Northern Ireland Assembly

Committee for Enterprise, Trade and Investment

OFFICIAL REPORT (Hansard)

Inquiry into Developing the NI Economy through Innovation, Research and Development: Almac

16 February 2012

NORTHERN IRELAND ASSEMBLY

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Members present for all or part of the proceedings:
Mr Alban Maginness (Chairperson)
Mr Daithí McKay (Deputy Chairperson)
Mr Gordon Dunne
Mr Phil Flanagan
Mr Stephen Moutray
Mrs Sandra Overend

Witnesses:

Mr Alan Armstrong	Almac Group
Professor Tim Harrison	Almac Group
Mr Colin Hayburn	Almac Group
Mr John Irvine	Almac Group
Professor Richard Kennedy	Almac Group
Miss Aine Rafferty	Almac Group

The Chairperson: I remind colleagues that the purpose of the research and development inquiry is to identity barriers to innovation, research and development and to make recommendations on how those barriers can be overcome. Briefing the Committee today are Mr Colin Hayburn, executive director of Almac Group; Professor Richard Kennedy, vice-president of experimental medicine; Professor Tim Harrison, vice-president of discovery chemistry, and Miss Aine Rafferty. We are very grateful to you for allowing us to visit your headquarters to get a sense of what you do as a business and for your input into the entire area of research and development, which we see as crucial to transforming business in Northern Ireland. We believe that you are a good example of how we can build business and create high-value jobs that will bridge the productivity gap between here and Britain. It is very important to create a step change in our economy. One way to do that is through the development of research and the creation of innovative business here in Northern Ireland. We are absolutely delighted to be here. We look forward to your comments.

Mr Colin Hayburn (Almac Group): Thank you, Alban. The Committee is very welcome at Almac. It is great to see you all here. We have a brief presentation. We hope that it gives you a flavour of what we are trying to do. I know that a paper was submitted to the Committee. Our presentation will try to cover in a more specific and detailed manner some of the points in that paper. We are very informal

bunch so please interrupt me or speak up. We will try to answer any questions as we go through the presentation. I will make some brief introductory comments. Then, these very clever professors will explain the complicated stuff. Some of this stuff is top secret.

[Laughter.]

We were not quite sure whether any of you knew much about Almac. Our global headquarters are here in Craigavon. Principally, we operate a range of services to the pharmaceutical industry. That starts off with biomarker identification. A biomarker might be something in your blood or a solid tumour, which might indicate a particular prevalence, or response to therapy, or recurrence of disease. We take that right through to making an active pharmaceutical ingredient (API), which is the main subject matter of a drug. We make those for third parties. The pharmaceutical company would ask us to try to formulate it into a tablet or some sort of medicine. It is highly complex work. We package that medicine and prepare it to go into a clinical trial. Nowadays, if you want a drug to be approved, it involves a heavily regulated clinical process. It is a global process. You have to show that the drug works, is efficacious and is commercially relevant. Our clinical trials operations are involved in doing that. That is very much done on a global basis.

At present, we are in our 32-acre Craigavon campus. There are six main trading divisions, which cover the main services to the pharmaceutical industry, right through from biomarker identification, API manufacture, formulation and development, and the management of clinical trials. Our R&D arm is slightly different to that. It is trying to develop technology that will allow us to stand alone and trade with the pharmaceutical industry, rather than as a service provider partner. My colleagues will give a bit more detail on that.

We have also recently launched a new North American headquarters in Souderton, Pennsylvania. Slightly under 50% of our global revenue comes from America. If you want to be a player and a main entity in the pharmaceutical industry, it is essential that you have a presence in America. We opened that very impressive facility in 2011. It is a 40-acre site in Pennsylvania, which we hope will eventually replicate most of the services that we carry out here. It will not take any jobs away from here. It will make us a global player. If we are not a global player, we cannot compete.

In the past five years, we have had very strong growth in revenue and employment. We are very proud of our group turnover figures, which, in this day and age and competitive environment, are very impressive. It took a lot of money and investment to achieve those figures. It involved a lot of effort and challenge. We are in a global economy. In the past few years, low-cost and developing economies, such as India, China and the Far East have really challenged us on cost. Therefore, we have to be more innovative. We have to be very smart. We have to be smart from a governmental perspective too, because the companies that we compete against have no regulatory barriers. We have regulatory barriers here, which have to be complied with. Therefore, although we face strong competition, we have had strong growth nonetheless. It takes a lot of effort to keep it up.

Our employment numbers are around 2,000 people on site here in Craigavon and around 1,000 people in North America. In the past few months, we carried out a bit of research. We found that 80% of the people who are based in Craigavon are from Northern Ireland. The other 20% per cent are from overseas. The guys might share with you that, in order to get high-quality research and development staff, we have to have a global reach. There is a high cost to that. I am not sure what our recruitment costs are in a year to find a high-class scientist. However, to find quality candidates costs hundreds of thousands of pounds. These two boys do not come cheap. You are lucky to get them today for half an hour.

[Laughter.]

I will now hand over to Tim and Richard. As I said, I hope that in the paper we submitted we addressed, in a practical and specific manner, some of the main points. Please feel free to engage with Tim and Richard as they go through the presentation and to talk through any points that you might want to raise.

Professor Tim Harrison (Almac Group): Thank you Colin, and thank you for the invitation to speak to you today. As Colin said, we work in a quite complex and high-tech industry. It is a high-risk and high-reward industry. However, it is also hugely worthwhile, because, ultimately, we are trying to produce drugs to improve people's quality of life. We are conscious that not everyone will be familiar with the details. Therefore, as Colin said, we will try to give to give you a context of the actual types of research that we do and identify some of the issues. We will also provide some real case studies and summary points that will hopefully lead to further discussion.

As I said, drug discovery and development is a complex and long-term process. To give you a quick overview of that process, it starts with discovery and then moves to a pre-clinical stage in which we work with animals, before moving to people. The first medical studies will be at the phase 1 level with healthy human volunteers. We then move to the first patient studies in phase 2, with expanded patient studies in phase 3. If we are very fortunate, drugs will be approved at the end of that process. Almac does not do the whole process, but you can see from the slide that 12 to 14 years would not be uncommon. On the latest estimates, the whole process costs around $1 billion.

I will now talk about one of the R&D divisions of Almac — Almac Discovery — which looks to develop new drugs. Richard will then tell you about our other main research division, Almac Diagnostics. In Almac Discovery, we look to develop new projects at the very beginning of the process. We look to identify new targets, and a current focus is on cancer. We bring those projects in, add value to them in a number of ways and license them out to bigger players who can afford to take them through the later stages of development. That is the business model: we get new projects, add value to them, and out-license them. We do deals to bring revenue into the company. Typically, there will be an upfront payment, milestones to success and, ultimately, royalties on sales. I will give you an example of what those numbers could look like later in the presentation.

The key point that I want to make is that we are selling oncology drug discovery programmes — not completed products. That is slightly different to some of the engineering-type R&D that you may be familiar with. Drug discovery requires a long-term investment, but the rewards can be very high when you get it right. Therefore, as we move further on in the process — if we can get to that point — revenues are really significant. Again, I will give you an example of that later.

Almac Discovery was a new venture for the Almac group. It is a drug discovery company. It is not a service company and we do not do research for anyone else. As I have described, it has a biotech-type business model. We got initial funding from Invest Northern Ireland (INI) and the McClay Trust to secure the company and established it in January 2008. Since then, we have created 31 new jobs at the Craigavon site. We took great care in recruiting an experienced management team from all over the world, and, as Colin alluded to, that was not the easiest thing to do. Getting those guys to move to Northern Ireland was not easy, but we waited and got the right team, and it is now in place. We also importantly established a strong network of technical and commercial outsourced contacts. We are very well linked into not only the UK and Europe but to America and the rest of the world.

As I will show you in a minute, we have established a number of innovative drug discovery programmes in the area of cancer with a potentially high value, and I will give you an indication of what those values could be. Our vision — it is grand, but I hope it is achievable — is to build a sustainable drug discovery R&D company in Northern Ireland. If can we achieve that, it could have real game-changing consequences for the economy.

The next slide shows our current portfolio. I will not dwell on it, but it shows the different phases of clinical development, beginning with the early pre-clinical and phase 1 stages. You will see that we have a product that has been through phase 1 and we partnered on that with a company for further development. The slide also shows our other two lead products. I will talk about one of those in a moment as a case study, and we hope that to be in the clinic this year. The other lead product is just behind that in the production process, and we also have a range of early-stage programmes. We also have another collaboration with a university in Sweden on column therapy, which is also in the clinic. Those projects represent possible partnering points according to the scenario that I showed you: we take it to a certain point and then partner it. Hopefully, you will see that we are not too far away from achieving potential value inflection points with some of those products.

I will show you an example of one of our programmes, which is the second one that will hopefully go into clinic. This is clinical cancer research. I picked this one because there was a bit of press around it last year. You may have seen some of that. A press release went out on the back of a paper published in the American Association for Cancer Research journal. The work was also presented at the American Association for Cancer Research meeting in the States in April. We have other publications to follow up, and this really made a splash last year. It was featured on local and national television and in the national press.

What was so interesting? It was a drug candidate to treat cancer: a so-called anti-angiogenic. Very briefly, if a tumour is going to develop, it needs blood vessels and nutrients to grow. Simplistically, if you can cut off that supply of nutrients, you can starve a tumour. I will show you some real data that we have to show that. The market leader in the anti-angiogenic area is a drug called Avastin, which you may have heard of. In 2010, the sales were worth around $7 billion; that figure represents one year's sales. Here is the first indication that, when you get it right, the kind of revenue you can bring in.

This drug was discovered at Queen's University and was licensed to Almac Discovery. It was a big protein, and we cut it down and found the active bit. It works through a different mechanism to Avastin. People get resistant to Avastin quite quickly, so we hope that this will be a differentiator. The sort of deal we did with Queen's included financing research staff there. The drug stops tumour growth in a range of pre-clinical models, and we plan to start clinical trials this year. As I said, if we can show good clinical data, we think there is the potential for a pretty big partnering deal after that.

I will show you this data slide, because I believe a picture is worth 1,000 words. This is a mouse model implanted with a tumor. These animals are dosed with vehicle and the tumour grows; you can see the size. This is two dosing schedules for our drug, either daily or three times a week, and you can see that not only does the tumour stop growing, but you start to see some regression. This is a simple animal model, and the hope now is that, when you take this drug into humans, you will see the same effect. We believe that this has application across a range of solid tumours because of the mechanism, so it is really quite an exciting drug.

What may something like this be worth? I am not going to walk you through the details. We got an independent company to build us a model for this and the projected revenue is shown on the slide. Peak sales are around $2·4 billion. The sort of deal that we might do on something like this would be worth, upfront, around $15 million, milestones with a total of $115 million, and then the 12% royalty on that would be something like as shown, so, it would be $300 million a year. Clearly, there is a long way to go with that drug; it has to go through those stages. However, if we are successful, this is the sort of revenue that can start to feed back into Northern Ireland on a long-term basis.

Mr Hayburn: Current INI funding will cover you for those three years, but just those three years. We are not making money until the time that I am pointing out. I will summarise this while that slide is up; there is a complete gap in funding from 2013 to 2020. We will touch on that later, but it is a very significant point. R&D funding is only a small part of our overall needs.

Professor Harrison: The other important point is that, the further you go along this axis before partnering, the bigger the deal will look.

Of course, there are potential risks. This is a risky business. This drug could show toxicity in the clinic; we may take it into humans and discover that it does not show efficacy, although it is showing efficacy in pre-clinical models; and we may not be able to find a commercial partner at this stage. If we are forced, because of funding to partner this early, we may not be able to find a partner. There are significant risks, but there is clearly also significant reward.

That is really just a flavour of Almac Discovery. Hopefully, it sets the context for the discussion at the end. We have summarised some matters and there are a few real case examples of some of the issues with R&D. I am going to hand over to Richard now to talk about Almac Diagnostics, which is the other major R&D division within Almac.

The Chairperson: Thank you very much.

Professor Richard Kennedy (Almac Group): Thank you for the opportunity to give evidence on our research today. I have a few comments especially on this first slide. I sit across a number of camps. I sit on a research group at Queen's University that I will talk about a little bit later; I am the vice president and medical director of Almac Diagnostics; and I also practice as a medical oncology consultant in Belfast City Hospital. There is rationale for doing all three, because it covers what is required to get something moved from basic science into the clinic. That is why I sit on that interface.

Almac Diagnostics, briefly, is a personalised medicine company. What we are trying to do is to develop tests in order to tell us the best treatment to deliver to patients. With increasing costs of drugs and therapies, we need to be able to target treatment better so that the right patients are benefiting. Unfortunately, at the moment, when I give chemotherapy in the clinic, probably only about 20% to 30% of people benefit from it; the rest are just getting the toxic effects, so we can do a lot better.

As part of the Almac Group, diagnostics has its own lab, which has all the quality systems to be able to deliver diagnostic tests internationally. It is one of the very few labs in Europe that can deliver tests to the US. The slide shows the research pipeline that I am responsible for. It is broken into two main groups: predictive and prognostic tests. Predictive tests predict the response to specific therapies, and prognostic tests predict the outcome for a patient following standard treatment such as surgery, so there is a slight difference between the two. I will not go into too much detail on that today, but they are two different programmes.

Today, I will focus on the test for stage II colon cancer. There has been quite a lot about this in the press and the media recently, so you may have heard a bit about it already. The issue is that, in patients who present with stage II colon cancer, the disease is confined to the bowel, which is a good thing. However, in that group of patients, about 20% will develop recurrence within five years, and that will, ultimately, lead to their death. We know that, if we offer chemotherapy to those patients, we can prevent recurrence of the disease. The problem is that we do not know who those 20% are. The options, then, are to treat everybody with chemotherapy, accepting that 80% of them will not benefit; or not to treat anybody, accepting that 20% will die from colon cancer. That is not a good situation to be in. Therefore, we have developed a test to try to sort that situation out.

Using technology developed by Almac, we have developed a test that can analyse the tissue from patients with colon cancer and predict the risk of recurrence within five years to help clinicians to make decisions on treatment. This was not straightforward. To do it, we had to collect a lot of tumour samples from a lot of different centres. There were about 16 or 17 centres involved. To give you an idea of the stretch that we had to make to get the samples, the slide shows the number of centres all over the world. The reason for doing that is that we did not want to develop a test just for Northern Ireland; we wanted to develop a test that would work throughout the world. To do that, we needed to collect patient material from throughout the world. A lot of work was needed to achieve that, but it was worthwhile.

The end result was that we developed a test that quite nicely separates patients between those who develop recurrence, and those who do not. The slide shows survival over time. It shows people who are predicted to have the worst outcomes, and you can see that they do badly.

This study was published by the American Society of Clinical Oncology. Its 'Journal of Clinical Oncology' is one of the premier journals on cancer medicine in the world. Our work got a splash in the journal, as well as an editorial. That was good advertising for Almac's capabilities.

The test has been licensed for a validation study in the US with a diagnostics company, and deal terms have been reached that I will talk about in a moment. The slide is just to give you an idea that developing one of these tests is not an entirely straightforward process. We started the process at the start of 2007. We are now in 2012, and we still probably have a year to go with the validation studies. It is a long process, which goes back to Colin's point: our funding covered about two years of it.

Mr Hayburn: We do not start making money at this point. The commercial return kicks in only five years from that point. The current structures in INI for funding, and even framework programme 7 (FP7), are a more traditional model. They do not suit this type of world-class research. The guys are maybe underselling themselves: there are countries around the world that are trying to do this, and we have been first in some cases. Those bigger companies have bigger support structures — they are massive billion-dollar companies. We do not have that. We have to work within tighter confines. The funding for two or three years really is vital for us.

Professor R Kennedy: I will not go through this in great detail. The slide shows a simplification of the process. The next slide shows the current deal terms and the projected returns on the test. That is just for the US markets — there is potential to take it into European markets as well. At 2016-17, you are looking at about $20 million coming back. That is the bottom line at that stage, coming back to Northern Ireland. That is an overview of the diagnostics.

While you are here, I thought that it was worth touching on the topic of this next slide. I think that it may be a good model for the way forward for some more basic research as well. Some of you may be aware of this, but Almac and Queen's University are collaborating on an initiative to try to improve research from the lab through to the clinic. That it funded by the McClay Foundation and Invest Northern Ireland. The idea is to facilitate the transition of innovation from academia to industry. Typically, what happens is that the academic will work up to a point, publish the data and that is it finished. Nobody is picking that up and taking it into the clinic, and there are numerous reasons for that. It may be that the research is not compatible with product development: it may have been done with the wrong technologies and in the wrong way; or it may be that industry and academia are just not talking properly.

To try to reduce those roadblocks, we are reflecting Allen McClay's vision, which is to streamline it. We are a small country. We have two universities, and one nearby that does this kind of work. Its work is highly compatible with the research that we are trying to bring into the market, so we are trying to streamline that process.

The other point is that it works both ways. Academia can educate the people in Almac research as well, to ensure that they do not end up in a bubble where they get disconnected from what is going on at the cutting edge of science, and they can share technologies. It is more than Almac. We are hoping to generate the next generation of entrepreneurs in Queen's University. Those are people who now have an idea of what industry is about and how to get products into the market. Hopefully, they will develop their own companies and have their own ideas. We are trying to encourage that way of thinking.

We are also building sustainable relationships. Those people will train up through the university, and they may go to other countries and become the CEOs of major pharmaceutical companies, for all we know. However, they know about Almac, our capabilities and what we can do, and, hopefully, that will create a sustainable business model.

Within the programme, we are developing a test for predicting the risk of dying from prostate cancer, which has been very successful. Queen's University has had a large input, and it looks like we will develop a test of worth. We are developing new drugs and lead compounds that fit into Tim Harrison's programme. We have a medicinal chemistry programme in Queen's University that is linked into this, which is helping to develop drugs. Hopefully, Almac will be able to pick up on the product-development pipeline and market. We are also developing new technologies for biomarkers and drug discovery in Queen's University.

That is what I wanted to cover today. I have partly addressed the questions that were originally put to us in the context of what was presented. Some of the discussion points may need to be addressed. Colin said that we are presenting pipelines, which can run seven or eight years. Typically, our funding is for two or three years. We are left with a deficit to try to fund — to try to get products to market. That is holding things back. Some of our programmes are very good but we cannot take them forward as we do not have the finance.

As regards the framework, when an application is put in, it can be two years before you get any funding. By that time, everything has moved on in basic research. What you put in is no longer relevant. That is an issue for us. The end part of the pipelines is the clinical trials in patients. Nobody is going to invest in a product that does not work when it goes into the patient. That is the most expensive part of research, and there is no funding mechanism for it at present.

When we launch into one of these research projects, we are often asked about the guarantee of financial return, and that frustrates us a little. You cannot give a guarantee; it is research. We do our best to try to de-risk it as best we can, but there has to be an acceptance that some of the programmes will fail. We are always asked how many jobs it will create. Some may create jobs if we bring in a technology where we are developing a biomarker. Some will be more around revenue creation, which comes back in.

We find the EU funding element very complex and time consuming. We do not get much support. To give you an idea, we looked at putting in a framework programme 7, and it was going to take a full-time equivalent six months just to do the paperwork. That is fine if you have a fairly good guarantee that you will get funded, but it is actually a fairly low guarantee.

The other issue is that those are, typically, academia or small to medium-sized enterprise led. We get only a proportion of the funding for the work that we do. Therefore, it has to be very much in line with our research programme. That puts us in a situation where you are putting an academic group in the lead of one of your lead programme in your commercial enterprise. There is a lot of risk attached to that, and we have had experiences where the academic group will just head off in a different direction. Sometimes, it is quite difficult to control.

Mr Hayburn: Richard, you might mention the oncology aspect of the calling of FP7.

Professor R Kennedy: It is worth mentioning that the current framework programme 7 does not have a relevant oncology calling for us. We cannot apply at the moment, and none of our programmes apply to the current framework programme 7.

Mr Hayburn: The new one, as you mentioned this morning, Alban, can apply. If we were looking for specific topics for action, one would be support from INI locally to help us to create an infrastructure internally with Almac, including staffing and resource. We have spoken to INI and its FP7 contact in Brussels. That is all very good, but there is no support there for that. It would take a heavy investment from Almac to even avail ourselves of that, and it would be time consuming. Europe-wide, it is highly competitive to try to get the funding.

Professor Harrison: If you think that you have made a new discovery, time is everything. If you want to avail yourself of European funding, you have to ask, first, if there is a relevant European call that you can put into — often there is not — and then, even if there is, you wait a couple of years and you have lost the edge. There needs to be something more relevant that can be applied more quickly.

The Chairperson: At the moment, oncology is not part of framework 7.

Professor Harrison: Not for this year's call. There are very minor, specific things, but it was excluded from this year's call.

Professor R Kennedy: We also feel that there is an important element in education. As Colin has already alluded to, we need a particular type of training for that kind of work. It is important that that is

being supported and that we are getting the right people coming through the universities. Tim, you have been involved in a committee on that, so maybe you want to comment on it.

Professor Harrison: It is really about developing the skills. I was involved in the original science, technology, engineering and mathematics (STEM) review and now I am involved in the STEM implementation group with Joanne Stuart. I chaired a workshop yesterday that was organised by the Department for Employment and Learning (DEL), which was great. It had all of the stakeholders from colleges, sector skills councils and the Department. It was fantastic. There is a fair amount of work in doing that, but business is committed to doing it. There are certain recommendations from the STEM review that actually require a limited amount of funding to really make a difference on things like scholarships, but now there is no funding at all. It is about working with Governments to try to make sure that, when we go through those processes, we actually do deliver something at the end of them. It took a long time for the STEM report to be published, and obviously the economy has moved on. We understand that, but, if it is important — I think everyone from Northern Ireland believes that the STEM subjects are important; they are right up there in the Programme for Government — we have to make sure that we work with the Government and that we can follow through on some of our commitments, otherwise it is going to be difficult to keep engaging with business. Business is very committed. It was a brilliant workshop. There was a real buzz around the place yesterday.

Professor R Kennedy: Point 2 demonstrates that those programmes are long-term things. They are not simple two-year or three-year projects, so it requires more of a long-term outlook. As the Assembly changes, those things are continuing, and I know that the views may change each time. It is about having some kind of continuity on it. Thank you for your attention.

The Chairperson: Thank you very much, Professor Kennedy. We will leave that slide up, because it is very helpful in focusing the discussion. I am going to start off the questions. Prior to the meeting, we structured a number of questions simply to try to focus on the issues that we are looking at in the inquiry. It might not flow directly from what you have just said, but, for the sake of our inquiry, we want to pursue that structure. Of course, you can bring anything in that you want, if you think it will be an appropriate response.

I was very interested in the interface between academic research, and business research and development. In your original submission you stated that there was a tension between the two: that academic research was not always directed towards business, and, indeed, that some of it was not contributing towards business development. I think that is, in essence, what you were saying. In that written submission you drew out that particular tension. Would you like to comment on that? How can we get academic research, business research and business application? How can we co-ordinate that so that we can maximise research?

Mr Hayburn: The QUB/Almac initiative is maybe the first step.

The Chairperson: That is very interesting. If you want to enlarge on that, that would be helpful.

Mr Hayburn: Richard has been put in the unique position of bridging industry and academia. That had to be very much an industry-led initiative. Sometimes, when you go into university settings, they are very political. There are various disciplines, and we need a crossover of various departments. We had to go into Queen's and put forward a very firm proposal that was industry led, with clear deliverables. That did cross over some departments, but it had to be industry led. We approached Queen's and talked for about 12 months to facilitate the structure that we wanted; not necessarily the structure that Queen's wanted. That was led by Tim and Richard, who are both experienced in working with academics, but who also know that there have to be deliverables from an industry perspective. From a strategic perspective, it took a bit of work to do that.

Richard, you may want to talk specifically about how that operates.

Professor R Kennedy: That is an important point. I can talk about the academic side. Most of my career has actually been in academia, so I can comment on that.

The first thing to say is that, in our current academic set-up, investigators are rated on what is called research excellence framework (REF) return. They are rated on their publication record. That is not unique to Queen's University; that is within the UK. Universities do not rate the commercialisation of research. It is a nice thing to have, but it is not one of the things that researchers are rated on. So, you get what you pay for, effectively, or you get what you expect. Interestingly, even within the programme, the pressure from the university was still to have so many high impact publications within a certain time. That is its interest.

The Chairperson: And that gives the university international standing and status.

Professor R Kennedy: Absolutely. It is an academic institution, so it needs academic standing. The commercialisation of that research takes somewhat of a secondary position to that. We have tried to show that you can do both. My argument is that, if you do proper research with a proper commercial end point, it will get into the clinic and will, therefore, benefit patients, but also, it should be the research that gets into the good publications. Therefore, you can marry the two, but it takes a little bit more creativity. In my experience, the university understands that now. A good example is maybe the paper I showed on the stage II colon cancer project. That has a clear deliverable for patients, a clear benefit and a clear product, and is probably one of the highest impact papers that has come out of the Department at Queen's in the past four or five years.

Mr Hayburn: There is a link there. That paper could be used as a marketing tool to commercialise the test. If a paper in an internationally renowned journal is picked up by the pharmaceutical companies, they would then contact us to speak to them about the test. That is an important linkage. However, not everybody can deal with those academic groups. We have had to invest in people like Richard and Tim, who can go in and — it is fair to say — speak the right language with the academic groups to achieve acceptance. We find that if too hard-nosed a commercial approach is taken with academic groups, they retreat into almost an ivory tower of academia.

Professor Harrison: It does not automatically mean more work for the academics. As Richard said, if experiments are done in a certain way, they do not have to be repeated, so it could actually mean less work. It is about working together with them to show them that that is the way forward and can accelerate commercialisation. You still get all the benefits for the academic group, but are now in position whereby, at point x, you can commercialise straight away.

One way in which we have done that, which is probably different to most programmes, is through Richard, who is seconded down there as team leader with a couple of his people. I am taking one of my key team leaders out of my drug discovery group for two years and seconding them to Queen's University. We are in the process of hiring three postdoctoral fellows to work under him. He will be in the academic lab bringing all his industrial experience. We have bought equipment that is industry standard and fit for purpose. Those postdocs are going to get fantastic training; everybody in that lab is going to get fantastic training. We think that we can start to expand that. People see, for example, that we probably produce purified compounds more efficiently because we have good automation. Once people in academia see that, they will say that they want to be part of that.
You have to be in there; you have to work together with the academics.

The Chairperson: Would that have happened if you did not have the McClay Foundation? This is an innovation in the way that universities do things.

Mr Hayburn: It is. However, it is the way that industry does things, and it represents an investment on our part. The people who the chaps talked about will not bring in any money for us for two or three years, but they occupy costly oppositions. It is a long-term investment on our part, and there is risk involved in that investment. As the guys have said, this is biological research. There are no gimmes with it and it could go wrong quickly.

We need funding support. The McClay Foundation has been set up to do things like that, and that is good. However, government should also be involved. Incidentally, INI has supported that venture and the Almac Group has also invested heavily, with almost £1 million. That is sunk money and a long-term investment. Those are early phase projects. We hope to get certain candidates for prostate cancer into Almac Discovery, and we will then enter into that five to seven-year commercialisation period. However, it may be 10 years before we get anything out of that. It will be high-quality stuff, but it will take a lot of investment.

Professor R Kennedy: We have been working in Queen's since May of last year, and it is fair to say that our colleagues from Queen's have been very supportive. They have actively supported the programme and see the purpose behind it. There has been very good interaction, and they are beginning to understand the benefits.

The Chairperson: Obviously, you hope that that will work well for Almac. Do you see that as a model that other firms could use in this area and in other areas of research?

Professor Harrison: That model is being used. Bombardier has set up a new research area at Queen's Island. That is on the Bombardier site, but it is a university building. That is a very innovative approach and they have set up labs there, so that people from Bombardier can effectively be seconded into academic labs. I absolutely think that that model can be applied in other areas, and it is.

It is expensive and only the big companies can even start to think about doing it. Almac has all sorts of demands on capital investment, and it is about balancing the investment against the research and development, and the risk. You have seen the kind of rewards that you can get, but you have to be conscious that there is a very big group. There are lots of other requirements, and trying to get that balance right is important. To my mind, because this has such potential for Northern Ireland, that risk should be shared, as it is being shared — at least initially — by government. However, these are long-term projects. If we want to develop the sector, there needs to be a partnership.

The Chairperson: What proportion of that funding comes for Invest Northern Ireland for that?

Mr Hayburn: About £1·5 million. A lot of work went into getting that, Alban. This ticks all the right boxes from a theoretical perspective, but not a lot of jobs are created by it. As I said, the revenue expectation is perhaps five to 10 years down the line, and there may be no revenue expectation. It does not fit INI's classic model, but it is the future.

The US companies are way ahead of us on this. They are engaged with academia and they have academic guys who are commercially minded and who want to create something with an eye to the market. We find that European academia is less market focused. They are more classic academics, and changing that will take some time. However, we have made a start.

Professor Harrison: One other potential advantage is that, with Richard working in academia, he can apply for external research grants and bring in funding from outside of Northern Ireland. That was another big plus and we are in the process of applying for that funding now. We can utilise his position as a academic to bring in revenue in the form of research grants.

Mr Dunne: Thank you very much to everyone at Almac. We have been very impressed by what we have seen so far and by your commitment and dedication to your work. It is obvious that you feel some frustration at the delays in processing funding applications. Can you give us some more information and evidence in relation to how those delays restrict your development work? What can we and others do to try to help you through that?

Mr Hayburn: There are two aspects to that. There is local Invest NI funding and FP7 funding. FP7 is a highly complex matter, as we shared earlier. We have not really fully engaged in that, but we would appreciate support, even financial support, to be able to do so. That is a secondary issue, and we will address it internally in Almac in the next 12 months.

On the issue of INI funding, we have worked very hard with INI. Almac is a very big group, and INI gives us a lot of capital support and a little bit of R&D support. However, sometimes it treats that as one basket of overall funds to Almac. In respect of capital return, the business plans for our more services-based businesses are more straightforward as there is a basic return on revenue. So if, for argument's sake, you build a bigger facility, your output and revenue ought to grow in relative size to that facility. This is different, however. We have found from engaging and even trying to understand the longer-term commercial models for validation and commercialisation that they do not fit the classic three-year model. There has to be persuasion. We are trying to get three-year funding even though we know that the revenue might not come in. There is a box with a revenue slot, and it is not realistic to expect a revenue return in three years. There needs to be a five to six-year programme. We have raised that point with INI. You are completing your own Budget exercise at the moment, and you know INI well enough to know that is very difficult for it to give you budgets for five years. However, we need that surety.

R&D programmes are heavily people-based, so we have to give the guys job security for five years. INI does not have a structure to work with something like that, so when we engage in an application process, there are issues about return, job numbers and average salary. The average salary in Almac is between £26,000 and £28,000, which, as you know, is a lot higher than the national Northern Ireland average. Our average R&D salary, to get good-quality people, is between £38,000 and £40,000. We had to recruit Richard from Harvard in the US and encourage him to come back. He is very happy about that as you can see. We had to recruit Tim from industry. A lot of investment goes in to getting such staff. So the average cost of R&D staff salaries is high, and the INI models do not naturally fit that.

Mr Dunne: Do you think that it could do more to adjust those models to fit that? Do you think that we should be encouraging it to do that?

Mr Hayburn: You could certainly have a go at it. We talk to INI and work hard to engage with it. We feel that when we present something like this to INI, it goes away thinking, "That is great".

Mr Dunne: Do you feel that it is very much geared towards manufacturing?

Mr Hayburn: Certainly. Manufacturing is, historically, more traditional. We have asked it to do something different here. We suggested that it look at the example of San Diego in America, where the whole industry was transformed by taking a very active, aggressive governmental approach to funding in the pharmaceutical industry. That transformed San Diego in 30 years from a being a fishing base to a high-tech, high-class, world-class pharma-research base. We have talked to INI, and it has to come back to talk to you guys. There are budget constraints. From talking to INI over the past two or three years, we know that its chief concerns are budget constraints.

We have a very exciting programme. We are collaborating with a Swedish company, Immune Therapy Holdings (ITH), on column therapy. We have not shared that work. We have had a lot of interest from

pharma companies. INI gave us a letter of approval for that. However, before we submitted the application, we had a meeting with INI and it told us, "Do not bother; we have no money". That is not a criticism of INI. I have always found that INI tries to work within very tight confines. Sometimes, it does not work, which is frustrating, and that adds to the laborious process. I think that that is fair to say.

We would like to get a new model for R&D programmes, even a five-year programme, which took into account a different format for the application form, with stretched-out revenues and support. INI will say that clinical trials are not supported from a European perspective, and that is true to an extent. We could push that a lot harder than we are pushing it. Those European rules are guidelines, so we could push a lot harder. There is no support for the commercialisation of R&D, and you would realise that if you asked a business development (BD) guy to out and sell R&D technology. It takes us around two years to try to sell a new technology to a pharmaceutical company. You will have an initial meeting and then you will have to go through various approval boards.

Pharmaceutical companies are worse than government; they really are. There are layers upon layers upon layers of approval required. It may take two years to get a meeting with the right people and then another year to try to work out a deal. They are very laborious and dinosaurian in how they approach things.

Mr Dunne: Why Is that? Is it because of regulation?

Mr Hayburn: It is just the nature of the pharma industry, Gordon.

Mr Dunne: Heavily regulated.

Mr Hayburn: They will approach anything new like this sceptically. They are licensing more now. However, if, for example, we wanted to recruit two really world-class, clever scientific BD people to go round the world selling it, we would have no support for that.

Mr Dunne: Do you get inquiries from pharmaceutical manufacturers for R&D work?

Mr Hayburn: Gordon, most of our work is R&D work for the pharma industry. However, this is different. This is stuff that we are doing ourselves. You make a good point. The R&D work that we do in sciences and pharma, which is highly complex, is not treated as R&D by INI. It is treated as a service business, and it is all about revenues.

I would like to focus on our sciences business. Our sciences business involves highly complex science. It is not always easy to get it right. It is highly complex science to make API and develop new ways of making API. If we do not get that right, a pharma company will sometimes say, "We are not paying you for that." You have to take that risk. Our revenues and profits from sciences may be relatively low. When we put in a business plan to INI, we are told that revenue and profit have to be growing. However, that approach does not suit that type of work in our group. Other companies in our group are more profitable. Sciences will never be very profitable, but it is a vital part of the group. It is the clever stuff, but it is treated under very harsh economic conditions.

Pharmaceutical companies might say, "We are not paying you for that. Your quality yield was supposed to be 95, and it is 90. We are not paying you." We have to absorb that. And to take it as a cost, or maybe our earnings before interest, taxes, depreciation and amortisation (EBITDA) projection for that quarter will not be as big as it should be. If you try to sell it to INI, it will be sympathetic and nod at you, and then someone will come down and say, "You need to fill that in. Your revenue and EBITDA have to grow. We have to show that to tick a box." It does not always work.

Professor Harrison: That leads on to a general point about risk. It is not just about funding bodies' approach to risk; it is a wider issue in Northern Ireland. We make funding applications, but people do not understand fully what we are trying to do. As Colin said, you put in a business plan, but it does not take account of the risk. Therefore, the funding bodies find it very difficult when they do their commercial assessment. The economists get involved and it cannot be done. It can be modelled, but not many people are familiar with doing it. It is a real struggle.

It would be interesting to develop something on risk attitude in Northern Ireland. If we are to become innovative, we will have to understand more about risk. It is a world problem. I do not think that anybody really understands risk apart from those who are involved in it. It is very interesting. More and more people are talking about risk. Your Committee may want to look at the approach to risk at INI and government level. We have to accept risk. It is about understanding risk and then placing bets so that risk is minimised. You cannot get rid of it. It is almost as though people want an R&D project that must succeed. However, it is then not an R&D project.

The Chairperson: We are coming into the whole area of risk now.

Mr Moutray: Absolutely. As a local representative, I am delighted to be here. I am delighted that my colleagues have had the opportunity to come and see this gem in Craigavon.

The Chairperson: He got us special permission.

[Laughter.]

Mr Moutray: Do you find that higher-risk, higher-return projects generally have a more positive impact on the economy than lower-risk projects?

Mr Hayburn: It is hard to know what that means, Stephen. If they work, of course they will. However, we have to consider the failure rate? For example, in the world pharmaceutical industry, 95% of all pharmaceutical oncology products fail at phase 3 clinical trials because they are not efficacious. As Tim alluded to, at a phase 3 clinical trial, it costs about $1 billion to take a drug to market. We are hopefully taking a smarter, biomarker, biological-based approach about what drugs the body will respond to.

You may be asking whether we, as a country, should invest in higher-risk, high-quality, world-class, skilled jobs as opposed to low-level service jobs that come in and give people jobs. There is no security in that for me, but there is security in this. If we get this to work, if the intellectual property (IP) and API are protected and patents are protected and you build a reputational brand, you have got a world-class business. There is no protection for the lower-level services such as the call centres, as we have seen on the TV this week. We need to build that IP creation and that higher value, higher risk element in our services business, or we are exposed. India or China could come in and put a bid in for some of that API manufacture for four times less than we can offer. We have to build up a reputation so that people know if they go to us, they will get quality, assurance, deliverability and long-term sustainability. All that costs money. It might not always work from a profitability perspective in the short term, but for the longer-term strategy, it is the right thing to do; there is no doubt about it.

Mr Moutray: We have talked quite a lot about financial assistance this morning; does a company such as Almac need any other form of assistance, or is it entirely financial?

Mr Hayburn: What do you mean?

Mr Moutray: Is there any other type of assistance that you would need from government, or is it simply finance that is required by a company such as Almac?

Mr Hayburn: Finance is a big part of it, to be honest. A lot of things come down to finance eventually. We can look at resourcing other things but ultimately, who pays for it? We have had recent issues about planning, as you will know because they have been well publicised. In the past 18 months, a planning application was a major distraction for senior management and a major risk to our business. We lobbied hard to try and get the planning laws changed and get support from government in that, and it was a bit sensitive. I hope it is going in the right direction, but issues to create a proper, more corporate-friendly environment in legislation take a wee bit of courage. It takes a bit of forward thinking and listening to and working with businesses. Legislative assistance in things like that are very helpful. Alan and John are other board members at the back; can you think of any other assistance?

Mr John Irvine (Almac Group): Anything that helps on the planning side of things would be welcome. We have had huge problems there. Purely from a business perspective, those were problems that we should not have had to face, to be honest. Some of the other problems we have are energy costs here in the Province compared with our unit costs in Pennsylvania, for example. Our energy costs here are something in the order of two to three times more than what it is costing us in Pennsylvania. It is very difficult to compete globally when you have that burden to carry. I am sure you have heard people say that some of the employment legislation is extremely bureaucratic and is not always particularly employer friendly in our experience. Generally, a much greater focus on trying to identify what businesses need and the provision of support in the areas that you are directed to would certainly help.

The Chairperson: Just for the record, could you give your name and position, please?

Mr Irvine: Sorry; I am John Irvine, the executive director of Almac.

Mr Hayburn: That boy in the corner is Alan Armstrong, CEO. He might say something in a minute.

The Chairperson: You are very welcome, Mr Armstrong.

Mr Flanagan: I am delighted to be here to hear about the work that Almac is carrying out. It is very exciting and interesting to receive such an update on the work that you are doing. There is massive potential in it, so good luck for everything in the future.

I have a number of questions, the first of which is very short. What is your annual budget expenditure on R&D?

Mr Hayburn: It varies, Phil, given the demands. We try to keep that expenditure down to a percentage of our profit. We have to do that or else it gets out of hand. We try and keep that down to around 20% to 25% of our EBITDA. We are a small company. These things that we are trying to do, they are very ambitious targets. The other companies that are involved in this research are multi-billion-dollar companies. We are trying to work on a shoestring compared with those guys. We have to control our funding; we cannot throw money at this. We have to try to throw intelligence at it, as you can see from these two intelligent chaps here. That is what we have to do; we cannot throw money at it. We try and keep it at a ratio, Phil, so we can keep it under control.

Mr Flanagan: Have you a ballpark figure?

Mr Hayburn: It generally varies from year to year, Phil, because it is chiefly people. I have figures here, but I think that we are spending somewhere in the region of maybe £8 million to £10 million a year.

Mr Flanagan: The reason I ask is that the latest figures show that the 10 biggest spenders on R&D here account for 60% of the total budget. If we really are going to achieve the targets that have been set, we need to see greater involvement from small and medium-sized enterprises (SMEs), as well as from larger businesses like your own. We have discussed the risks that a company such as yours takes, which is, obviously, a calculated risk to some extent. For an SME that is going to get involved in R&D, would the risks be much greater for that smaller business than for a company, other than your own, apart from the obvious differences between limited and unlimited liability?

Professor Harrison: It depends on the project. It has to. It depends on the company. It depends on the business plan. It is difficult to generalise. What stage is the project at? What needs to be done? That is what determines risk; it is the business plan of the company.

Mr Hayburn: That is not an easy one to answer. In our industry, as I hope that we have laid out, it is a very long time from discovering something to patenting it. In the past two or three years, our patent costs alone have been well over £1 million. You have to patent or you have nothing to sell. Smaller companies have fewer overheads, but it all depends on how smart the idea is and what type of industry they are in. However, there is no easy way round our industry. I know that you guys have a strategy to get SMEs involved in R&D. We have mentioned that to INI and think that that is a good thing. There is no doubt that that is a good thing. However, the danger is that you dissipate the budget and there is no real achievement. We, then, ask for money for ambitious targets and far-reaching projects, and the money is not there. I know that it is a difficult job for you to try to balance that.

Professor R Kennedy: If I can comment on the SMEs. Part of it depends on the business model, which is why I have seen people setting up spin-out companies. There are two models: one is setting up a business to become a sustainable business that grows; the other is to sell the business as quickly as possible to a big company. The second model is very high risk, because it is all or nothing.

Professor Harrison: That is an important point. What we are trying to create in drug discovery is not the usual model. The usual model is what Richard has just said: you take a product like this, develop a company and sell it. We are not trying to do that. We are trying to do something sustainable for Northern Ireland. That has challenges, because that timeline really comes into play. Usually, you make a product, within three years you sell it and are done, and you start another company. We are not trying to do that. It is an interesting model, what we are trying to do here.

Mr Hayburn: Another good point is that, because of the way Almac is structured, we invest all our profits back into the business. Almac is owned now by the McClay Foundation. Nobody is in here to get rich quick. In a classic entrepreneurial R&D company, the focus is to get up to a certain stage, get rich and get out. In the LM21 project, the inventors at Queen's were approached by AstraZeneca and by us to take the compound. They chose us, because we decided that we would keep working with them over a period of time and for five years would let them be involved in the product. AstraZeneca offered them more money, but said that they should give the compound to them and just walk away. The inventors decided to stay with us. I think that Almac is unique in that way, Phil. In our first INI letter of offer for drug discovery, we guaranteed that we would put all the profits back into the business and not have any other use for those profits, which was unique for INI. Part of the reason for offering that was to try to do something different.

Mr Flanagan: Going back to the participation of SMEs in R&D, do you think that there is anything that the academic side of things or the industry itself can do to encourage or improve that participation?

Mr Hayburn: We have done a bit of outreach.

Professor R Kennedy: We are working with another company, PathXL, which is an SME spin-out from Queen's. We have grant applications with them, combining our approaches. We do work with other SMEs on various projects, where they fit, but they need to have something complementary to what we do.

Mr Flanagan: You have also referenced the cost and length of time it takes to apply for grants under the European funding frameworks, and you referred to the potential for a grant to cover the costs of having a full-time equivalent for six months. Is such a scheme being run anywhere else in Europe, and do you have a rough figure for the percentage of applications that are successful?

Mr Hayburn: I am not sure about that; I do not know. However, there is nothing to stop us from doing it. We could lead the way on that one.

Mr Flanagan: Would you be happy to do that?

Mr Hayburn: Yes.

Professor Harrison: A really interesting review of framework programme 7 came out at the end of last year and is on your website. It is probably in there, I suspect.

Mr Flanagan: Aidan has given us another couple of books that look like that. Aidan and Fergal have not been too shy about giving us books about research and development.

Professor Harrison: Last night, I was reading about Singapore's five-year investment strategy, 2011-15. It might be worth having a look at that. It is quite an interesting approach. If anyone would like it, I have a summary here. It is very R&D driven; how you get SMEs and how you link it all up.

The Chairperson: It would be very helpful if we could have that.

Professor Harrison: I will pass it to you at the end. If you need details of the website, I will provide you with them.

Mr Hayburn: A Chinese company is currently interested in one of these compounds. We have been engaged in a few interactions with Chinese companies in the past few years, particularly last year. Chinese companies come with a 25% stake by the Chinese Government. State aid rules limiting the amount of state aid given to private and public companies do not apply to them. The Chinese companies are funded by the state, with no rules or regulations, and they are competing against us, backed by the Chinese Government and their 25% stake. Europe has to wake up a bit. China will not always play by the rules. It will be smart. That is who we are competing against.

Professor Harrison: I will give you a headline figure. From 2011 to 2015, their budget is $16·1 billion for R&D, which is up by 20%. I think that the population of Singapore is approximately 5 million. Then, there is a whole host of things that go with it. It is really serious stuff. I think that you need a seeding incentive to get the SMEs going. They have a budget for seeding. They call it investing ahead of industry, and elements go towards that. I suspect that rather than reinventing the wheel, there are things that we can learn from economies such as that. Then, of course, there are Finland and Sweden, which are interesting models to look at. There is another case study on your website on EU innovation policy best practice, which looks at Finland, Sweden and Germany. It is very useful for us to look at. There are some good reports there.

Mr Flanagan: Finally, Chairman, I would like to tease out the co-operation that exists between the company's operations here and in America. Are they working on similar projects, or are they operating in isolation from each other? What barriers or opportunities does that present, apart from having a foothold in the North American market? Perhaps you would give us an overview of the differences that a company involved in this sector faces in America compared with a company here as regards bureaucracy, financial support from government, and things like that?

Mr Hayburn: Our business is global, so there is high integration between the companies. We may have a contract to offer global services to a pharmaceutical company, so that would be managed between both sites as one project. That has to be the way it is. For us to compete, we have to be seen as a global company.

One thing that we did not mention today but will be a costly focus for us in the next two or three years will be to try to establish something in Asia. We have something in the west, something here, and we will need something in Asia. There will be a heavy degree of internal investment and internal management time involved in making sure that we are seen as a global company

We have the same management structure in the US and at our Craigavon site. We are over there on a steady basis. Continental is staying alive because of Almac at the minute, because we are back and forth every week. It is a global industry.

What was your second question, Phil?

Mr Flanagan: It was on the differences in government support and bureaucracy between here and America.

Mr Hayburn: We get a high degree of support for our Souderton headquarters. There is a high degree of interaction. It is slightly different. It is bureaucratic, but perhaps a wee bit more business focused in the States. We have no R&D function in the US at the moment, so we have not availed ourselves of any R&D activity there. We may look at that in the future, but at the moment our R&D hub is here. It is harder to spread your R&D hub between two centres.
From a commercial perspective, support for Souderton was reasonably good. Some very good local government and federal schemes were offered.

Mr Irvine: If I can just pitch in on that as well, the Souderton project was the largest capital project that we have undertaken within Almac. It represents an investment of $120 million. A lot of interest was shown by the Commonwealth of Pennsylvania, right up to the Governor, who was Ed Rendell at the time. He went out of his way to meet with us, first in London. We had a number of meetings at the Governor's office in Philadelphia. There were roads issues and utilities issues that had to be dealt with in addition to the financial support we got. We were very impressed with the whole business approach to things and the fact that the Governor of Pennsylvania himself got involved personally to make sure that what needed to be done was done and sorted out. It is just different from here, in our experience.

Mr Flanagan: So, he did not just turn up just to cut the ribbon.

[Laughter.]

Mr Hayburn: The Governor has an action team there, and the woman who ran that team, Gail Kronig, gave me, John and others her personal mobile number. She said that we were to call her if we had any hassles. It was all above board. You could call Gail to say that you were having a bit of issue with this local township or funding, and she would be straight there. The government is more directly accountable and less layered. The guys will get involved straight away.

Mr McKay: Thank you very much for your presentation. It has been an interesting debate. Risk, and research and development are the two issues that stand out for me. We are very risk-averse as a local economy. We are risk-averse as people, and we should be trying to break through that tradition. Investing in pharmaceuticals is viewed as a high-level risk, and you need to ensure that politicians and stakeholders have an idea of what the returns are going to be. I think we still need to work on that.

The point about Singapore was interesting; Committee members met representatives from Singapore towards the end of last year. They are very focused on pharmaceuticals and have a very business-oriented approach to the economy in general there. We have a lot to learn from them and there are certainly comparables in the size of the country. You mentioned India and China, and going beyond the regulatory barriers that we face here in R&D, what can we do as politicians to address those? Corporation tax is perhaps the obvious one. Are the BRIC countries being viewed as our greatest threat?

Mr Hayburn: It comes and goes, Daithí. Yes, from the standpoint of being able to produce services at a lower cost, it does. They have some way to go in being able to be trusted from a quality perspective. India and China have not yet developed their own pharmaceutical companies, but that will come. China will produce a pharmaceutical company within the next few years that will be a major, global company. I am more interested in your comment there about there being no regulation. Particularly in China, governmental support for those companies would be very strong. It would be unregulated. You would not be having a meeting like this; one guy would come in and help fund the company and take a stake in it.

You mentioned work we needed to do in risk analysis and maybe the education process. How could we take that forward? You mentioned that there was some work we had to do, perhaps on understanding what the risk elements are.

Mr McKay: The history of the economy here is different from other parts of these islands, for obvious reasons. Traditionally, we have a higher percentage of people involved in the public sector, so to introduce the degree of risk taking, like I always say, nothing ventured, nothing gained. Even at the level of small and medium-sized enterprises, we cannot get them to break out of that shell into the global companies as we see in other countries. It is about creating that culture. Invest NI and smaller groups in local council areas have a big responsibility in trying to develop that entrepreneurial spirit and to provide that support. If support is given at that level, it places an onus on those who receive it to reinvest, as they will owe something to where they come from. It is about doing that at a government and a community level.

Mr Hayburn: That is a good point, as is your point about education. INI's very fixed revenue and job growth three-year plans do not fit our R&D business model. It has a very controlled risk model and you have to show that you will grow your job numbers and revenue in order to tick a box. Ours is a longer term goal, and it requires others to enter in to an education process and a risk-taking and strategic process. That is good, but it will take some time for government to do that and that is not good for us.

We have a highly competitive two-year window for some of these projects and need to act quickly. We are more than happy to engage and share more and to see whether there are other models that we can look at.

Mr McKay: You said that that sustainability needs to be built into the education system right up to the colleges and universities. I always remember an example that came from Wrightbus, which is based in my constituency. Willy Wright always said that he had all these guys coming to the company from the universities, who did not have a clue in practical terms when they hit the factory floor.

Mr Hayburn: That is right; I can hear Willy saying that.

Mr McKay: Do certain parts of the curriculum need to be changed or steered in a different direction?

Professor Harrison: Tuition fees are going up in Britain. They are not necessarily going up here, but who knows what will happen in the future. As that happens, it will make people think more about whether they need to go to university. Everyone is saying that fees going up is a bad thing, but there is a flip side to that in that not everyone should go to university.

At the meeting yesterday, DEL placed a huge emphasis on apprenticeships. Catherine Bell is very keen on apprenticeships and the Department is doing a great job in that area. One of the things that we, as an industry, have to do is to stress the importance of vocational training, and some of those mechanisms are happening through government. Those who want go to university should go. However, others may say that they do not want to spend £30,000 going to university and may want to do an apprenticeship instead. I think that will naturally happen and it is starting to happen.

Professor R Kennedy: Traditionally, universities courses have been very academically driven. It is almost as if the courses are set up for students to have academic careers, yet, obviously, most people will not do that. The US universities that I worked in offered modules in entrepreneurship, setting up companies, project management and all of the things that really matter if you go into industry. That has not been the tradition here. Perhaps government can look at that again and understand what we are teaching people in universities and whether we are educating them in the right way. We need academics and we have that, but we should also set up tracks for those who want to go into industry. When I interview for jobs in Almac, I notice that those who come from outside of Northern Ireland seem to have been better trained for industry than local people. Local people are equally clever if not cleverer, but they have a much more academic view.

Professor Harrison: That is a big focus of the STEM business subgroup, and we spend a lot of our time dealing with that. One of the big issues that we have in Northern Ireland, because 95% of businesses are very small, is in engagement. If we could find a way to engage more effectively with the whole of the business community in Northern Ireland, it would be great. We tend to engage with the bigger companies because we know where they are and we know where to go, whereas we do not engage with the thousands of small businesses that may only have 10 or 15 people and may be family run. It would be fantastic if government could help us to engage with other businesses. As I said, that is a major challenge and we are trying to address that with DEL and through that subgroup.

As to how we change people's perception of risk, my own view is that you show them success stories and role models. That is why funding some of the big companies to make that work will, ultimately, pay dividends. There is no better way to do it than by showing them what others have done, and they will want to do it themselves.

Mr McKay: You referred to the fact that Invest NI funds projects for the first few years, and that that funding then, effectively, disappears off the edge of a cliff. You also said that 95% of the projects fail

at phase 3. What should Invest NI do? Should it cover the funding for the middle part, or would it make more sense for it to fund the latter stages? As you approach the latter stages of those projects, do the failure rates decline? Would that be more of an incentive?

Mr Hayburn: We know that there is a big failure rate and a high cost for those trials, Daithí. However, we suggest that there should some support, maybe with a policy of capping. We will do a phase 1 trial and a phase 2 trial, and the costs are a lot lower. There is phase 1 support, but there is not phase 2 support. With phase 2 support, you are starting to look a wee bit at efficacy and dosing. They should be able to look at giving us phase 2 support; they really should.

Phase 3 has massive costs — hundreds of millions. Those are global trials. It would be reasonable to fund phase 2 trials with a capped level and a control to ensure that you are not giving a company numerous trials. There is something there that should be looked at that is more focused. The 95% failure rate in those global pharmaceutical companies is why they are changing to a more biological-type focus, and that is what we are doing here.

Professor R Kennedy: The failure rate is quite a bit less with those biological-focused projects.

Mr Hayburn: It is 95% for the global industry, but it is a lot less for the biologically focused ones. That is what we are trying to do at the moment.

Professor Harrison: Colin has just made the point that I was going to make. Those are historical rates. Stephen asked about how you can de-risk things and how much risk you should take. What we are saying is that the business models are not quite right here. Our business model reflects an inherent de-risking by going down the route of personalised medicine. If Richard can select patients who will respond to the drug, you do not need thousands of patients; you might need 100 patients or even fewer.

The inherent business model that we are working towards is about how you make this better. It is not how we do more of the same. There is no point in doing that, and no one should ever fund that. It is not about that. This whole company is built around personalised medicine. If we get that right, all those ratios and success rates will change. Northern Ireland, as a country, will have to buy drugs, which are very expensive. It has to change. If we can get this right, there will be knock-on effects all over the show.

Every week, there is a debate from the National Institute for Health and Clinical Excellence (NICE) about whether we should approve this drug or that drug. Actually, if you really look into the way that drugs have been developed in the past, it is not surprising that they are expensive. Just give them to the patients who will benefit and they will become cost effective. That is what this whole business is about.

Mrs Overend: Thank you very much for having us here today. I have really enjoyed it. I am always very proud of our home industries. The late Allen McClay lived near my home, so we in mid Ulster can claim a little part of that. Your reference to San Diego was very interesting. I was on the Committee for Employment and Learning right up until last week. We were looking at how the mindset has changed there to reinvigorate San Diego. That needs to be done here in Northern Ireland; at least that is the way I see it.

It seems that Invest Northern Ireland needs flexibility to invest in companies such as yours. They are quite structured and need to be able to look at companies and see the potential, whether it is large companies such as yours or small industries. Is that your take on it? How do you think Invest Northern Ireland should look at that? Your briefing paper mentioned the establishment of an official group tasked with supporting all organisations to help improve R&D. Will you tell us more about where you see that coming from?

Mr Hayburn: I do not know who wrote that last part.

[Laughter.]

You are absolutely right about the first part, Sandra. It is about flexibility in R&D. The way that we specifically focused on our two projects to date shows you the length of time that it takes for an R&D project here. That is totally different if you go to Bombardier or somewhere else. The R&D structure in INI for companies in Northern Ireland does not work for us. The big businesses are availing themselves of it, but they have a totally different model. Flexibility would be highly advantageous for us.

The groups are good, but we will not have groups that have the same issues as us. They could certainly be groups that set up in generally the same way as we approach things, such as the educative process and FP7, and that would be very useful. However, you have to come out of those groups and look again at your specific business. Our approach would be very different to that of those other industries. So I am not a great fan of groups, because, sometimes, you just spend a lot of time talking. Very specific flexibility within INI would be really useful.

Mrs Overend: In the submission, there is a reference to Northern Ireland needing its own national contact point. Are you aware of any such provision in Invest Northern Ireland?

Mr Hayburn: Invest NI has a woman who is very good and very helpful for FP7. However, you could learn the same stuff from the internet. It comes back again to the idea that you have to get stuck into it yourself; you have to go out there and submit an application. The help is there, but it is not specific enough. Bombardier shared with us what it did, which is something that we need to do. In Bombardier's first foray into FP7, it submitted four applications and failed them all. It resubmitted, having engaged with and invested in people internally to go out and find out about it. Of its next five submissions, four were successful. We will have to do the same. We held off slightly, until the oncology call was relevant, and I hope that it is relevant in the 2020 Horizon initiative. However, getting support even to do that would be useful for us.

I am not quite sure what the role of a central NI contact would be. If you spoke to INI today, it would say that it has that.

Professor R Kennedy: One big advantage we potentially have is that, within the EU grants, typically it will be for two member states. So, we can use collaborations with the South of Ireland. That could be encouraged as well. There are companies in the South of Ireland of comparable size. The problem is that, at the moment, setting those things up is quite laborious.

Professor Harrison: For example, the Marie Curie grant would fit into that, but that is under the FP7 people category. There are issues there. You could get the grant, but would have to send your people off for two years. That is all about knowledge transfer, which is brilliant, if you have the resources to do it. However, you can then hire new people only on the basis of how much transfer you do. You end up losing your own skilled researchers for two years and bringing in someone to train up for two years. That is great, but you still have to run a business. You cannot easily avail yourself of that grant, unless you have people you can spare to do it. It could work, but, in practice, it is quite difficult.

Mrs Overend: I am sure that, in the current economic climate, it is more difficult. I hear about Invest Northern Ireland giving money back to the Government. What if that additional flexibility had been there?

Mr Hayburn: That is true. When we hear that, we find it strange.

Professor Harrison: Is it true?

[Laughter.]

Mr Hayburn: We do find it strange.

Mr Flanagan: Just a quick question, Chairman, before you move on. I am interested in what role you envisage venture capitalists playing in the future development of R&D here? Is there a role for them?

Mr Hayburn: There might be, but not with us.

Mr Flanagan: Not with you, but in the sector as a whole?

Mr Hayburn: Those guys come in for a very fixed term for a very fixed return. It sometimes works. The venture capitalist model is the classic model in the US. They go in for a very fixed term, put their own boards in, make money and get out again. However, if you want to grow a proper economy in Northern Ireland, for me, that is not the right way to go. Even in some UK companies, it has not worked. Venture capitalist houses have been into this space. They go in, and, if the return is not there in three years, they go. The venture capitalist model is not good for growing indigenous talent, because board members would probably be brought in from other countries to manage it, and manage it in a way that is focused not on the growth of a good indigenous business, but on getting money and getting out again. I do not see it, but I do not know what anybody else thinks.

Professor Harrison: If you look at the way that small biotechs are being funded in the current climate, you will see that that is not necessarily through venture capitalists. It is through corporate venture funds. If you want to find a way to do this, I suggest that you talk, as a Government, to some of those corporate venture funds. For example, Novartis and GSK, the big pharma companies, are now putting up $0·5 billion — big, big venture funds. Those are the guys who are investing. You are still getting venture capitalists, but I think that the ratio has changed. For pharmaceutical R&D, it is the corporate venture funds that you should definitely consider talking to.

The Chairperson: I had a couple of points that I wanted you to reflect on. Your written submission referred to the benefits of having:

"Enhanced all-Ireland support for European funding".
Will you elaborate on that?

Professor R Kennedy: At the moment, the SMEs, the companies in the South of Ireland and Almac work independently. I know that InterTradeIreland is trying to do something about this, but it is very difficult to set up those connections. We do not move in the same circles a lot of the time and we will not be in the same conferences, so the question is how we get those introductions. We are not even certain what research a lot of these companies are doing because it is not in the public domain. There needs to be some sort of mechanism or an independent broker who can look at what they are doing and say that it is very compatible with what Almac is doing and introduce us. It is as simple as that.

Professor Harrison: There is a potential mechanism there. There is a trade body called BioBusiness based in Belfast. It has recently become an all-Ireland body and has lots of networks into Northern Ireland. It recently co-opted two board members from the Republic of Ireland, and one of the ambitions is to develop that. For example, you could take that kind of network and it could be a mechanism for doing this.

The Chairperson: Professor Kennedy, you have made the point that we have a ready-made situation here with two jurisdictions, we can have these partnerships and we should take advantage of that. Do you think that the situation is not being maximised?

Professor R Kennedy: At the moment, I do not think that it is.

The Chairperson: So we need something to bring companies together and get this co-operation going, thereby usefully exploiting the funding that is available in Europe.

Professor R Kennedy: It needs to be done in an intelligent way. To go back to Colin's point, we have had these meetings where lots of companies will come together, but you do not necessarily have the right people in the room or people who are able to divulge information, because some of this research is quite sensitive.

The Chairperson: You do not want to reveal what you are doing.

Professor R Kennedy: You need to have the right people talking at the right level.

The Chairperson: If framework programme 7 did not exist, would it make any difference to you?

Mr Hayburn: At the minute, no.

The Chairperson: Is that simply because framework 7 does not cover oncology?

Mr Hayburn: We are collaborative members in a number of FP7 applications through customers and partners, but, I would say that the oncology calling is not relevant at the moment. We have not yet invested time to focus on it because of the distraction and the time involved. We have to do that and we are planning to do that in preparation for the next calling round. There is money there and we have to try to get it, and we may need assistance to do that. It has no bearing on us at the moment but we want to get involved in the future.

The Chairperson: Will there be a significant drive from your company to get involved in Horizon 2020 to get funding?

Mr Hayburn: Yes.

The Chairperson: What assistance would you require from the Northern Ireland Administration to do that?

Mr Hayburn: Off the top of my head, because of the investment in time and money to get involved in that, grant support for somebody to be involved in that full time would be good.

Professor R Kennedy: Because of the nature of these frameworks, that person would not just be supporting Almac; they would be supporting that framework. The point is not just to seek Almac funding; it could be across more than one company and possibly include an academic institute as well.

Mr Hayburn: Start with Almac.

[Laughter.]

Professor R Kennedy: I am saying that there is more than one benefit.

Mr Hayburn: Even that alone is a starting point. We can work on something more around that, but that would be useful for us.

Professor Harrison: As of April 2011, 110 projects in Northern Ireland had received EU funding totalling €30 million. The amount of funding per company is not that high. Some companies get more but others do not get very much. You must also have the right projects. If you are going to invest that much effort in trying to get one of those programmes, the salaries that you have to put in could be close to what you actually get and there is no guarantee —

The Chairperson: It is hardly worth it.

Professor Harrison: Yes, so you have to come up with the right proposals. Those projects are very big and necessarily require more investment. I thought that was quite a startling figure.

The Chairperson: It is a very low drawdown.

Professor Harrison: It is.

Mr Hayburn: We are probably not availing ourselves of that funding as we should in Northern Ireland. We attended a few FP7 meetings in the past year with local companies and only a few companies have become involved strategically in that programme. As a country, we have been a bit lax in getting involved in that. We have to look at it.

The Chairperson: Do you think that we have to up our game generally?

Mr Hayburn: I think so. Almac certainly does, and it is representative of the market.

The Chairperson: Does industry and business generally in Northern Ireland have to do the same?

Mr Hayburn: Yes, I think so.

The Chairperson: Does government have to be a bit more proactive in encouraging firms?

Mr Hayburn: Yes, I think so.

The Chairperson: I think that is everything that we wanted to bring to your attention. Thank you very much; that was very interesting and very useful. No other colleagues have questions. Once again, thank you very much for the invitation to come here; it has been of great benefit to us. We wish you good luck.