

EUROPA BIO™

# Sustainable Biotech SMEs

Drivers for European Innovation



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Drivers for European Innovation

For the EU to achieve its goal of becoming the foremost knowledge-based economy in the world and a true 'Innovation Union', biotech Small and Medium-sized Enterprises (SMEs) are vital. Some of the most valuable innovation happens in SMEs which then go on to form relationships with larger companies, paving the way for improved health, cleaner energy, products and processes and sustainable farming for Europe's citizens.

However, to make sure Europe's biotech SMEs thrive, there needs to be an appropriate regulatory and policy framework within which these companies can operate. EuropaBio's SME Platform aims to create just that.

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## Championing Smart, Sustainable and Inclusive Economic Growth

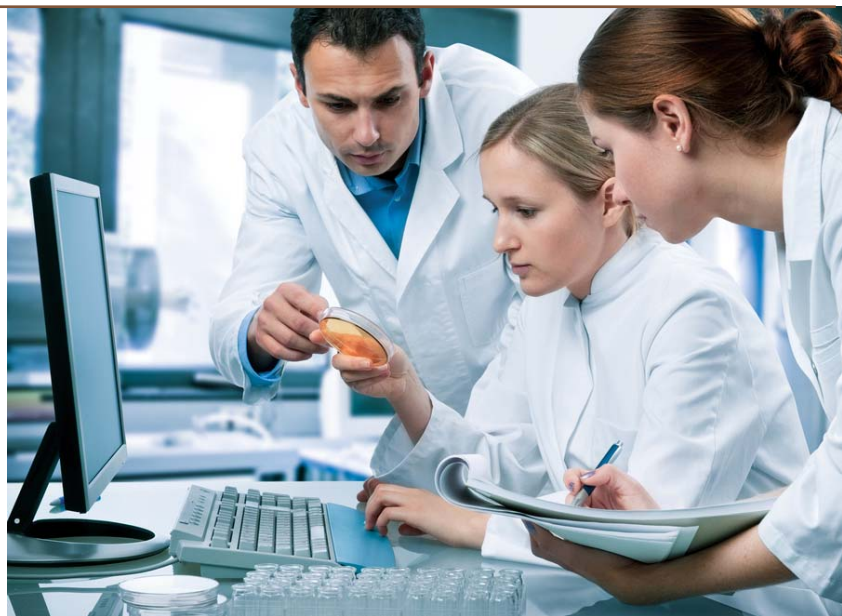
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In the EU, SMEs comprise approximately 99% of all firms and employ about 90 million people. Globally, SMEs account for between 40% and 50% of GDP. Most European biotech companies are micro or small, research-intensive firms and thus they fall squarely into the SME category. Whilst small, they are also knowledge-based enterprises that provide the high value-added jobs that will help the EU achieve its goal of becoming the foremost knowledge-based economy in the world.

Biotech SMEs in Europe are active in all sectors from healthcare to industrial and agricultural applications, often working with larger companies to develop solutions for longer, healthier and greener lives.

**Biotechnology is therefore a key component in research, development and innovation activities which generate novel products and production processes in many industrial sectors.**

However, whilst there is growing recognition that biotech SMEs are important innovation drivers within the EU, they still face long and difficult pathways towards the financial sustainability and success that allows delivery of the innovative products and services that Europe is seeking.



### Healthcare as an example

**Larger biopharmaceutical companies are increasingly relying on external R&D, mostly performed by emerging SMEs. These externally-initiated programmes now represent as much as 30% to 50% of the pipeline for many major companies.**

## EuropaBio's SME Platform

EuropaBio has set up an SME Platform to ensure that Europe's biotech SMEs not only weather the economic storm, but also remain sustainable in the long term. The Platform brings together stakeholders with an interest in SME issues such as SMEs themselves, national associations, venture capitalists and financing bodies to work towards providing policy makers with recommendations on how to best tackle a range of issues of particular importance to SMEs.

For biotech SMEs to flourish in Europe, there is a need to attract more venture capital, to work towards making the European Research Area a reality and for commitment of funding at an EU level. In addition, it will be essential to ensure that the process of applying for funding under the FP and structural funds becomes simpler, faster and less resource intensive. Finally, the ongoing work towards creating a European Patent, if successful, will represent a significant advantage for SMEs, freeing up both financial and administrative resources.

### Our six main recommendations

**1. Make the EU funding instruments more accessible to biotech SMEs**

This could be done by improving the awareness of EIB loans, setting up professional assistance and reconsidering the basis on which the Risk Sharing Finance Facility & European Investment Bank loans are granted.

**2. Develop a short term investment vehicle, via for example the European Investment Bank, to increase risk capital for Venture Capitalists**

Co-investing in existing VCs or co-investing together with VCs in innovative biotech SMEs is also essential.

**3. Make maximum use of the European State Aid rules at member state level**

Better informing member state policy makers of exemptions for research, development and innovation, and actively promoting the adoption of the Young Innovative Company (YIC) status in all EU member states is of critical importance.

**4. Develop measures and opportunities to capture the value of research within Europe**

This can be achieved by developing grants for 'translational research' and 'proof of concept' studies, as well as public/private funding schemes.

**5. Make the EU Framework Programme for Research more attractive for biotech SMEs**

An important step will be the adaptation of FP consortium requirements, with calls targeted towards SMEs and towards setting up specific grants for SMEs to finance research projects designed to improve existing products or processes as well as adapting FP with a 'graduation scheme'.

**6. Bring down unnecessary administrative and cost barriers**

Developing the Enhanced Single European Patent will be critical in this regard so that SMEs can file for patents across Europe without having to cover often prohibitive translation costs.

## Obstacles facing biotech SMEs

1. **Biotech is high-cost, high risk and long term.** As a result, many biotech companies remain non-profit for quite some time and this in turn means that they are often perceived as being too high-risk for external investment or that they simply cannot fulfil the criteria to sign financing contracts available through the various funds on offer.
2. **Most biotech SMEs are funded by capital, rather than by cash flow.** This means that when sources of capital dry up the day-to-day funding for biotech companies also evaporates.
3. **Biotech products have to undergo long and expensive development and approval procedures** and funding for these stages has often proved insufficient in the past. This situation has now been further aggravated due to increased global economic uncertainty.
4. **Many biotech companies are not simply SMEs (less than 250 employees) but are micro-enterprises** consisting of 10 or fewer employees and their capacity to deal with administrative burdens is thus often very low.

## Main achievements to date

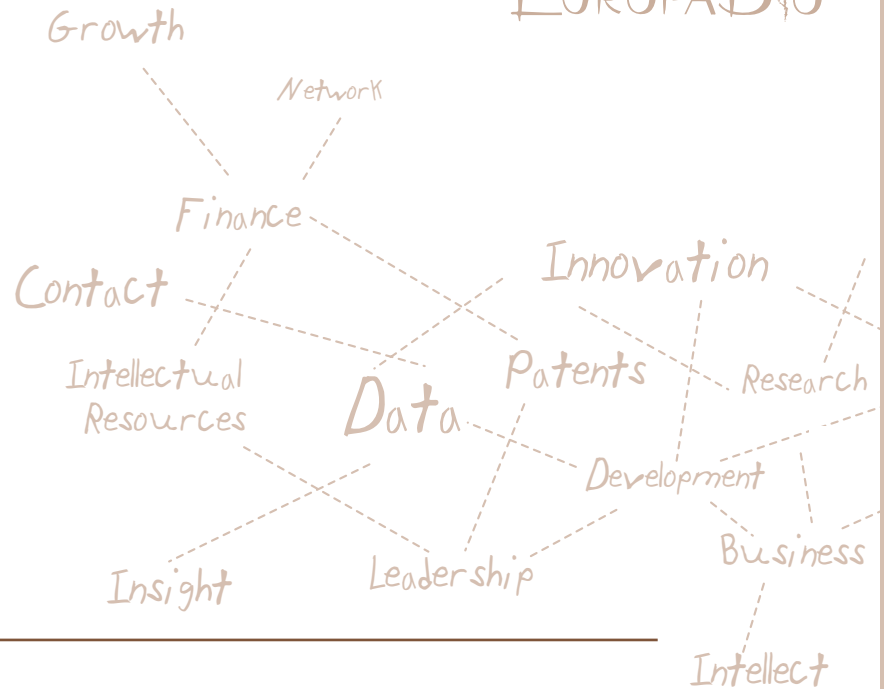
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### SME-specific initiatives

- **EMA SME Office:** EuropaBio was one of the driving forces behind the establishment of the 'SME Office' at the European Medicines Agency (EMA), which is dedicated to assisting SMEs submitting dossiers for EU-wide approval of products.
- **European Commission Young Innovative Company Status:** EuropaBio, together with a group of national associations, initiated the discussions around the need for a Young Innovative Company (YIC) status at EU and national level that would provide, amongst other things, tax exemptions to entrepreneurs, employees, investors and companies across Europe to reward risk with incentives and benefits. EuropaBio is now actively promoting and encouraging the adoption of the EU's YIC tax status in all EU member states.

### Recommendations

- **Access to Finance:** EuropaBio has issued recommendations on how member state policy makers can make better use of the State Aid Framework, as well as on how to improve awareness of European Investment Bank loans across the European Union.
- **Patenting:** EuropaBio interacts with the European Patent Office and has conducted workshops on patent-related issues to facilitate a dialogue between SMEs and the Patent Office Officials.
- **Framework funding:** EuropaBio has issued recommendations on how to improve access to Framework Programmes for SMEs for example through less stringent criteria or conditions for applying for FP grants (such as a minimum number of member states and the participation of large companies and SMEs). In collaboration with the European Commission's DG Research, we have produced a leaflet on FP7 for SMEs, now translated in 15 EU languages and widely disseminated.



## Communications

- **Online one-stop shop:** EuropaBio has set up an 'SME Centre' on its webpage which functions as a one-stop shop for biotech SMEs, informing them about available funding at EU and individual member state level as well as other topics of relevance to SMEs.
- **'Most Innovative Biotech SME Award':** 2010 will see the first ever EuropaBio 'Most Innovative European Biotech SME Award' aimed at showcasing the innovative work being carried out by Europe's Biotech SMEs and honouring their achievements.
- **'Brussels Day':** every year, EuropaBio organises a meeting in Brussels for all its national associations and their members. On this day, CEOs from SMEs from all over Europe come to meet their local policy makers in Brussels and to discuss biotech issues from their national perspective.





The European Association for Bioindustries

is the European Association for Bioindustries, bringing together bioscience companies from all fields of research and development, testing, manufacturing and distribution of biotechnology products. It has over 65 corporate and 7 associated members, 4 BioRegions and 22 National Biotechnology Associations representing some 1800 small and medium sized enterprises.

For more information on SME issues, visit our SME Centre:

[www.europabio.org/SME/index.htm](http://www.europabio.org/SME/index.htm)

For further information, please contact:

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