

H2 2015

Discovery

NEWS, VIEWS AND EVENTS AT QMB

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EDITOR'S WELCOME

Welcome to the latest issue of the QMB Newsletter.



Antibody Drug Conjugates (ADC) are a massive game changer in how cancer can be treated, potentially reducing and in some cases eradicating the need for chemotherapy and its debilitating side effects. At QMB we are lucky to have not one but two companies carrying out pioneering research in this area: Spirogen and ADC Therapeutics (ADCT).

In this issue, we speak to Dr Phil Howard, Chief Science Officer at Spirogen about how he got into cytotoxic warheads. We also catch up with Themis Kallos, MediWise's Chief Science Officer, to see how the company is expanding its range of products.

We caught up with our latest tenants, BioRelevant, who moved into the centre in July to see what they've got planned for 2016. Quite a lot, as it happens, including the launch of a new product in January.

In other news, ADC Therapeutics (ADCT) has bolstered its Board with the appointment of Dr Hans-Peter Wild and Jacques Theurillat to its Board of Directors as Non-Executive Directors. Elsewhere, hVIVO raised £20.5 million in an equity share placing and acquired a stake in PrEP Biopharm Limited (PrEP) for £14 million.

We also have coverage of a very interesting panel discussion from QMB's BioWednesday event with One Nucleus which looked at the challenges the new Mayor of London will face when they assume the post in May 2016.

For more updates and the latest news from QMB, including Dr Ramsay Richmond's life sciences sector blog, please visit our website. And we're eager to hear your perspective too, so please share your feedback in the comments section on our website, or join the conversation on our Twitter page.

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 #QMBInnovation

Double milestone for ADCT

ADC
THERAPEUTICS

ADC Therapeutics SA has announced a double milestone in pre-clinical results for two of its novel ADCs, ADCT-301 and ADCT-402.

The Company recently received clearance from the US Food and Drug Administration (FDA) to begin clinical trials with ADCT-402, a novel antibody drug conjugate targeting CD19, a cell-surface antigen, which is over-expressed in many patients with B-cell non-Hodgkin Lymphoma (NHL) and B-cell Acute Lymphoblastic Leukaemia (ALL).

It also presented pre-clinical results for both ADCT-301 and ADCT-402, at the 57th American Society of Hematology (ASH) Annual Meeting, December 5-8, in Orlando, Florida.

ADCT-301 is currently in Phase I for lymphoma and leukaemia. ADCT-301 combines HuMax[®]-TAC, a human monoclonal antibody targeting CD25 (the alpha chain of the IL-2 receptor) created by Genmab A/S, with a dimeric pyrrolobenzodiazepine (PBD) warhead. The data confirms the mechanism of action of ADCT-301 and provides relevant pharmacodynamic assays for use in clinical development.



Dr Patrick van Berkel, Senior Vice President Research & Development at ADC Therapeutics, said: "We are highly encouraged by these data which demonstrate the potential of ADCT-301 and ADCT-402. As we continue development, early indications are that our PBD-based ADCs could offer superior efficacy with a reduced resistance profile for the treatment of haematological tumours."

ADCT-402 combines a humanised monoclonal antibody targeting CD19 with a pyrrolobenzodiazepine (PBD) warhead. ADCT plans to initiate Phase I clinical trials in both NHL and ALL.



In preclinical *in vivo* models, ADCT-402 exhibited strong dose-dependent anti-tumour activity against CD19-positive leukemic and lymphoma cell lines at low single doses, and it outperformed other CD19 targeted ADCs currently in clinical development, the company said.

The first of the Phase I clinical trials for patients with B-cell NHL will commence at eight leading oncology centres in the USA and two centres in the UK. The initial study will evaluate the tolerability, safety, pharmacokinetics and antitumor activity of ADCT-402 in patients with relapsed or refractory B-cell NHL. Subject to study results, ADCT intends to rapidly expand the numbers of patients in the trial and expand the number of participating clinical centres.

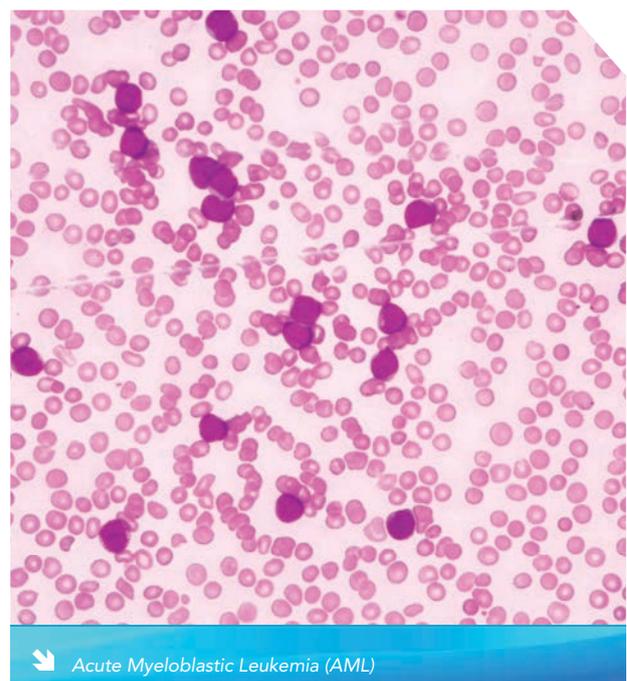
Dr. Owen O'Connor, Professor of Medicine and Experimental Therapeutics, and the Director of the Center for Lymphoid Malignancies, and Co-Program Director of the Lymphoid Development and Malignancy Program in the Herbert Irving Comprehensive Cancer Center at Columbia University Medical Center, is the Principal Investigator for this Phase I study.

Dr. O'Connor said: *"There is significant unmet medical need for patients with relapsed or refractory disease in B-cell NHL. An ADC targeting CD19 with a potent PBD warhead, is a sensible approach in this difficult to treat population. We are delighted to be working with ADC Therapeutics to bring this potential treatment to patients."*

The second study, a Phase 1 trial for patients with relapsed or refractory B-cell ALL will commence simultaneously at 10 centres in the USA and EU to evaluate the tolerability, safety, pharmacokinetics and anti-tumour activity of ADCT-402 in this patient population. Dr. Nitin Jain, Assistant Professor in the Leukaemia Department at MD Anderson Cancer Center in Houston, Texas, the Principal Investigator

for this Phase 1 study, said: *"We have made significant strides treating patients with B-Cell ALL but we are still seeking new treatment modalities to improve the prognosis for patients. We are excited to be working with ADC Therapeutics on this program."*

Dr. Jay M. Feingold, Senior Vice President and Chief Medical Officer at ADC Therapeutics, said: *"This is the second ADC we have advanced into clinical development in the past eight months. Preclinical data suggests that ADCT-402 may have significant activity against B-cell NHL and ALL and we are pleased to progress our pipeline by beginning these two clinical studies and, hopefully, to bring significant benefit to patients with these diseases."*



Acute Myeloblastic Leukemia (AML)

hVIVO raises cash and acquires stake in start-up



hVIVO plc, pioneers in human challenge models of disease, had a very busy November.

The company raised £20.5 million in an equity share placing and acquired a stake in PrEP Biopharm Limited (PrEP) for £14 million to continue the development of the prophylactic compound PrEP-001 (previously JNJ-43260295). In addition to hVIVO, lead investors in the UK-based start-up company include Johnson & Johnson Innovation – JJDC, Inc. and US-based angel investors.

The company placed 9.1 million shares with existing institutional shareholders at 225 pence per share. hVIVO will use the money to back its development portfolio, which includes progressing including PrEP-001 to Phase IIb, start asthma stratification and advance the flu pathomics outputs into product candidates.

The proceeds are expected to be invested in the research and development programmes over the next two years.

PrEP-001 is a nasally administered, broad-spectrum agent that leverages the innate immune system to prevent upper respiratory tract viral infections (colds and flu) and is designed to help the large number of patients that suffer substantial morbidity and mortality as a result of upper respiratory viral infections.

A successful proof of concept study of the compound was conducted by Janssen using hVIVO's platform in 2013-14. PrEP is developing infectious disease products and technologies licensed from Janssen and will take the compound's development forward. It will conduct phase IIa studies in flu and asthma patients in hVIVO's facility during 2015 and 2016, further leveraging the hVIVO platform's speed of trial conduct and ability to generate clear efficacy signals.

Licence

With this investment, hVIVO takes a significant stake in a new company developing a product that hVIVO has already helped to advance and is well placed to support in transitioning into later phase trials in at-risk patient groups.

Janssen is granting a worldwide license to PrEP in exchange for equity in PrEP, together with downstream milestones and royalties. hVIVO is acquiring equity in PrEP for £14 million and PrEP is contracting with hVIVO Services Limited to conduct a £10 million phase IIa clinical programme of work in 2015 and 2016.

hVIVO's investment will be accounted for as an investment in associate in its balance sheet and, in the application of the equity method as an associate, the £10 million phase IIa clinical programme of work will be recognised as revenue.

hVIVO CEO Kym Denny said: "We are delighted at the response and immense support we have received from our shareholders to raise these funds. This has been a remarkable year, one where the growing recognition regarding the value of the hVIVO platform culminated in our PrEP Biopharm announcement and we gained access to an innovative Phase IIa compound, PrEP-001."

hVIVO is exploring a technology platform of human disease models to speed up drug discovery and development in respiratory and infectious diseases.

hVIVO hires Mandy Higgins as Business Development Director for Europe

hVIVO has appointed Mandy Higgins as its new Business Development Director for Europe, working predominantly across the UK and Western Europe.

She joins from BARC Global Central Laboratories where she held the position of Executive Business Director. At BARC, Mandy was responsible for generating new business within the UK, Scandinavia and Israel in addition to looking after further key accounts outside of these locations.

Mandy comes from a lab background, having held roles at ICON Central Laboratories and at PPD Global Central Labs. Mandy's role at hVIVO will see her focused on its human challenge models services business.

Mandy said: "I am delighted to join hVIVO and look forward to working with the team."

Biorelevant set to launch new product in January



Biorelevant, the makers of powders which simulate the juices found in the stomach and small intestine, is launching a new product in January aimed at the veterinary canine market, which has the potential to reduce the need for invasive animal testing.

The Biorelevant team, headed by brothers Daryl and Louis Leigh, took up residence at QMB in July, taking over 800 square feet of purpose built lab and office space.

As the name suggests, the Company's products test the 'biorelevant' solubility and dissolution of drugs, predicting how they will react in the human body. Their powders simulate the juices in the stomach and small intestine both before and after eating – the so-called fasted and fed states - by replicating very closely what is happening inside the gastrointestinal tract.

"We're working hard to introduce an exciting raft of new biorelevant products with amazing predictive power that will transform the way oral drugs in particular are developed, and we've got an exciting new product which we are launching in January," Daryl told QMB.

Fast Dog

The new product - Fasted Dog - is a complex powder made up of different bile salts and phospholipids. The new solution will simulate the conditions of the fasted, or without food, canine stomach and intestinal fluids.

"We've got veterinary customers but they tend to buy the human version and then marry it up with the dog. But this is a specific product for the veterinary industry and for developing dog medicines," said Daryl.

"Fasted Dog" will be used to investigate drug behaviour by indicating how and to what extent a drug enters the bloodstream. It is hoped the product will ultimately improve and decrease drug investigations on dogs, essentially doing away with invasive investigations, and hopefully moving the pharmaceutical industry towards reducing tests on animals.

"Fast Dog is an accurate simulation of the dog's intestine and stomach and we believe it will provide a viable alternative for the clinical testing of dogs. So it could be really helpful in saving money and more importantly, saving the lives of the dogs," said Daryl.

Biorelevant is a spin-off from a contract research organisation and has close ties with Goethe University of Frankfurt. 'Biorelevant media' has been around as a testing tool for quite a few years, but Daryl and Louis saw an opportunity to

commercialise it globally and three years ago decided to move the business back to the UK.

Their client list now reads like a Who's Who's in the world of pharma, with customers in industry and academia stretching from North America, Europe, the Middle East and beyond.

Educate

"Most of our business is centred in Northern Europe and North America, because the institutions there are possibly more in tune with what we can offer and how it's developing as a tool, but we're seeing really good growth in Asian markets as well. Our challenge is to educate the industry about the benefits of using accurate biorelevant media," said Daryl.

Biorelevant's products include FaSSiF, FeSSiF and FaSSGF which, to date, have focussed almost exclusively on products for human ingestion. Their products' close similarity to what's inside the human body makes them very valuable for pharmaceutical companies (CROs, Drug Developers and Generics Manufacturers in particular) but also extremely helpful to the Functional Food, Vitamin and Medical Device industries.

The team includes Warren Peakin as head of logistics and Mark Berlin, who joined in July from Goethe University of Frankfurt, where he worked with Professor Jennifer Dressman. Mark has also just completed his PhD in Biorelevant Media.

The Company is also being advised by their father, Steven Leigh, an industrial pharmacist with a long and successful history in the industry. During his student days, Steven came up with the idea for a night-time remedy for colds and flu which eventually became Night Nurse. He also came up with the Witch Doctor Skin Treatment range, including Witch Hazel.

The Biorelevant team used to be based on an industrial estate in Croydon, which suited their needs at the time. But as the business expanded, they made the decision to move closer to London. So why choose QMB as a base?

"We're a pharmaceutical business but we're also a pharma tech business, so we really like the physical location and the fact we're in an innovation centre. That really appealed to us. We're also planning to hold seminars and workshops at some point next year, so the facilities at QMB will really help with showcasing what we're doing," said Louis.

Daryl added: *"Queen Mary University of London is one of our customers from before we moved in, and I think going forward, maybe in the next year or two, we would like to work more closely with QMUL. It's got a very good Pharmaceutical course, so being so close to the University will also help us with recruitment as we expand the business."*

MediWise makes strides



Themos Kallos

MediWise is making great strides on a number of fronts having recently completed its first animal trials for its non-invasive glucose monitor, GlucoWise, and securing funding from InnovateUK for a number of other projects.

GlucoWise is a first of its kind glucose monitor which safely detects the concentration of glucose in the blood stream without having to draw a blood sample. The trials were held at Northwick Park Institute of Medical Research in north London in July 2015, overseen by Themos Kallos, MediWise's Chief Science Officer.

The trials were conducted on pigs as they can be safely sustained in a hypoglycaemic state, which, for humans, might prove fatal, but is perfectly harmless for the pigs.

"We chose pigs for two reasons. Firstly, you can sustain lower glucose levels in pigs which in humans you are not allowed to do, so it was a good test to see how sensitive our device is. It's very easy to measure high glucose levels, but it's when glucose levels are low that you get a real test. Pigs allow you to do that because they can be sustained in what, for humans, would be a hypoglycaemic state but for them it's perfectly healthy," said Themos.

The trials compared the accuracy of MediWise's non-invasive glucose measurement method against the highest accuracy lab based method available (ILab 650 Chemistry Analyzer).



Nadine Geddes

The GlucoWise monitor works by gently cradling the skin between the thumb and the index finger. Once the monitor is in place, the user simply presses the end of the monitor to begin. In the final clinical device, it is hoped that, after a few seconds, an accurate reading of the user's current blood glucose levels is displayed on the device.

Correlation

The animal tests proved there was a clear correlation between the glucose measurement in the GlucoWise prototype and the lab analyser. The test showed they were able to detect similar glucose levels without drawing any blood.

The plan now is to press ahead with the first human trials in early 2016. These will be conducted in collaboration with Dr Richard Mackenzie at the University of Roehampton in south of London and managed by Themos and Nadine Geddes, a fellow co-founder of the company.

The trials will involve a controlled study of healthy human subjects. The trials will compare the accuracy of MediWise's non-invasive glucose measurement method against the traditional finger prick monitors, as well as the highest accuracy lab based method available.

As well as GlucoWise, MediWise also has two other products in development: MammoWise, a breast cancer imaging system, and MetaSurface, which aims to cut down on the time it takes to do a MRI scan by at least 50%. MetaSurface was patented in July.

"The MetaSurface technology has been patented and we're now developing our first prototype ahead of conducting our first trials hopefully some time in late 2016," said Themos.





Funding from InnovateUK

The company has also received nearly £700,000 in funding from Innovate UK, formerly known as the Technology Strategy Board and sponsored by the Department for Business, Innovation & Skills, to explore projects in each of the three areas the company is pioneering its research.

For example, the team is developing a material called MetaSurface - or "smart" material technology, which is a proprietary non-ferrous metallodielectric grid compact structure. The team is investigating the feasibility of this breakthrough invention to drastically increase MRI efficiency by improving its signal-to-noise ratio (SNR).

It is a thin mat-like structure, positioned underneath a patient's body as they lie flat on the MRI table. It is a passive device with no electrical or mechanical parts and can be easily repositioned or moved from one machine to another.

The project will expand on preliminary experimental and pre-clinical data and will deliver a new prototype to be used on human subjects for the first time. The technical feasibility study will demonstrate MetaSurface's performance enhancement reporting on SNR, MRI image acquisition speed, sensitivity and image resolution.

MetaSurface is also machine-agnostic, which means it can be used with any commercial MRI scanner for any field-strength and has the potential to increase the patient throughput by 50%, which could translate into millions of pounds worth of cost savings per year for the NHS.

MammoWise

For MammoWise, the team is also looking to develop a new medical imaging prototype based on microwave imaging (MWI) for cancer detection, particularly in breast cancer.

MWI uses low-power, non-ionizing radio frequency microwaves to obtain clinically meaningful images in a way that addresses the patient's needs for speed, safety and comfort.

While there is considerable progress in medical MWI systems under development by various research groups worldwide, there is no commercial MWI system available today.

"The proposed prototype will be designed around the patient experience to deliver a pain-free, safe and accurate system. The novel clinical prototype targeted by this project will be first applied to breast cancer screening," said Themis .

The research will allow younger patients - aged 20 and over - to be screened as often as they wish and to be monitored for a longer period of time, thus maximising the success rate for the early screening of cancer.

"This is an important benefit that is currently not available in a cost-effective, safe and sustainable manner using today's technology. So we're very happy with the progress we've made so far. We've been very efficient with the use of our funds and we look forward to reporting on our progress in due course," said Themis.

Interview with **Dr Phillip Howard,** Chief Scientist, Spirogen

Spirogen's journey from nomadic research unit to the forefront of antibody-drug conjugates (ADC) research has been remarkable, but it also mirrors the career of its Chief Scientist, Dr Phillip Howard.

Following an undergraduate degree in Applied Chemistry in 1982 at Kingston Polytechnic, Howard completed a PhD at the University of East Anglia in synthetic chemistry, an area of research that even he describes as "very, very esoteric".

After his PhD, Howard went to SmithKlineBeecham (now GlaxoSmithKline) to conduct post-doctoral research in north London. From there he moved to Portsmouth University to work with Professor David Thurston who, since 1987, led the research into pyrrolobenzodiazepine (PBD), and John Hartley, now the Professor of Cancer Studies at University College London (UCL).

Howard joined the team in 1993 to work on Spirogen's now proprietary PBD molecule which, once attached to an antibody, can directly target chemotherapy at the tumour. These highly potent cytotoxic agents, or 'warheads', attach themselves to specific cancer-targeting antibodies using biodegradable 'linkers'. This targeting optimises the delivery of the cancer drug to the tumour cells only, and provides the greatest degree of tumour killing while minimising the toxicity to the patient.



➤ Dr Phillip Howard, Chief Scientist, Spirogen.

How did he make the leap from synthetic chemistry to working on ADCs?

"My PhD was so esoteric that, whatever I did afterwards was always going to be a huge leap. But what I'd always wanted to do was to work in pharmaceuticals and cancer therapy. Whereas my PhD was about how you made something, at SmithKline it was simply about just making it. It was about using whatever chemistry you had at your disposal, using whatever's going to work, to make that molecule. So that really broadened my horizons, it was a real education," said Howard, who serves as Deputy Director of the Cancer Research UK Gene Targeting Drug Design Research Group.

Spirogen's journey has been no less impressive. While the bulk of its research took place under Professor Thurston at the University of Portsmouth, Spirogen was technically "founded" at the University of Nottingham, in conjunction with Cancer Research, or Cancer Research Campaign as it was known then.

Thurston's PBD research group moved to Nottingham University in December 2000, but when Nottingham accepted £3.8 million in funding from British American Tobacco (BAT) for a new 'International Centre for Corporate Social Responsibility', the political fallout was considerable.

News of the donation led to the resignation of Dr Richard Smith as Professor of Medical Journalism from the

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university. More crucially, Cancer Research cancelled a £1.5m fundraising appeal to replace out of date buildings, and Thurston announced that his research group would also be making tracks.

Dr Chris Martin, an entrepreneur and chemical engineer, joined the team as Chief Executive around the same time and Spirogen was born. Responsible for fundraising, it was Martin's commercial drive that culminated in Spirogen's \$200 million deal with MedImmune in 2013, and its entry into Astra Zeneca's family of companies.

"It's been a very exciting and fruitful collaboration with MedImmune. We'd worked with their scientists prior to the acquisition, so the deal has given us the opportunity to broaden and deepen our relationship. We now work very closely with MedImmune's scientists in Gaithersburg, Maryland, but also up the road in Cambridge," says Howard.

Since the acquisition, Spirogen's headcount has, give or take, remained steady at 25. These include conjugation chemists specialising in joining the small molecule to the antibody, biologists to test the molecules, analytical chemists to check that the molecules are doing what they think they should. While in the early days it was all about the chemistry, Howard concedes the biology now represents the future side of the research.

"Most projects in big pharma companies are biology driven, but in the early days of Spirogen it was really driven by what PBDs we could make. So for us, it was all about the chemistry. Although the chemistry side of the research has been a constant, ever since our days at Portsmouth, our biological expertise from UCL has been invaluable, and it'll become increasingly more so over time," said Howard.

Much of what Spirogen is working on is bound by confidentiality agreements. However, what is in the public domain is that, through collaborations, it has two ADCs currently in clinical trials. In December 2014, Seattle Genetics presented data from an ongoing phase 1 clinical trial evaluating SGN-CD33A, an ADC in development for the treatment of acute myeloid leukaemia (AML), an aggressive type of cancer of the bone marrow and blood which can progress rapidly without treatment.

"The Phase 1 trials we've seen at Seattle Genetics are very encouraging," said Howard.

Spirogen's work saw them scoop Best Scientific Innovation at the World ADC Awards in San Diego in October 2014. The awards showcase excellence within antibody drug conjugate research, rewarding innovation, leadership by companies, teams and individuals in the industry.



➤ *The bulk of Spirogen's research took place at the University of Portsmouth*

ADCs are a massive game changer in how cancer is treated, potentially reducing and, in some cases, eradicating the need for chemotherapy and its debilitating side effects. To date, just two ADCs have been approved for patient use; ADCETRIS, for Hodgkin lymphoma and systemic anaplastic large cell lymphoma, received approval from the U.S. Food and Drug Administration (FDA) in 2011, and T-DM1 (Kadcyla) for breast cancer, in 2013. Yet there are currently 40 to 50 new compounds in clinical development, meaning many more ADCs could be on the market within five years.

Still, back when Professor Thurston and his team began working on PBDs, there wasn't much of an appetite from Big Pharma to get involved in ADCs, despite there being a massive unmet clinical need. Howard says this was probably because the chemotherapy agents being used were so different from the mass market agents that were generally being used to lower cholesterol or control stomach acid pH. What changed, he says, was a fundamental change in biological research.

"Through biological research we've been able to develop a much better understanding of the signalling pathways in cancer cells, and that created targets which the big pharmaceutical companies now feel they can go after. Now, whether its large, medium, small or even a start-up company, virtually all of them have got some application against cancer, and they're all different strategies and ideas. That's so different from when I got involved," said Howard.





WHAT DOES THE LIFE SCIENCE SECTOR WANT FROM THE NEW LONDON MAYOR?

London's Life Science Sector has made great strides in the last 10 years, with millions of pounds spent in developing the capital's science infrastructure and capability.

Ken Livingstone, the first London Mayor, used the London Development Agency as a delivery vehicle to create "BioLondon" as a brand, overseeing and coordinating the creation of incubator space and grow-on space in the capital, while Mayor Boris Johnson oversaw significant change in governance of London's economic development landscape.

London now boasts state of the art business incubation and R&D space allied to world-class higher education institutions and leading specialist teaching hospitals. But the prevailing mood in the industry is that the government could be doing a lot more to realise the capital's scientific potential, tapping into the wealth of expertise already in London and making the city a world leader in scientific research.

Challenges

The next Mayor of London, from whichever political party they come from, will have their work cut out when they take up the position in May 2016. But the challenges facing London are also similar to the challenges facing the life science industry: a lack of funding, sky high rents, a paucity of affordable accommodation, a lack of space to grow an innovative business and training and retaining the best and brightest people. QMB therefore asked a panel of experts: 'what does the Life Science sector want from the incoming Mayor?'

The event was part of QMB's BioWednesday, and co-hosted with One Nucleus. It covered topics like the need for commercial R&D space, an investment fund for Life Sciences in London, tax incentives to encourage company growth and the coordinated promotion of London's Life Sciences offering.

To a packed house of industry professionals, One Nucleus' Tony Jones directed the questions at Ken Powell, Executive Chairman of reViral Ltd; Nigel Banister, Director, Science Developments Ltd; Professor Bill Spence, Vice Principal (Research) Queen Mary University of London, and Nigel Stokes, Managing Director at deltaDOT.

Tony Jones asked the panel what the main issues were facing the London Life Science sector and if it was important for companies to retain a laboratory base in London.

Nigel Banister said the main issue the sector faces in London is around finding space and securing funding. Banister noted that between 2005 and 2009 the London Development Authority invested around £40 million in the London Life Science Sector, which was matched by another £40 million. But those days are gone, said Banister.

"We may have incubators which weren't there in 2005 but we still haven't got space for the companies to move out or move into, and it will now be even harder to solve the [capacity] problems facing the sector under the present economic climate," said Banister, who was the Head of Science and Technology for the London Development Agency and responsible for creating investment programmes to boost business growth from London's knowledge base.

Unique

He added that London is unique in terms of the UK in that it is the only region where there is more university research than business research.

"The scale of the university research in London is bigger than Oxford and Cambridge and those surrounding areas put together," said Banister.

Ken Powell, Executive Chairman of reViral Ltd, said that while space was an important issue, the biggest problem facing the sector in London was finding the right people to launch a life sciences business.

"While it's limited, there's always space, it's just a matter of persuading somebody to give it up. But that's not the biggest problem. The big problem is actually gaining access to the kind of entrepreneurial energetic, young scientific staff that you need to get companies going," said Powell, who has set up several companies over the years and was the Founder and CEO of Arrow Therapeutics, a specialised antiviral drug discovery company which was sold to Astra-Zeneca PLC in 2007 for USD\$150 million.

EVENTS

Discovery

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NEWS, VIEWS AND EVENTS AT QMB

Powell said the new Mayor needs to make education and entrepreneurship training a top priority when he takes up his role in May 2016.

"What we need is more entrepreneurship training. A lot of people would say you can't train entrepreneurs but we have an awful lot of redundant chemists and biologists who, with the right training, could be the seed stock for a new realm of biotech companies. It happens in the US, why doesn't it happen here? Why don't people think they can set up their own company and do it?" said Powell.

"What I would ask the Mayor to do is to look at education. Why do we have the silicone roundabout phenomenon in London? Does it have anything to do with politicians? Well, actually no, nothing at all. Kids do what they want to do, and right now it's about computer design and innovation in ecommerce," Powell said.

Queen Mary University's Bill Spence said there are opportunities around proof of concept grants and funding, but universities' hands are restricted in where they can put their money, which makes any initial investment difficult.

"Universities can pull resources into that but they're under a lot of pressure at the moment to put resources into student support. And, in the sense, the students are paying for their education, they've got to have decent resources and high quality education, which is perfectly right. So it's hard for universities to divert large sums of money into some of these concepts. We try but it's not enough to really make any difference," said Spence.

Tony Jones asked if the new Mayor should explore the possibility of a strategic investment fund similar to the £10 billion megafund announced by Mayor Boris Johnson in June to encourage the growth of emerging health-care companies in the U.K. in an effort to catch up with the biotechnology clusters in the U.S.

"That would be fantastic but I wish he'd start with a £1 billion investment fund and then move on to the £10 billion. I think it's just a headline. Sadly, I don't honestly ever believe that it will ever materialise," said Banister.

Nigel Stokes said the hefty business rates seen in London could be put to good use under new legislation announced in October which will allow councils in England to keep the £26 billion raised from business rates through devolving political power from Whitehall to local government.

"There could be an opportunity for the new Mayor to knock a few heads together, particularly in the central London boroughs, and say: look, you're going to lose this money unless you can come up with something to do with it. And it could be that is the way of funding facilities and accommodation for life science personnel," said Nigel.

He added: *"The strategy of the Mayor has always been to support Life Sciences as an alternative model to finance in London. And that's a bold aspiration. So if he wants to do something positive, the next Mayor should grab this money and do something with it."*



R&D AND THE SPENDING REVIEW

The research community was braced for bad news in November's Spending Review, but it never came to pass. With the unprotected Department for Business, Innovation and Skills (BIS) expected to face severe cuts, the announcement of a 17 per cent cut was less than many feared. George Osborne then followed this with a commitment to protect the budget for science "in real terms so it rises to £4.7 billion."

Other research-related announcements in the spending review include:

- A new £1.5 billion Global Challenges fund to ensure UK science takes the lead in addressing the problems faced by developing countries;
- £5 billion invested in health research and development, as well as up to £150 million to launch a Dementia Institute and a new £1 billion Ross Fund, partnered by the Bill and Melinda Gates Foundation;
- A Global Antimicrobial Resistance Innovation fund, to be launched in partnership with China;
- £250 million for the 100,000 Genomes Project to introduce whole genome sequencing technology in the NHS;
- Innovate UK will be brought into the new Research UK umbrella body and some existing Innovate UK grants will be replaced with loans, to reach £165 million per year by 2019-20, so that total support is maintained in cash terms;
- A reaffirmed commitment to long term science capital investment of £6.9 billion between 2015-2021;
- Taking forward the recommendations of Sir Paul Nurse's independent review of the research councils which, subject to legislation, will introduce a new body – Research UK – which will work above and across the seven Research Councils;
- In addition, government will initiate a review of the Research Excellence Framework in order to examine how to simplify and strengthen funding;
- No further announcements on departmental R&D, despite plans for this in the Government's 2014 Science and Innovation Strategy.



Sajid Javid invites applications to conduct science and innovation audits across the country.

We'll soon have a clearer idea of what scientific know-how we have, as Business Secretary Sajid Javid recently unveiled plans for a new national panel of innovation expertise alongside a regional review of the UK's science capabilities.

Speaking at Innovate UK's Annual Conference, the Business Secretary explained that the national panel would help to direct funding to improve the outcome of investments in innovation.

He also invited applicants from across the country to conduct science and innovation audits for their region. These audits will map research and innovation strengths, highlight areas with competitive advantages and provide an evidence base for decisions about innovation.

The move is the next step in plans to make Britain the best place to innovate in Europe. The government has committed to invest almost £7 billion in science capital up to 2021. However, Javid is said to be considering converting some or all of Innovate UK's £600 million annual budget into loans. If he presses ahead, it is feared that companies might move elsewhere in Europe where grants are still available.

Javid said: *"The UK is embracing new technologies and leading the world in innovation, but we must not be complacent and must look to the long term future of research and development to support our jobs and industries."*

"As a one nation government we want every region of the UK to maximise opportunity for its local people through its innovation strengths, and the new science and innovation audits will ensure that public investment is doing just that. By taking stock of our assets and supporting best practice and expertise, we will propel the UK to the forefront of the global innovation race."

The Business Secretary also revealed plans for a new Smart Specialisation hub, which would see experts, businesses, universities, investors and Innovate UK's Catapult networks working together to share best practice.

Jon Rees, CEO at OBN said: *"Taken together, the public markets and venture financing data combined demonstrate the resurgence of financing in UK life sciences. However, the relatively small proportion raised for enterprise financing rounds strongly supports the case for continued financing mechanisms to support innovative R&D firms through the equity gap, such as the Biomedical Catalyst. Nevertheless, OBN welcomes this banner year for UK life sciences."*

Jim Mellon, entrepreneur and fund manager said: *"This latest research confirms the record year that we are having in the life sciences sector. Building on the very high levels of mergers and acquisitions we've seen in our existing fund, these new funding rounds will give us many more companies to look at as potential investments for our new fund."*



LIFE SCIENCES M&A SEES NEW HEIGHTS IN 2015

This year we have seen record-setting activity in both the frequency and value of M&A deals involving pharmaceutical companies, and in the Life Sciences sector in general.

According to a report published by PricewaterhouseCoopers, the combined value of closed M&A deals in the Life Sciences and Pharmaceutical Sectors surpassed USD \$320bn in the first three quarters of 2015.

Indeed, US drugs giant Pfizer Inc recently agreed a deal to buy Botox-maker Allergan PLC for \$160 billion (£103 billion), making it the biggest pharmaceuticals deal in history. The merger will see the company renamed Pfizer PLC to create the world's biggest drug maker by sales.

The takeover will also be the largest inversion ever. Such deals enable a U.S. company to move abroad – in this case Dublin - to take advantage of a lower corporate tax rate elsewhere, and have remained popular in the face of U.S. efforts to curb them.

Last year, Pfizer made an offer to buy UK drugs group AstraZeneca, which rejected the offer, arguing it undervalued the company.



Pfizer boss Ian Read will be Chief Executive and Chairman of the merged company, with Allergan boss Brent Saunders becoming president and chief operating officer.

"The proposed combination of Pfizer and Allergan will create a leading global pharmaceutical company with the strength to research, discover and deliver more medicines and more therapies to more people around the world," said Mr Read.

The merger will create a pharmaceutical behemoth, with top-selling products including Pfizer's Prevnar pneumonia vaccine and Allergan's anti-wrinkle treatment Botox and industry-topping R&D budget. The company's drugs and vaccines would cover a range of diseases, from Alzheimer's to cancer, eye health to rheumatoid arthritis.

The deal brings together two pharmaceutical powerhouses with more than \$60 billion in combined sales. Last year, Actavis, which bought Allergan and took its name, had more than \$13 billion in sales, while Pfizer had nearly \$50 billion in revenue.

A finalised deal would be the latest in a series of mergers and acquisitions in the sector, as pharmaceuticals companies struggle to cope with patents on a number of major drugs expiring, while a better understanding of genetics and disease has led to more targeted medicines with a smaller market.

Against this backdrop, Biopharm Insight and Mergermarket recently issued a report titled **"Life lines: Life-sciences M&A and the rise of personalised medicine."**



Record-setting activity of M&A deals.



The report surveyed 100 senior executives (CEO, CIO, Director of Strategy) in biotechnology and pharmaceutical companies across the US (34%), Europe (33%), and Asia (33%). The representation by company size was \$100m-1bn (34%), \$1bn-5bn (33%) and \$5bn+ (33%).

Based on their research, the survey concluded:

Focus on Asia: 28% of those surveyed indicated that their next acquisition was most likely to target an Asian company, 19% of respondents indicated intentions to acquire companies based in North America and Western Europe.

Drug discovery/R&D and diagnostics in demand: Over 70% of respondents indicated drug discovery, early stage R&D, and a focus on diagnostics as the factors major pharmaceutical producers will most likely look for when selecting candidates for acquisition.

Personalised medicine on the rise: 26% of respondents indicated that they saw an opportunity to charge higher prices for more targeted drugs, and 24% suggested that personalised medicines allowed them to make more convincing cost-benefit cases to buyers than conventional pharmaceuticals.

Brain drain: 69% of respondents cited the monetary costs of retaining high-level scientific/R&D expertise as a major challenge in sustaining a broad drug portfolio, and 56% indicated their ability to maintain and support multiple specialist sales teams as a chief concern.

The report concludes that, partially due to the favourable financial climate, the M&A boom in life-sciences is likely to continue, and that the volume of deals in 2015 is on track to surpass last year's results. However, the report's authors also advise caution. The shape of the life-sciences sector of tomorrow remains unclear, regulatory regimes in key markets are likely to see change, and many survey respondents indicated that they were anxious about economic and political uncertainty.

QMI files patent for biomarkers in detection of pancreatic cancer



Queen Mary Innovation (QMI) has filed a patent application for the detection of pancreatic cancer.

Dr Tatjana Crnogorac-Jurcevic and her colleagues have identified three novel biomarker proteins that have shown to be associated with early-stage pancreatic cancer in a urine-based test, with more than 90% accuracy.

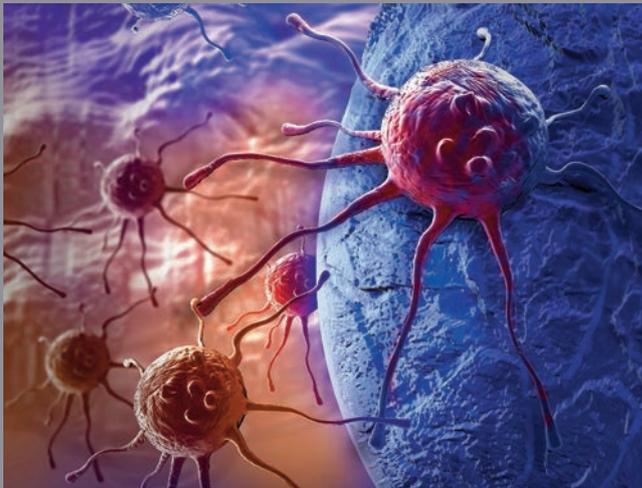
Pancreatic cancer is associated with poor prognosis. If pancreatic cancer is diagnosed at Stage 1 the survival rate for tumours can be up to 60% yet currently only 6% survive beyond 5 years due to the fact that there are usually no early warning symptoms of the disease and reliable diagnostic tests do not yet exist. When diagnosed, the majority of patients display locally advanced disease or have established metastases and so surgery is possible in only 10-20% of patients.



Dr Tatjana Crnogorac-Jurcevic and her colleagues published the study in the 'Clinical Cancer Research' journal (1 August 2015). The researchers analysed 192 urine samples from patients with pancreatic cancer, alongside 92 samples from patients with chronic pancreatitis and 87 samples from healthy individuals. The team also assessed 117 additional samples from patients with other benign and malignant hepatobiliary conditions.

The team identified around 1,500 proteins in the urine samples. Three of these - LYVE1, REG1A and TFF1 - were found at significantly higher levels in the urine samples of patients with pancreatic cancer, compared with the samples from healthy individuals.

Patients with chronic pancreatitis, however, had much lower levels of all three proteins in their urine than patients with pancreatic cancer.



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