EuropaBio Response to the European Commission Call for Evidence for the EU Startup and Scaleup Strategy

EuropaBio, representing European biotechnology companies, welcomes the opportunity to contribute to the EU Startup and Scaleup Strategy call for evidence. Through its national associations and SME Platform, EuropaBio represents over 4500 biotech small and medium-sized companies, including startups and scaleups.

Startups and scaleups are a core part of the biotech ecosystem as a source of innovation in delivering new products to the market[1]. These companies are key contributors to the European economy, industrial transition and society.

Through their contribution, the gross value added from biotechnology activities hit €38,1 billion in 2022, almost doubled since 2008. Whilst healthcare biotechnology remains the dominant sector, reflecting the maturity of the sector, industrial biotechnology is the fastest growing GVA rate, at 5.3%, over double that of the EU total economy. Biotechnology across sectors generates €160,000 per person employed. This is 2.85 times higher than the total EU economy.[2]

Biotechnology startups and scaleups face the hurdles identified in the call for evidence *(Question 1)* and as detailed within this response. EuropaBio is committed to providing solutions to resolve these challenges. This response builds on our startup and scaleup members' insights and showcases proposals to overcome each challenge *(Question 3)*.

Access to finance: Capital Markets and the role of IPR

Biotech industries are highly research-driven and capital-intensive. Compared to other sectors, they have long timeframes for the delivery and deployment of products and services. Such timeframes impact return on investments and commercial profitability. Some companies report operating for decades before generating revenue or becoming profitable.[3]

Access to finance remains one of the most reported challenges for European biotech startups and scaleups. This issue is particularly critical in the upscaling and commercialisation stages.

[1] Entrepreneurship and small and medium-sized enterprises (SMEs), What the European Commission does for SMEs

[2] Measuring the economic footprint of the biotechnology industry in Europe, WifOR Institute, 2025

[3] Examples of a biotech company operating for 25 years before turning a profit.

For healthcare applications, there is a lack of accessible venture capital in Europe for funding the significantly expensive clinical-stage development.[4] As a result, many companies will seek funding in other regions with well-developed capital ecosystems, such as the USA or UK.

Intellectual property rights (IPRs) are the only asset for startups and SMEs to leverage the necessary access to sufficient finance. IPRs confer company value and investor predictability. IPRs also help to finance the multi-layered ecosystem through technology transfer and transforming basic research into cutting-edge innovation, with a significant spillover effect.

As an example: Ogura seed was developed and patented by the French research institute INRA. The institute granted non-exclusive licenses to several seed companies. The first seed based on the technology was placed on the market in 2000. From 2000 to 2012, 83% of farmers adopted Ogura varieties. A 56 million Euro investment with over 15 years of dedicated development led to over 1.0 billion euros of societal benefits.[5]

Recommendations

Biotech SMEs wishing to stay in Europe have asked for urgent action in Capital Markets, advocating for *an "EU NASDAQ equivalent for the sector.*[6,7] As suggested in the Letta Report,[8] assess the support for the **creation of a stock market in the EU for Deep Tech companies**, including for Biotech and Life-Sciences.

Ensure the **Savings and Investments Union** boosts capital for biotech. Build on the existing pan-European personal pension product, with higher caps on contribution limits. Include dedicated mechanisms towards high-risk innovation, early-stage discovery, and scale-up.

On IPR: **Accelerate the roll-out of the Unified Patent System**. Including creating a **one-stop-shop for patent protection and enforcement** across the EU. Encourage all Member States to ratify and implement the Agreement rapidly.

Explore and further support **strategic partnerships**. Build greater small company recognition and engagement from current initiatives, such as the Circular Bio-Based Europe Joint Undertaking (CBE-JU), Innovative Health Initiative (IHI) and European Rare Disease Research Alliance (ERDERA). Align public and private priorities and funding.

Ensure future EU projects and policy proposals are aligned with the UN Sustainability Goals and the Green Industrial Deal.

[4] EuropaBio: Impact of the EU's General Pharmaceutical Legislation on Europe's innovation ecosystem and biotechnology companies (2024)
[5] Biotech Letter: Biopatents, Deutsche Industrievereinigung Biotechnologie (2023)
[6] A global Europe: the role of transformative legislation - EuropaBio Spain Council Presidency event report (2023)
[7] AseBio's proposals to the Ministry of Economy to promote capital markets as a means of growth for Spanish biotechnology companies
[8] Much More than a Market, Enrico Letta report (2024)

Access to market: the EU's fragmentated regulatory landscape

Biotech companies accessing EU markets face a fragmented and inconsistent regulatory framework. Uneven implementation and enforcement of regulations create delays and, in some cases, prevent products from fully accessing the EU Single Market.

According to the IMF, intra-Single Market barriers are tariff equivalent of about 44% on average for goods and 110% on services.[9]

These challenges are particularly evident in areas such as novel foods, biocontrol, and new biological medicines. Delays are across sectors. They include lengthy and untransparent EFSA risk assessments for biotech products, but also longer timeframes for the approval of clinical trials and authorisation of biotech therapies.

Innovators also face fragmented implementation of regulatory requirements. Most EU startups and scaleups operate with a "just-enough" funding stream linked to the financing constraints detailed above. Any factors that cause delay or additional cost may be existential for companies with a short-term cash flow capacity, accelerating their exit from the EU for other markets or their failure as a company.

EuropaBio supports the Commission's simplification agenda but underlines the importance of regulatory frameworks in fostering trust and public acceptance of biotech innovation. We believe the Commission should focus on addressing incoherence and unnecessary delays across regulatory frameworks and stronger enforcement of EU legislation in Member States.

Recommendations

We urge the European Commission and Member States to **streamline and harmonise regulatory requirements.** Perform regular monitoring and evaluation of new regulatory proposals to ensure no undue burden on startups and scaleups through lack of predictability or clarity on timeframes.

Ensure **faster product approvals** and stronger support for innovators. Innovators need more structured and regular **dialogue** with regulatory agencies.[10] **European regulatory agencies**, such as ECHA, EFSA and EMA, must be **further resourced** (human and financial) to improve efficiency and responsiveness.

Given the disproportionate impact on SMEs, startups and scaleups, we propose introducing **"*competitiveness*"** and **"*fit for SME*" criteria** within the **Better Regulation guidelines**.

[9] Europe's Choice: Policies for Growth and Resilience, IMF (2024)
[10] Net-Zero Industry Act, Article 34 - Measures for SMEs and start-ups

Research: bridging the innovation and industrial gap

Technology and knowledge transfer remain a critical challenge in Europe's innovation and industrial ecosystem. While the EU leads in scientific research, including in biotech,[11] this excellence is not translating into economic activity and commercial success. The EU lags behind its competitors (particularly the USA and China) in its global share of biotech patents,[12] highlighting a persistent and widening gap between research and commercial scale.

Over 15 years ago, the EU was a pioneer in the field of ATMPs. Now, it lags behind the USA and Asia in the number of developers, clinical trials, and investment.[13,14] EU accessibility across Member States for scale-up is a limiting factor. Countries, including Belgium, through the Bio-Based Europe Pilot Plant,[15,16] support the development, manufacturing and scale-up of startup companies. However, small companies from other Member States still struggle to access these providers. Thus, know-how, capacity and investments are not being leveraged.

Moreover, translational research in the EU sometimes lacks commercial alignment with market demands, lacks critical mass for rapid commercial development or is commercialised elsewhere. To reverse this trend, the EU must strengthen incentives for spin-offs and startups while improving the overall attractiveness of its innovation ecosystem. Prioritising biotech, given its research-driven nature and its cross-sectoral applications, is essential. This approach is already evident in leading biotech hubs in the UK, the USA, and China.

Recommendations

We propose **targeted EU funding for universities with strong tech transfer and spin-off activity**, encouraging the development of national and regional innovation clusters.

Additional **late-stage funding and incentives** should also be made available **for spin-offs and startups** to **develop, manufacture and scale-up** across other European countries.

This effort should be complemented by a **fast-track framework for building authorisation** for new R&D and manufacturing sites, alongside efforts to **harmonise permitting requirements and timelines**. The EU also needs further support for accessible **pilot facilities and biomanufacturing capacity suited to the needs of smaller, pre-market producers.**

[11] CWTS Leiden Ranking (2022)
[12] JRC: Exploring the global landscape of biotech Innovation: preliminary insights from patent analysis (2024)
[13] EuropaBio: Boosting Attractiveness of the EU for ATMP Developers – Paper (2025)
[14] Alliance for Regenerative Medicines: Sector Snapshot (December 2024)
[15] Bio-Based Europe Pilot Plant: Services, Technologies and Certifications
[16] "FlexFactory" in Poland, Cytiva and SyVento Biotech

European talent and skills: scale-up success

Biotech startups and scaleups consistently report shortages of skilled professionals.

Despite this challenge, successful regional models exist and should be replicated. Belgium, has become a thriving biotech hub in health, agriculture and food by bringing together universities, businesses, and investors. In Flanders, it has attracted over €10 billion in 40 years.[10] In Wallonia, life sciences is responsible for 27% of regional exports, supported by a strong healthcare, research and distribution system. In the Netherlands, the Biotech Campus Delft[17] is the largest open innovation campus in Europe focused on the bioeconomy. The National Institute for Bioprocessing Research and Training (NIBRT)[18] in Dublin, Ireland, offers a wide range of training for industry.

At a smaller scale, some companies have even partnered with local universities to create joint Master's and PhD programmes in order to meet their own employment needs. These initiatives highlight Europe's entrepreneurial potential and should be scaled across the continent to strengthen the talent pipeline.[19]

Recommendations

To build on Europe's strong scientific foundation, we call for **pan-European programmes focused on strategic technologies**. Such programmes should be developed in partnership with industries to meet their needs and can be integrated into Erasmus and the European University Area. These programmes should also focus beyond scientific maturation and into process and scale-up skills development, with integration across disciplines.

Strengthening the sector's competitiveness also requires better **mutual recognition of professional qualifications** in these sectors, both within the EU and with key partners, including the EEA and countries with strategic agreements.

EuropaBio and its members remain available to provide further feedback, case-studies, or to connect the European Commission with biotechnology startups and scaleups.

[17] Biotech Campus Delft
[18] Irish National Institute for Bioprocessing Research and Training
[19] EuropaBio SME BioForum on Advanced Therapy Medicinal Products (2022)