# Reaping the Rewards of Agricultural Research



REPORT BY THE COMPTROLLER AND AUDITOR GENERAL HC 300 Session 2002-2003: 23 January 2003

# executive summary

- In 2001-02, government departments invested some £7 billion in scientific research and development. General responsibility for science policy rests with the Department of Trade and Industry but individual departments are responsible for commissioning programmes of research. The Government encourages research establishments and other public bodies, in co-operation with the private sector, to make commercial use of the outputs from publicly funded science. In 1999 the Government published the Baker Report on "Realising the Economic Potential of Public Sector Research Establishments" which made a number of recommendations on how this could be improved.
- 2 This report focuses on one sector of government sponsored research agriculture specifically how the Department for Environment, Food and Rural Affairs (previously the Ministry of Agriculture, Fisheries and Food)<sup>1</sup> is responding to the challenges of commercialisation. As part of this review we also examined the commercialisation of the nuclear transfer technology following the birth of Dolly the Sheep, the early research for which had been part funded by the Ministry and where the Department is a part owner of the nuclear transfer patents.



- 3 Annual expenditure by the Department on agriculture related research and development has been in the region of £100 million a year throughout the last ten years. In this work the primary focus has been to develop efficient markets in which agricultural industries can thrive; to protect public, animal and plant health; and to sustain rural and marine environments. Research funding normally ceases before the stage at which something to sell might emerge, the primary purpose of the research often being to inform policy making or to provide information for the public good with results widely disseminated, for example, to improve the health of farm animals or benefit the environment. In those circumstances, the Department regards the scope for commercial exploitation of research results as very limited.
- 4 Receipts from commercialisation of intellectual property have been generally small. In 2001-02 the five research contractors we reviewed had received in total some £450,000 from intellectual property arising from typical research work for the Department (the nuclear transfer technology "commercialisation" was exceptional), representing just some 2.4 per cent of their total commercial income. The Department received £15,000 in royalty income.

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Throughout this report we refer mostly to the Department rather than the Ministry, which ceased to exist in June 2001.

5 There are many other aspects of commercialising scientific research, such as winning contracts, collaborative research with the private sector, and consultancy work which have generated income. The resources for commercialisation activities and the commercial income derived from intellectual property - generally from licensing, royalties and 'spin out' companies - may be small but what has been achieved should be commended as a first step.

### Our key findings

### Commercialisation requires active support and management

- 6 The research contractors we visited were committed to increasing their royalty and other income from intellectual property, driven in part by the additional revenues this could generate to support their wider activities, the motivational impact for many scientists in seeing products developed from their work, and the greater understanding of customer needs which this can bring.
- 7 Nevertheless, contractors face significant challenges in commercialising their intellectual property, including:
  - a Identifying the best opportunities. This is not easy, and requires active management of intellectual property portfolios. Scientists may have the best understanding of the science involved and the collaboration required to take ideas forward. The experience and expertise of business staff can, however, be key to determining which ideas have commercial potential and should be pursued and which dropped, and to developing exploitation strategies and business plans. Attracting and retaining business staff of sufficient quality for these purposes may stretch resources in an area where income from commercialisation can not be guaranteed to meet the costs.
  - b Obtaining further funds to develop ideas. Research funding from the Department often ceases well before the stage at which something to sell has been developed. Significant sums are usually needed to demonstrate commercial feasibility, for example to produce prototype products or processes. The Central Science Laboratory, for example, estimates that the technology it develops can cost more than £500,000 to take an idea from proof of concept to prototype product stage. Other technology, for example developing prototypes of machinery, might require millions of pounds to develop to commercial feasibility.
  - c Winning over scientists to the concept of commercialisation. Many are supportive of commercialisation, recognising the satisfaction and benefits it can bring to them and their research organisation. Others, though, are motivated chiefly by scientific endeavour, their objective being to gain the recognition of their peers through publication of research papers,

perceived as a less risky approach than success through exploitation of intellectual property. They see the confidentiality needed to develop commercial projects as hampering collaboration with other researchers, and hence progress on the research topic, and also as a time consuming distraction from their pure science roots.

d Managing finance and resources to administer knowledge transfer activities, identify commercial opportunities and to file and protect intellectual property, for example, patents. Over its lifetime a patent can cost some £250,000 to file and maintain, more if action has to be taken to defend the patent against challenges and infringements. Expert legal aid and financial advice is often required to support negotiations with outside investors, as generally such skills are not readily available within the research contractor or the Department.

executive summary

- e Gaining the Department's support where relevant. Some research contractors considered that the Department's approach could be too "hands on", resulting in delays, and putting business opportunities at risk. The Department, however, may be concerned about whether, for example, the research contractor has identified the key risks associated with the proposal, and managed them appropriately so as not to leave the Department with any potential costs of failure. There are other potential conflicts of interest which have to be managed, for example, commercial partners may want their work to be prioritised over core research funded by the Department, and incentive schemes to encourage scientists to look for exploitation opportunities can potentially be divisive.
- f Managing risks when making deals including finding a partner, selecting the right type of deal, obtaining sound independent advice and managing conflicts of interest. Licence deals have tended to be the preferred option, but the use of joint ventures and spin-out companies is growing. In seeking partners relatively little competition is applied. This may be due to the difficulty of finding interested and appropriate partners; to the costs of exploring partnership deals or to the reluctance of research contractors to widen their search beyond existing contacts with whom they know they "can do business". This could mean that better deals with other partners are not necessarily being identified but may reflect the limited number of commercial firms willing to invest in agricultural products.
- 8 Prior to 2000, the Department tended to adopt a cautious approach to commercialisation but has since taken steps to encourage exploitation in line with, and in part anticipating, the recommendations of the Baker Report. Research contractors are able to retain 90 per cent of net revenues from exploitation of research funded by the Department. The Department has given its executive agencies responsibility for managing intellectual property and is amending contract terms to vest ownership of intellectual property in contractors in line with the Baker Report recommendations. Even so the Department's agencies receive little financial support from the Department to manage their intellectual property.

### Agricultural research can lead to commercial opportunities

- 9 Some structural issues exist. Whilst public sector research establishments have the freedom to, for example, set up joint ventures and spin-out companies for exploitation purposes, not all sponsored non-departmental public bodies own their assets, and in those cases their borrowings count against the Departmental Expenditure Limit. As a result any proposals have to be evaluated against the Department's other spending priorities. Executive Agencies have been similarly constrained. However, the Department is now increasing the freedoms of such bodies and seeking to encourage the identification of commercial opportunity.
- 10 Despite the difficulties, contractors have successfully developed research into commercial opportunities. A stripper header patented by the Silsoe Research Institute in 1985 has generated more than £1.25 million of gross receipts. A project to develop a robotic mushroom harvester has, however, stalled due to the lack of a partner to meet the funding gap of some £250,000 to develop a pilot laboratory system into a commercial product (mushrooms are the United Kingdom's single most valuable horticultural crop, worth some £300 million a year).

- 11 Horticulture Research International negotiated successfully a licensing agreement with a Dutch company to produce, market and distribute commercial quantities of a hybrid leek seed (leads to greater uniformity and quality of product at harvest). And the Centre for Environment, Fisheries and Aquaculture Science has entered into a joint venture with a private sector company to capitalise on its "smart buoy" technology, originally developed to record a range of marine-related chemical and physical measurements over long periods at sea. Probably the highest profile commercialisation in recent years has been that of nuclear transfer technology, used to develop Dolly the Sheep, by the Roslin Institute.
- 12 Dolly, its licensing deals and nuclear transfer technology are not representative of the size or significance of discoveries generally made through government sponsored research. Between April 1998 and May 1999 the technology which had led to Dolly was commercialised in two deals.
  - The first deal was a partnership between the Roslin Institute and venture capitalists, 3i Group. This created a spin-out company, Roslin Bio-Med. The shares in Roslin Bio-Med were owned 42 per cent by the Roslin Institute, 42 per cent by 3i Group, and 16 per cent by the company's management team and two scientists at Roslin.
  - The second deal involved the sale of Roslin Bio-Med to the Geron Corporation (Geron), a biotechnology firm based in the United States.



## Private sector involvement in Dolly achieved a number of outcomes

13 Deals with the private sector were essential as the value of the technology was in its potential and not in the original purpose of the research (to explore the scope for identifying and disseminating genetic improvements in livestock of benefit to the agriculture industry). Developing the technology had cost some £3 million of which the Department funded about £2 million. The Roslin Institute funded the final steps which resulted in the major breakthrough leading to Dolly. The Biotechnology and Biological Sciences Research Council increased Roslin's core funds to strengthen the basic biology of nuclear transfer, and also invested about £1.5 million over three years to a national effort involving Roslin, four universities and the Babraham Institute to improve the efficiency of cloning mice as part of the Council's initiative in gene technologies underpinning healthcare. Nevertheless, Roslin felt it needed additional funds for developing the research further (bio-medical rather than agricultural applications were seen as having the most commercial opportunity). Competitors in the United Kingdom and abroad were developing similar technologies, and the risk for the Roslin Institute was that its intellectual property would become outdated and worthless and its ongoing research would become uncompetitive.

- 14 Roslin's deal with 3i Group to create Roslin Bio-Med provided the necessary investment to continue the research. The allocation of shares to two scientists (at a cost to them personally of £20,000 in total) and the management team (at a cost to them of £204,000 in total) was a requirement of 3i Group in order to ensure those individuals were involved and to improve the chance of success in the next development stage. The subsequent transaction with Geron (a US company with net assets of some \$64 million in 2000) arose because Roslin, Roslin Bio-Med and Geron recognised their respective research was complementary, and that an early partnership would increase the potential for commercial exploitation. Again, there was a risk that other companies or research teams in the United States or elsewhere on their own would develop the technology, leaving Roslin's work without any value.
- 15 The Roslin Institute's financial advisers for the transaction with 3i Group, KPMG, told the Institute that in the absence of competition, it was difficult to know whether the partnership offered the best value for money. Roslin chose 3i Group due to its history of investing in biotechnology companies and as a United Kingdom group with a strong focus in Scotland. In Roslin's view, the alternatives were unsatisfactory and could have lost valuable time when rivals were working on similar technologies. Our consultants, Morgan Harris Burrows, advise that the funding of research for three years, and the equity given to the Institute, was higher than usual for a deal involving such an early stage of research into unproven technology.
- 16 Roslin did not seek any independent valuation of Roslin Bio-Med at the time of the Geron transaction. Instead they accepted a valuation undertaken by Geron's financial advisors, J P Morgan (of approximately £29 million). 3i Group had also expressed an aim to obtain at least double their planned investment in Roslin Bio-Med, from £6 million to £12 million, or a 100 per cent return on their planned investment. As 3i Group owned 42 per cent of the shares in Roslin Bio-Med this would have implied a value on the company as a whole of £28.6 million. At the time of the deal, shares in Geron allocated to the vendors were worth some £16.8 million, and the Institute also received research funding of £12.5 million.
- 17 The value of the shares in Geron allocated to 3i Group at the time of the Geron transaction (4 May 1999) was some £2 million lower than their expressed aim. It represented a gain of just over half of their investment. The two scientists and the Roslin Bio-Med management team received shares worth £3.7 million at that date some 16 times their original investment of £224,000. The commitment of individuals was required by Geron, as it had been by 3i in the earlier deal. Roslin took Geron shares worth some £3.3 million at the time of the transaction and, spread over six years, £2.5 million of undirected research funding, and £10 million of research funding to be directed by Geron on nuclear transfer technology. In the event of successful exploitation of the technology, Roslin will be entitled to a share of royalty payments and joint ownership of intellectual property rights. The Department also received £120,000 of research. Therefore the public sector received some five times the value of a research investment of £3 million over a ten year period.
- **18** The transactions relating to nuclear transfer technology ensured its further development thus helping in the search for radical new treatments for disease, and hence of benefit to the public and the United Kingdom economy. The outcomes are set out in Figure A.



### A Outcomes from the deals to commercialise nuclear transfer technology

- The nuclear transfer patents (applied for and granted between 1995 and 2000) are co-owned by the Roslin Institute, the Biotechnology and Biological Sciences Research Council and the Department.
- In 1998, the Roslin Institute granted PPL Therapeutics, a British company based in Scotland, a licence to develop and commercialise nuclear transfer as a better way to create transgenic animals producing theraputic proteins in their milk. From 1998 the Roslin Institute received some £100,000 a year in licence fees from PPL Therapeutics.
- 3i Group, the venture capital company, planned to invest some £6 million into developing the Dolly technology at Roslin. Roslin Bio-Med - a spin-out company was set up by Roslin and 3i in 1998 to commercialise the technology and was granted a licence to exploit nuclear transfer patents.
- When Roslin Bio-Med was sold in 1999 to Geron, a United States company, the Roslin Institute received 400,000 Geron shares worth some £3.7 million. Some 60,000 shares were later sold by Roslin for over £1 million. Other United Kingdom based shareholders received Geron shares worth some £13.1 million.
- The Roslin Institute received £12.5 million in research funding from Geron over a six-year period from 1999-2005 of which £10 million was to be used on developing nuclear transfer technology. New intellectual property arising from the nuclear transfer programme is co-owned by Roslin and Geron and some royalties will accrue to Roslin if any products are developed.
- Geron was granted an exclusive research and licence agreement for six years to exploit the nuclear transfer technology for all human-based biomedical applications, excepting PPL Therapeutic's interests. Geron and Roslin would become joint owners of all intellectual property arising from future research (except that arising from a specialist pigs project, the rights to which belong to Geron).
- The Department for Environment, Food and Rural Affairs received £120,000 worth of research to be carried out at Roslin and a share of any royalties.
- Nuclear transfer research continued to be carried out by Roslin staff at the Roslin site in Scotland. Over the past two years the focus of research at Roslin directed by Geron has changed to stem cell technology.
- **19** To sum up, significant additional financing was needed to develop the nuclear transfer technology to any commercially usable level, and others around the world were working on similar projects. It is unlikely therefore that government funded research would have been an option for the longer term, apart from basic underpinning research funding. There were clear benefits for the United Kingdom from the deal done with Geron but the lack of really independent advice on the value or about the potential market at the time of the transaction with Geron means that we cannot say conclusively whether the best sale value was obtained. In crude terms the public sector received about 5 times the value of their investment in the initial research, 3i received a return of 1.7 times their investment, and the scientists and management 16 times their investment without them, and the scientists were clearly essential to the future as well.
- 20 The deals with the private sector avoided the risk that the technology would be overtaken before any benefit could accrue to the public sector. They ensured that research could continue in the United Kingdom. It is not possible at present to put a valuation on this aspect. The research and the successive deals were in many ways ground-breaking, requiring robust leadership and personal commitment. Each new venture required lessons to be learned and shared in the handling of commercialisation.

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- **21** Our principal recommendations are set out below. While our focus has been on the work of those public sector bodies carrying out research for the Department, the recommendations may also apply to others.
  - i To increase awareness of exploitation opportunities, and to reduce the risk of staff inadvertently compromising intellectual property, public sector research organisations should provide regular expert training on the stages and good practice involved in commercialisation.
  - ii Furthermore, the Department should facilitate the sharing of good practice between its research establishments on matters such as:
    - assessing ideas for exploitation potential;
    - how pre-seed financing may be obtained (particularly within the public sector, for example the University Challenge Fund, the Regional Development Agencies and other sources);
    - the nature of deals best suited to particular circumstances; and
    - identifying and working with partners.
  - iii Public sector research establishments should assess intellectual property systematically for commercialisation opportunities, documenting for future reference and transparency the key reasons for pursuing or dropping ideas.
  - iv Public sector research establishments should develop exploitation or business strategies, identifying key risks, and how these are to be managed.
  - v Sponsors should review progress by their research contractors in exploiting research funded by the public sector. Reports by contractors might outline exploitation strategies and demonstrate the extent to which intellectual property has been reviewed for commercialisation opportunities, been exploited commercially, or benefits derived in other ways, for example knowledge shared in the public interest. The Department will in future require its contractors, through revised standard contract terms to report on exploitation activities regularly. Where similar reports are produced for other public bodies, for instance Research Institutes, or where similar reviews are undertaken by Research Councils, every effort will be made to avoid duplication.

The following recommendations arise from the key findings from our review of the commercialisation of nuclear transfer technology but take account of subsequent changes as a result of the Baker Report, for example, that responsibility for and benefits from commercial exploitation should fall increasingly to the research provider. It can be difficult to demonstrate whether the maximum return has been achieved in the commercialisation of intellectual property. However, where public funds are involved, research providers and sponsors should explore how best to satisfy taxpayers that the best returns all round have been achieved.

vi When making commercial deals appropriate expert advice should be obtained. This can be expensive and the cost will need to be justified by the risks and benefits involved. Expert independent advice in the private sector in the relevant field and Partnerships UK, a joint private/public sector organisation, may provide a source of practical guidance and can provide more in-depth support. Specialist legal advice may also be required by research contractors to review compliance with legal requirements and detailed terms and conditions of agreements.

- vii Where a commercialisation opportunity carries significant risks, or deals are likely to be novel or the potential costs/income are large, research contractors should make sponsor bodies aware (even though no prior approval is required) at an early stage. If consultation with sponsors is appropriate (as applied at the time Dolly was commercialised), the nature and timing should be agreed at the start. This consultation can run in parallel with other expert advice to avoid delay.
- viii Detailed negotiations with potential commercial partners should be carried out by research contractors (as was the case with nuclear transfer technology), supported by experts as appropriate, rather than the sponsor, as they are better placed to understand the nature of the underlying science and who is key to a successful outcome (such as the scientists), and as they will be the ones working day to day with the commercial partners.
- ix Whilst recognising that the ability to work together and the need to protect new technologies are important in choosing a partner, potential partners should in principle be subject to competitive pressures to obtain the best deal for the taxpayer. However, in exceptional circumstances a single partner approach might be appropriate to avoid potential damage to the value of new technologies by revealing information to too many people in applying open competition. Where only one possible partner exists it is particularly important to obtain expert independent professional advice on the terms and conditions of the deal to ensure maximum value.
- x Commercialisation deals may require research contractors to consider trade-offs between cash and non-cash considerations such as guaranteed research funding, royalties, taking equity. To ensure any deal meets wider public sector interests as well as those of the individual research contractor, contractors should consider the options at an early stage and seek expert advice on the risks and benefits of each.
- xi When a spin-out company is being sold on, the public sector shareholder(s) should obtain an independent assessment of the spin-out company's value prior to entering negotiations and not rely on the valuation offered by their potential partners. Specific valuations of intellectual property may be difficult to assess but equally important are independent assessments about the market in which the spin-out operates, who the buyers might be and why, and how much they might be willing to pay for it.
- xii Where a public sector research organisation is offered non-cash (e.g. equity) consideration for a spin-out company, then the risks, alternative options and the implications of such offers and conditions attached to them should be evaluated in detail by expert advisers.
- xiii In setting up a spin-out company, representation of shareholder interests should take account of public sector involvement. In addition the management team of spin-out companies is crucial to their success. It is essential to choose a team with the requisite skills, experience and knowledge of the industry they are working in. Specialist recruitment agencies can help in this regard.
- xiv All research contractors should put in place procedures to cover the disclosure of interests by staff, and the monitoring and handling of conflicts of interest. Guidance on these matters has been issued by the Office of Science and Technology<sup>2</sup>. Where the Department has funded the originating research, it may need to be satisfied that its contractors apply appropriate procedures on potential conflicts of interest, without interfering with the freedom to exploit research in the public interest.