



**LAMBERT REVIEW OF BUSINESS-UNIVERSITY COLLABORATION  
RESPONSE BY THE BIOINDUSTRY ASSOCIATION (BIA)**

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## 1. RECOMMENDATIONS

- *Government grants* are too small and restrictive and take too long for a sensible business creation cycle. The BIA recommends a grant system like the Small Business Innovative Research grants in the US run by the NIH: Funding of \$70k (Phase 1) and \$500k (Phase 2) is available for commercially relevant applied research.
- A clear strategy or framework setting the variety of funding schemes in context is recommended. This would assist in comparative evaluation and show where gaps exist. The process of developing such a strategy should involve wide ranging consultation with the biotechnology industry and academia.
- Raise the ceiling of the *University Challenge Fund* awards from £250k to £1m (with some additional “quality control” for the larger sums, e.g. venture capital co-investment). In addition, there is a need to recapitalise these scheme when the initial money runs out, which in at least one case happened at the end of 2002.
- Help universities streamline their procedures for *spinning out companies* by removing 25% equity ownership limit on UCF funds and providing support to attract high quality people into the tech transfer offices and into the spin-out companies.
- *Patents* help secure financing for the biotechnology industry. The existence of appropriate patents or patent applications can be a *sine qua non* for an investment. The patent system must therefore be usable and strong enough to support industry’s needs.
- *Support entrepreneurial teaching* and education of scientists (at undergraduate and post graduate level) – expand the Science Entrepreneurship Centre by providing funding for more than three years.
- A greater spectrum of *medical charities* could be incentivised to commercialise their IPR and research through start ups and to invest in such companies.
- Good progress has been made on *R&D tax credits* to help the small, emerging companies and we were pleased to note the measures to extend the scheme to more companies announced by the Chancellor in his Budget speech on 9 April. Given that R&D is cost-intensive – it takes around \$600m-\$800m and 8-12 years to bring a drug to market – bioscience companies who are not yet profitable need to be able to take the tax credit in cash in those early years when the company needs it.
- There is a requirement to find a mechanism to plug the *funding gap* between start-up and mainstream stage. A scheme such as the US Small Business Innovation Research Grant, which aims at the \$1-3 million level, sometimes with clauses that the money should be matched, in some fashion, by private money, could help to plug this gap.
- The problem is at the university stage, the companies at the very early *start-up stage*, which is desperately short of cash, and if we do not fund, e.g. with proof of concept funding, then from the UK point of view we will not have the companies that we can then finance differently later.

- We would also like to see a further reduction in the *capital gains tax on investors* in this industry, to encourage more early stage, pretty high risk investments by individuals or by institutions. We believe that this sort of package would help to fund this vulnerable, early stage company development, before the companies then are the critical mass, where they can attract serious finance, in the tens and hundreds of millions, from the private investment market, and eventually the public market.
- *Angel networks* are very limited and on the whole have little experience of the biotech sector. The Government could do more to encourage more angels, including more attractive capital gains tax treatment and changes to the EIS scheme to encourage investment, especially from those who are prepared to be more actively involved in mentoring/interim management of the business, which some of the existing EIS rules discourage. Some of the FSA rules for Business Angel Networks could also be extended. Making grants available to companies or angel networks to allow proper 'due diligence' and legal costs to be justified for small investments would also help.
- The *business asset taper relief* for capital gains tax is a powerful incentive to hold shares, but the relief may be lost once the company's shares are listed, and we would like to see the relief retained for a period, say five years, when R&D companies are listed under the special Stock Exchange procedures.
- The BIA would also like to see measures to permit *tax transparent vehicles* to attract funding on a tax favoured basis by means of allowing the losses representing the R&D expenditure to be relieved against the taxable income of the investors.
- Encourage *seed stage VCs* to stay in this risky investment space through greater availability of applied research grants, a matching fund for smaller investments, or financial support of 'low management fee' funds.
- *Tax incentives* for people to manufacture biotechnology products in the UK and to encourage inward investment for countries to be able to manufacture here for the supply of biotechnology products into the whole of Europe.
- Review *planning regulations* to avoid repetition of Hinxton / South Cambridgeshire District Council fiasco so that world class commercial/academic scientific centres can be established.

## 2. INTRODUCTION

The BioIndustry Association (BIA) is the trade association for innovative enterprises in the UK's bioscience sector. Established in 1989, our mission is to encourage and promote a thriving, financially sound sector of the UK economy, built upon developments across the biosciences. We seek to create economic growth, increase employment opportunities, and expand the skills base.

The UK biotechnology industry is second only to the US worldwide and is the clear leader in Europe. In all there are more than 550 bioscience companies operating in the UK, employing over 40,000 people. From this growing base, we have attracted over 350 members, the majority of which are involved in realising the human health benefits that biotechnology promises. Our UK headquarters are in central London but we also have an office in Edinburgh serving the interests of our Scottish members.

The market cap of the UK bioscience sector has increased from £2.7bn at the end of 1996 to £13 billion at the end of 2001.<sup>1</sup>

The BIA congratulates the Government in asking Richard Lambert to examine how the long-term links between business and British universities can be strengthened to the benefit of the UK economy. The BIA is delighted to make a formal response to the Lambert Review consultation.

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<sup>1</sup> Oxford Business Publishing

### **3. BEST PRACTICE AND EXAMPLES OF EXCELLENCE IN BUSINESS-UNIVERSITY COLLABORATION**

#### **Background**

There is general agreement that the quality of UK medical research continues to be high. The UK has much to recommend it as a location for research and development (R&D) with strong links between university and business. It has a strong university research base located at world class universities, such as Cambridge, Oxford, Imperial and Edinburgh. Also, Fortune 500 companies like GlaxoSmithKline and AstraZeneca conduct high quality corporate research in the UK. International pharmaceutical companies conduct research in the UK with Pfizer operating in Sandwich, Kent and numerous small technology and biotechnology enterprises undertake R&D in all parts of the UK. These pools of highly qualified employees are a significant attractant to other ventures, increasing the competitiveness of the UK. The UK is also attractive because of its sensible regulatory approach to key issues such as stem cell research.

Businesses and Universities throughout the UK need to continue to work together to ensure that the success and reputation of the bioscience sector can be maintained and continually built upon.

The patent system must be strong and usable, as universities may become an even more important source of new drugs in future years. A patent application is, however, only the start of the process and there is much additional work to be done, often by a commercial partner, to ensure successful development and commercialisation.

The development of spin-out companies is generally hindered by the lack of finance available for their establishment and growth. It can be argued that among some universities there is an automatic reference to spin-out. This may not always be the correct approach, other options may need to be considered in terms of licensing. This reliance on spin-out also means, in effect, too many companies seeking the same limited finance. Fewer, better funded, companies may be a better option to increase the levels of success.

#### **Contacts**

The BIA membership includes several academic institutions, such as the Universities of Dundee, Leicester, Nottingham, Southampton, Surrey and Sussex, as well as organisations straddling the interface between academia and industry, such as Manchester Innovation.

A significant number of BIA members originated as university spin-outs, such as Oxford Biomedica, Oxford Glycosciences, Inveresk Research and Q-One Biotech.

The BIA and its members have established good relations with other institutions and academic departments across the UK and research organisations such as the Wellcome Trust and the MRC. We also have good links with RDAs and business groups, such as ERBI and the Oxfordshire Bioscience Network, which are plugged into the needs of local business.

Many academic clinicians will also have good links with industry due to their involvement in clinical trial procedures. This will often result in academics being sought for a consultative appointment, for example.

The BIA welcomes the announcement made in the Chancellor's recent Budget

speech that the Secretary of State for Trade and Industry has asked has asked Sir Tom McKillop (Chair of the Regional Science and Industry Council) to work with the RDAs to ensure that best practice in promoting innovation and knowledge transfer is shared and spread rapidly between the regions. This is a very welcome move and should assist in bringing business and education together.

### **Joint Ventures**

The BIA strongly favours programmes like LINK that require both an academic and an industrial partner to foster a positive relationship. A recent example is the £1.96m grant under the LINK Applied Genomics Programme jointly awarded to Oxagen and the University of Warwick.

Programmes such as LINK and the Teaching Company Scheme are value enhancing to both industry and the academic centre. Companies need to guard against disregarding grant-funded programmes on the grounds that such projects will take longer than one funded and managed solely by the company, but better consultation is required with all parties before the introduction of Government initiatives to ensure the most appropriate grants and programmes are available. We feel that this would have improved the previous and existing Science and Technology grants and programmes.

Encouragement is required for both universities and industry to make the best use of the expertise available; more consultation between the representatives of these two important groups would help to achieve this. Science and Technology grants and programmes often seem to industry to be too academic-led. In addition, initiatives like TCSs are perhaps not as fully conversant with the issues facing the bioscience industry in terms of commercial milestones, funding and an often speedy change in direction. Macroeconomic factors can play a role in companies that result in their pulling out of academic interaction; the rest of the sector should not be viewed as a risk element based on a few instances.

A number of universities, such as Oxford, Cambridge, Imperial and Manchester, have developed excellent technology transfer processes. But there is a need for all universities in the UK to be brought up to that standard, such that the medical/bioscience base within the UK is properly commercialised. Problems arise in universities where there are no proper intellectual property technology transfer procedures in place. In order to get good commercialisation of R&D, which will help the dialogue between universities and industry, role models are required. If the UK loses entrepreneurial academics to other countries, there will be a dearth of role models that show that it is respectable to be both an academic and a developer of ideas that feed into companies. This is an area where the US is much stronger than the UK.

A successful biotechnology industry depends on a two-way flow between academia and industry. This form of dialogue is particularly strong in the USA, where there is not such a discrepancy in terms of remuneration between academia and industry. This also impacts on dialogue, and inequalities hinder its expansion. It is very important for a healthy understanding by academics of the business world in biotechnology, and vice versa, for the business world to be totally current in the latest science. In the UK, it is much more a one-way flow, with people coming out of academia going into industry, and not the other way round; this is not helpful for the UK industry.

This lack of dialogue is not helped by each of the two sectors being viewed as distinct by the other. This can be demonstrated by a lack of many institutions to

attract high calibre employees, on many occasions from industry. There are centres of excellence where this is less of an issue, but many universities are failing to attract and retain high quality researchers. In terms of moving to the interface between universities and industry, because of the lack of the two way flow, there is a great deal of ignorance and suspicion in the academic community about the role of intellectual property (*detailed later in this response*). It is seen in some way as inimical and destructive to academic inquiry, which those who have been on both sides of the fence truly do not believe to be the case.

This is an obstacle that can be overcome - for example, IP training could be introduced as part of all university science courses. Most IP problems in universities arise from a fundamental lack of understanding of IP law. There is often a fear that filing a patent will result in a delay in the publication of academic papers. This need not be the case if there is understanding of the IP system early enough in the process.

Some businesses may currently be deterred from considering business-university collaboration because of a perceived inability of universities to agree arrangements other than under a 'standard' model. The BIA believes that there should be no such thing as a 'standard model'. Instead, the expertise should exist, either in-house or through outside assistance, to develop the model most suited to the type of work being undertaken. Government assistance to identify and spread that best practice would be useful.

Business-university collaborations should be encouraged to review each potential venture on its facts, and consider the arrangements needed which would be most appropriate to each case. Flexibility and innovative solutions should be encouraged wherever possible. Both businesses and universities may benefit from a dissemination of successful case studies and guidance/training as to what might be achieved in particular cases.

There is a lot more the Government can do to encourage entrepreneurship, in terms of training academics that do have the tools to be a successful entrepreneur and need the expertise to do so. We should not take for granted our leading position in particular areas of science, and it is not just going to remain here because of past academic successes; it has got to grow and thrive.

### **The Entrepreneurial Environment**

The UK needs to maintain its competitiveness in terms of undertaking or exploiting research and development. The US and Germany (or, for basic research, India and China) have much more favourable environments. The UK needs to take comprehensive action now on all these fronts in order to maintain the world leading position of the UK biotechnology industry.

A vibrant research environment needs entrepreneurs to manage the small companies that carry out research and to service larger companies' research efforts. Both large and small companies are required to exploit the benefits of R&D. It should be of little surprise that the US has the greatest concentration of entrepreneurs. The UK, by contrast, offers entrepreneurs low pay and benefits. Unfortunately this low pay extends to the research bench compared to the US. In a number of instances successful academics have retained the ability to have a foot in both camps – this would be helped by flexibility on the part of universities in handling academic and commercial appointments/sabbaticals.

The US Federal Government provided over \$26 billion of support for

medical/biological research in 2001. The UK would have to provide almost \$4 billion of support to match in GDP terms what the US Government provides – it currently spends some £650m per annum on bioscience research<sup>2</sup>. This gap at the start of the research process is a serious deterrent to medical research. Similar comparisons can be made in the electronics and technology areas.

The Government has sponsored many schemes and initiatives to assist R&D but they are all small and not well publicised. For instance in regional schemes Scotland is coming to the end of a three-year plan worth £40m for the development of the biotech cluster while the US State of Michigan offers \$50m per annum for its biotech corridor. This Scottish scheme is large by UK standards as most of the UK schemes are below £3m per annum. In contrast, Texas has a budget of \$800m for science, engineering, research and development. Total DTI expenditure on science and technology in 2000-01 was just over £353m<sup>3</sup> (excluding Science Budget allocations). The BIA welcomes the £1.25bn addition in spending on science by 2005-06 compared to 2002-03 - including an increase of an average of 10 per cent a year in real terms for the Science Budget.

There is a clear danger of the UK being left behind unless suitable finance and funding packages can be put in place. If no action is taken to ensure the competitiveness of the UK as a location for R&D activities, this could affect companies' decisions on locating R&D facilities. There is strong link between industry and universities that needs to be maintained to ensure that the UK can remain a leader in the bioscience industry and encourage further investment in the UK.

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<sup>2</sup> 'Biotechnology Clusters', DTI, August 1999

<sup>3</sup> Science and Innovation Strategy 2001

#### **4. MAIN BARRIERS TO STRENGTHENING BUSINESS-UNIVERSITY RELATIONSHIPS**

##### **Management and Organisational Issues**

In terms of management and organisational issues, more radical measures are required to encourage entrepreneurship. This means looking at quicker decision making processes to take advantage of scientific opportunities and a management structure which is able to react quickly and arrange finance where required.

Universities have been slow to pick up best practice from business, and before graduates can be expected to be more entrepreneurial, the lessons need to be examined. In addition, universities have in the past not had to deal with matters such as raising finance. This can now be a full time occupation for many in business and years of dealing with, for example, financial institutions and venture capitalists, have brought valuable experience. Not all universities have this experience and organisational structures should ensure that finance (and the need to raise and manage it) is given sufficient emphasis. This is where the collaboration can be of benefit to both sides as they learn good practice from each other.

Of major importance is the fact that all universities are managing technology transfer activities differently. There needs to be a streamlining of these activities in the UK to:

- Facilitate interaction with business, i.e. business “knows what to expect” from “the University”;
- Enable better inter-University commercialisation collaborations, e.g. University A has a company which needs to expand. University B has a company which has synergies with company from University A. If a University of UK procedure for managing technology transfer was more streamlined, collaborations between Universities A and B would be easier to facilitate.

Universities may require assistance in streamlining their procedures for spinning out companies by removing the 25 per cent equity ownership limit on UCF funds and providing support to attract high quality people to tech transfer offices and spin-out companies.

##### **Technology Transfer and Intellectual Property**

Bioscience, particularly as it applies to healthcare, is a high investment business. Innovation is crucial in honing and maintaining the competitive edge, but innovation is costly; it is always cheaper to imitate than to innovate. In these circumstances, effective IP protection, particularly patent protection, is of vital importance to industry and universities if the necessary investment for innovation is to be encouraged. IP underpins almost all investment decisions made in biotechnology, and it follows that if the industry is to make a major contribution to relative GDP growth, the patent system must be usable and strong enough to support industry's needs.

Many young bioscience companies are spun out of universities, and there are frequent major collaborative ties between bioscience companies and academic laboratories, e.g. Renovo, which still maintains close links with many University of Manchester science programmes. Effective technology transfer from universities and other public sector laboratories is vital for these spin-outs and collaborations and IP is the vehicle by which technology transfer can be made to happen. A good patent system is vital, and the involvement of academic laboratories underlines the importance of protection being available at reasonable cost. It is also important not to forget the value of intellectual capital, i.e. academic know-how, in a commercial setting.

## **Current IP Practice**

There are a number of issues affecting the current IP practice, these are listed below.

- **Ownership Issues**

The BIA notes that different universities have different arrangements concerning the ownership of “university” inventions and the rights of university employees in those inventions. Different arrangements may apply within a university concerning different areas of technology and may also differ between universities. In addition, many universities will receive funding from third parties (e.g. from businesses, charities and other sources of government or EU funding), which may affect the ownership of IP in a particular university laboratory or department.

- **Types of Collaboration**

Business-university collaborations cover a wide variety of situations. A business may provide research funding for early stage research and require a first option or right to the results of that research. The university may have existing IP which it wishes to license or transfer to a business for exploitation. In connection with the transfer of existing IP, a business may be willing to fund further research by the university in the relevant field. In many cases a license to a business will not terminate the work of the university in that field and issues will arise concerning future IP developed in the same field and the rights of existing licensees to access that future IP (if any). What is essential for any successful business transaction is that the issue of IP ownership and/or assignation is clear and unambiguous from the start.

- **Exploitation Arrangements**

In connection with the IP arising or relating to business-university collaboration, the parties may determine that a non exclusive license, an exclusive license or an assignment, is appropriate in the relevant case. The form of grant of rights to the business will vary depending on a large number of factors including the use and application of the technology, the number of potential licensees, the potential return from exploitation, the contribution of the licensee to the costs of research and/or development, the conduct of the patent process and, post grant, the conduct of claims against infringers. All too often valuations and expectations with regard to royalty generation are beyond the status of the particular technology and the work that is still to be undertaken by the commercial partner.

- **Flexibility**

It is important to retain flexibility of arrangements with regard to ownership, types of collaboration and exploitation arrangements. This enables businesses and universities to consider the arrangements appropriate to the collaboration in question. Some proposed business-university collaborations might founder at an early stage due to one or other party being unwilling to adapt a ‘standard’ form to the circumstances of the particular case.

At present there is no standard practice relating to IP issues adopted in Business-University collaborations. It is difficult to see how any such standard might be imposed. Guidance to universities may be of assistance, but there is a concern that guidelines may impose a standard form, which would be inappropriate. Similarly it is difficult to determine “best practice”; what may be best practice on the facts of one particular case, may not be appropriate for another case.

## **Knowledge Transfer**

A criticism increasingly heard is that too many of the Government's support initiatives for bioscience are insufficiently well thought out and targeted, require responses on an unrealistic timescale, are insufficiently funded or do not last long enough to be of real value to the academic research or biotechnology industry communities they are meant to serve.

British universities are aware as never before that the developing knowledge economy needs all the input that they can provide. It is generally accepted that commercialisation of science is now the third objective of the university sector alongside teaching and research and yet the funding required to achieve this objective is inadequate. The Government has done much to facilitate technology transfer and company start-ups from the university base and should, in particular, be given credit for the University Challenge Fund.

However, barriers also exist here. An example of the inadequacy of an apparently well-regarded initiative is the limit of £250,000 imposed on investments by University Challenge Funds in new start-ups. The ceiling for awards is too low in comparison to other country's initiatives. The BIA believes that this should be raised to £1m. In addition, there is also a need to recapitalise these schemes when the initial money runs out, which in at least one case happened at the end of 2002, meaning that the issue needs to be addressed as a matter of some urgency.

The BIA also proposes that those UCFs whose funds are running out should be audited. If they have met their objectives, they should be re-funded at three or four times the original amount. Furthermore, the BIA thinks that the whole University Challenge Fund scheme should be audited, with a view to extending the scheme to cover more university consortia – e.g. a further 15 UCFs could be set up at the original level of funding, i.e. a total of £30m.

The relationship between academia and industry in the UK has often been difficult with mutual suspicion about motives – an apparent “snobbishness” on the part of academia and an apparent shallowness and excessive profit orientation by industry. This can also be a significant barrier to successful knowledge transfer. There needs to be mutual trust between the two parties and the benefits of collaboration must be made clear.

## **The 'Brain Drain'**

The current 'brain drain' of scientists out of the UK is a matter of some concern to the bioscience sector, e.g. the recent examples of Dr Paul Nurse moving to the USA and Alan Colman of PPL Therapeutics moving to Singapore. An association called British Expats in Life Sciences has been set up that aims to connect and foster relations and interaction among British expatriates who are involved in the life sciences in the US and Canada ([www.belsgroup.com](http://www.belsgroup.com)).

There has been no definitive study on the flow to and from the UK, so the magnitude of the 'brain drain' is difficult to assess, but there are various sources offering some information on this:

- The Roberts Review of the supply of scientists and engineers in the UK found some evidence that increasing numbers of top scientists and engineers are leaving the UK, particularly in comparison to migration in other areas of expertise. The Report concluded that “SET graduates are more likely to move abroad for employment than graduates in general, which is consistent with the view that R&D employers recruit internationally to obtain the best.”

However, the Report also found that significant numbers of scientists and engineers enter the UK each year from abroad, e.g. 10%, or 6,626 of work permits granted in 2000 were for engineers and technologists. The Report also cited statistics from 'The International Passenger Survey' Office of National Statistics, which showed a net increase in 2001 of almost 5,000 scientists and engineers.

The Review can be found at: <http://www.hm-treasury.gov.uk/roberts>

- In its report 'Europe and the Challenge of the Brain Drain', the Institute for Prospective Technological Studies (IPTS) found that the UK topped European countries in the number of professionals migrating to the US (2,934), followed by Germany (1,501) and France (688). Of these, around 25% went to California, making the largest single group, around 10% went to New York state, and around 8% went to Massachusetts (*US INS sources*).

The report also showed that 8,760 of science and engineering PhD students graduating between 1988-95 were from European countries. Half of these were still in the US five years after graduating, according to US Department of Labor statistics.

The report revealed that UK graduates have the highest stay-rate in the US – 30% return to the UK, compared to 75% of Germans graduating in the US.

The implications of this should be taken seriously, the IPTS found: "The fact that significant numbers of top European scientists are abroad could pose a serious challenge for Europe in certain emerging sectors such as the biosciences."

The report can be found at:

<http://www.jrc.es/pages/iptsreport/vol29/english/SAT1E296.htm>

- The Biochemical Society's survey in 2000 of initial graduate employment found clear indications that research careers are becoming less attractive to some of our best young biochemists. It found that the proportion of undergraduates starting research appointments in industry (7.2%) or in academia (5.8%) were both a little lower than in 1999. The most notable feature of Ph.D. employment was the decrease in proportion continuing academic research (from 43.7 to 35.7%), since this figure has consistently been in the range of 40-45% for a number of years. The proportion entering industrial research (8.5%) was also lower (13.2% the previous year), and this represented the third consecutive decrease.
- The Save British Science Society published in March 2002 a selection of recent evidence on recruiting and retaining scientists in the UK.

A study carried out by the society and published in *Nature* in 2000 analysed a sample of 770 people who had been awarded a doctoral degree in a science subject from a UK university in 1998. 252 were traced as still publishing scientific papers in 1999/2000. Of these, 157 still resided in the UK, 43 in the USA and 52 elsewhere in the world.

A press release issued by the society in January 2000 revealed that 26.1% of Fellows of the Royal Society were based outside the UK in 1999, compared with

16.1% in 1969. The proportion of Fellows based in the USA rose from 5.5% in 1969 to 12.4% in 1999.

The society also published in *Research Fortnight* in October 1999 an analysis of the destinations of the research students and postdoctoral researchers to have left a world-leading materials science research group at the University of Cambridge since 1970. Of the 33 people whose careers had been tracked, 14 were in the USA, three in Europe and one in Japan.

This information can be found at: <http://www.savebritishscience.org.uk/>

### **Incubator Space**

Incubator space for spin-outs remains at a premium with the inevitable result that many spin-out companies reside too long inside academic departments and are then completely separated from them as they often move far away to affordable premises. When newly created start-up companies stay too long in their founding academic departments, they impose space pressure on that department – limiting the latter's ability to generate new cutting edge science. When prematurely forced apart, the fledgling company's risk of failure is greatly increased.

There has been substantial effort, with DTI support, to catalyse exploitation of university-based research through the formation of spin-out companies. These are often based in incubator space. The growth in the rate of new company formation puts pressure on the need for expansion in the provision of incubator space. In addition the shortage of follow-on space for these companies prevents incubator space from being recycled and used by new spin-out companies.

Research into incubators conducted by the BIA in 2002 confirmed that the average stay is two to three years, although in some cases it can be up to five years.

Providing appropriate infrastructure at affordable prices and reasonable leases is one way in which RDAs could stimulate the growth of the biotechnology sector. There is a role for RDAs to either gap fund or assist the construction of suitable premises, otherwise UK companies will leave UK incubators.

Incubators need to be part of a continuum – funding basic science research, providing adequate tech transfer mechanisms, having the physical/personnel/funding infrastructure to allow company formation in the incubator and then sufficient facilities for these companies to grow into.

### **Regulation**

- **Animal Extremism**

The BIA was very concerned by the refusal of planning permission in February 2002 for a proposed primate research facility at Girton College Cambridge on the grounds that it would be difficult to maintain public order following mounting opposition from animal rights groups. This is the first instance to the BIA's knowledge that planning permission has been refused for such reasons. This clearly sets a dangerous precedent and encourages protest groups to use threats to block the construction of any building with whose eventual purpose they do not agree.

More vigorous and timely action against criminal elements in the various extremist groups is vital. There have already been a number of vicious attacks on researchers, both academic and industrial, and the focus of some of the protestors is shifting to supporters, funders and clients of companies carrying out medical research using

animals. If permitted, this type of protest action will undermine research and the viability of the UK bioscience industry in the UK.

Adequate police funding is essential if local police forces are effectively to deal with violence and intimidation by animal extremists, and so avoid a repetition of the rejection of planning permission for animal research facilities.

The BIA has welcomed the changes in legislation introduced by the Government in relation to animal extremism. However, the police must have the resources to properly enforce these laws and extend current legislation, which was passed to protect the private home addresses of directors of companies that are being targeted, to include small shareholders of those companies.

The BIA would like to see the international sharing of information about this type of terrorism, much as we have seen efforts to prevent football hooliganism. It is important in terms of the image of the UK overseas and in terms of the attraction of inward investment that animal extremism is dealt with and a robust response continues to be made.

- **Insurance**

The BIA is also concerned that there is an insurance problem with businesses, e.g. on science parks, where composite panels are in place. Following the attack on the World Trade Center, the insurance market suffering some recent substantial losses and a rise in fire claims in recent years, underwriters have taken a hard line on properties containing composite panels. As a result, premiums and excesses have risen dramatically, potentially putting insurance beyond the reach of many businesses.

## 5. HOW BUSINESS CAN ATTRACT THE BEST GRADUATES AND POSTGRADUATES WITH THE REQUIRED SKILLS

### Skills

There needs to be a link between providing students with the scientific understanding and research skills they need and providing them with the commercial understanding to put those skills to use in business. This must be done throughout the whole process looking at all areas of business from the timescales involved in product development, through to patenting and financial considerations.

The creation of 'scientists' is not the only issue. The generation of IP or development technology (*as detailed in the previous section*) which can be transferred are very important and should be central to the university debate.

The UK produces some of the best scientists, researchers and business people in the world. If the UK is to remain at the forefront of the bioscience sector it is imperative that every possible effort is made to keep the best people in the UK and also to attract talent from abroad. This means setting the right financial environment for those who work in the sector in the UK so it compares favourably with the incentives offered abroad but also fosters commitment to the company.

### Career Paths

Apart from the loss of skilled researchers to academic posts abroad, there is evidence of a decline in the numbers of skilled researchers remaining in UK academia (*please see previous section on the 'brain drain' for further information*). Poor university salaries seem to be the main cause and while some of those affected undoubtedly take up better remunerated posts in industry, there is anecdotal evidence that many abandon science altogether for unrelated careers in commerce. This will likely have adverse long-term consequences for industries such as bioscience, which rely on an intensive scientific base.

The BIA is also concerned that the level of academic salaries for researchers is uncompetitive both within Europe, within industry and internationally, with the US. We do see long-term problems with this. There is a need to stop students going overseas to continue their careers. Some science sectors have been much more forward-thinking on this issue than have others and there are discrepancies between how various science sectors are treated and also how well business interacts. Universities, particularly careers offices, also need to be more aware of the opportunities in science.

### Incentivising Talent

The UK produces some of the best scientists, researchers and business people in the world. If the UK is to remain at the forefront of the bioscience sector it is imperative that every possible effort is made to keep the best people in the UK and also to attract talent from abroad. This means setting the right financial environment for those who work in the sector in the UK so it compares favourably with the incentives offered abroad but also fosters commitment to the company.

- **Share Options**

Share options are an important element of the reward package offered to employees engaged in Research & Development activity. Encouraging employee shareholding is necessary in achieving longer participation and greater productivity from workers in parts of the company. The Government's *Share Incentive Plan* has been a valuable part in achieving a fair tax treatment in order to encourage the take-up of shares.

Share option packages also help UK companies to attract and compete on an equal footing for talent in the global marketplace. These also help to 'buy-out' the existing packages of senior recruits who join from the larger pharmaceutical companies. Cash remunerations are often more difficult from young firms until they are cash flow positive. This is often the situation in which biotech firms find themselves. Share options are, therefore, required in the early stages of company development. The team-based culture of biotech firms will normally mean that share option packages are offered throughout the companies. The BIA is also calling for an increase in the value of approved share options an individual may receive from £30k to £100k.

Rules around share option scheme dilution limits (the rate at which share option schemes are offered), such as the ABI guidelines, are clearly helpful in preventing cases of abuse. However, these too need to be looked at in the light of assisting companies in the early stages of their development. The BIA is conscious that removing the current 5% dilution limit (5% of unissued share capital for executive incentive plans) could raise shareholders' concerns that some companies might use the pool of shares available to them too quickly within the 10 year period. There is also concern that 10% (of unissued share capital for all plans, employee and executive) in 10 years is not sufficient to meet the companies' development needs. The BIA believes that its proposals provide the necessary protection for shareholders against dilution together with the necessary flexibility in incentivising employees.

- **National Insurance Contributions**

The Government has recognised the problems caused by the National Insurance Contribution scheme on share ownership packages. The BIA has previously called for the removal of the charge to National Insurance Contributions on the exercise of employee share options. Whilst we would prefer this charge to be removed entirely, we recognise the cost implications of this.

- **Business Entrepreneur Initiative**

This important five-year £20 million scheme is jointly funded by the Department of Trade and Industry's Office of Science and Technology and the Wolfson Foundation, and administered by the Royal Society. The initiative aims to help institutions to attract researchers of outstanding achievement or potential in order to create a 'brain gain rather than a brain drain' (*Melanie Johnson MP, Parliamentary under Secretary of State for Competition, Consumers and Markets, 12 July 2001*).

The BIA believes that the Business Entrepreneur Initiative should be extended and enhanced to include the emerging business as well as the academic sector, similar to schemes which exist in countries such as Ireland. Possible solutions may include the creation of a 'tax holiday' for British researchers or entrepreneurs who return from the US through to match funding from those invested by returnees.

The scheme was created after the Royal Society recognised in August 2000 that it has more Fellows based in the US than there are Fellows of the US National Academy and looked to establish a scheme to address this. When applying for the scheme nominees must include details of the risk to UK science of losing the scientist or the benefits of the recruit if coming from overseas. Those successful receive an award for salary enhancement and research expenses on top of their current wage from the host university. The average award is around £40,000 and

recent winners include Professor Richard French-Constant, Department of Biology and Biochemistry, University of Bath; Professor David Goldstein, Department of Biology, University College London and Dr Timothy Karr who left the University of Chicago for the University of Bath's Department of Biology and Biochemistry.

### **Investment in the Skills Base**

In terms of our universities, a systematic examination should take place that ensures that the right courses and teaching are available for those involved in specific industry sectors, i.e. for people in biomanufacturing processes. For example, investment in Liverpool, which has a history of pharmaceutical manufacturing, would be a natural place to encourage the development of biomanufacturing, to make sure that that skills base is utilised. This requires, once again, a constructive dialogue between industry and universities to check the requirements of the sector and gaps in provision by universities.

The BIA expert advisory committee structure is an effective way for member companies to highlight perceived problems or requirements. A good example of this was the BIA's Biomanufacturing Advisory Committee's investigation in 1998 into the UK biopharmaceutical requirements, which highlighted skills shortages in biomanufacturing and developed a series of recommendations to address this.

## 6. FINANCIAL CONSIDERATIONS

### Under-Funding of UK Universities

There is general agreement that UK scientific research is of a high quality, especially in medicine, although there is a concern over whether it can remain so given the chronic under-funding of UK universities.

The recent Treasury Transparency Review carried out by the Funding Councils showed that UK universities teach at a loss and conduct research at a loss (against funding received from the funding councils), the result of which is the progressive degrading of universities' physical and organisational infrastructure.

There is a growing realisation among UK universities that inadequate funding of research by the funding councils is creating a research "crisis" which will impact negatively on UK industrial competitiveness unless quickly resolved. In their recent response to the White Paper on The Future of Higher Education, Universities UK highlighted the "substantial investment needs of the sector, particularly in research and teaching infrastructure".<sup>4</sup>

Much of the research in the fields of medicine and bioscience is funded by medical charities which typically pay little or no contribution to the overhead cost (university overheads can be crippling to small companies) of doing the research they purport to fund. These contracts have to be subsidised from the already inadequate funding council income, greatly exacerbating the universities' deficit problem - and the more successful a university is at winning the medical charity contracts, the worse its long term financial position will become.

The industrial funders of research in universities, who should, from their own internal experience, have an understanding of the true cost of conducting research, often limit their overhead contribution to little more than the Research Council rate. This is done on the grounds that they pay their taxes and expect these taxes to fund the university infrastructure necessary to support the research they are sponsoring. Sadly, that assumption is unfounded and this is contributing to the "hollowing out" of our great centres of research excellence.

UK universities are under-funded compared to other leading G7 nations. For example, Yale University has a budget of \$1.2 billion, compared to Cambridge's budget of £220m. In 1997 the proportion of GDP spent on higher education in the UK was 1%, compared to 2.7% in the US<sup>5</sup>.

Although University funding is now starting to rise, there are years of funding reductions to neutralise. Practises such as Cambridge University not being able to pay staff more than £50k discourages high quality researchers from coming to the UK. In comparison, US universities have the freedom to pay and charge as they like.

The BIA understands that the Government is currently examining new ways of funding universities and students. Government press notices point to increases in university funding – HEFCE has announced an increase in overall funding for higher education institutions, and also the real terms increase in the unit of funding for teaching overall. However, this masks huge differences across the HE sector. Professor Roderick Floud, President of Universities UK, has said: "A significant

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<sup>4</sup> Universities UK, April 2003.

<sup>5</sup> Centre for Educational Research and Innovation (2000), *Education at a Glance: OECD Indicators*

number of universities are now facing a real terms percentage cut in their total HEFCE funding, but the figures are difficult to interpret because the range is so wide.”<sup>6</sup>

### **Current Sources of Funding for Bioscience Companies**

- Medical research grants (MRC, Wellcome, CRC etc). Grants vary from £10k per annum to over £1m over three years and typically fund the inventive part of academic research but can rarely be used to translate clever new inventions into commercial propositions, i.e. the applied research.
- Government grants/awards. Grants like LINK, SMART awards are useful small sources of funding for limited applied research (less than £100k).
- University Challenge Schemes offer funding to seed companies of £250k, but are limited to the richest and largest universities and in general have limited biotech experience or access to credible biotech advice. In addition, there is currently no plan to recapitalise these schemes when the initial funding runs out, which in some cases will happen as soon as later this year.
- Friends/family/angel funding: in some of the main UK biotech clusters, e.g. Oxford and Cambridge, angel funding can be sought from successful entrepreneurs or angel syndicates with experience in building companies in the biotech industry. Sums of £100k can be raised, possibly collectively providing fund of £500k-1m, e.g. Cambridge Angels. In these cases, the angels involved may well give the founding entrepreneur commercial, strategic and organisational help in addition to providing the early funds. Most other angel groups are inexperienced in biotech – more experienced angel networks with a heavy presence of biotech specialists are needed.
- Seed Venture Capitalists, e.g. Avlar, Sitka, some VCTs. These seed groups tend not to be economically viable if only focused on seed deals. There are not many players in this category and in many ways having a small seed venture fund is unattractive to its management team, as management fees are a percentage of fund size, therefore there is a strong incentive to raise large funds, which means that small investments become very difficult to manage and justify.
- Investment funds aligned alongside research funding bodies, e.g. the Wellcome Trust Catalyst fund, the Medical Research Council MVM fund, and the CRC fund.
- Proof of Concept Fund in Scotland, financed by the Scottish Executive, provides funding of up to £250k for commercially focused projects that would not secure investment from traditional sources at early stages in projects.

### **Problems with Current Sources**

The returns demanded from these different sources of capital vary dramatically. Grants require no returns. Friends/family money is typically not very aggressive in terms of return expectation but can be poorly structured, hampering future funding rounds. Sophisticated angels and seed VCs understand that these very high-risk investments are highly likely to fail (more than 50% failure rate at least) and so they demand returns of eight to ten times the amount of cash invested. Sophisticated investors from the sector understand the achievements and valuation structures

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<sup>6</sup> Universities UK press release, 8 March 2002, ‘Universities UK response to HEFCE grant announcement’.

necessary to attract the next round investors who are so essential for continued company growth.

### **Gaps in Funding**

Gaps in funding therefore occur in:

- **Seed Funding**

Overall there are insufficient funds (less than £500k-1m) to pay for applied research, securing IP and founding new high quality companies – this is a major gap that needs to be met by proof of concept funding. Although there are a lot of spin outs (four times more than the US per research \$ according to Quester<sup>7</sup>) they are typically poorly set up, run by inexperienced teams, undercapitalised and have narrow (unsustainable) technology platforms. The Government can help to leverage this early stage risk.

- **Start-up Funding**

Well conceived companies can always find finance. Borderline companies that lack commercial vision and entrepreneurial flair struggle.

- **Equity Gap Funding**

The real gap in early stage funding for biotechnology companies is in the space between creation of the originating technology/intellectual property, possibly in an academic environment, and reaching a development stage that they are able to attract 'lower risk' venture and/or development capital backing. There is a requirement to find a mechanism to plug the funding gap between start-up and mainstream stage.

Funding for the creation of the originating technology/intellectual property is primarily provided for through academic budgets and the various government grants and early stage initiatives. However, this funding is barely enough to demonstrate very early proof of concept.

Venture capitalists are increasingly unwilling to devote the time to early stage ventures unless it is in the form of a 'super start-up'. The characteristics of these are an established and known management team, minimum level of funding from say, £10m upward and a broad technology platform.

Business angel funding is very sketchy at best and there are very few venture funds dedicated to early stage start-ups, hence the gap.

There is also very little support for biotechnologies outside of therapeutics. Medical devices and diagnostics struggle for support, whilst the agriculture and environmental sectors fare even worse.

- **Mid-Expansion Stage Financing**

Generally well covered, although recent regressive changes in stock options legislation make the UK a less favourable tax environment for more established biotech companies (and their senior management teams) than the US.

Biotech sectors that attract least investor interest include animal health, diagnostics, environmental, agricultural and industrial biotech (i.e. non human healthcare).

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<sup>7</sup> An independent venture capital group.

It is a matter of concern to the BIA that UK companies are not able to raise a 'war chest', which US companies are able to do. Research and development is capital-intensive – it takes \$600m - \$800m and 8 –12 years to bring a drug to market.

The fact that UK companies are kept on a tight rein in this respect by fund managers, who will not allow them to raise more than two years' worth of money, means that they are constantly involved in fundraising. This is a burden which CEOs in the US do not have to bear and it also means that US companies have significant funds available to make strategic decisions such as mergers and acquisitions. There are a number of structural reasons why this is not a problem in the US, i.e. pre-emption rights in general and the availability of Private Investment in Public Equity (PIPE) in the US – the latter is quicker than having to do a second or third round of funding, which UK companies are forced to do.

### **Cost of Regulatory Standards**

Government has also directly added to the problem through the unreimbursed cost of meeting the higher regulatory standards it imposes. Two examples demonstrate this:

- **Laboratory Safety**

The importance of improved safety standards in laboratories is undeniable – the health and safety of students and researchers is of paramount importance. However, the progressive upgrading by HSE of the minimum accepted standards of laboratory safety over recent years has imposed considerable extra costs on universities, which are not reimbursed by the Funding Councils.

- **Animal Testing**

The UK has the highest standards of animal welfare in animal research facilities, and the BIA fully supports this. However, the tightening of standards by the Home Office over recent years (requiring, in many cases, the hiring of additional technical support staff) has imposed significant costs on universities (usually at the forefront of medical research) with such facilities. These costs are not reimbursed by the Funding Councils.

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