinant blood clotting factor VIII as foreign, and stop it from working. For the big players in the currently US$15.8bn field – Shire, Biogen/Bioverativ, Novo Nordisk, Pfizer and others (see table, p. 14) – new approaches to solving those problems could have a big impact on revenues. The market is growing. Analysts from Transparency Market Research predict it will surpass US$25bn by 2024.

ZOE WAIBLER **Head Product Assessor for Immunologic Drugs, Paul Ehrlich Institute, Langen (Germany)**

? Why is it important to find factors in the blood that boost factor VIII inhibitor formation?

! *It's a prerequisite for developing new approaches to haemophilia therapies, which prevent the formation of these inhibitors against factor-VIII products.*

The huge unmet medical need and associated potential has triggered major acquisitions, with former market leaders under new ownership. Biogen haemophilia spinout Bioverativ, for instance, was taken over by Sanofi for US$11.8bn. In a US$62bn acquisition, haemophilia amd haematology giant Shire plc agreed in May to a takeover by Takeda. Approaches for circumventing the immunogenicity and inhibitor problem – such as factor VIII products with fully human glycosylation patterns, gene therapies or bispecific antibodies that mimic the effects of factor VIII with less or no potential for inhibitor formation – have the potential to change the field dramatically.

Predicting inhibitor formation

However, current claims involving reduced immunogenicity and reduced […]

›› **Read the full story in the printed issue.**

Pictures: PEI (right), selvanegra/istockphoto.com (left)

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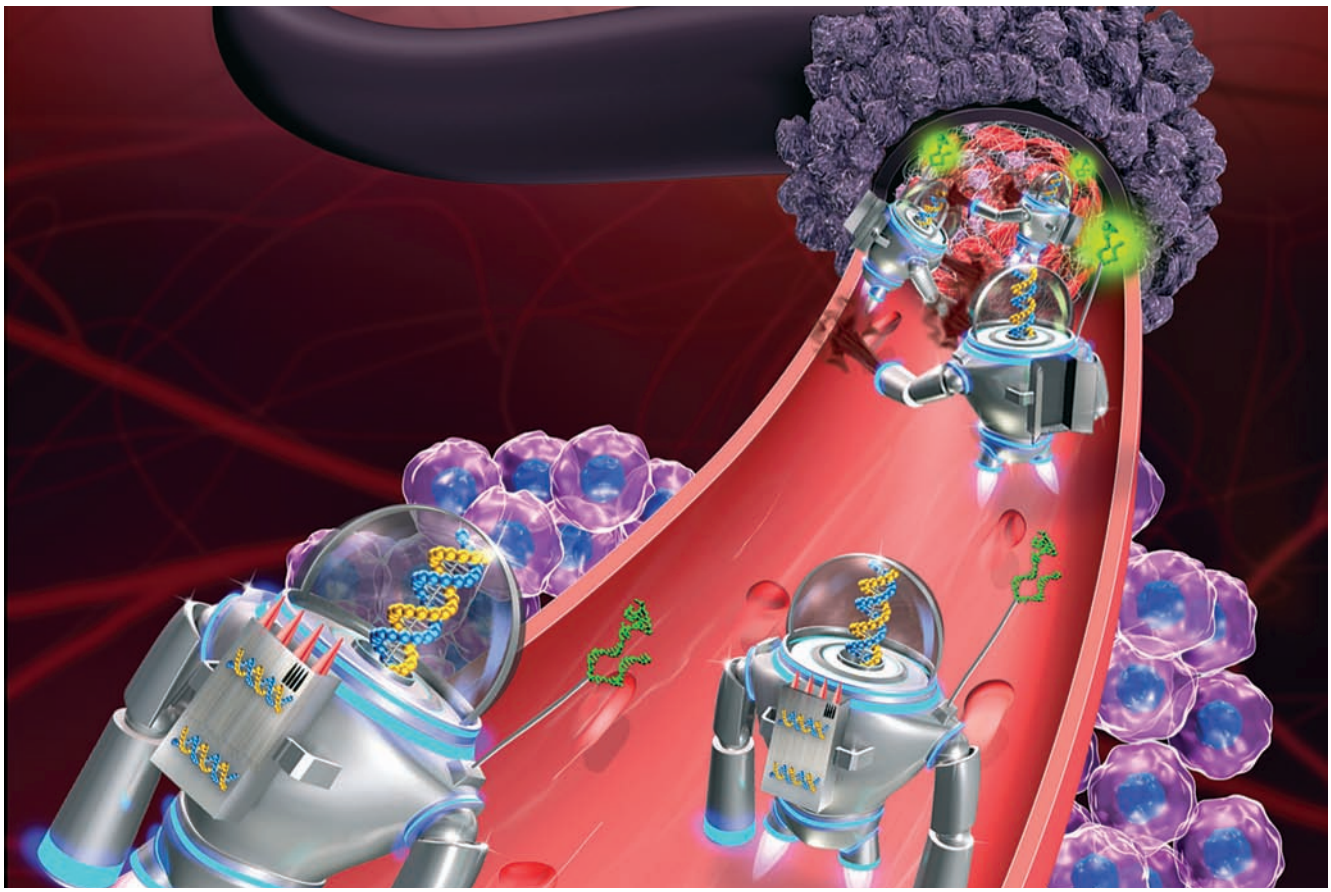

Nanobots: Fiction becoming reality

DRUG DELIVERY Once confined to speculative and science fiction, miniature micro- or nanobots targeting pathogens or conditions directly have now become reality in research labs worldwide. But to enter clinical trials, scientists still have to overcome two major hurdles – visualising the tiny machines inside the body, and preventing a potential immune response.

›› **Read the full story in the printed issue**.

Pictures: Biodesign Institute, Arizona State University

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A tractor entailing a fog of pesticides – a rare sight in a couple of years? Precision distribution of crop protecting agents via for instance drones could soon usher out mass spraying.

The future of agrochemistry

PESTICIDES & SEEDS One of the world's largest and most controversial mergers in the past few years was sealed in early June. German pharma and chemistry company Bayer has taken over US competitor Monsanto, forming the largest integrated provider of seeds, agrochemicals and digital farming solutions on the planet. The acquisition is part of a recent US$170bn deal binge that is already having a profound impact on the future of global agriculture.

›› **Read the full story in the printed issue**.

Picture: fotolia.de/ValentinValkov

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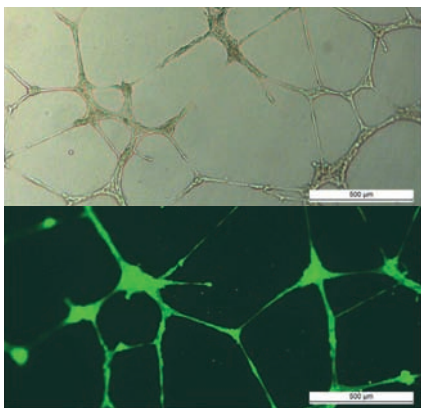
Pictures: PromoCell

Cancer research

PROMOCELL PromoKine's Angiogenesis Assay Kit provides a simple, robust, easy to perform and semi-quantitative method to determine angiogenesis *in vitro* in less than 18 hours. It can be used for screening of angiogenesis modulators or studies of angiogenesis related signal transduction. The assay is based on the measurement of the ability of endothelial cells to form 3D structures (tube formation) under the influence of distinct stimulators, and uses a proprietary endotoxin-free and growth factor-reduced Extracellular Matrix Solution.

The Cell Migration/Chemotaxis Assay Kits are easy to use, sensitive and high throughput-adaptable systems. They utilize a Boyden chamber, where the cells migrate through a semi-permeable membrane (three different pore sizes available) in response to stimulatory or inhibitory compounds.



The Cell Invasion Assay Kits also utilize a Boyden chamber that is coated with a layer of BME (Basement Membrane Extract), laminin, fibronectin, Collagen I or Collagen IV. The cells first traverse the matrix and then migrate through the semi-permeable membrane in the Boyden chamber in response to different stimuli. Cell migration as well as cell invasion can be analysed directly using a fluorescence plate reader.

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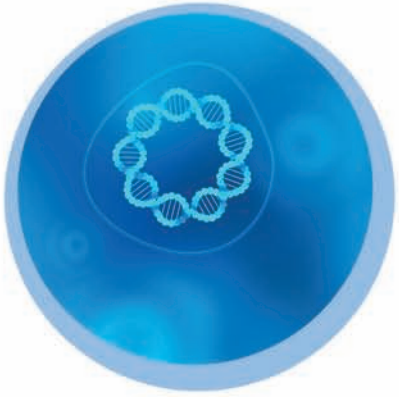

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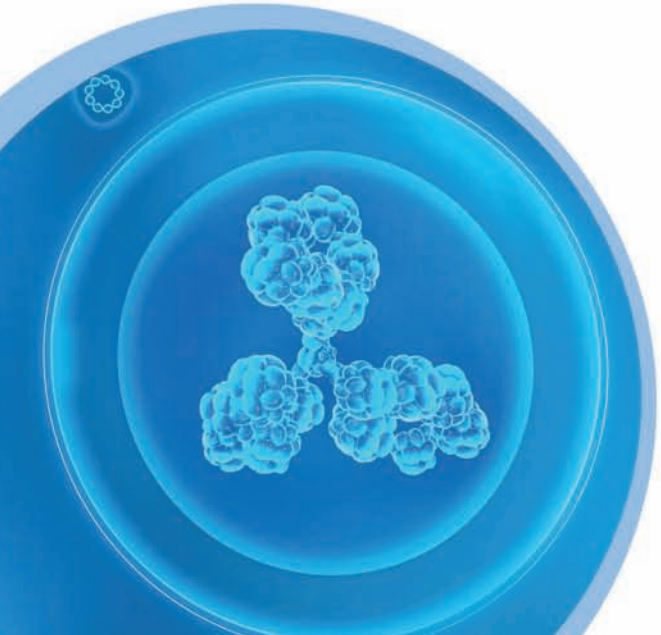

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