



SME Platform

Access to Finance: A Call for Action

27 May 2009

Table of content

OVERVIEW OF THE MAIN RECOMMENDATIONS	2
1. INTRODUCTION	3
2. THE CONSTRAINED CAPITAL ENVIRONMENT: FACTS AND FIGURES	4
3. MAJOR PROBLEMS FACED BY BIOTECH SMES IN TIME OF ECONOMIC CRISIS	6
4. RECOMMENDATIONS	8
4.1. Make the EU funding instruments more accessible to biotech SMEs	8
4.2. Increase VC funding via co-investment	9
4.3. Make maximum use of the European State Aid rules in these difficult times	9
4.4. Develop measures and opportunities to capture the value of research within Europe	11
4.5. Make the EU Framework Programme for Research more attractive for (biotech) SMEs	12
Annex I – SMEs, High-Tech SMEs and biotech SMEs	14

Overview of the main recommendations

1. Make the EU funding instruments more accessible to biotech SMEs by
 - Improving awareness of EIB loans and encourage take-up by (national) banks,
 - Setting up professional assistance for (biotech) SMEs in order to better inform them about the available funds,
 - 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. The European institutions such as the EIB should develop a short term investment vehicle to increase risk capital for VCs (in time of crisis)
 - By co-investing in existing VCs, or
 - By co-investing with VCs in innovative biotech SMEs.
3. Make maximum use of the European State Aid rules in these difficult times by
 - 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,
 - Looking into the possibility of making some of these measures obligatory – on a temporary basis - for the Member States,
 - Actively promoting and encouraging the adoption of the YIC status in all EU Member States.
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
 - Developing public/private funding schemes in Europe for demonstration projects.
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. Smaller consortia under Framework 7 are likely to build more lasting and substantial links between the biotech sectors of European countries than a broader group with a more complex structure.
 - 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,
 - Adapting FP7 with a graduation scheme to continue successful projects,
 - Speed up payment to SMEs to be in line with the Commission’s own proposal.

1. Introduction

The financial crisis is having major consequences for the real economy, and it might stretch over a long period of time, affecting particularly high-tech SMEs (see annex I for characteristics of SMEs, high-tech SMEs and biotech SMEs).

High-tech SMEs and start-ups are confronted with three types of risks:

- Technological risk, resulting from the explorative nature of R&D and production of high-tech products,
- Market risk, as a result of the high uncertainty in the high-tech product market,
- Financial risk, high-tech innovation usually requires huge investment. However, most high-tech start-ups lack long-term investment capability. They require larger markets to generate revenue to recover high development costs.

The risks for biotech SMEs are concentrated at the sector and operational levels. Even before the financial crisis, funding for biotech SMEs was different from other industries and the risks they face reflect unique challenges and circumstances. In this high-risk environment, investors have historically had to develop different metrics in valuing biotech companies. A specific characteristic of the biotech industry is the long and costly development process. While larger biotech firms already have products on the market, young and innovative biotech SMEs need significant funding to develop a product before generating significant potential for commercialization, and this funding - through risk capital - has proved insufficient, especially in times of economic and financial crisis.

Recent studies in several member states¹ have shown that biotech companies are facing a tough financial climate and a large portion will soon run out of capital. As a result, society risks the loss of potential new drugs and effective treatments. For this reason, it is extremely important to take measures to minimize the impact and especially to improve access to finance. As we come out of the economic downturn, the innovative biotech industry could be one of the sectors which will emerge to lead the recovery. Europe has the science and the entrepreneurs to develop a competitive biotech industry, but is facing the principal constraint in the availability of capital. With these recommendations, EuropaBio is seeking to build a sustainable biotech sector by ensuring the resources are large enough to have an ongoing benefit. And biotechnology is still one of the important sectors to realize the Lisbon commitment to the knowledge based economy

Financing Drug Development

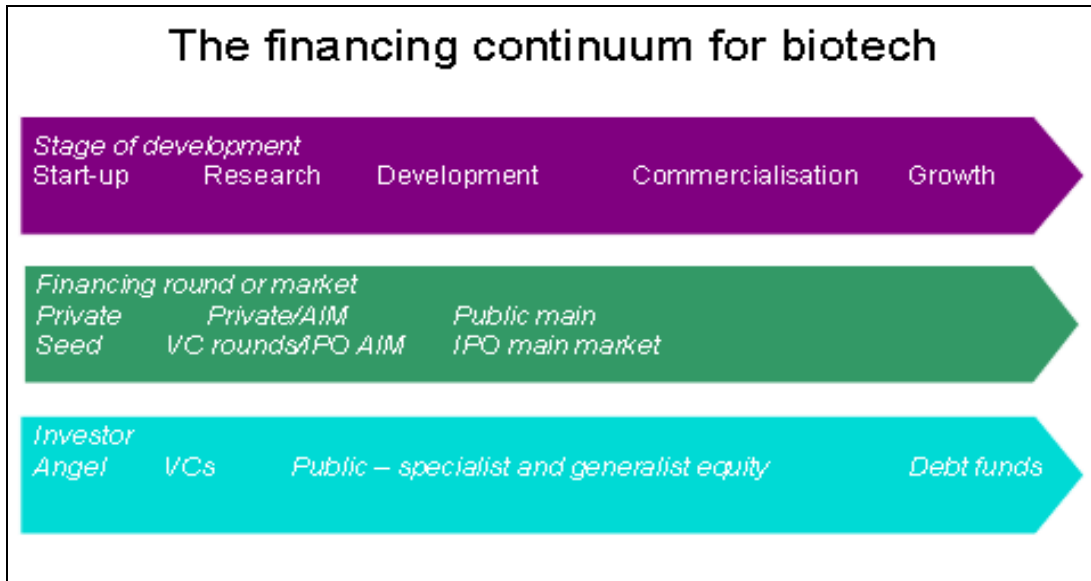
Taking a drug candidate from the research lab to product launch takes from 10 to 15 years. Therefore, building a successful bioscience company requires significant funding from third party investors over a long period of time. Typically, a bioscience company needs different types of funding as its pipeline matures, and the level of funding increases dramatically over time.

The academic spin-out or very young company needs seed funding to proof a concept before starting with the development of a drug. In order to progress to the later stages of discovery and pre-clinical development, the most common route would be to approach venture capitalists (VCs). This usually includes more than one round of venture funding with various options for exits for investors to recoup their investment. VCs have historically often looked for an exit through Initial Public Offerings (IPOs), thereby generating value in the public markets. A buoyant public market place also allows companies to raise funding for the next stage. However, we have seen a decline of the public market in bioscience over the past five years. Trade sales are another form of exit for VCs. Recently there has been a rise in the number of European bioscience companies exiting through a merger or being acquired by companies outside the EC.

¹ such as the UK, Norway, Germany, Sweden, Spain, Italy, etc.

2. The constrained capital environment: European facts and figures²

The crisis in worldwide capital markets has adversely affected the biotech sector by limiting access to capital, and this problem is all the more urgent for emerging biotech companies the vast majority of which are net cash flow negative. Especially for start-ups, access to venture capital is vital. Nevertheless, the early stage venture capital market in Europe represents only about 2bn EUR per year – about 25% of its US equivalent.



Some numbers:

1. Today, around 87% of biotech SMEs worldwide are in the pre-profit phase, and this is a natural consequence of their business model. The last 5 years, the trend has been for the larger players to place greater reliance on external R&D, performed by emerging companies. These externally-initiated programmes now represent as much as 30 to 50% of the pipeline in many major companies. But this business model also transfers the risk of R&D further upstream to the small innovators and their funding sources. This new company business model anticipates years of negative cash flow, and future liquidity is necessary through public offering, licensing or partnering.
2. More than 1 in 4 of the 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.
3. At this moment, the IPO financing model (public market) does not exist, and it is unpredictable when it might resume.
4. 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. Even more worrying is the fact that half of this decline was in the month of October 2008 alone. 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.

² E. Bellott. A season of turbulence. European Biopharmaceutical Review, February 2009.

5. In the current economic recession and capital crisis, assets and investments are depressed. For the VCs, this presents a severe capital sourcing problem for their funds. Institutional investors are having difficulties meeting their capital calls for existing and new venture fund commitments. For the VCs, this presents a clear and present capital shortfall, demanding prioritization of investments.
6. Although stocks have not fallen so far as in other sectors, small and mid-caps biotech stock indices plunged 30% in late 2008. This decrease in share prices not only made the public companies more attractive acquisition targets, but also reflected a lower valuation on the assets of all smaller firms, private as well as public.

The positive point is that large life-sciences and pharmaceutical companies are well positioned with revenues, cash, low-debt and an appetite for partnering, licensing and M&A. In preceding decades, the drug industry has been consistently profitable, with sales steadily increasing at about 7% per year and a long term return on equity exceeding 2.1%.

However, market analysts anticipate that although the demand for healthcare and pharmaceutical drugs will continue to grow, revenues will reduce the next 5 years, due to loss of patent protection and an increased market share of generics.

Funding dries up for UK biotech groups

Nearly two-fifths of British biotechnology companies have been unable to obtain any finance over the past year, according to a survey highlighting the growing threat to the industry's future. A poll of 295 life science companies conducted by the BioIndustry Association, the UK trade body, said nearly three-quarters had experienced difficulties in raising funding.

Clive Dix, chairman of the association, said: "It's grim. If we want to come out of this recession with an economy that is not based on financial services, we have got to look at the medical sciences sector as one that can expand. A little push could really kick-start the industry." He said that even US biotech companies were now approaching him for the first time for help identifying UK-based investors willing to provide support, even as UK venture capitalists who had long focused on the sector were now withdrawing or paring back.

The latest survey adds to the industry's pressure on the government ahead of next month's Budget to take tougher action to support the sector, which has frequently been cited by Gordon Brown, the prime minister, as one with great strength in the UK. It highlights a particular gap in funding to biotech companies after initial support, when they are entering drugs into costly early-stage testing in humans, and require typically up to £10m in support before generating sufficiently strong results to interest larger investors or big pharmaceuticals companies.

The association recently wrote to Alistair Darling, Chancellor of the Exchequer, warning of the "severe threat" to the sector and calling for support through research and development tax credits, greater public funding for small companies with drugs being tested, and new tax incentives to keep intellectual property rights in the UK. "A biotech crash, if it comes, could threaten an industry that plays a vital role in turning scientific advances into usable medicines," it warned.

The Swedish Life Science Industry Financial Status January/February 2009

(by The Swedish Life Science Industry Organisation)

To assess the question “**How are the Swedish life science companies doing financially?**” in today’s tough financial climate, a study was performed based on a survey directed to members of SwedenBIO. It reveals that:

- 25% of the companies have less than 6 months’ cash on hand, and 49% of the companies have less than 12 months’ cash.
- 79% of the companies still rely on external funding. These companies report a need for in total approximately 3.3 billion SEK (around 310 million EURO) to reach positive EBIT.
- 53% of the companies expect external sources of capital from VCs.

3. Major problems faced by biotech SMEs in time of economic crisis

1. The averseness of institutional investors for high risk investments is growing. This means that **VCs themselves receive less funding to invest in “risky businesses”**, and this hurts in particular young and innovative biotech SMEs in need of external financing. Institutional investors retreating from risk is a trend which started in 2008 and is continuing.
2. Today, the environment for **raising capitals on stock markets is becoming extremely difficult**, and because of this, VCs invest less because of a **more difficult «EXIT»**: it is not the right time for an IPO, and large companies are concentrating more and more on their key products (short term).
3. The **value of biotech shares dropped** dramatically during the last few months. This decrease in share prices reflected a lower valuation on the assets of all smaller firms, private as well as public. On the other hand, this made it the right time for consolidation.
4. 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**. Another point to note is the issue of IP being moved away from the EU to other parts of the world (mainly the US) in acquisitions, which are on the up.
5. **Lack of development finance** - Commercial banks, an important source of loans and credits for smaller firms, are increasingly reluctant to provide fresh money or have tightened lending conditions³. The risk assessment criteria, like all the requested information and securities, become more specific and numerous, and have reduced substantially the amounts that can be lent. Although there is a clear lack of mutual confidence between banks and SMEs, the situation differs significantly across member states: in countries in which banks operate at a local level, the level of mutual confidence is higher and the financing situation for SMEs less worrying (e.g. Germany, Austria).

³<http://212.3.246.117/docs/1/EADMDAGBIMCDKOOKOJAMODGPPDBG9DBYG39LTE4Q/UNICE/docs/DLS/2009-00147-E.pdf>

Bank loans alone are insufficient as banks have been extremely reluctant to finance risky SMEs (which was a problem in the EU even before the crisis).

6. Although not specific for biotech SMEs, in the current economic situation, the amount of **late payments** is increasing rapidly as all companies and authorities (national and European) follow their cash positions closely. SMEs are also hit by the drastic order freeze and production stops undertaken by larger companies for which they often are suppliers⁴.

Norwegian government steps in to rescue biotech

The Norwegian government has responded to lobbying from its biotech sector (the Norwegian Bioindustry Association), unveiling a package of measures to help the industry through the economic crisis.

The key measures in crisis package are:

1. 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. Innovation Norway is the country's main industrial development agency. Normal commercial criteria will apply to the loans.
2. £7 million for R&D contracts. The aim is to stimulate increased cooperation within industry on research and development. These are to be focused on industry development in the health sector and internationalisation.
3. Tax breaks for individual small and medium-size enterprises: companies may deduct now up to £0.58 million in tax breaks, an increase from the current £0.42 million.
4. 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.

A new fund for technology in Britain⁵

A £750m investment fund to focus on emerging technologies and biotechnology to promote research and development will be set up.

On Monday 20 April 2009, the government published a new industrial framework, whose aim is to remove the barriers holding back innovative and fast-growing companies - and to help markets work better. "To support this industrial activity and strategy, I can announce the creation of a new £750m Strategic Investment Fund to help the country seize the opportunities ahead."

This new fund will provide financial support, focusing on emerging technologies and regionally important sectors in, for example, advanced manufacturing, digital and **biotechnology**. It will encourage exports, support inward investment, and promote research and development.

⁴ <http://www.ksfp.org.pl/upload/KSFP/AECM%20Declaration%20on%20Financial%20cr.pdf>

⁵ <http://www.ft.com/cms/s/0/a5d482ca-2fa1-11de-a8f6-00144feabdc0.html>

4. Recommendations

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

The European Commission has developed useful instruments to improve access to finance, also for innovative SMEs. One of the examples is the Risk Sharing Finance Facility (RSFF)⁶, a joint initiative of the European Commission and the European Investment Bank (EIB). RSFF is an innovative scheme to improve access to debt financing for private companies or public institutions promoting activities in the fields of:

- Research, Technological Development Demonstration, and
- Innovation investments.

RSFF is built on the principle of credit risk sharing between the European Community and the EIB and therefore extends the ability of the Bank to provide loans or guarantees with a low and sub-investment grade risk profile (involving financial risks above those normally accepted by investors).

While projects to be financed by the EIB need to be technically, economically, financially and environmentally feasible according to the Bank's project evaluation criteria, RSFF loans or guarantees can involve higher risks than typically accepted by the EIB and many other financial institutions.

The current market situation is challenging and is, amongst other things, leading to:

- A sharp decline in commercial bank financing supply due to funding as well as capital constraints of banks
- significant increase in credit spreads (higher risk premiums)
- decreasing RDI investment due to expected economic down-turn

Therefore, the RSFF could well be an important investment instrument for SMEs, and, indeed, RSFF has been mentioned in the EU's European Economic Recovery Plan as one of the instruments to stimulate investment in R&D and innovation.

However, it has been shown to be very difficult for biotech SME to benefit from this instrument as the beneficiary needs to demonstrate that his/her regular activity or the implementation of the RSFF project will generate sufficient free cash-flow in order to cover loan interest payments, capital reimbursements and/or other charges payable under the RSFF financing contract and under its other financial obligations, something which many SMEs are unable to do.

For these reasons, EuropaBio proposes:

- 1. To improve awareness of EIB loans and encourage take-up by (national) banks,***
- 2. To set up professional assistance for (biotech) SMEs in order to better inform them about the available funds,***
- 3. To reconsider the basis on which the RSFF & EIB loans are granted to better suit the reality of biotech SMEs that are often not yet profitable.***

⁶ <http://www.eib.org/products/loans/special/rsff/?lang=en>

4.2. Increase VC funding via co-investment

The averseness of institutional investors for high risk investments is growing. This means that **VCs themselves receive less funding to invest in “risky businesses”**, which in turn hurts in particular young and innovative biotech SMEs in need of external financing. Institutional investors retreating from risk is a trend which started in 2008 and is continuing.

Biotech SMEs must be assured that VCs are able to invest in a sustainable way, even in times of crisis. To ensure this, it is important to find ways to guarantee enough VC funding in the EU for the biotech sector.

For these reasons, EuropaBio proposes that the European institutions such as the EIB develop a short term investment vehicle to increase risk capital for VCs (in time of crisis)

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

This could be introduced as a temporary/emergency measure until recovery has commenced.. A similar initiative has been launched in Norway ,where Argentum⁷ – the government-owned investment company, and the only investor in Norway solely dedicated to investing in private equity funds – has been given increased equity capital to the tune of approximately 225 million euros, allowing it to increase its investments in private VC funds focusing on life sciences both in Norway and abroad.

4.3. Make maximum use of the European State Aid rules in these difficult times

The European Commission’s Framework to clarify to Member States how best to give state aid to not only research and development⁸ but also innovation projects without infringing EC Treaty state aid rules, has been in place since 1January 2007. The Framework sets out a series of guidelines for specific types of state aid measures, such as aid for R&D projects, aid for technical feasibility studies, aid for industrial property rights costs for SMEs, or aid for young innovative enterprises. Although these guidelines allow individual Member States to tailor aid measures to particular situations, they are still not widely translated into national measures or initiatives.

With the **Temporary Framework for State Aid measures to support access to finance in the current financial and economic crisis**⁹, Member States may grant - under certain conditions and until the end of 2010 - subsidized loans and loan guarantees at a reduced premium, direct aids of up to €500,000 per company for the next two years to relieve them from current difficulties, and risk capital aid of up to € 2.5 million per SME per year (instead of the current €1.5 million) in cases where at least 30% (instead of the current 50%) of the investment cost comes from private investors.

⁷ <http://www.argentum.no/index.php?struct=37&lang=eng>

⁸ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2006:323:0001:0026:EN:PDF>

⁹ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2009:083:0001:0015:EN:PDF>

Based on Member States' reports, the Commission will evaluate whether the measures should be maintained beyond 2010, depending on whether the crisis continues.

Most of these opportunities created by the Commission have to be implemented and used at a national level. Currently, however, many Member States make no use of these opportunities to support their industry, and it is thus crucial to inform them of the possibility and availability of these aid measures.

The YIC (Young Innovative Company) status is a special tax category that allows access to state aid through tax incentives for R&D intensive start-ups. As the European Commission's new State Aid rules recognize the Young Innovative Companies (YIC) status as an eligibility criterion for state aid, this enables Member States to provide extra public funds like tax and other financial incentives to their young innovative biotechnology companies without running into trouble with EU competition rules.

The new EU rules enable governments to give extra incentives to companies that are:

- less than 6 years old, and
- spend 15% or more of their revenues on R & D.

The EU rules, which are not sector specific, have been in place since 1 January 2007 and have opened the path to benefit research, development and innovation across Europe.

More than two years later, however, only France, Belgium and Spain have adopted the YIC status. Therefore, the adoption of the YIC status in the other Member States should actively be promoted and encouraged.

For this reason, EuropaBio proposes that the European Commission:

- ***Better informs 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,***
- ***Looks into the possibility of making some of these measures obligatory – on a temporary basis - for the Member States,***
- ***Actively promotes and encourages the adoption of the YIC status in all EU Member States.***

EuropaBio calls for the creation of a strong coalition of national and EU level groups (industry and industry associations, policy makers, other stakeholders) asking Member States to adopt the YIC status and to implement State Aid rules at the maximum level.

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

Transforming knowledge into innovative products is seen as a major weakness in Europe. The EU is investing a lot in research (via FP7, national research programmes, industry), but a lot of the created knowledge is then transformed into new products (i.e. commercialized) in other parts of the world by our European companies or worse by non-European enterprises harvesting the fruits of European investments..

To improve the competitiveness of the economy and the human health, scientific discoveries must be translated into practical applications. In Europe, public funding is available for fundamental and applied research. While basic research is more speculative and takes a longer time to be applied, applied research is characterised as being capable of having an impact in practice within a relatively short time-frame, but would often represent an incremental improvement to current processes rather than delivering radical breakthroughs.

In Europe, the public funding stops often at “pre-competitive” level. Especially in the medical area there is a need for **“translational research”**, where researchers seek to shorten the time-frame and conflate the basic-applied continuum to ‘translate’ fundamental research results into practical applications. It is a much more iterative style of research with low and permeable barriers and a great deal of interaction between academic research and industry practice. The concept of translational research has received very strong focus in the biomedical community over the last few years, as a new way of thinking about and conducting life sciences research to accelerate healthcare outcomes. The NIH, through its Clinical and Translational Science Awards¹⁰, is funding major infrastructure and support for Translational Research in the United States.

“Proof of concept” studies may be simple or complex depending on the technology and the types of reaction involved. Costs of this kind of study are often covered by University grants or specific grant structures in start-up companies. This kind of grant, however, is not as readily available for SMEs developing innovative products once they are no longer under the umbrella of a university or institute. Consideration could be given to the creation of a grant foundation with a mandate to give preference to industrial applications listed in a regularly reviewed hierarchy of industrial “hot spots” relating to key enabling technologies for maximum economic, social and environmental impact. This is also an important step to finding new investors.

Demonstration activities are able to close a critical gap between scientific feasibility and industrial application. They enable us to measure actual operating costs, and specific strengths and weaknesses of technological processes before costly, large-scale facilities are built. They dramatically reduce the risk of introducing new technology on an industrial scale and therefore make a biorefinery venture much less risky for investors. Stimulating the construction of demonstrators via public-private partnerships is therefore one of the most important measures that can be taken to ensure the value of research is captured within Europe.

For these reasons, EuropaBio proposes

- ***To develop grants for “translational research”, so the European economy can benefit from its own investment in research and innovation***
- ***To develop specific grants for “Proof of Concept” studies for biotech SMEs***
- ***To develop public/private funding schemes in Europe for demonstration projects.***

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

The European Commission recognises in its recently published report¹¹ on the progress made under the Seventh European Framework Programme for Research (FP7) that progress towards reaching the 15% target for SME participation has been below expectation. The adjusted overall share of SMEs participation in retained proposals under the specific programmes "Cooperation" and "Capacities" is around 11% in terms of requested EC contribution.

There are several reasons why SMEs are still hesitating to participate in such large projects – ones frequently cited by our members include the bureaucracy, the severe conditions and criteria, the frequently late payments, etc.

More flexibility and less stringent criteria or conditions for applying for FP7 grants (such as a minimum number of member states, the participation of large companies and SMEs, etc.) could stimulate SMEs to participate.

Furthermore, there is a need for more directed calls towards SMEs with **a better level of funding**, so that there is no need to include large companies to support the project. This will facilitate the consortium negotiations (especially for IPR reasons) and lower the bureaucracy, one of the major reasons why SMEs are difficult to convince to participate - they simply do not have the capacity to deal with all the paperwork. To help SMEs, the supervision from the Commission could take the form of "support", and less as "control" (**supportive control**).

Also, the **delayed payment** is often a problem for biotech SMEs as these companies do not make any profit and all funding is invested in research. Based on a commitment in the Small Business Act, the Commission recently suggested a new policy approach to tackle the situation on late payments and proposed substantial changes to the late payment directive of 2000.

The Commission suggests that public authorities should lead by example and should – as a rule – pay their bills within 30 days. In parallel, the Commission commits itself to speed up payment of goods and services so to fully respect the targets for paying bills and, in a number of cases, even shortening payment times to under the current legal period. This should also be the case for the research projects within FP7. Higher pre-financing or more payment on progress/delivery with simplified reporting could be a solution.

In times where it is difficult to find enough funding for SMEs to continue or finalise the research needed, FP7 could (temporarily) **fill the gap between "pre-competitive research" and commercialization** of the end-product. SMEs should be able to benefit from specific grants that could take the form of a 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.

To capture the value of the investment and support the development of new businesses, FP7 could be adapted **with a graduation scheme to continue successful projects**. This could make FP7 the first step in a series of programmes to launch successful businesses.

¹¹ <http://ec.europa.eu/research/index.cfm?pg=reports>

For these reasons, EuropaBio proposes following measures to increase the participation of SMEs to the Framework Programme for Research:

- ***Improve 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. Smaller consortia under Framework 7 are likely to build more lasting and substantial links between the biotech sectors of European countries than a broader group with a more complex structure.***
- ***Set 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,***
- ***Adapt FP7 with a graduation scheme to continue successful projects,***
- ***Speed up payment to SMEs to be in line with the Commission's own proposal.***

France Biotech looks for help as funding tanks

February 6, 2009 – FierceBiotech – By Maureen Martino

The funding crisis has hit France's biotech companies hard. France Biotech--the country's professional association for life science companies--is reporting that funding fell by 79 percent in 2008, relative to 2007 (€143 million in 2008 versus €694 million in 2007). Investment in listed companies collapsed a staggering 98 percent to just €12 million, while venture capital investments fell 27 percent to €132 million in 2008. And the situation isn't expected to improve in 2009.

In response to those grim numbers, the group says France's government must support the industry by implementing a stimulus plan that will benefit small biotech companies. France Biotech made several recommendations:

- Double OSEO Innovation's budget for 2009 and a tripling for 2010 (OSEO is a fund that provides financial assistance to small French companies);
- Reform the research tax credit to distribute the credit more evenly between SMBs and larger companies;
- Designate half of the government's Strategic Investment Fund to innovative French SMBs so that they may acquire undervalued foreign companies and technologies;
- Removal the caps on tax-efficient investments in young, innovative companies; and
- Extend the "young innovative company" fiscal status from 8 to 15 years.

ANNEX I

SMEs – high-tech SMEs - biotech SMEs

1. Definition of a SME

There is no universally agreed definition of Small and Medium Enterprises. It can be defined on the number of employees or on the number of turnover and assets. Currently, the European SME definition, which entered into force on 1 January 2005, considers the following categories of enterprises¹²:

Enterprise category	Headcount: Annual Work Unit (AWU)	Annual turnover	or	Annual balance sheet total
Medium-sized	< 250	≤ €50 million (in 1996 € 40 million)	or	≤ €43 million (in 1996 € 27 million)
Small	< 50	≤ €10 million (in 1996 € 7 million)	or	≤ €10 million (in 1996 €5 million)
Micro	< 10	≤ €2 million (previously not defined)	or	≤ €2 million (previously not defined)

In the EU, SMEs comprise approximately 99% of all firms and employ between them 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.

2. High-tech SMEs

High-tech SMEs play an essential part in the development of national economies, not only as a source of employment and a means of being an alternative to declining traditional industries, but also as a source of innovation, creativity and international competitiveness. High-tech SMEs are of particular interest to governments and others as they can generate new economic activity, new industries and new means of sustainable competition, both within local and global markets.¹³

¹² http://ec.europa.eu/enterprise/enterprise_policy/sme_definition/sme_user_guide.pdf

¹³ <http://www.managementjournals.com/journals/entrepreneur/article222.htm>

High-tech SMEs and start-ups are confronted with three types of risks :

- Technological risk, resulting from the explorative nature of R&D and production of high-tech products
- Market risk, as a result of the high uncertainty in the high-tech product market
- Financial risk, high-tech innovation usually requires huge investment. However, most high-tech start-ups lack long-term investment capability. They require larger markets to generate revenue to recover high development costs.

3. Biotech SMEs

The risks for biotech SMEs are concentrated at the sector and operational levels. Even before the financial crisis, funding for biotech SMEs was different from other industries and the risks they face reflect unique challenges and circumstances. In this high-risk environment, investors have historically had to develop different metrics in valuing biotech companies..

A specific characteristic of the biotech industry is the long and costly development process. While larger biotech firms already have products on the market, young, innovative biotech SMEs need significant funding to develop a product before commercialization and this funding - through risk capital - has proved insufficient, especially in times of economic and financial crisis.

The Ernst & Young risk radar for biotechnology¹⁴

The radar is divided into three sections: (1) **macro threats** that emerge from the general geopolitical and macroeconomic environment; (2) **sector threats** that emerge from trends or uncertainties that are reshaping the industry; and (3) **operational threats** that have become so intense that they may impact the strategic performance of leading firms.



¹⁴ [http://www.ey.com/Global/assets.nsf/International/Industry_Biotechnology_StrategicBusinessRisk_2008/\\$file/Industry_Biotechnology_StrategicBusinessRisk_2008.pdf](http://www.ey.com/Global/assets.nsf/International/Industry_Biotechnology_StrategicBusinessRisk_2008/$file/Industry_Biotechnology_StrategicBusinessRisk_2008.pdf)

The mission of EuropaBio's SME platform is to develop and propose policies supporting the development of biotech SMEs in Europe and to facilitate the access to finance.

Members of the platform are representatives from biotech SMEs, National Biotech Associations, and venture capitalists and private banks.

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