By Amber Kerkhofs & Peter Thijssen



The biotech sector in Europe is at a tipping point. With the announcement of the EU Biotech Act, European Commission President Ursula von der Leyen has made a bold statement: Europe must, and will, capitalize on its biotech potential. But how? This question was central to a lively panel discussion at Innovation for Health on 3 April, where policymakers, investors, and entrepreneurs questioned and challenged each other openly.

The panel, led by Hans Schikan from Health~Holland, featured representatives from the European Commission, established biotech companies such as argenx and Stoke Therapeutics, the Flemish Biotech Institute as well as a biotech investor with experience in both the US and Europe. The conversation was organised as a follow-up from an earlier conversation at the European Health Summit in December 2024. The common thread: Europe has strong science, but it has historically lagged in capitalizing that knowledge into marketable products. How can we build a biotech ecosystem that competes globally?

From scientific strengths to global biotech companies

According to Jerome Van Biervliet (VIB), science has never been the problem: "We have top scientists in the Benelux and across the EU. But crossing the bridge from academic concepts to investable companies remains difficult.

In Europe, I feel we need to build more investable opportunities, nurture ambitious entrepreneurs, and boost venture capital markets to invest."

Beth Del Giacco (argenx) agrees: "Europe is not short of talent, in particular when it comes to science, and we have strong partnerships with leading researchers and universities as part of our Immunology Innovation Platform. We also benefited from funding in Europe, in particular European investors and through our first IPO on EURONEXT. However, to reach our ambition to build a global immunology company, we needed significant funding. US investors understood the opportunity and were willing to support us. To give you an idea of the scale; we raised over five

billion dollars since our inception in 2008 to both build our pipeline and build our organisation". This difference in risk appetite and in investment capacity was a recurring theme.

Ed Kaye (Stoke Therapeutics): "True biotech investors know that nine out of ten companies fail. But the tenth one pays it all back. You need to be critical: does the science make sense? What is the unmet need? Is it feasible? Are the right people on board? If the answer to all of these questions is 'yes', we should get all in".

Faster and smarter regulation

Another opportunity to accelerate innovation lies in the European regulatory landscape. Mark Quick (Flerie) explained the direct effect on investment decisions: "The US is the largest pharmaceutical market and many trials are and will be carried out there to gain access to that market. That weighs in on our choices." Van Biervliet took another perspective on this: "Our healthcare system is the best in the world. I would rather get cancer in Europe than in the US. However, innovative entrepreneurs are prioritizing the US massively over the EU. We should really reinvent our regulatory system to maintain a competitive edge. For example, panels to evaluate innovative treatments such as gene therapies could be constituted with experts of different member states. Reimbursement for novel treatments for high unmet needs developed in the EU could be pre-financed from an EU fund ahead of member state approval across areas with similar willingness to pay. Regulatory reform can therefore be a major driver for the EU's competitiveness agenda." The European Commission sees





opportunities, stated Thomas Van Cangh (European Commission): "We have instruments like the European Health Data Space Act and joint HTA assessments. Let's make use of them, test them, and learn from them."

The EU Biotech Act: how can it help Europe to innovate?

The upcoming EU Biotech Act – soon under public consultations – aims to anchor biotech as a strategic sector in Europe. Van Cangh: "We are now having conversations with key players about what the sector needs. What we're hearing in the field is a better recipe based on five key ingredients: need for speed in market authorization, improving access to capital, investing in STEM skills as well as business skills for scientists, using the economy of scale in Europe, and stimulating AI and data sharing." The best recipe comes from collective action, Van Cangh stressed: "We don't want a rule-

free system. But without a proper framework, there is no market. Let's do it right together."

How do we build momentum?

According to the panel, it's time to make fundamental and daring choices:

- Dare to invest, even in early-stage biotech. This involves having more private funds (European and non-European), for instance by setting up public-private funds that share risks and attract capital towards young promising biotech. This also requires a European Tech Stock Exchange, which will allow companies to tap into more funds as they scale-up.
- Simplify existing regulation and consider piloting new regulatory pathways, with the goal to accelerate clinical development, as well as regulatory approvals.
- Enhance European collaboration, in particular in connecting existing biotech ecosystems across Europe to accelerate the flow of research, capital, ideas and innovation.
- Make biotech visible and tangible for both the public and policymakers, stressing the importance of new innovations for patients and society as a whole.

Let's act on biotech

Europe has strong foundations: excellent science, a growing number of start-ups, and political attention. But that's not enough. If we want to build a strong ecosystem, we need to make choices now. As Beth Del Giacco put it: "The foundation is

strong science. That exists here. What we need is a regulatory and policy framework that keeps pace with the science, that can accelerate innovation into a reality for patients and healthcare systems. Especially in areas of high needs" Jerome van Biervliet adds: "We need a coalition of the willing across the EU and mobilize both private and public



funds to enable more venture capital in Europe". The EU Biotech Act can strengthen collective action and incentivize investments. But it must be accompanied by a shared vision for European biotech. The act can then establish a critical mass of biotech success stories across Europe. Van Cangh expressed this ambition clearly: "We establish KPIs when defining new policies. Wouldn't it be great to have five argenx's in Europe?"

THE BIOTECH MOMENT IS NOW, LET'S SEIZE IT!

