

BioPartner Discussion Forum Notes

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Weston Manor, Oxfordshire

Chairman

Enda Gribbon – Atelix Partners

Panel

Meredith Lloyd Evans (BioBridge Limited and BioScience for Business KTN)

Crispin Kirkman (Emerging Technologies Network Agency)

Will Watson (Teva Pharmaceuticals Limited)

Ederyn Williams (Warwick Ventures, University of Warwick)

What is necessary for the future of early stage drug research funding in the UK? And how will new companies succeed in replacing those lost to M&A?

University research and technology transfer is healthy

Despite the difficult recessionary climate, Universities have not been affected. Research Councils are still making payments. Funding from Research Councils remains strong, Universities are generating as many ideas as before and there are a variety of schemes of funding available to support tech transfer including the Higher Education Innovation Fund. There is increasing follow on funding available from the likes of the BBSRC.

Biotechnology commercialisation falters at the first step

The next stage, i.e. business angels and early stage funding is now much more difficult to attract. External enquiries about university talent are consistently low. Universities approach Pharma first, as they may have known contacts – they should make more biotech contacts. VCs are looking for better security and are making fewer and larger investments; which does not assist Universities in early spinouts. Technology transfer units have had to be selective about which projects to support regarding value and long-term prospects. Hence they will tend to give most support to concepts that will require the least time and money to develop into marketable entities (i.e. not medicines). If an innovative life science project presents itself which requires a great deal of funding, then a university is less likely to choose that as a spin out opportunity. They say “Oh no, not another Professor with a cure for cancer,” even if the Professor really does have a cure for cancer.

Universities do not position their biotech propositions effectively

University research outputs are interesting but the benefits are not thought through. Ventures are based on very narrow ideas often from particular professors at Universities with large egos rather than good business judgement. There are follow-on issues in products reaching the market and one of these is an over rigorous regulatory system. Lengthy regulation processes kill ideas off early; there should be “sieving” at a much earlier stage in order to determine which are good scientific companies and which are bad scientific companies.

Research funding is still orders of magnitude higher in the US. There is a mature proposition for VCs and a better chance of success.

Another problem is that at University level there are sophisticated tech transfer departments e.g. Imperial innovations and ISIS, with good people but somehow these departments aren't impressive. There is more competition between Technology transfer offices (although this has not led to rationalisation – good and bad tech transfer offices still get level funding).

At present there is no joined up thinking. Universities only a short geographical distance from each other are not talking to each other. Not only do they not know what is going on in their backyard in the UK, but they do not know what is going on globally. One of the questions which arises in the present model being used for the spinning out and creation of life science companies is whether follow on funding should come from research bodies. This does not seem to be the best way forward. More collaboration is needed to identify shared resources. In bringing products to the market complementary skills should be used to generate a coherent story: not just one professor in one University.

Early Stage Support

Should Universities be banned from spinning out companies? Is this model wrong? How will this translational science work? In the UK it is not clear, as it is in the US, how commercially exploitable innovation will be produced. It is certainly the case that for Universities who are seeking spin out Biotech companies that there are insufficient monies for these companies to properly be developed and to become sustainable. Spinouts are now being replaced by proof-of-concept funding, which is good. But the NIH patent budget is \$30b; compared to the US, UK translational research is under funded. The task of the Technology Strategy Board is to carry out this translational science from ideas to commercially exploitable inventions. But to date only 12 grants have been given out. This is not enough; the money that has been provided is insufficient. There should be more collaborative research and development. The Technology Strategy Board produces “calls” which are seen as narrow. One of the difficulties of the funding system in relation to grants was that in order to be able to qualify for a grant the company must be in exactly the right area. It often seems to be the case that prior to the calls being produced, it had already been worked out in advance which companies would obtain these grants. Regional agencies have no money and the OLS sounds bureaucratic: too hard to get money. FP7 grants are written for specific groups who already know who’s going to apply. Government advisors should not work out calls: rather, we should have a national panel or government subset. If there is a good concept the grant system should provide funds of 50% to fund the science leaving 50% for the VCs.

We also still suffer from a lack of places to conduct translational research – this is despite nearly 15 years of government attempts to address the issue, starting with the TNO: the genesis of the Faraday Partnerships that led to the KTNs. Institutes like that are needed. In the US there is much greater focus on translational medicine, there are significant funds available for patent prosecution work compared to the UK

Biotech valuations are way down. There is great science here, but VCs are going to the US, where they are saying there has never been a better time to invest in biotech. Big Pharma wants to pick up a bargain, waiting for Biotech simply to collapse and then to pick up the pieces on the cheap. A way forward to make or to obtain investment in Biotech companies in the UK could be for the Government or relevant trade body to advertise that now is a good time to invest in Biotech companies. An advert could be put into national newspapers to say simply “Come and invest in the Biotech Sector”. On the other hand, UK visibility is important, but the UK is a small part of the global market. Are we being arrogant to think we should have a large share?

Early stage evaluation

leading edge, bleeding edge or a damp squib?

We should be asking why certain companies are still in business. We are in a transition phase. We remember the good times pre 2000; the mindset was that we have a right to spin out companies and the VCs should fund us to do so. There have been a lot of complaints addressed to VCs but one of the difficulties has been that VCs in the life science sector have not received a return on their investment. There have been some situations where companies have gone a long way before they have collapsed, e.g. Lion BioSciences, without proper evaluation of whether they had good science or had the technology that was capable of reaching the market. The mindset that Biotech should be a “get rich quick industry” needs to change. Academic ideas are research projects, not companies. We should harvest IP and build small, sustainable companies that will get the VCs to return. We need to forget politeness and have public debates about what makes a good commercial opportunity. There needs to be robust discussion about what is an investable proposition as opposed to commentators remaining silent on whether there is good science or technology within a company. Robust ideas and ‘keepers of keys’ are needed to ensure that bad prospects do not get funded.

In the US there is a mature (early stage) proposition for VCs and a better chance of success. Business Angels here are looking for ‘close to market’ - but they can’t work out if a proposition is leading edge, bleeding edge or a damp squib. Cherry picking happens too early: we need to place bets widely. Overall in the UK there is an attitude to risk, where nobody will stick their heads above the parapet; there is no commitment without a certainty of success. There will be reduced innovation with no risk.

The present model to bring new technologies to the market is therefore unrealistic: how do we make ideas robust at an early stage? Money should be spent on screening and validation of early stage projects for proof of principle and proof of concept. There should be funding at a central level with national assessment. We need the luxury of enough funding for a balanced portfolio of innovation can be two things:., or an existing low risk sure-fire products that can be used in a different way, and high risk, new, cutting edge concepts.

Company building needs the right management

Another problem is the quality of the management in life science companies – which is one of the key factors in building a successful company. Robust technology platforms are one thing but good management is needed to establish an attractive company. For example, Ablynx spent just £30m on a lead therapy, Adana Bioscience sailed past milestones and Domantis sold for an excellent return; by contrast, Affibody in Sweden had a technology just as good, but were too early and didn't do so well.

Common problems include:

- The interface between research and development needs to be smoothed over - it shouldn't feel like a life's work is being given up.
- AIM boards are often on a gravy train – most of these people are not entrepreneurs but political operators who have managed to obtain their positions from having done well in Big Pharma.
- Unsuccessful translation of Big Pharma managers to smaller Biotech companies
- Poor communication between and within management teams;
- Bright MBA investors who have never had a proper job, yet they quote mismanagement and can't accept, for instance, that they should marry up the CSO and CEO roles.

Traditional management skills are needed and there should not be fashionable management taught for scientists. Young companies can't afford professional development. Teaming up with eg Roche can be a good way to fill the gap but scientists will always tend to make intuitive steps, and don't have a programmed approach. There are, however, schemes for scientists to learn management skills. Good MBAs are educational, not just a qualification - but it is not a question of whether an individual has an MBA or not, it comes down to whether the individual is the right individual. [show of hands – only 5 or 6 had MBAs]. There also needs to be improvements to the educational system, and funding to innovate and reward innovation. It needs to be able to reward scientists properly for doing scientific jobs. The right management could come in the form of a properly trained manager from another sector. An example might be a manager that had been through the fast track system at Unilever or other management training programmes where they have had to take a large number of decisions in a short period of time. However the bringing in of management from the likes of Unilever or Proctor and Gamble has never become accepted in the Biotech industry.

Selling: Value vs momentum

Pharma seeks *momentum*, for Biotech it is *value*

There are a number of companies out there that never look too far into the future as regards building value with turnover and royalties included in their projection. It is very often the case that the Biotech companies simply refer to value being built within the company. In the past, flotation would increase a valuation ten-fold. Now we need to create companies that can sell, not (create) financial vehicles. A common complaint is that in the UK we are not building a life science industry with significant companies, and that small companies are usually sold abroad as soon as they get to a certain valuation. But big fish eat small fish - it's the way of the world and we have to accept that the lifespan of a biotech company isn't long.

VCs are looking for 20+% returns but they have difficulty understanding the risk/reward ratio. The big rewards come with bigger risks and not with those investments that are very close to market which are likely to succeed. We should remember that VCs in using their money have made promises to their own limited partners. Value is therefore the key driver for any venture-backed company.

The most favoured exit route is currently a trade sale to Big Pharma, often with a licence deal en route. It is important to recognise that for Big Pharma the key driver is *momentum* whereas for Biotechs it is *value*, and to rationalise these drivers. If there is a clinical need, a drug will be successful, and a biotech company can drive down eg clinical trial timelines by a third in a niche market. But focus should be on the value for smaller Biotechs rather than thinking about [far distant] revenue royalties that could be completely unrealistic since this is such a long distance into the future. If it is in the right therapeutic area its share price can move considerably - a recent example is HGS (Human Genome Sciences), whose share price trebled on a promise of a Lupus therapy that isn't marketed yet. For Pharma, a biotech asset may be the only thing they have. Internal programs are often politically driven and due diligence will therefore be three times as stringent for an external prospect. The common customer is the regulatory authority, to whom the biotech company should be looking and producing its data accordingly. When pursuing deals with pharma, talk of inflection points to mask inadequate milestones set by VCs (the 8-patient clinical trial...) does not translate into momentum however high the share price.

Grumbles:

- No venture money commitment without a certainty of success. Leads to reduced innovation
- Technology transfer units driven away from commercialising 'far-from-market' ideas
- Lack of collaboration between Universities on high-return, long-term propositions
- Translational science funding unclear and misdirected
- Lack of rigorous commercial evaluation of early stage projects
- Interface between research and development is still a difficult transition
- Absence of quality management and Board entrepreneurs
- Medicines regulation a major force against innovation

Solutions:

- Public debates about what makes a good commercial opportunity
- Robust ideas and 'keepers of keys' to ensure that bad prospects do not get funded
- Cash for screening and validation of early stage projects for proof of principle and proof of concept
- Funding at a central level with national assessment.
- Harvest IP and build small, sustainable companies to encourage VC return
- A mindset change from Biotech as a "get rich quick industry"
- More collaboration to identify shared resources, particularly at University level
- Global advertising by Government and trade bodies: now is the best time to invest in UK Biotech
- A national panel or government subset to issue calls and decide grant funding
- Institutes are needed, to address a lack of places to conduct translational research
- Improvements to the educational system: traditional management skills for scientists
- Encourage recruitment from management training programmes in other sectors
- Funding to innovate and reward innovation: reward scientists properly
- Universities should make more biotech contacts
- Encourage companies to accept the regulatory authority as the customer, and produce data accordingly
- Ensure there is a Pharma partnership or element to provide regulatory focus

Future topics:

Merged models for life science companies – proprietary and generic, platform and discovery

Regulatory burden: a structural issue. The USA is protectionist, why can't we have a reciprocal regulatory system between the EMEA and FDA?

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