



Public funding policies: which options for small innovative companies in 2009



Biotech SMEs in the EU: how to improve access to finance

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Who Are We?

Created in 1996, EuropaBio, the European Association for Bioindustries represents:

72 corporate members operating worldwide

5 associate members

4 BioRegions

25 national biotechnology associations



Through our national associations, EuropaBio is also the voice of over **1800 small and medium-sized enterprises** involved in research, development, testing, manufacturing and commercialization of biotechnology applications

Who are our members?



Healthcare Biotech Companies



Agri Food Biotech Companies



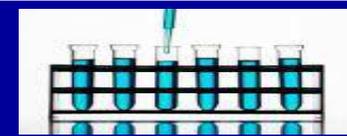
Industrial Biotech Companies



National Associations

Drivers for Growth and Public Policy

Better Science



Better Regulation

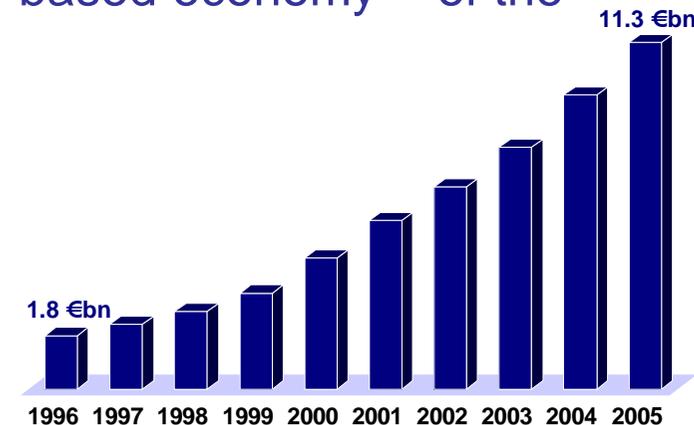


Better Access



Why is (healthcare) biotech important for Europe?

- **To ensure availability of first class healthcare to Europe and access to innovative medicines.**
 - Almost half the pipeline of new drugs are biologicals
- **To establish the base for employment and growth** in one of the key sector sectors of the « knowledge-based economy » of the future.
 - The market for biopharma increased more than 6 times in the last 10 years
- **To improve the efficiency of healthcare delivery** through prevention, diagnostics and treatment of disease as an aging population places increasing demands upon public resources.
 - Biotech offers the tools for improved treatment of some of the important (and costly!) conditions affecting our population including (early diagnosis, tailored medication, rare and chronic diseases)



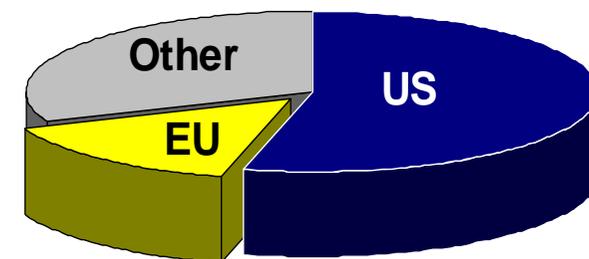
The setting ...



- Opportunities for European healthcare biotech could never be greater, but significant challenges stand in the way of realization of Europe's potential
- Achievement of Europe's potential will depend upon strategies tailored for the European situation
- There is tremendous potential to facilitate realization of Europe's potential in healthcare biotech drawing upon existing European resources

BUT

- The US has the largest pharmaceutical market share by value (~50%), and other regions are showing rapid growth
- The EU lags in product development
 - 15% of biopharmaceuticals were developed by EU companies compared to 54% by US companies
 - US companies have twice the number of drugs in clinical trials than EU companies



European Biotech in the Global Economy 2008 (US\$M)

Public Biotechnology Companies	Global	US	Europe	Canada	Asia & Japan
Revenues	89,648	66,127	16,515	2,041	4,965
		73.8%	18.4%	2.3%	5.5%
R&D expense	31,745	25,270	5,171	703	601
		79.6%	16.3%	2.2%	1.9%
Net income (loss)	-1,443	417	-702	-1,143	-14
		-28.9%	48.6%	79.2%	1.0%
Number of employees	200,760	128,200	49,060	7,970	15,530
		63.9%	24.4%	4.0%	7.7%
Public companies	776	371	178	72	155
		47.8%	22.9%	9.3%	20.0%
Public and private companies	4,717	1,754	1,836	358	769
		37.2%	38.9%	7.6%	16.3%

Source: Beyond borders: Global biotechnology report 2009, Ernst & Young

The challenges

- 
- Growing costs of healthcare and **resistance of payers**
 - **Fragmented European markets** for capital, expertise and end products
 - **Slower economic growth**
 - *Keeping the “infant industry” alive to provide a basis for long term growth*

Biotech SMEs and the financial crisis : some numbers ...

- Around 87% of the biotech SMEs are in the pre-profit phase (unprofitable).
- More than 1 in 4 of the small biotech firms have less than 6 months cash in hands, and 45 % of the publicly traded biotech SMEs have less than 1 year cash available.
- The IPO financing model (public market) does not exist at the moment, and it is unpredictable when it might resume.
- VC investment is declining: almost 57% in 2008 compared to 2007.

The main problems faced by biotech SMEs

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- The averseness of institutional investors for high risk investments is growing. This means that **VCs themselves receive less funding to invest in “risky businesses”**.
 - The environment for **raising capitals on stock markets is becoming extremely difficult**, and the **value of biotech shares dropped** dramatically.
 - As many cash-starved firms are **seeking licensing and partnering deals** for cash to extend their runway until additional private investment becomes available again, asset values have diminished.
 - Small companies with minimal asset values are beginning to take more stringent measures, including **bankruptcy, workforce cuts or scaling back R&D**.



EuropaBio's SME Platform

- Mission:

To develop and propose policies supporting the sustainability of biotechnology-based SMEs through access to finance.

- Members:

Representatives from

- SMEs
- National Biotech Associations
- VCs and private banks
- Invited stakeholders (European financial institutions, EC, etc.)

Main projects

- **Project 1 : How can biotech SMEs survive the current financial crisis ?**
- **Project 2 : How to increase SME participation in FP7 & FP8 ?**

Access to finance: A call for action



The European Association for Bioindustries

SME Platform

Access to Finance: A Call for Action

27 May 2009

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The Financial Crisis and Biotech SMEs: Time for Action

Small and Medium-sized Enterprises (SMEs) are a pipeline to create innovative and sustainable biotech products and processes. Cutting the pipeline of this strategic industry will have repercussions – both the EU and industry will suffer if we do not find a way to secure investment in biotech innovation, a sector which could lead the economic recovery.

Why should we worry about SMEs?

- In the EU, SMEs comprise approximately 99% of all firms and employ about 75 million people. In many sectors, SMEs are also responsible for driving innovation and competition. Globally, SMEs account for 40% to 50% of GDP.
- Biotech SMEs are knowledge-based enterprises and provide the jobs that will help the EU achieve its goal of becoming a knowledge-based economy.

How hard are Biotech SMEs hit by the financial crisis?

- According to recent figures published, around 20% of Europe's biotech companies, the overwhelming majority of which are SMEs, could be gone within the next year if no immediate action is taken.

Why is there such a big impact on biotech SMEs?

- The EU is working hard to develop policy tools to assist SMEs through the financial crisis, but those that have emerged or been announced so far are poorly suited to deal with the specific situation for biotech SMEs or are not being implemented effectively at national level.
- Young, innovative biotech SMEs are often pre-profit for many years due to the high levels of investment for R&D and product trials needed to develop a biotech product. This means that biotech SMEs need significant levels of funding to develop a product before commercialization. Even before the financial crisis, funding a new product often proved insufficient. This situation has now been further aggravated.
- Most biotech SMEs are funded by capital, rather than by cash flow. This means that when sources of capital dry up, as has happened in this current crisis, day to day funding for the biotech company concerned also vanishes.

More than 1 in 4 of small biotech firms have less than 6 months cash in hand, and 45 % of the publicly traded biotech SMEs have less than 1 year's cash available. These firms rely on private equity sources for continuous growth funding, but the current financial crisis has made access to capital very difficult.

VCs are one of the primary sources for risk investments in biotech start-ups, but the VC investment is declining, by almost 57% in 2008 compared to 2007. All forms of investment (including VC) raised by biotech firms decreased by 54% for the first nine months of 2008, compared to the previous year.

The healthcare sector as an example...

For the last 5 years, larger biopharmaceutical companies have tended to place greater reliance 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. If these SMEs do not survive then the R&D and potentially life saving treatments will either disappear or be significantly delayed, resulting in fewer innovative treatments to further develop, and finally to fewer treatments for patients in dire need.



Overview of the recommendations

1. Improve accessibility of Biotech SMEs to European funding vehicles
2. Develop a short term investment vehicle to increase risk capital for VCs (in time of crisis) through EIB
3. Pragmatic use of the European State Aid rules
4. Develop measures and opportunities to capture the value of research within Europe
5. Make the EU Framework Programme for Research more attractive for (biotech) SMEs

Recommendations (1)

1. Improve accessibility of European funding vehicles to biotech SMEs

- Improving awareness of EIB loans and encourage take-up by (national) banks.
- Reconsidering the basis on which the RSFF & EIB loans are granted to better suit the reality of biotech SMEs that are often not yet profitable.

2. Develop a short term investment vehicle to increase risk capital for VCs

- By co-investing in existing VCs, or
- By co-investing with VCs in innovative biotech SMEs.

Recommendations (2)

3. Pragmatic use of the European State Aid rules

- Better informing the Member State policy makers of the exemptions for State Aid for Research, Development and Innovation, and the Temporary framework for State aid measures to support access to finance.
- Actively promoting and encouraging the adoption of the YIC status in all EU Member States.

Recommendations (3)

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

- Developing grants for “translational research”, so the European economy can benefit from its own investment in research and innovation.
- Developing specific grants for “Proof of Concept” studies for biotech SMEs.

Recommendations (4)

5. Make the EU Framework Programme for Research more attractive for (biotech) SMEs by

- Improving access for (biotech) SMEs by adapting FP7 consortium requirements and have more directed calls towards SMEs with better levels of funding, so that there is no need to include a big company to support the project.
- Setting up specific grants for SMEs to finance research project designed to improve existing products or processes, or a demonstration project designed to prove the viability of new technologies in order to prepare commercialization.

Some positive signals from Member States (2009)

- Norway:
 - Innovation Loans governed by “Innovation Norway”: funding increased from £32 million to £95 million. These loans may be used as working capital for the biotech companies.
 - Argentum – the government-owned investment company and the only investor in Norway solely dedicated to investing in private equity funds – will get increased equity capital of £200 million, allowing it to increase its investments in private VC funds focusing in life sciences in Norway and abroad.
- UK:
 - A new a £1 billion strategic Innovation Investment Fund to focus on high tech start-ups (emerging technologies and biotechnology).
- Flanders (B):
 - Gimv launched the Gimv-XL fund, backed by the Flemish Government, to support larger companies that typically show healthy activity and have the potential to expand their business from the Flemish to the international market.
- France:
 - Strategic Investment Fund (Fonds Stratégique d’Investissement, FSI): setting up a partnership with the industry body France Biotech, to consider how best the fund can support the sector.
- Etc.

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Time is money ...!

For more information:

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