BBSRC Bioscience Exploitation Guide

bbsrc
biotechnology and biological sciences research council

"Making sense of business

Making business sense"

Introduction

Welcome to the BBSRC Bioscience Exploitation Guide. The aim of this Guide is to provide a readily accessible source of information and practical advice that a researcher might require when considering the commercialisation of his/her research. It is stressed, however, that scientists in universities and institutes should always discuss commercialisation or intellectual property IP issues at an early stage with their university/institute technology transfer office or equivalent.

The BBSRC Exploitation Guide Booklet

This Guide is aimed at BBSRC-funded scientists. We have produced this booklet as a general overview of the process of bioscience research commercialisation. The aim is to provide the researcher, who is perhaps new to commercialisation issues, with a sound background to the major considerations. It will hopefully be of interest to all researchers, those who are interested in taking an idea forward commercially and those who simply want to be more aware of what's involved. It is also hoped that this Guide may be useful to professional staff in university/institute technology transfer offices as a source of information and contacts relevant to the commercialisation of bioscience research. The emphasis in the booklet is on the issues that are most relevant in the initial phases of the commercialisation process.

This Guide aims to bring together all aspects of commercialisation. However, it is not intended to be prescriptive. Rather, we aim to explore all the avenues open to the entrepreneurial researcher as there is frequently more than one 'right answer' when it comes to deciding how to take ideas forward. Most importantly, although a Guide such as this serves a purpose, there is no substitute for talking to and working with experts in the field.

We have produced this Guide in response to the needs of our research community and as an aid to the effective commercialisation of publicly-funded research for the benefit of the UK economy and society. We hope you find it useful.

"What motivates me is to get a brand new idea off the ground and then show that not only can you reduce it to practice but that people will actually take it up and use it."

Chris Lowe, University of Cambridge, Founder of Smart Holograms

The BBSRC Exploitation Guide Booklet

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Introduction

The market potential for your business idea is the most important issue to address. If no-one wants your product/service you have no business. If they're not prepared to pay you an economic rate, you have no business. If others can satisfy your customers' needs as well as or better than you, you may have no business either.

It is thus critical to have a good understanding of the market for your product or service from the outset of the commercialisation process. The better your understanding of the market environment the more likely you are to succeed and the less likely you are to make costly mistakes. It's thus equally important once your business is underway to keep the market environment in which you operate under constant review.

Technology push or market pull?

A business idea may be spawned from research that was specifically developed in response to an identified market need. For example, cellular phones were a direct response to consumers' requirement for easy access to telephony services while on the move. This is known as a market pull for the technology. Alternatively, an innovation in more basic research may lead to a discovery that fulfils a previously unmet market need. 'Teflon' is an example of technology push.

This section is split into two parts. The first covers the pertinent questions you will need to ask in order to assess the market potential for your business idea. The second part covers how you can begin to address these questions.

"The market is one of the most difficult things to understand and of course it changes from day to day."

Jeff Errington, Oxford University, Founder of Prolysis

The key questions:

Evaluating your product/service

- Who is the customer for your product/service? You need to bear in mind that your immediate customer may not be the ultimate end-user of what you are providing. You therefore need to identify who those intermediate users are and understand their requirements as well as those of your end user.
- What is unique about your product/service?
- What benefits will this provide to your customer and other users (for example, product efficacy, efficiency, ease of use, durability, etc)?
- What makes it a better solution than competing products or services? Are customers prepared to pay for those benefits and, if so, how much?

Evaluating the competition

- Who are the *current* competition?
- What are their strengths and weaknesses?
- What have they done, or are they likely to do, to defend their market position? Don't expect competitors to sit back and watch as new solutions are developed that cut into their market share!
- Who are the *potential* competition?
- Who else might have the know-how, expertise and resources to develop competing solutions?
- What differentiates you from the competition and what is your competitive advantage?
- How strong is your IP position relative to the competition?

Evaluating the market

- What is the size of the market?
- Is it growing/ stable/ declining?
- What are the key drivers in the market?
- What are the key external influences on the market, for example legislation, regulation?
- What are the key market segments? All markets can be divided into sub-groups ('segments') made up of particular groups of potential customers with similar requirements.
- Which of them are you best able to reach and serve?
- What will each market segment be willing to pay for your product/service?
- What share of your target market can you achieve, and how long will it take to achieve it?
- How does your business idea fit into the supply chain? Businesses do not operate in a vacuum. Define what your business is going to do and then identify how it will integrate with other elements in the supply chain.

In short, you must identify a unique position in the market which you can establish and defend.

Finding the answers to the questions!

DIY (little or no cost)

It is possible to get a lot of information without any financial cost. You can get valuable information from the internet, patent information, company prospectuses, annual reports, financial media and journals, investment reports and 'perhaps most importantly' networking.

Also, don't underestimate what you already know about the market place! Often a brainstorming session will reveal just how much information you and your colleagues already have from talking to industry, following the literature, attending conferences etc.

Internet

The World Wide Web can be an excellent source of market information. Most companies have a presence on the web, with information on their products. Biotechnology industry portals and networks (e.g. www.biospace.com, www.canbiotech.com, www.i-bio.gov.uk) can be ideal starting points. Trade Association sites, such as those of the UK Biotechnology Industry Association or its US counterpart, BIO, can be useful. Also check relevant online biotechnology publications for business news. Remember though that your competition may exist outside the biotech sector, so don't limit your reading just to biotech publications.

Be aware too that some information on the internet needs to be treated with caution. This is particularly so with market size estimates. The rigour underlying many such estimates does not withstand close scrutiny, so check it carefully, particularly if you are including it in your business plan.

Patent Information

(For more details, see section on Intellectual Property) Patent information can tell you a lot about competitor activity. Patent filings tell you not just what the invention is but who filed it and where. Some patent databases are free to access (e.g. www.espacenet.com), so it is worth starting with these. Bear in mind though that there are limits to what this information can tell you. For example, patent applications are not published until 18 months after filing so applications made within the last 18 months will not be shown on databases.

Prospectuses

When companies seek a flotation or subsequent fundraising on a stock exchange they produce a prospectus aimed at target investors. It gives detailed information of the conditions and future prospects in their target market. Prospectuses are worth obtaining for relevant companies which operate in the same or similar markets to yours.

Annual reports

Your competitors may include publicly-quoted companies. They will produce an annual report that you can obtain free of charge either from their website or through the Financial Times. The larger companies often show geographical coverage of their activities, profits by market areas and R&D spend, although you probably won't be able to pin this spending to specific products. Many reports include a management commentary on the key trends, outlook and growth prospects in their markets.

The annual reports and accounts of publicly-quoted US companies are extremely detailed – far more so than those of UK companies – and are thus a potentially rich source of information, so a check of the free EDGAR database of US company filings (www.sec.gov/edgar.shtml) may be very worthwhile. Sadly, the reports and accounts of small companies rarely provide much, if any, of this kind of information, although information on their financial performance may clearly be informative and valuable to you. UK company reports can be obtained from www.companieshouse.gov.uk and from commercial databases such as FAME.

Financial media and journals

Newspapers, such as the Financial Times, and more specialist industry/business publications carry a lot of useful market information. Apart from trawling through trade journals in business libraries, the other route is through various online suppliers such as OVID(tm) that provide access to ABI/INFORM®, which is a comprehensive database of business and trade literature. Alternatively, a good business library may carry ABI/INFORM®

Brokers reports

Investment reports produced by City analysts on specific companies are also good sources on market trends and market outlooks. These reports are produced by analysts for their investor clients. Some reports can, however, be obtained from online subscription databases.

Networking

Discussed in the section on Help and Support Networks, this can be an invaluable way of finding out market information. Networking events and conferences are ideal opportunities to make contacts with potential buyers, suppliers, competitors, collaborators and advisers. Networking can give you a wealth of qualitative information and insights to all aspects of the market. Most Regional Development Agencies (RDAs) hold biotech-focused networking events which are either free or modestly-priced and designed to stimulate their region's commercial bioscience activity.

DIY (with some financial cost)

You will be able to gather a lot of valuable information from the free sources described above. However, you will find that you need further or more detailed information from sources that are not available for free. This information may include patent information searches from companies such as Delphion or market reports that cover specific market sectors.

Introduction

This section of the Guide is not a comprehensive review of Intellectual Property (IP). Rather it builds upon the IP booklet produced by BBSRC and distributed to all BBSRC grant holders. More detailed information on biotechnology patents can be found on the UK Patent Office website: www.patent.gov.uk

This Guide aims to provide you with a clear and concise outline of IP issues that are particularly relevant to bioscientists, concentrating on the practical aspects of how to protect IP and the value in doing so.

The key message is that appropriate protection of IP is fundamental to the successful commercialisation of technology. Unless you properly safeguard your IP you're unlikely to be able to exploit your technology. Make sure, therefore, that you are aware of your funding body and university/institute's policy on IP and the safeguards that should be put in place to ensure that an invention can be protected. In particular, ***make sure that you understand what constitutes disclosure of IP in to the public domain, and how to avoid it, as patent protection is not available once an invention has been publicly disclosed.***

IP takes a variety of forms, but we will focus on patents, the form of IP protection that is probably the most relevant to the bioscientist.

"If it's your invention, your science, it's your responsibility and if you want to make any money out of it, you need to make sure it's protected."

Alan Kingsman, Oxford Biomedica

Why patent?

This is probably the most important question to address because it is a challenging and potentially expensive process to go through. Moreover, the traditional measure of academic success - the publication of results - constitutes public disclosure and prevents the grant of a patent for that invention if it occurs before a patent application has been filed. There is, therefore, an inherent tension between the academic desire to publish and the commercial imperative to protect novel IP. So why bother patenting? Well, let's take a look from a number of different perspectives:

From the academic perspective

Patenting your invention can be an extremely rewarding experience, financially, personally and intellectually. Without a secure patent position, it is unlikely that your research can be commercialised. Why? Because licensees and investors are very unlikely to fund the development of technology that has not been protected by a patent. At the same time, patents are, in effect, publications and carry their own level of kudos and recognition from universities and funding bodies.

From the university perspective

There is increasing pressure on universities and research institutes to show a commercial output from their research activities. There is more emphasis on this activity than ever before and universities are naturally keen to see a financial return on the investment put in. Your university, research institute or funding body will be interested in patentable research and may be able to provide funds to take the process forward. It is worth bearing in mind, however, that most institutions have very limited budgets for filing and maintaining patents. You will therefore need to provide a compelling case as to why your institution should finance the patenting of your invention rather than those of your colleagues. Alternative means of funding patenting costs may have to be sought (see section on Funding and Investment)

BBSRC Policy on Intellectual Property

BBSRC delegates the responsibility for, and ownership of, IP to the host institution where the work is carried out. BBSRC advise that a flexible approach is adopted in subsequent commercialisation with ownership being best determined by individual circumstances.

In virtually all UK universities and research institutes the IP you create in the course of your work belongs to your institution, rather than you. It's thus essential that you contact your technology transfer office at an early stage to discuss the commercialisation of your research outputs.

The patent process

Patent filing

The first step on the road to obtaining a patent is the initial application. You will need to work with a patent attorney (usually through your technology transfer office) to put the application together.

What will you need to put an application together?

You will need to provide your technology transfer office/patent attorney with sufficient information to complete the following elements of the patent application:

Title: a short, clear description of the invention (note that the title may deliberately conceal the details of the patent to make it more difficult for competitors to identify patents in a particular area).

Background: This describes the 'prior art', all published work that forms the background research to your invention. Add references where possible and don't try and conceal any published work that is close to your invention.

Summary of invention: Here is where you can explain what makes your invention patentable. Briefly describe the invention itself and, by comparison with the prior art, (see above) show its novelty. Show the 'inventive step', the features that distinguish the invention from the 'logical step' from the prior art. Finally, list as many of the applications of the invention as you can, with descriptions of further work that should be done to allow for the various applications.

Specific description of the invention: Here, you can describe the invention in full and include research results.

Further work: Detail any further work that you intend to do, or would need to be done, to realise the applications of the technology.

Contributors: List all those involved in the invention and describe the nature of their involvement.

Application procedure

The first application establishes the 'priority date', the date that confirms in law when the patentable rights were created. The minimum that is required by the UK Patent Office at this initial application is a request to file a patent form 1/77, and a description of the invention. You then have twelve months to file the claims (the part of the patent application which describes the protected parts of the technology) and the abstract to your patent. During this time, further developmental work and market research may be carried out to see if the invention is indeed worth patenting. If it is decided before the end of the twelve-month period that the application is not worth pursing, the application may be abandoned without incurring any penalties.

Remember that once the patent application has been filed, the clock starts ticking! It is vital to seek professional advice on this issue so that you file at the right time; not too early so that there is insufficient time for reduction to practice and not too late that someone has got there before you.

If the decision is to go ahead, then a second application can be made, claiming the priority date of the first application. In this way, additional information that may have been generated in the year may be added to the specification and this second application becomes the substantive application (additional information cannot be added to the description in the first application).

A search request is also submitted at this time and within about twelve weeks the Patent Office will issue a preliminary examination and search report.

"Even if you've got a confidentiality agreement be cautious of what you say. It's not an obligation to disclose!"

Jan Chojecki, Plant Bioscience Limited

At eighteen months, your application will be published and within six months of this date, you must request an examination report, a more technical examination of the application. There will then be a period of working through the examination of the patent with your patent attorney and the Patent Office, until the examiner is completely satisfied with the application and the patent is granted. For UK patents this can be within four years of your initial filing date.

Patent filing in the UK only gives you patent protection in the UK, so you will need to file your patent in other countries if you wish to extend the geographic coverage of patent protection. This process has been made easier via the Patent Co-operation Treaty (PCT) which offers protection in member countries. Filing outside the UK takes place up to 12 months after the initial filing in the UK.

The United States

The patent situation in the US needs to be borne in mind, given the importance of this market. The patent system is very different in that, unlike Europe, in the US patents are granted to the first to invent, not the first to file. Thus if there is a dispute with an identical invention in the US, to decide who gets the patent, the Patent Office will need to establish who was the first to invent. What this means in practice is that in the event of a patent dispute, you will need to provide evidence of when the invention was made. Therefore, laboratory notebooks, all data and other evidence that describes the invention must be able to confirm when the invention was made. This evidence has to be able to stand up in a court of law. Laboratory note books should thus be signed, dated and counter-signed and all extra data that is included should be permanently attached to the book, signed and dated. Ink should always be used and mistakes crossed through, not erased by Tippex or other means (for further details on this, see www.innovationlogbook.gov.uk). Some of these measures may appear to be a little impractical, but given the size of the US market and the commercial potential for a US patent, can you afford not to follow them?

Costs

The minimum costs are the fees payable to the UK Patent Office (for UK patents). However, you will need to use the services of a patent attorney during the patenting process. Drafting a patent specification is a skilled operation and the wording of the patent is crucial in defining the scope of protection. As a ball-park figure, initial filing can cost between £2-5k, the second application (PCT) can cost between £5-6k. Negotiations with the Patent Office over claims can cost anything between £10-20k, and costs increase considerably depending on the range of countries in which the patent is to be filed. This covers negotiations with local Patent Offices, local patent agents and translation fees.

Other forms of Intellectual Property

Copyright, Design Rights, Trademarks are other forms of intellectual property that can be registered and protected. 'Know-how' is a valuable form of IP in its own right. However it cannot be registered and protected in the same way. It is therefore essential that 'know-how' is not disclosed to third parties except on an absolute need-to-know basis. This protection depends in a large part on maintaining good staff relations, backed formally through employment contracts and Non-Disclosure Agreements (NDAs).

Introduction

There are various options open to the bioscience researcher for taking a business idea forward.

This section will cover each exploitation strategy in turn, discussing what is involved and some of the key considerations that should be taken into account.

The following factors will need to be considered in all cases:

- The potential of the technology and its stage of development
- Financial situation (your own and that of your laboratory/university/institute)
- The amount of time, effort, money and the skills required to turn your technology in to a marketable product/service
- Your personal circumstances and preferences, including your attitude to risk, your ambitions and those of your family

"It is about finding that one person or group of people/organisation that gets as excited by your technology as you do. It's not about forcing your technology on someone, it's about them wanting it and adding value to it."

Douglas Robertson, University of Newcastle

Collaborative research

There are many Research Council and other schemes to encourage and facilitate collaborative research between academia and industry. This may be by sponsoring the transfer of personnel between academia and industry through schemes such as BBSRC's *Industry Interchange Programme* or the Royal Society's *Industry Fellowships* scheme, or alternatively supporting collaborative research projects with industry through *Industrial Partnership Awards* or the *LINK* scheme (see the BBSRC Innovation Portfolio or website for a full description of schemes sponsored by BBSRC). Working closely with one or more industrial partners offers a potential route for the commercialisation of any research outputs as there will often be the interest, financial resource and capacity from the industrial collaborators to fully exploit any new technology. Issues involving the ownership of IP should be agreed before the project gets underway (indeed this may be stipulated by the funding body). Model contracts - launched by the Department of Trade and Industry in 2004 to facilitate research partnerships between academia and industry and covering a range of IP ownership scenarios, exploitation of results and licensing rights issues - can be found at www.innovation.gov.uk/lambertagreements.

This route provides a low risk option for the academic partners to see the exploitation of research outputs. There is no financial risk as this is borne by the industrial partners. Given this, there is little financial return for the academic partners, though if the IP is retained by the academic institution, there may be future licensing opportunities. This route usually requires the ongoing involvement of the academic in further developing the technology. Remember that collaboration is very much a two way process and depends heavily on developing constructive relationships between all the parties concerned.

Key considerations:

- No financial risk to academic partner
- Requires involvement of academic researcher
- Little or no financial return to the academic
- Little or no influence over the ultimate commercialisation of the technology as control will rest with the industrial partner

In short, collaborative research is the lowest risk option financially, professionally and otherwise for the academic researcher. Equally, it offers the lowest personal financial reward for the academic, although, of course, the rewards to his/her lab and department can be significant.

"If you just want money out of a company the collaboration will never work."

Chris Lowe, University of Cambridge,
Founder of Smart Holograms

Strategic alliance

Although similar in some ways to a collaborative research agreement, a strategic alliance tends to be more far-reaching, involve a deeper commitment between the parties and will often operate over a longer timeframe. It will usually involve the commitment of resources, financial or otherwise, to the alliance by both parties. As with collaborative research, the terms of the alliance, such as ownership of the IP and split of revenues on commercial outputs, should all be negotiated and finalised before work begins. Funding schemes such as Knowledge Transfer Partnerships (www.ktponline.org) may be useful in this situation.

Key considerations:

- Little/no financial risk to academic partner
- Will require ongoing, probably significant, involvement by the academic researcher in developing the technology
- Financial return to academic partner varies depending on relative level of inputs and risk assumed by the parties
- Financial reward negotiated by the academic researcher likely to be based on his/her institution's rewards to inventors scheme
- Limited control over the commercialisation of the technology

Outright sale of technology

This may be the most appropriate option in some cases. For example, where the academic has no continuing interest in developing the technology, or where the institution has neither the resources nor the inclination to fund or maintain patent protection, or where the prospect of an immediate cash receipt is more attractive than a longer-term, albeit higher, return.

Key considerations:

- Simple, straightforward
- Relieves academic researcher of any ongoing involvement with the technology
- Care needs to be taken, however, not to constrain his/her freedom to undertake further research in that area
- No control or influence over commercial exploitation of the technology

Licensing

A licence grants a third party the right to utilise your IP for a defined purpose. Licensing will generally provide some financial return to you as the inventor whilst leaving you free to continue your academic career. Multiple licences allow the exploitation rights for your technology to be divided into parcels and licensed to different parties, depending on their areas of expertise, level of interest and resources, thus maximising the upside for you and your institution. This tends to be the exception rather than the rule however, as the challenge is often to find a licensee at all rather than choose between potential licensees. Care needs to be exercised in selecting the licensee as commercialisation of your technology will only occur if the licensee actually exploits it. Assessing the licensee's commitment is thus a critical part of the due diligence and negotiating process. The terms of the agreement should protect against a company simply sitting on your technology, usually by revoking the licence and allowing your institution to grant a new licence(s) to someone else.

Key considerations:

- Allows the academic researcher to pursue his/her academic career and receive a financial reward for the commercialisation of his/her outputs
- Can be a useful mechanism for 'dipping your toe in the waters' of commercialisation in a low risk fashion

Types of licence

There are different types of licences: exclusive, non-exclusive and sole.

An *exclusive licence* gives the licensee exclusive rights to the technology (including exclusion of the licensor from exploiting the technology).

A *non-exclusive licence* enables the licensor to license the technology to more than one party.

A *sole licence* permits only one licensee to exploit the technology, but retains the right for the licensor to use the technology as well.

The terms of a licence, as with any commercial deal, are infinitely variable, so it's vital to seek professional help. Key points to consider :

- Who exactly is the licensor? An important consideration in the case of a large industrial group with many operating subsidiaries.
- The timescale of the licence - when does it start, when does it finish, under what circumstances may the parties terminate the licence?
- What exactly is being licensed?
- What can be done with the technology - what restrictions should be placed on its use by the licensee?
- In what areas can the licensee use the technology - what geographic, application area, market sector or other constraints on its use are required?
- What terms regarding costs and payments are needed - who is responsible for what costs associated with the technology (for example, maintaining patent costs or pursuing patent infringements by third parties); what payments will be made when, and on what basis will they be calculated?

The terms of the deal are thus crucial. Your technology transfer office and its advisers will have experience of negotiating such deals and be able to advise on the most appropriate terms.

Spin-out company

Your technology may have sufficient potential to be the basis upon which a new company can be set up. Alternatively you may be able to combine your technology with complementary IP to create a greater critical mass of IP to support a new company.

The latter option is increasingly popular, and is often driven by the demands of investors who rightly want to back companies that have the greatest possible strength, and hence likelihood of success. Setting up a new venture is a far from trivial task: it is stressful, time consuming and risky. However, it can be exhilarating, challenging and financially very rewarding.

The process will be daunting and you will need to take professional advice in many areas.
How much personal involvement you have with running the company will be a joint decision between you, your institution and the investors. It's important to understand that no-one will expect the academic researcher to be a commercial wizard. In fact, most investors will actively discourage the academic founder from assuming the CEO mantle, preferring instead that he/she adds value to the company by continuing to develop the science that underpins the business. The most probable outcome, therefore, is that you will remain free to continue your academic career while participating in the development and success of the business.

Key considerations:

- Initially requires a high level of personal involvement from the academic founder, though the subsequent level of involvement can usually be reduced
- The most risky and complex option, but can be the most financially rewarding, and intellectually every bit as stimulating as your academic work
- Requires significantly more investment than other exploitation routes
- Depending on role chosen in the company the academic has more control over the exploitation of the technology than via other exploitation routes
- It can be a challenge managing the demands made on your time by your academic responsibilities on the one hand, and your duties to the company on the other
- It is essential that your close family are aware of what is involved and support you because they will share in the ups and downs too
- May give the academic more control over the exploitation of the technology than other exploitation routes, although ultimately it will be the investors who call the shots

"I would say that I have enjoyed it enormously because it's been a very different experience."

Janet Thornton, European Bioinformatics Institute, Founder of Inpharmatica

What are the legal aspects?

Most spin-outs are formed as a limited liability company. The company is a legal entity and thus able to hold assets, assume liabilities and enter into contracts in its own right. It is managed by its Board of Directors but owned by its shareholders. How the company's business is to be conducted is governed by its Memorandum and Articles of Association which are, in effect, its constitution. A company is required to be legally incorporated. This is done through registration under the Companies Act, a process which will be handled for you by a solicitor or company registration agent.

The business plan

Creating a company is the easy bit. Turning it in to a viable business is the tricky part! A venture such as this requires very careful planning. You should go through this process with an experienced technology transfer team. You will need to work closely with your university or institute's own team, who may suggest calling on the services of external consultants and/or business support companies.

All aspects of the business need to be very carefully thought through, objectives set, weaknesses acknowledged and addressed, and strategies formulated. These issues, and more besides, need to be set down in a written business plan.

Every new business needs a business plan, and for your spin-out company it will serve two very important purposes. First, it crystallises your business idea, enabling you to state clearly and succinctly what the business is seeking to achieve and how it will get there. It should set objectives and targets and will become the benchmark by which your performance is judged. Secondly, if you are seeking external investment, it must honestly convey the essential elements of the business and explain how it is going to make a good return for the investors. Your business plan is the primary sales tool in securing investment, so it's vitally important that it presents a realistic, coherent and compelling case.

Contents of a business plan

A business plan is divided in to sections, usually appearing in the following order:

- Executive summary
- Description of the product or service
- The market for the product/service and analysis of competitors
- The management team
- The business strategy
- Resources required
- Financial projections

"Having a team that you trust and where you are honest and frank with each other is absolutely essential."

Alan Kingsman, Oxford Biomedica

The executive summary always appears at the beginning. Unless it sets out a convincing case investors are unlikely to read any further.

If your business idea is in its formative stages you may want to consider entering the *Research Councils Business Plan Competition*. In addition to the opportunity to win £25k to advance your business, it provides a unique opportunity to hone your commercial knowledge and skills through training and mentoring provided by a network of contacts experienced in all aspects of bioscience commercialisation.

A BBSRC *Enterprise Fellowship* may also be of interest. The scheme provides business training and mentoring to help develop your business plan and a year's salary to allow you to concentrate on developing the commercial potential of your research, hosted at your university or research institute. Fellowships can thus be a very useful means of providing you with the time and money to shape and progress a spin-out company based on your research.

Introduction

The commercialisation of new technology is likely to require significant financial investment. How much you, as the inventor, will be required to raise yourself will depend on the exploitation route you choose. The different exploitation routes carry different levels of financial risk; from an industrial partner in a research collaboration bearing the full cost of commercialisation through to the inventor and management team 'going it alone' with a new start-up company and raising finance from equity investors.

This section of the Guide focuses on the various commercialisation routes and the funding sources that are likely to be most appropriate.

Financing collaborative research projects and strategic alliances

With these types of arrangement there is little or no financial risk to the academic partner. Financial resources are usually provided by the industrial partner. The key challenge is to find a partner who is committed to the technology, able to maximise its potential and with whom you can forge a close working relationship.

Financing a licensing deal

As with other exploitation routes, your first step will be to assess the market for your licensing opportunity, so you may need to commission a market study (see Evaluating Market Potential). This is likely to focus on two key topics. First, identifying the nature and scale of the market opportunity. Secondly, identifying potential licensees. Although potential licensees will have their own views on the commercial potential of your technology you need to have an informed view in order to be able to strike an appropriate deal. The greater the market opportunity of your technology, the greater its value and the better the deal you will be able to strike. Good market research is therefore vital, and various sources of funding are available for this purpose. For example, several of the RDAs set aside monies to support market assessment and feasibility studies.

If a licensing partner is found after your patent application has been filed the licensee may be prepared to bear the ongoing costs of obtaining and maintaining the patent, which can be very significant. In return, though, the licensee will expect to pay lower up-front and ongoing payments than would otherwise be the case, so there's a careful balance to be struck.

Plant Bioscience Limited (www.pbltechnology.com) has a remit to assist in the commercialisation of plant and microbial sciences technologies developed by BBSRC institutes. Much, but not all, of its work is focussed on licensing activity. It has access to funds to assist in the further development and marketing of plant and microbial technologies with either licensing or spin-out potential.

The Research Councils' *Follow-on Fund* is similar in that it aims to support the further scientific or technical development of recent RC-funded research activities to the stage where commercial opportunities such as licensing, seed or venture finance can be obtained. The Fund typically makes grants of up to £100k.

Financing a spin-out company

A spin-out company may require substantial investment. It may be possible to raise much of the initial funding for patenting costs and market evaluation from your university/institute or from your own sources. After this though, you will probably need to raise substantial amounts of investment to start and run a successful company.

There are two key types of funding for a spin-out company: grants and equity. As will be seen, debt finance is less likely to be an option.

Grants

The advantage of grants is that you don't have to repay them and you don't have to give up shares in your young company. The RDAs administer two grant schemes in England (Scotland, Wales and N Ireland have similar schemes):

Grant for Investigating an Innovative Idea help finance a feasibility study and action plan for businesses who have an idea to develop an innovative product, process or service, but are not sure whether they are ready to take it forward successfully.

Grant for Research and Development helps individuals and small and medium-sized businesses research and develop technologically-innovative products and processes. Awards can be anything from up to £20k for low cost development projects, through to £500k for strategically important development projects.

Such awards add credibility to your business and, more importantly, should add value to your company. However, they are unlikely to be sufficient for your company to gain real momentum, particularly if it is focused on the healthcare sector.

Equity

For more substantial amounts of money, you will need to tap into equity finance - that is money given in return for shares in your company. Different sources of equity are available at different stages in a company's development.

Early-stage funding

The main early stage sources of equity, other than family and friends, are Business Angels and specialist seed-corn funds. Seed-stage investments tend to be between £50k and £250k, sometimes more.

Business Angel funding

Business Angels are usually successful business people in their own right with funds to invest in new businesses that offer the potential of a high and tax-efficient return on their investment. They operate individually or as part of an investor collective. Many Angels prefer to invest in their sector, and thus bring significant industry knowledge to their investments. They usually require a sizable equity stake to reflect the high risk nature of their early-stage investment and often take quite an active role in the company. Their business skills, industry knowledge and contacts can be invaluable in helping you get your business on the right track and, importantly, making it attractive to subsequent investors.

Seed-corn funds

A number of technology transfer groups and many universities and institutions now have access to their own professionally managed seed funds, many of which were established through the OST University Challenge Initiative. The Rainbow Seed Fund was formed to support the formation of businesses based on research developed by the research establishments of a number of public sector bodies, including the BBSRC (see www.rainbowseedfund.com).

Later-stage funding

Seed funding will get your business going. To make it really fly you will probably need significant additional funding. This is particularly so if you are developing a healthcare-focused product or service that requires extensive development and trials.

The three main later-stage sources of equity are Venture Capital, strategic partner and public equity.

Venture Capital

The main practical difference between Venture Capital and seed funding is the amount of money involved. While Business Angels and seed-corn funds invest in the tens or low hundreds of thousands, Venture Capitalists (VCs) tend to invest from £2million to £20million and more.

They raise their money from, and invest it on behalf of, pension funds and institutions. Their primary objective is to make as much money as they can for their investors, so they tend only to be interested in opportunities serving very significant markets and where the technology offers a distinct and compelling advantage over existing offerings. Typically, they will be seeking a 5- to 20-fold return on their investment over a five-year period, so you clearly need a compelling case to attract their interest. VCs make a return on their investment by selling their shares on to third parties, usually via either a trade sale of your business to another company or an initial public offering (see public equity).

VCs can bring invaluable experience to the business, including helping identify the right management team to drive your company forward. The extent to which VCs get involved in managing the business varies from fund to fund, but the vast majority will want to appoint a non-executive director to the board to represent their interests.

Some RDAs have established *Regional Venture Capital Funds* whose remit is to invest in promising businesses within their region. These funds tend to be smaller than mainstream venture funds. They may be able to provide sums that sit between the upper and lower investment limits of the seed-corn and mainstream venture funds respectively.

Strategic partners

Collaboration agreements with other companies are vital in enabling many biotech businesses to access the skills and resources needed to successfully develop and bring a technology to market. One of the resources that strategic partners sometimes provide is finance - by purchasing shares in the business. This is most likely to happen when there is a powerful strategic reason for the partner to invest, for example where your technology is so essential to its business that the partner may in due course want to acquire the business in its entirety.

Public equity

Public equity is raised by offering shares in the company for sale on a stock exchange such as the Alternative Investment Market (AIM) in London, often referred to as Initial Public Offering (IPO). It is an expensive and complex process that is unlikely to be appropriate, in most cases, until the business is at least three or four years old.

And finally, there is.....

Debt finance

Debt or loan finance is unlikely to be a viable source of finance until the company has assets which can be offered as security against the loan. Most early-stage biotech spin-outs tend to have little in the way of physical assets to offer as security. Few lenders will even consider intangible assets, such as patents, as collateral until you can at least demonstrate their value via the generation of sustainable revenues. Thankfully, fewer lenders now expect entrepreneurs to offer their home as security and you should avoid doing so, for obvious reasons. One scheme that may be worth exploring is the Small Firms Loan Guarantee Scheme. The scheme provides a Government-backed guarantee for 75% of the outstanding value of loans of up to £250k provided by certain commercial lenders to small and medium-size firms. Some businesses involved in agriculture, horticulture and forestry are, however, ineligible.

Introduction

This section aims to identify some of the key sources of information and outlines how to use them effectively.

Help and advice and sources of information are available at all stages of the commercialisation process; from using publications to gain a general awareness of how the biotechnology and other industries operate, to using professional services for specific tasks.

Your technology transfer/ business development office

Your technology transfer office (TTO) should be your first port of call whenever you are considering commercialisation. As noted earlier, the technology you have developed will usually belong to your institution, so its technology transfer managers will be closely involved in decisions regarding how it can best be exploited. They will be able to advise on commercialisation issues, put you in touch with advisers such as patent attorneys and solicitors, guide you through the process and play a central role in deciding the best way forward.

In particular, it is essential that you consult your TTO before engaging in any form of commercial discussion with third parties. They can help you ensure that

information isn't inadvertently disclosed that prevents the subsequent patenting of your invention and provide appropriate forms of confidentiality agreement to protect your interests.

Most institutions have an intellectual property budget which you may be able to tap into. Some also have additional funds to support early-stage commercialisation activities (for further information on this, see Funding and Investment).

Resources do, however, vary from institution to institution. Most TTOs are over-worked so you may, with their encouragement, need to rely more upon some of the other sources of support described below. Bear in mind that you will be competing with other academic colleagues for a share of your TTO's time and resources. The advice below about meeting preparation applies just as much to your interactions with your technology transfer personnel as to any other meeting.

Other technology transfer organisations

There are many commercial technology transfer companies who can provide your support, and your TTO may well recommend suitable firms to you. The technology transfer arms of funding organisations such as Cancer Research UK and the Wellcome Trust are also a potentially important source of advice and help for their grantholders.

Networking

There is no substitute for effective networking. It is the best way of making useful contacts, surfacing opportunities, and finding out market sentiment and what is happening at the coal-face of commerce in general. The 'clustering' of biotechnology-related industries in certain areas (such as Oxford, Cambridge and the North-West) has spawned regional networks and associations. They bring together scientists, entrepreneurs, business managers, property developers, financial investors, IP specialists and other interested stakeholders via regular networking events.

Your institution's business development unit may also organise networking events as part of the process of marketing the institution's services to local industry and encouraging academic-industrial liaison. So tap in to their knowledge of the marketplace and network of contacts too.

Keeping abreast of biotechnology news

It is important to gain and maintain an awareness of the commercial, as well as the scientific, developments in your field of research. Publications such as *Pharmaceutical Business News*, *SCRIP* and *Biocentury* are a rich source of information on the commercial and business side of the biotechnology industry, while some journals and research publications (such as *Nature Biotechnology*) regularly carry articles relating to commercial developments.

Professional services

There are many specialist professional service providers, such as accountants, lawyers and patent agents, active in the biosciences. Your TTO should be able to recommend suitable firms. If not, consult your regional networking association who will be able to identify suitably qualified firms. Ensure that you consult experienced advisers; bioscience commercialisation is a highly specialist field, and not one in which the average High Street firms is qualified to advise.

A note on preparing for meetings

It is important to ensure that you extract the maximum benefit from meetings with any of the advisers described above. Regardless of who you are meeting, following the simple steps below will help you – and them – get the most from your time with them.

Ask yourself the following questions:

- What am I trying to find out?
- What information do I need to provide in advance of the meeting?
- What information can I get from this meeting?
- What questions do I need to ask?

In advance of a formal meeting send your contact a brief description of your idea, with an introduction to yourself (and colleagues), your objectives for the meeting and an indication of the type of information and help your require. Make sure that you are well-prepared – do some background research on the contact and think carefully about what information you need to provide in order for him/her to be able to advise you.

Biotechnology incubators

The formation of Biotechnology 'clusters' has seen the development of biotechnology incubators. There are now many such operations around the country. Their managers know what it takes to make it happen commercially, have excellent networks of contacts and will be happy to speak to aspiring tenants. They are thus well worth investigating if your chosen business strategy is to form a spin-out company.

Incubators provide office and laboratory space within a specialised environment with the flexible rental agreements that a young spin-out company requires. There is usually access to shared facilities. Such premises allow for a supportive environment to a young company (a 'can-do mentality'), and exposure to other entrepreneurial scientists with excellent networking opportunities.

Finding out more about commercialisation issues

There are many workshops/seminars on commercialisation issues that you might attend. For example, BBSRC supports universities to hold *IP Workshops*, many of which cover other topics on commercialisation in addition to IP information. Many technology transfer and industrial liaison departments in universities run similar events to raise awareness of commercialisation. They often involve external speakers from industry and professional organisations such as patent attorneys, a useful way to make contacts. Regional networking bodies and associations run similar events at modest cost and are an excellent way of meeting people in your region who may be able to help you crystallise your plans and move forward.

In addition, the *Biotechnology Young Entrepreneurs Scheme* (www.biotechnologyYES.co.uk) aims to provide postgraduate students and post doctoral research scientists with an awareness of how research is commercialised. Participants attend residential workshops during which they develop business plans for hypothetical biotechnology businesses.

We very much hope you have found this Guide helpful - good luck!

An electronic version of this booklet containing additional information can be found at www.bbsrc.ac.uk/biobusiness_guide.

Information on all of the BBSRC schemes included in this booklet can be found on our website at www.bbsrc.ac.uk/business or within the Business & Innovation Unit Portfolio (copies can be requested by emailing business.unit@bbsrc.ac.uk or calling +44 (0) 1793 413275).

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