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Interview

Kai Pohlmeyer, CEO of Richter Biologics, on how biopharma service providers can grow even when times are hard.

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Deals & more

Signs of recovery

RNAissance
Innovation makes RNA drugs attractive to bold investors

European Commission
How von der Leyen plans to support Europe's biotech sector

Special: CRO/CDMO
The new US Biosecure Act will transform the growing industry

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The West's wake-up call to China's biotech dominance

DR JEREMY M. LEVIN has held leadership roles in major pharmaceutical and biotechnology companies. He is currently Chairman and CEO of Ovid Therapeutics and Chairman of Opthea. Previously, he served as President and CEO of Teva Pharmaceutical Industries and was on Bristol-Myers Squibb's Executive Committee. He has also been Global Head of Strategic Alliances at Novartis. Besides numerous board positions, Dr. Levin serves on the Board and Executive Committee of the Biotechnology Innovation Organization as Emeritus Chairman.

The U.S. House of Representatives recently passed the BIOSECURE Act, prohibiting U.S. biopharma companies from working with Chinese contractors due to national security concerns, including data leaks and intellectual property theft. The Act is expected to pass the Senate.

This legislation reflects shifting political, economic, and military forces. U.S. companies will need new suppliers, leading to immediate challenges in the biopharma supply chain. However, the broader impact involves rebalancing global biotech dominance, with long-term implications for competitiveness and supply chain sustainability.

China has invested in biotech for decades, positioning itself as a global leader. In contrast, the West was slow to prioritize biotech. The BIOSECURE Act may shift this, encouraging the U.S. and Europe to bring resources back home. Yet, in the short term, the consequences for manufacturing, clinical trials, and intellectual property are significant.

Western companies heavily rely on Chinese Contract Development and Manufacturing Organizations (CDMOs) for biotech productivity. A survey of U.S. biopharma companies revealed that 79% rely on at least one Chinese CDMO. China also supplies APIs and antibiotics to the U.S. and Europe, raising national security concerns. Shifting manufacturing out of China will be slow, taking years to establish new suppliers and affecting millions of patients. Geographic diversification of clinical trial sites also faces delays, increasing challenges in drug development.

China's growing dominance in clinical trials may lead to data sharing restrictions under the BIOSECURE Act, affecting patient access and trial timelines. China's share of global clinical trials grew by 57% in recent years, while Western Europe's share dropped by 21%. Further tensions could slow innovation and limit access to treatments.

Biopharma executives must continue to carefully monitor China's efforts to acquire Western biotech IP which threatens the industry's competitive edge. The BIOSECURE Act also provides an opportunity. The West must respond with a comprehensive "BIOBUILD" strategy to maintain biotech leadership. This strategy should include tax incentives, regulatory reforms to accelerate drug development and approval, and investments in education of a biopharmaceutical workforce. It should also provide concrete support to ventures affected by BIOSECURE including providing incentives to those reliant on low-cost Chinese suppliers. China is committed to becoming the global biotech leader. If the West remains uncoordinated, it risks falling further behind a superpower that began its push decades ago. The BIOSECURE Act is a critical wake-up call. The West ignores it at its peril. We need a BIOBUILD plan. ■

You will find a detailed discussion after the publication of this issue at www. European-Biotechnology.com.

Picture: © Jeremy Levin, Ovid Therapeutics

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COVER STORY

A new dawn for biopharma financing?

The first half of 2024 is history, and experts are divided on whether the financing nadir has been reached or even passed. There are very different figures for different types of treatments under development. ADCs and radioligands are on the rise, while cell and gene therapies are way down. Are larger financing rounds and a few IPOs a good sign for all? Some European companies hit the jackpot, but most still struggle. Amidst the positive news, one major uncertainty remains: interest rates.

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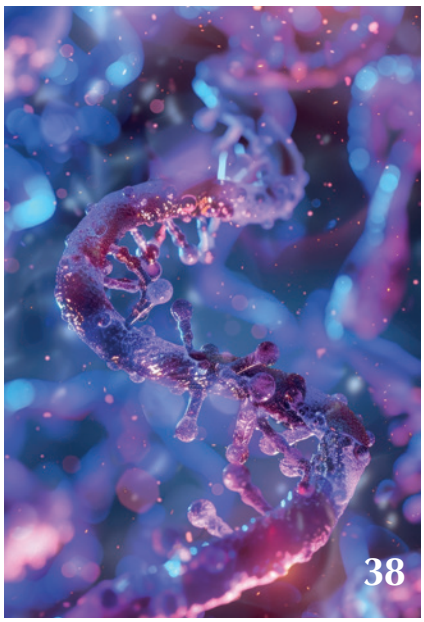
EU COMMISSION

Playing catch-up

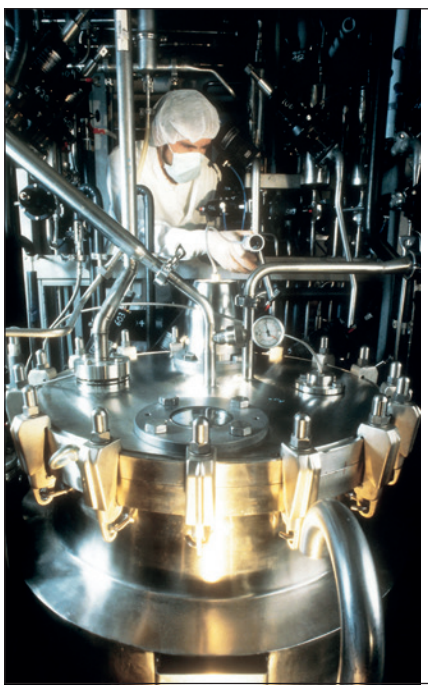
Ursula von der Leyen didn't mention biotechnology a single time to the European Parliament in her election speech – likely because she wanted support from the Greens, whose members often have a general aversion to the industry. That makes binding political guidelines – including an extra budget for the financially ailing sector – all the more important.



RNA DRUGS

A second RNAissance

It took 20 years for RNA-based therapies to catch investor attention. Unlike small molecules or biologics, RNA drugs that can also target 'dark matter' in the human genome can be produced and screened fast, and easily scaled up.



SPECIAL

CROs & CDMOs

Pictures: Boehringer Ingelheim (left, below); UE 2024 - PE (left, above); © Justlight - stock.adobe.com (middle); BIOCOM AG (right)

EDITORIAL

A new hope

Ursula von der Leyen will not have an easy time of it in her second term as EU Commission President (see p. 12). Weakened by gains made by anti-European far right parties in the European Parliament and selfish moves by Member States, announced breakthroughs in biotechnology and the defence of democracy will grow more difficult to achieve. In a setting where the bloc is preoccupied with national sensitivities and fears about inflation, requested increases in budgets look less likely. Even if they're vital – and not only to finally strengthen Europe's competitiveness by cutting red tape.

A potential ally in those efforts is the US, which is trying to curb China's growing supremacy in biomedicine and geopolitics. A new Biosecure Act (see pp. 3, 46). has already been approved by its House of Representatives. Will advancing biotechnology in terms of manufacturing and clinical trials in US-European research and production cooperations finally become more than just talk? After all, the world's biggest dictatorship is no longer just breathing down the neck of the US in a range of fields, but increasingly in its face.

Whether EU heads of state and the next US President will support von der Leyen in promoting biologisation and digitisation in industry is rapidly becoming a broader geopolitical question.

Thomas Gabrielczyk
Editor-in-Chief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M&A and IPOs – resurrection ahead?

FINANCING The first half of 2024 is history and the experts are wavering as to whether the trough has been reached or even passed. Are things looking up again in terms of financing innovation? Is the slight upward trend stable enough to take a more positive view of the future? And are larger financing rounds and a few IPOs good signs for everyone? In the midst of positive news, one uncertain factor remains: interest rates.

Mergers and acquisitions (M&A) in the biopharmaceuticals industry rebounded even more in the first quarter of this year after a US$76.9bn increase in total deal value from 2022 to 2023. In the first quarter of 2024 alone, biopharma M&A reached a total deal value of US$43bn. There was also a 71% year-on-year increase in mega-deals totalling US$1bn or more compared to the first quarter of 2023, according to GlobalData.

Alison Labya, Business Fundamentals Analyst at the leading data and analytics company, commented earlier this year that "the recent uptick in biopharmaceutical M&A activity signals a return of dealmaking confidence, as Big Pharma companies are also looking to mitigate challenges such as the Inflation Reduction Act and upcoming patent expirations."

GlobalData has also interviewed healthcare industry professionals who expect M&A mega-deals to be one of the factors that will have the greatest positive impact on the pharmaceutical industry in 2024.

Novo goes shopping

The largest M&A deal reported in Q1 2024 was Novo Nordisk holding and investment company Novo Holdings' $16.5bn acquisition of US-based contract development and manufacturing organisation (CDMO) Catalent, which was announced in February 2024. Another notable M&A deal was Gilead Sciences' US$4.3bn acquisition of US-based CymaBay Therapeutics, completed in March 2024.

Outside the CDMO sector, companies developing antibody drug conjugates (ADCs) and radiopharmaceuticals attracted high levels of M&A investment. For example, Johnson&Johnson acquired US ADC company Ambrx Biopharma for US$2bn in March, and Anglo-Swedish AstraZeneca announced the acquisition of US radiopharmaceutical company Fusion Pharmaceuticals for US$2bn in the same month.

According to GlobalData and other sources, oncology was again the top therapy area for M&A deals in Q1/2024, with total deal values of US$29bn. However, immunology-focused M&A saw the largest increase in deal activity compared to Q1/2023, tripling with a 314% increase in deal value to US$14bn in Q1/2024 alone.

Labya concludes: "The rest of 2024 is poised for continued M&A investment by large biopharmaceutical companies, which could accelerate R&D and the launch of innovative drugs."

Some of the billion-dollar acquisitions took place in the European space. Among them were the takeover of Cardior (Hannover, Germany) by Novo Holding for US$1bn, and the asset spinout of Numab (headquartered near Zurich, Switzerland) via Jersey Therapeutics to Johnson&Johnson for another US$ 1bn.

VC funding on the rise

GlobalData revealed in the early months of the year that private biotech rebounded in terms of venture funding in Q1/2024. The sector saw a 46% increase in the total value of VC deals in the first quarter of 2024 compared to the fourth quarter of 2023. The analytics company viewed this increase as a sign of progress towards a recovery in venture funding as investor confidence improves.

Times have been tough before. In the face of macroeconomic challenges such as high interest rates and inflation, which led to increased investor caution, private biotech venture financing saw downturns in both 2022 and 2023. However, the trend appears to be reversing, as the area in Q1/2024 showed an increase in larger funding rounds compared to Q4/2023. This uptick could be interpreted as an improve-

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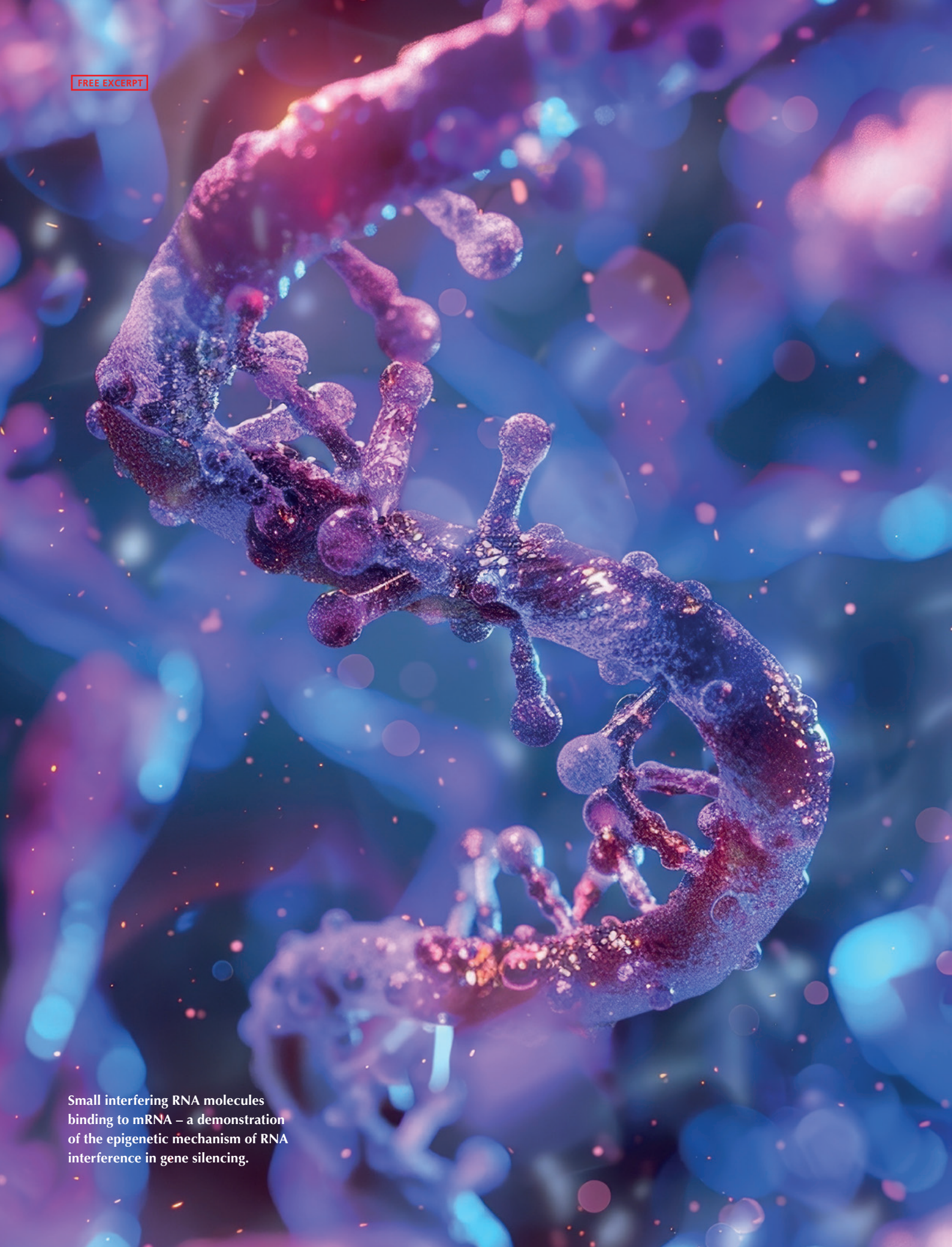

Small interfering RNA molecules binding to mRNA – a demonstration of the epigenetic mechanism of RNA interference in gene silencing.

A 'RNAissance' in drug development

NEW MODALITIES It took 20 years for RNA-based therapies to really catch investor attention. Initial action came in 2016 with Biogen's US$1.7bn SMA antisense nucleotide blockbuster Spinraza and – two years later – the first approval of an siRNA drug (Onpattro). The pandemic boosted M&A activity dramatically, and pipelines began shifting from orphan to common diseases. It's a revolution. Unlike other biologics, RNA drugs can be produced fast, screened automatically and easily scaled up.

RNA medicines have been *en vogue* since mRNA vaccines during the COVID-19 pandemic showed that they are safe and effective, can be scaled easily, and be developed in record time. Between 2020 and 2021, the class of preventive mRNA vaccines alone triggered an 11-fold increase in M&A activity.

Together with four further non-protein-coding RNA drug classes, mRNA vaccines against cancer or infections can be easily adapted to tap into a target universe that appears 'undruggable' for other biologics. That's the reason why Big Pharma companies such as Eli Lilly, Roche, Boehringer Ingelheim and Novo Nordisk are currently pumping billions into innovative SMEs that develop RNA drugs like:

- antisense oligonucleotides (ASOs), which block translation
- drugs that regulate the expression of proteins by RNA interference (RNAi)
- RNA aptamers that bind proteins and other targets, and finally
- RNA editing drugs such as CRISPR- and ADAR-based RNA editors.

"RNA therapeutics have gone from being a promising concept to one of the most exciting frontiers in healthcare and pharmaceuticals," explains Mikael Dolsten, outgoing CSO and President at Pfizer Research & Development. The momentum in the field is being fueled by huge advances in genetic engineering and delivery systems, which are allowing companies to take on more ambitious development efforts at an unprecedented pace.

The potential of all RNA medicines lies primarily in the fact that the approach differs from any previous drug strategy. Unlike small molecules or biologics, which generally bind to active sites on proteins in order to therapeutically modulate their function, RNA-based therapeutics can target any site in the genome – including the non-protein-coding regulatory areas that are involved in many orphan and common diseases. And they can do so by simply changing the nucleotide sequence of the RNA involved – without having to change the manufacturing process, as is the case with biologics. Coding for proteins makes up only 1.5% of the human genome, and at most 14% of the proteins it generates have binding sites that are accessible to conventional drugs. RNA drugs can modulate any target encoded in the human genome, while AI can automatically screen it to exclude unsuitable hits.

MIKAEL DOLSTEN **Pfizer's outgoing CSO and President of Pfizer Research & Development**

? What makes RNA therapeutics so interesting for drug developers?

! *"RNA platforms are unlike those that have come before, as RNA-encoding novel proteins can be quickly made at clinical scale and quality with few small modifications in automated, modular manufacturing units."*

Reshaping healthcare

Although they have clear benefits, RNA-based therapeutics also face several challenges. These include delivery issues (being addressed by providers like Acuitas Therapeutics, Capstan Therapeutics, Leon nanodrugs or Etherna), as well as off-target effects and immunogenicity issues. The young RNA therapeutics market stood at US$13.8bn last year. Com-

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