SUPER NORTH

Call to action

PM told of need to accelerate NHS adoption of new medical products

by **Mike Cowley**

PRIME MINISTER THERESA MAY HAS BEEN advised that unless the booming life sciences sector is given better access to help the NHS with innovative products, not only will the Health Service continue to suffer but some UK medical companies will struggle to stay in the UK as they grow.

The message was delivered by Bernard Ross of Sky Medical Technology, a leader in deep vein thrombosis (DVT) prevention and wound healing, who was part of a delegation of members from Bionow in a round table discussion chaired by the PM. Bionow is the voice of the Northern life science sector which contributes £10.9bn to the UK economy and employs 38,000 people across 1000 companies.

He explained further: "If the NHS accelerates its evaluation and adoption of new medical products UK medical companies will be encouraged by their investors to stay and grow in the UK rather than be pressurised to relocate operations overseas to markets that adopt new medical products faster."

The comment came during a meeting chaired by the PM following her first regional cabinet meeting held at STFC's Daresbury Laboratory, part of the Sci-Tech Daresbury campus, at which she launched her Government's new Industrial Strategy consultation and announced a further £556m injection for the Northern Powerhouse.

Whereas much praise was given for tax credits and EIS schemes by attendees, she was left in no doubt about the challenges facing the life sciences sector including the need to open up the NHS market and tackle the long-term skills shortage. While the Government should continue to support businesses with grants and incentives for innovation it must also enable scale-up to turn innovation into sustainable jobs, growth and prosperity for the future.

The select nine-strong SME invite list for the discussion also included Bionow members Samantha Westgate of Perfectus Biomed, a microbiological contract testing company working in health care and Jan Rogers of Arcis Biotechnology, experts in DNA sampling, who were joined by Dr Diane Cresswell, Bionow's Executive Director Business Development.

The venue for the high security meeting was Daresbury's new Campus Technology Hub, a state-of-the-art advanced engineering centre, specialising in additive manufacturing, where Bionow has a presence.

All this revealed the growing importance of Bionow, which was formed almost six years ago and has built relationships with eight university sponsors and a further seven university members facilitating engagement and collaboration.

Bionow's northern company members are consistently among the high performers in the UK and appropriate measures within the Industrial Strategy will amplify and build on the success to date:

- Redx Pharma plc, the UK's fastest growing biotech company which listed on AIM in 2015 raising £15m which valued the company at more than £50m. Last year it raised a further £10m and grew to 190 employees.
- Premaitha Health which generated £2.5m in sales in 2016, the first full year of commercialisation of its IONA non-invasive prenatal test for Downs Syndrome.
- Zilico, its Zedscan device used in the diagnosis of cervical cancer has been adopted by hospitals across the UK and has recently secured funding to develop a new device to detect oral cancer.
- Shield Therapeutics, which began trading on the AIM market after completing a £32.5m fundraising in 2016 and the launch of Ferracru®
- Manchester Science Partnerships, which is transforming the 400-acre former AZ site at Alderley Park into a world-class hub for the life sciences.

"Our members have shown what is possible with early stage support and we welcome that Life Sciences remains a priority sector for this Government and the Prime Minister," says Dr Geoff Davison, CEO of Bionow.

"But the UK has not capitalised on its innovation and we are now looking to the Government to unlock opportunities to deliver growth. Routes to faster commercialisation must be found and changes to government procurement policy – specifically harnessing the purchasing power of the NHS – are needed to drive SME growth in Life Sciences."

Salute to advances in life sciences

The winners celebrate their success at the 15th Bionow Awards ceremony

Bionow acknowledges the support of the sponsors:

Bionow Awards sponsors: Appleyard Lees, AstraZeneca, The Innovation Agency, QIAGEN, RSM, Sci-Tech Daresbury, Seqirus, The Skills & Growth Company, TrusTECH and Waters.

Event sponsors: CY Partners, Manchester Science Partnerships, Redx Pharma and World Courier.

Outstanding innovations in the life sciences sector – which showcase major medical breakthroughs – were recently recognised at the 15th Bionow Awards Dinner

by **Michael Cape**

With longer life expectancy and the development of new treatments, all developed economies are facing sustained increases in demand and expectation and ever-rising healthcare costs. Harnessing the innovation of the buoyant life sciences sector, which is increasingly developing not only life-saving but often cost saving breakthrough products and projects will help underpin better health across the UK for all.

Several significant medical advances were judged outstanding at the 15th Bionow Awards Dinner – the annual showcase from Bionow, whose objective is to help write a new chapter in terms of health for the UK population – with each of them winning an industry "Oscar".

A sensor which rapidly diagnoses urinary infections in the elderly, so potentially reducing the number of hospital admissions; a revolutionary cardiac stent which "dissolves" in the body eliminating problems of rejection; a new way to enable genetic therapies on time and under budget – these are just three of the new wave of medical breakthroughs singled out for commendation in the North of England alone.

InfectDetect, the breakthrough sensor product from Manchester-based Microbiosensor, which won the Bionow Project of the Year in 2016, will save the NHS £9.5m per annum through reduced A&E admissions and hospitalisation costs for urinary tract infections alone.

A revolutionary metal alloy from Swinton-based Magnesium Elektron which "does its job then disappears" is currently being used for coronary implants and picked up the Bionow Product of the Year Award. Magnesium Elektron, a world leader in the provision of magnesium alloys for a range of industries including aerospace, has taken knowledge from another industry and applied it to healthcare *(see facing page)*.

Cobra Biologics picked up the Bionow Project of the Year award for the "Scalable AAV Production using Novel Hollow Fibre Bioreactors." In layman's terms it means this specialist medical manufacturer – based in Keele and the only facility of its type in the UK – can provide processes to enable gene therapies for life threatening conditions to progress to clinical trials at scale, on time and under budget.

The global challenges of antimicrobial resistance are being addressed by Perfectus Biomed, based at Sci-Tech Daresbury and winner of the Bionow Technical Service Award. Perfectus have developed a quality standard for laboratory testing that closely mimics medical bacterial contamination.

Also recognised for offering support was the Innovation Nexus from the Greater Manchester Academic Health Science Network. This won the Bionow Business Services Award for providing a single point of access to information, specialist support and funding to develop, test and deliver innovative products and services in collaboration with the NHS across Greater Manchester, East Cheshire and East Lancashire.

Naturally the success of the northern ecosystem has in turn spawned a new wave of start-ups. Aptus Clinical based at Alderley Park, specialises in the provision of expert clinical research professionals and carried off the Bionow Start Up of the Year Award. The company has already shown significant growth and has a client base which includes large pharma and newer, agile businesses like itself.

Raising funds – critical to any sector but more difficult in life sciences than others – has also benefited from the increasingly high profile of the Northern sector thanks to Bionow, with Manchester based anti-fungal company F2G securing investment of $60m. This will enable them to take a new class of anti-fungal agents to treat life threatening infection through to regulatory approval on both sides of the Atlantic. It also saw them pick up the Bionow Investment Deal of the Year.

But none of these success stories could have been achieved without a constant new wave of talent coming through to maintain the momentum for the life sciences sector in the North. Singled out as the Bionow Promising Technologist of the Year was Dr Bianca Price of the University of Manchester. Recognising existing soft tissue infection models were inadequate, she has developed an innovative "infected wound in a dish" which has helped evaluate novel wound fillers and antimicrobial dressings to the point where commercialisation is a very real possibility.

The winners are quick to credit their membership of Bionow as being a key part of their ongoing success. And not simply due to the direct help on offer but because the organisation is instrumental in facilitating an ecosystem in which they can all thrive. The future success of life sciences in the North – and hopefully its ongoing contribution to easing the burden for the NHS – still seems then to be in good hands.

Shield is setting AIM still higher

One of the pace-setters in the northern life science sector – Shield Therapeutics, named as Bionow Company of the Year for its ground-breaking work in providing solutions to as yet unsolved medical needs – has successfully gone into financial orbit.

The company has completed an Initial Public Offering on AIM, raising gross proceeds of £32.5m, with a further potential £17.5m in the pipeline. Since then Shield has launched its lead product Ferracru® in both the UK and Germany and significantly increased its head count.

To cap this all off, it has also recently reported its first UK revenues of £240,000.

"Shield Therapeutics is an exceptional example of what is possible from a company operating out of the North of England and we anticipate them continuing to go from strength to strength and leading the way for other key companies across the North" says Dr Geoff Davison, CEO of Bionow.

Pharmaceutical pioneer takes well-deserved bow

Whereas the life science sector in the North – as in the rest of the UK – thrives on the buzz of the latest breakthrough medical products which can transform patient health outcomes, none of this would have happened without the pioneers who helped lay the foundations for success.

One such person is Professor Alan Boyd, an active practising pharmaceutical physician for more than 30 years, having worked across all phases of drug development and therapeutic areas.

He has worked within large pharma and smaller biotech organisations, and to date has been involved in bringing around 15 medicinal products to market with experience that also extends to the development of biological, cell and gene therapy products.

More recently Professor Boyd has focused on growing a consultancy business to support biotechs and institutions focused on early development and translational medicine, supporting clients globally.

It was his contribution to the development of medicines and pharmaceutical medicine as an industrialist, an educator and an inspirational leader which saw Professor Boyd receive the Bionow Outstanding Contribution Award for 2016, the highest accolade in the sector.

In an honorary capacity, he is a Fellow, Board Member and former Chair of the Specialist Advisory Committee in Pharmaceutical Medicine at the Faculty of Pharmaceutical Medicine, Royal College of Physicians.

He was responsible for establishing the Postgraduate Specialty Training Programme for doctors in Industry and the MHRA, which has resulted in more than 300 doctors achieving Consultant Specialist status.

He is an Honorary Professor in Pharmaceutical Medicine at the College of Medical and Dental Sciences at the University of Birmingham, a Fellow of the Society of Biology and a Council Member of the Academy of Royal Medical Colleges.

Paul Treloar, right, presented the Bionow Outstanding Contribution Award to Professor Alan Boyd, centre

Graham Wardlow and Paul Lyon were prepared to take a decade-long journey in order to achieve a breakthrough product that has been enthusiastically received in the life sciences industry

Innovation that's getting to the heart of the matter

Magnesium Elektron has developed a unique alloy for devices that are revolutionising the treatment of difficult conditions such as coronary heart disease

By **Mike Cowley**

WHEN GRAHAM WARDLOW and Paul Lyon made their way to the stage to receive the Product of the Year Award on behalf of their company, Magnesium Elektron, at the Bionow Life Science Industry dinner – the ultimate accolade in what are the Oscars for the sector – for them it was not only a punch the air moment but also the final endorsement for a relatively high-risk, decade-long breakthrough project.

The revolutionary SynerMag® alloy developed by Magnesium Elektron, which carried off the top prize, is now set to make the company a leading supplier to the global bioresorbable metallic implant market because it dissolves safely in the human body.

It is currently being used as the key structural material in Magmaris, the world's first clinically proven, bioresorbable metallic cardiovascular scaffold, which is manufactured by Berlin-based Biotronik, a leading international manufacturer of implants.

Because it is made of magnesium, which occurs naturally in the body, the Magmaris scaffold has key advantages over conventional permanent stents that can develop complications. These are caused by the risk of activating the immune system, which can lead in turn to conditions known as late stent thrombosis and restricted coronary vasomotion, which are both as unpleasant as they sound. When the Magmaris device is used to repair an artery, the scaffold resorbs naturally up to 12 months after the procedure. It simply disappears after it has done the job.

The fact that one of Magnesium Elektron's SynerMag alloys is now used in a CE-approved device opens the door for this and further developments to be evaluated and potentially applied in a vast range of other medical implant procedures in which the implant is required only on a temporary basis. In fact, its full potential will only be exploited once the medical world has become fully aware of its capability and headed to Magnesium Elektron at its 35-acre plant in Swinton, Greater Manchester, to work out a joint solution.

Yet it is in the treatment of coronary heart disease where the benefits of SynerMag will first be realised. Since the early 1970s, major operations were performed to treat coronary heart disease. The move towards minimally invasive procedures and the implantation of stents to reopen clogged arteries has been a successful and positive step forwards. In more recent years, the desire to avoid restrictions and potential risks of permanent implants has led to the development of a product which will achieve the repair function of a stent, but then disappear.

That's why Biotronik's Vascular Intervention Division first approached Magnesium Elektron 10 years ago. The reason was obvious. Magnesium Elektron was already the established world leader in magnesium alloy production, holding more global patents on specialised magnesium alloys than any other company – and magnesium, because it is already present in the body and bioresorbable, was on the medical radar as a potential solution.

Magnesium Elektron was also known to have charted new metallurgical boundaries of magnesium alloy technology to take full advantage of magnesium's unique chemical and physical properties, including its strength and its high specific stiffness. And the company was already a household name in global industries including aerospace, its lightweight corrosion-resistant and flame resistant products having set an innovation standard.

The end result is that the range of products in which the company's solutions can be found appears endless – and possibly is – ranging from Apache helicopters to Rolls-Royce engines. It is currently working on a new range of lightweight seating alloys for airlines to help them meet their mantra of lower fuel costs and emissions.

It was the ability to apply the technology from its existing marketplaces to create the new platform technology for the life sciences arena which – according to Dr Liz Mear, Chief Executive of the Innovation Agency, which sponsored the Product of the Year Award – saw Magnesium Elektron get the nod against tough competition from other products, including those used to treat cystic fibrosis and iron deficiency anaemia in patients with IBS.

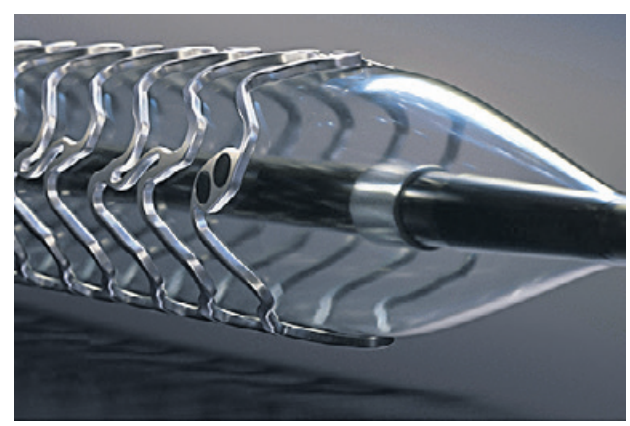
However, when Biotronik first came knocking in terms of finding a bioresobable magnesium implants, the life science arena was an entirely new and untried market for the British supplier. And as with any solution that involves patient health, it proved no easy ride.

With a significant track record in R&D – some 15% of Magnesium Elektron's 150-strong workforce in Swinton is dedicated to core research – the original thought was that it would take around five years to develop.

To find a solution, in addition to the core R&D that was undertaken by Elektron, the company invested US$2.5m in establishing a dedicated manufacturing facility, incorporating state-of-the-art laboratories, casting, extrusion and heat treatment facilities, and named it the SynerMag Technology Centre. No other comparable facility can be found anywhere in the world. This has enabled Biotronik to produce scaffold struts just 150 microns thick, around the thickness of a piece of paper.

During the life of the project, the company achieved ISO 13485 certification, an internationally recognised quality standard for medical devices – so ensuring partner Biotronik conformed to the required regulations.

Patients have already been treated using Magmaris scaffolds as far afield as Australasia, but as yet it is not available in the UK. Early last year, 55-year-old Trevor Fairhurst received a Magmaris bioresorbable magnesium alloy stent in his native New Zealand. The operation was urgent as 90% of one of his heart vessels had become blocked, causing ongoing angina and chest pain.


SynerMag alloys are made in a $2.5m dedicated manufacturing facility that is unlike any other in the world

"Since the procedure, I have felt over the moon, because the energy has returned, everything is coming back," he said in a subsequent interview after returning to work.

Meanwhile, the success of SynerMag has also fulfilled the vision of both Graham Wardlow, who took over as managing director for the company shortly after it diversified into the bioscience arena, and Paul Lyon, who heads up the programmes technology team.

When the two put together the team to run with the Biotronik programme, they set out a vision to become the world's leading supplier of bioresorbable metallic materials for the medical industry. With a unique capability to carry out core R&D in collaborative partnerships and then scale this up to full commercialisation, it is a vision that has been achieved.

"We have an amazing group of talented individuals who have a real desire to make something happen," says Graham Wardlow. "While we are very proud of our industrial heritage, in more recent years we have created a culture where we think of ourselves as a fresh, agile, technology company that is totally focused on the needs of our customers and capable of bringing new platform technologies to market."

Partners in healthy growth

A Manchester-based law firm has been central to the development of breakthrough technology at life sciences company Blueberry Therapeutics

Simon Wallwork at Slater Heelis which, unlike charging similar fees to larger corporate law firms, works on a fixed-fee basis on the principle that building long-term relationships brings its own rewards

by **Michael Cape**

When AstraZeneca announced it was to close down its North West operation in Alderley Edge back in 2013, the shock and awe headlines which followed masked the fact the move offered some benefits to the burgeoning regional life science community which had grown up around it.

These came in the form of research scientists who opted to stay and go it alone rather than pack up and move to Cambridge or by the sudden influx of talent that became available to local fledgling operations finding their way in the commercial world.

One company to benefit was Blueberry Therapeutics which had been set up two years earlier by CEO John Ridden, himself a former AstraZeneca Director of Discovery Sciences, to find a more effective ways of delivering drugs in order to reduce or even eliminate harmful or potentially life threatening side effects.

The AstraZeneca closure saw husband and wife team scientists Dave and Julie Cook move over to strengthen the Blueberry team at Alderley BioHub. Here they joined the focus on a breakthrough technology to reformulate a market leading treatment for fungal infection of the skin and nails, which came with serious safety problems including liver and gastric damage which, in extreme cases, had proved fatal.

Originally prescribed as a 250mg tablet to be taken orally, Blueberry Therapeutics have since successfully developed an effective formulation in the form of a revolutionary non-harmful spray which they aim to prove is just as effective. The product now has the potential to target a global market estimated to be worth $3bn in the US alone and this figure is based on treating only 20% of those who suffer from the condition.

Yet John Ridden readily admits non-scientist, lawyer Simon Wallwork of Manchester based Slater Heelis has been a key member of the Blueberry Team from the start. Slater Heelis is certainly not one of the big players in the corporate league although it is a well established name in the North, with its roots going back almost two and a half centuries and first coming to prominence when the firm represented the Manchester police after the Peterloo massacre.

However, Simon Wallwork just happens to be one of the most experienced lawyers in the life sciences sector in the UK, having cut his corporate mergers and acquisitions teeth on the listing of the Oxford Molecular Group plc more than 20 years ago. This subsequently lead to him working on several successful spin-offs including Sense Proteonic which became Lexus Therapeutics and over four funding rounds raised £15m and was eventually sold to a Belgian pharma company for up to £50m.

Today, as the head of Life Sciences for Slater Heelis, Simon Wallwork has a portfolio of 35 client companies. His division specialises in nursing start-ups through the legal and commercial minefield which they face in the early days, when they have little or no money for the fees charged by heavyweight corporate lawyers.

Instead Slater Heelis work on a fixed fee basis based on the principle that building long term relationships brings its own rewards.

It was Simon Wallwork who helped successfully steer the company through two rounds of funding to date and is currently working on the third to take the product to clinical trial.

The first round involved raising £1m pounds which came from high net worth individuals based in Switzerland. Next came a further £3m which was raised from a combination of UK venture capital fund Catapult, US venture capitalist Inclin Investments and further high net worth individuals.

An indication of the level of global interest in Blueberry was the fact that Inclin is based on the US West Coast where the largest cluster of life science companies in the world can be found.

Simon was also involved with John in attracting Andrew Kay to the chairman's role at Blueberry. Andrew had previously been on the pharmaceutical board of Novartis and over the past 14 years had many senior roles at Biotech most recently as CEO of one of Europe's largest Biotechs, Algeta, which was sold to Bayer for US $2.9bn in 2014.

Now Blueberry have advanced to the stage where they have won regulatory approval to move to human clinical trials to prove efficacy of the product, the company are seeking an additional £30m funding to support their phase III clinical development program in the US. Andrew Kay is expected to play a key role in this as he led the commercial team that brought the oral version of the drug to Blockbuster status while working at Novartis, a global healthcare company.

> *At Slater Heelis we tend to focus on start-ups, nursing them through the critical early stages*

Whereas Simon Wallwork has been actively involved in the commercial evolution of Blueberry, he points out there is a difference between the way his firm works in comparison to the household name corporate legal players.

"At Slater Heelis, we tend to focus on start-ups, nursing them through the critical early stages," he says. "These are companies with good ideas but who need help. There are not many law firms doing this sort of work as there is not much around in the way of fees. We take a view of building up long-term relationships, so we are happy to do things on a shoestring, fixed-fee basis."

So how does Slater Heelis pick winners like Blueberry from the losers in the burgeoning life science sector?

One way is to work closely with the leading universities in Manchester and Liverpool who often call on Slater Heelis to help spin-offs.

"We believe that if the university has decided there is merit in whatever the discovery is then who are we as lawyers to disagree?" he says.

It is this approach combined with Simon Wallwork's in-depth experience of the market over two decades which has seen him successfully ride the roller coaster experienced by the sector over that prolonged period.

When he first got involved life sciences 20 years ago, it was riding high only to go into a dip a decade later when a number of interesting projects failed to materialise and funding effectively dried up.

Today it is on a high once again as successive governments – and investors – have begun to fully appreciate its potential. The upsurge experienced over the last 10 years means it is now seen as a key area of the economy.

"To give David Cameron his due, he was one of the most proactive PMs in terms of life sciences. He saw it as a way to ease burden on NHS, so he set up the Life Sciences Office" recalls Simon Wallwork.

Nor has the resurgence been confined to the traditional life science clusters found in Oxford and Cambridge but has also seen it become a force in the North. This is reflected in Simon Wallwork's portfolio which was once predominantly made up of companies from the South – even though he has always been based in the North – but these have now been overtaken by firms closer to home.

The current excitement around life sciences in the UK in terms of investors is the realisation that if a company makes a breakthrough it will have a serious and often immediate impact on its bottom line. And then there is always the added frisson of the potential for further success for research-based companies.

Blueberry Therapeutics just happens to be one of these. For what it is about to achieve in terms of a treatment for skin infections is likely to be eventually eclipsed by its early stage work on blocking the resistance to antibiotics and creating new antibiotics, so solving a problem which is posing a threat to mankind as a whole.

This project will not only open up the use of old antibiotics but also facilitate the development of new ones – and early results give every indication that it works.

The company's plan then is to use its success in the skin infection markets to help fund an answer to a problem so vast that it is impossible to even estimate what it might be worth in commercial terms.

"And Simon Wallwork of Slater Heelis will remain very much an integral part of the Blueberry team that achieves this," says John Ridden.

For more information visit *slaterheelis.co.uk*

Allergan Biologics staff at the company's main site in Speke, Liverpool

On a mission to transform lives

Allergan Biologics is a leader in Growth Pharma and there is a buzz about the company as it tackles a series of debilitating diseases that have global effects

by **Mike Cowley**

When Linda Randall arrives at work in Speke each morning, a stone's throw from Liverpool's John Lennon airport, she could well be considered unusual in that she always starts her day with a sense of excitement as to what might lie ahead. However, she is not alone: so do all the other 100-plus white-coated development scientists to be found at the uber hi-tech, life science facility Allergan Biologics.

The buzz that seems to permeate the workforce is because they are all on a mission, which could help transform the lives of people who face a series of debilitating diseases which afflict a sizeable part of the world's population.

A potential treatment for macular degeneration, an age related eye disease which leads to blindness, and currently affects circa 200 million people worldwide according to The Lancet, is one of three key areas of development going on in the Liverpool suburb. The drug, Abicipar, is in the final stages of clinical testing and with the prospect that administration maybe as infrequently as every three months, some analysts are predicting blockbuster sales potential.

This Liverpool team are also focusing on gastrointestinal medical conditions such as Crohn's disease, which affects close to 250,000 people in the UK (NHS stats); and finally dermatology – including psoriasis – which the World Health Organisation estimates has 100 million sufferers globally.

For Allergan Liverpool is the R&D centre of excellence for the design and development of new biological drugs working with their sister lab in Irvine California. Alongside modern laboratories with state-of-the-art equipment, sits their modern multi-product clinical manufacturing unit that produces the bulk drug substance – the active ingredient in the pharmaceutical product, for use in groundbreaking clinical trials.

It is the UK R&D arm of Allergan plc, a global pharmaceutical company with headquarters in Dublin, Ireland and an administrative head office in New Jersey, USA, which is a leader in the new industry model – Growth Pharma. This sees it developing, manufacturing and commercialising innovative branded pharmaceuticals and biologic products for patients around the world including treatments for Parkinson's disease and Irritable Bowel Syndrome.

Operating in more than 100 countries, Allergan plc has more than 16,000 employees with a branded revenue for 2016 of $15bn and branded R&D investment of $1.5bn with a growth target of 10%.

Its CEO Brent Saunders is also on record as pledging that Allergan will conform to social responsibility in its drug pricing policy. Last year, Allergan Biologics celebrated its 10-year anniversary in Speke, the site has gone through a series of name changes through acquisitions which is not unusual in the pharma industry, but it is probably best known in the area as Eden Biodesign. This was launched in the early 2000s as a contract manufacturing business, and several of its original founders can still be found in senior positions at Allergan.

What makes Allergan Biologics different, if not unique, among pharma companies in the UK is that via its Open Science model it enriches the internal R&D pipeline through collaborations and partnerships enabling them to work on a full range of product technologies, such as antibodies and gene therapies. For Allergan's staff this offers the challenge to work in overcoming a wide range of technical problems that will deliver the products of the future.

Allergan's Linda Randall sits on the strategic advisory board of Bionow

Allergan has an open door policy in working with SMEs active in related drug fields in order to partner with them to achieve its and their objectives and welcome any approach.

The company also has a policy of acquisitions to meet its objectives with one of the latest deals involving the $60m up-front payment to purchase the Ann Arbor Michigan, US, based company Retrosense whose expertise includes gene therapy for an inherited rare eye disease which results in loss of peripheral and night vision, so essentially a perfect fit for Allergan as a leader in eye care. The team in Speke are now actively supporting the development of this exciting new therapy.

Investment at the site of some $90m in research facilities in general and analytic tools such as mass spectrometry in particular has ensured its scientists have the cutting edge techniques to understand these complex molecules, which is seen by many as the key to success. The company now has one of the most advanced Bioassay laboratories in the UK which was opened in September last year and the robots they have working is enabling them to speed up the development process.

Through their Open Science model they regularly work in close collaboration with Northern Universities including the University of Manchester, Liverpool University, Liverpool John Moores and the University of Sheffield.

Allergan actively takes in seven work placement students annually from the universities which is mutually beneficial to the company, the student and the university as well as sponsoring MSc and PhD students working in the universities.

And the company also has an eye on the future, with six apprentices on the payroll at any one time and its younger scientists regularly going out to speak at local schools and colleges about exciting career opportunities in pharma because of the pipeline of some 14 projects on which Allergan is currently working.

This is all part of ensuring that it is still very much part of the Liverpool and Northern scene to which it is making a significant contribution and which involves it working with Liverpool LEP and being a key member of Bionow – from who the site were previous recipients of the Company of the Year Award – the membership body which is the voice of the Life Science sector in the North and on whose strategic advisory board Linda Randall sits.

Yet what people might find distinctly odd outside the pharma sector is that Allergan Biologics has been up and running for all these years and has yet to see any of its projects get to market.

However, as the average length of time is in the region of a decade to get a drug to market this seems of little concern. But just how close are they to getting there? Confidentiality is critical to the industry so the company line is held at "late stage development" but it says "there is a healthy pipeline of drugs."

Though the potential for success in the near future may well account for the spring in the step of Linda Randall when she arrives at work each morning to pursue a career in drug development, she admits she fell into by accident. For when she left the University of Sheffield with a degree and a PhD in chemistry, she had no idea what she wanted to do.

"The first offer I got was from a drug company and that's how it happened," she recalls.

"But I have never regretted it for one minute. There is something about drug development and how it can affect people's lives; it is the difference it could make that makes it so exciting and fulfilling.

"Every day I am excited to go into work because of the scientific advances we will make in drug development and not everyone can say that ..."

For more information visit *allergan.co.uk*

Firmly focused on safety

Launched in 2008, Panacea has gained an enviable reputation in pharmacovigilance, offering a true level of security both for drugs companies and their customers

by **Mike Cowley**

When Stuart Colligon launched his company Panacea in Douglas on the Isle of Man back in 2008, it was a time when his chosen sector was – as he recalls – "about as popular as the poll tax" which clearly indicates the regard in which it was held as this had resulted in riots in the UK.

For pharmacovigilance, the process of collecting, monitoring, researching and evaluating the adverse effects of medications, was then viewed as a necessary evil, effectively a grudge purchase by his potential clients in the booming generic drugs marketplace.

And having previously worked in business development in the pharmaceutical industry internationally, Stuart Colligon had identified this as a niche market with considerable commercial potential. He chose the Isle of Man not only because he was living there at the time but because the government were helpful and there was an established Manx life science cluster.

Here was a market that he was aware had exploded with the proliferation of generic pharmaceutical companies and generic product licenses in the early 2000s as a result of a raft of medicinal product patents expiring after 20 years of protection (based on a 15-year patent timeline and a further five-year special protection certificate) which saw the originators have to give up their market monopoly of the drugs on which they had spent multi-million pounds to develop.

Even over-the-counter drugs such as hay fever remedies that once sold for £4 were now available at a quarter of the price. So everyone appeared to be happy – the users, the health service because it drove costs down and certainly the generic license holders. However, the same did not hold true for the companies who had spent years researching and developing the original products, only to lose market share to rival commercial operations who reverse engineered the products. That is why many of the original developers have in fact now included the generic route in their portfolios themselves.

While a few of the giants like Pfizer fought back by patenting both the colour (blue) and the shape(diamond) of their blockbuster pill Viagra, even they eventually lost dominance in what was eventually the pharmaceutical equivalent of the gold rush.

However there still remained real concern over the potential for another Thalidomide disaster which took place in 1961 when thousands of congenitally deformed infants were born as the result of being exposed in utero to the medicine when it was prescribed to pregnant women to combat morning sickness. That in turn sparked the first systematic international efforts to address drug safety issues and the ultimate emergence of the practice and science of pharmacovigilance.

When the generics boom started at the turn of the century, the problem, though, was that this concern appeared to be confined to the regulatory authorities rather than the generic drug companies themselves, who seemed convinced they could rely on the safety track records – often over two decades – of the products they were licensing. But they still had to comply when powerful bodies such as the EMA in Europe, the MHRA in the UK and the FDA in the States acted to ensure that mandatory pharmacovigilance was properly applied by the generics players.

So initially in their collective frustration they saw the answer lay in 'buying cheap' and consequently pharmacovigilance companies either willing to provide a 'bare minimum' service, or in countries with low wages reaped the financial rewards.

However, the sector did not escape without incident and with the threat of product recalls and potentially being closed down hanging over them if safety standards were not met, eventually companies experienced a change of heart amid a growing realisation that here was a situation that needed to be taken seriously – and that pharmacovigilance offered a true level of security, both for their businesses and their customers.

Stuart Colligon, founder of Panacea, says the company's service is 'quality first'

In recent years, this has seen an increasing number of companies willing to pay for quality. "There has been an acceptance within the industry that cheap is not necessarily best when it comes to pharmacovigilance. Quality is now seen as key – and our service is very much quality first," insists Stuart Colligon.

Just how important pharmacovigilance is for the end user of drugs was illustrated when Panacea became the first company in the world to spot significant problems with an antiseptic solution used on the skin. It discovered the appropriate remedial action when it found cases in which the product caused burns to premature babies when used at times of catheter insertion and is why Panacea today finds itself in the top five pharmacovigilance companies operating in the UK and Europe.

Working from secure, dedicated offices in the island's capital, Panacea is responsible for monitoring the safety of medicines with marketing authorisations in every EU country and beyond and does so from its Isle of Man HQ and United Kingdom offices. From here it is currently concentrating on expanding its customer base across the EU.

It has experience of successful inspections from the UK's Medicines and Healthcare Products Regulatory Agency (MHRA), the Irish Medicines Board (IMB), and the Food and Drug Agency (FDA).

The company has extensive disaster recovery plans in place which involve real-time off-site backup of all its operations and data. This means that in the event of an emergency all its critical pharmacovigilance processes can continue uninterrupted and its clients' critical data is protected at all times.

Two senior members of its management team have postgraduate qualifications in pharmacovigilance, while other employees are currently studying for the same. As part of the requirement to work in the EU pharmaceutical industry, it is necessary that a company has experts living within the EU. And as the Isle of Man is not a member, they currently reside in the UK itself. Now, with Brexit looming, Panacea is already making contingency plans to recruit additional experts in other parts of the EU.

This is all part of Panacea's ongoing strategy to ensure that they are at the leading edge of pharmacovigilance.

"We have a dedicated quality management function which ensures that all our work – at every level – is checked, audited, and compared with best practice and complies with the highest and latest standards," says Mr Colligon.

"We invest significantly in training. Each member of staff has modular training that is tailored to their role within Panacea and is modified if their responsibilities change. Training is updated on an annual basis or earlier, as necessary. I am deeply proud of the people that we have in Panacea; they are exceptional and this, ultimately, is what enables us to deliver such a high level of service to customers."

Panacea's professionalism also seems to have won fans in high places.

A recent conference on pharmacovigilance saw an attack on the quality of the service available to companies from one of the delegates.

This brought a quick response from a panel representative who singled out Panacea as an example of the high quality that is now available to generic drug companies today.

For more information visit *www.panacea.im*

Swift action a life saver for client

When a leading UK generic pharmaceutical firm with more than 100 drug products learned they were due for an inspection by the MHRA regulatory body, they called in Panacea to make a pre-inspection audit.

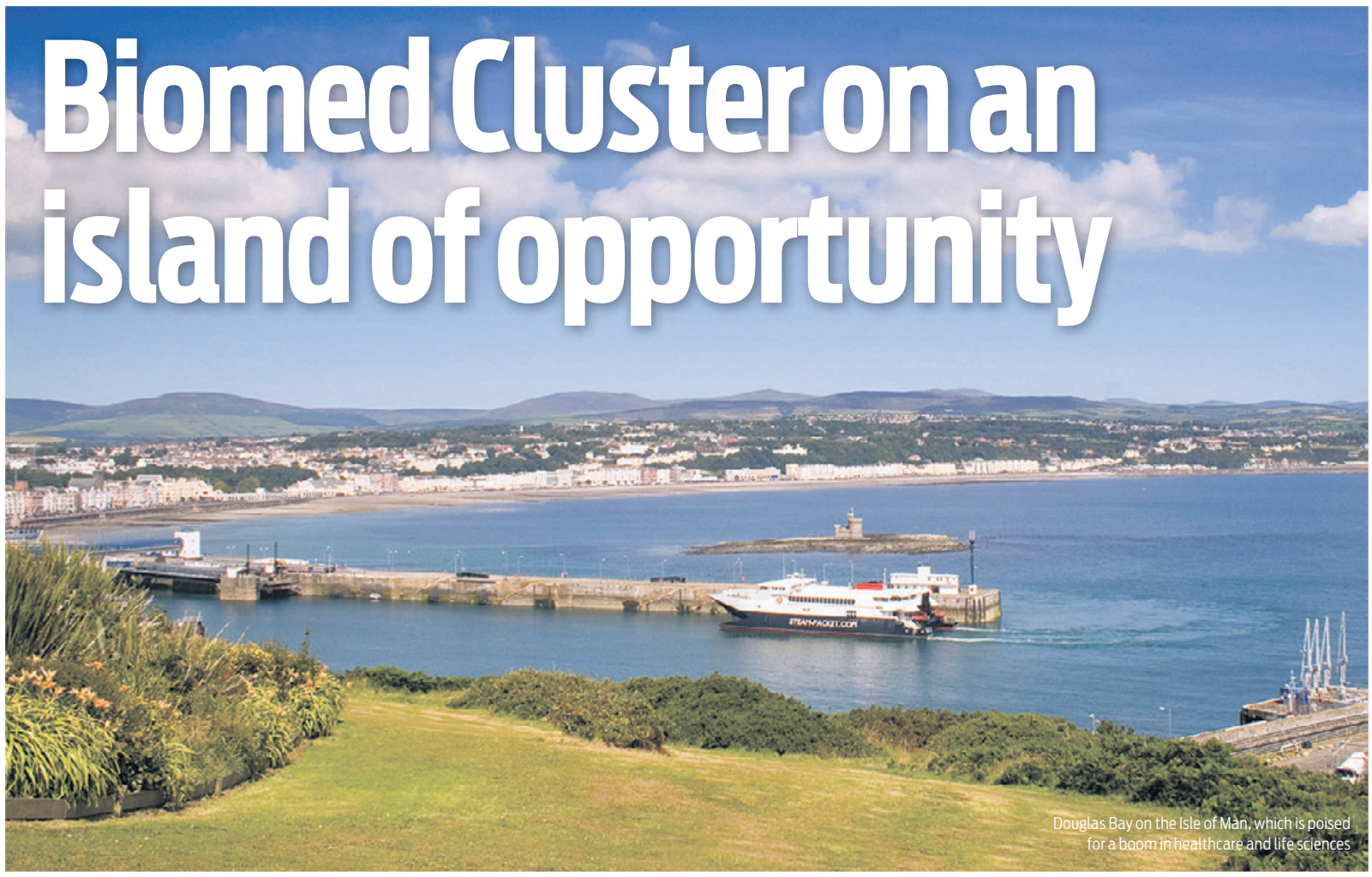
This proved fortunate for them as the Panacea inspection team found a situation so serious that if it had been allowed to carry on unnoticed could have resulted in the closure of the operation.

Normally a red alert would ensue if there was one "Critical Finding" in the internal processes but in this case multiple were found. In addition, there was also a large amount of "Major Findings" requiring prompt attention.

Having identified these, it is normal practice for the MHRA to give the offending company 90 days to correct the situation or face closure.

However, because of Panacea's trusted reputation in the sector, this was extended to nine months and the company's future was guaranteed.

Biomed Cluster on an island of opportunity



Douglas Bay on the Isle of Man, which is poised for a boom in healthcare and life sciences

Companies such as Glycyx Pharma Ventures are at the forefront of a vibrant biomed sector on the Isle of Man

by **Mike Cowley**

THE FLOURISHING ISLE OF MAN Manx Biomed Cluster is poised to experience a boom which could eventually see it join and complement BioHub in Alderley Edge in making the North West a centre for innovation in health and life sciences.

Key to this growth will be Glycyx Pharma Ventures, an investment and consultancy company focused on early stage biotech companies, and its new pharmaceutical development and commercialisation group: Glycyx Therapeutics.

The Glycyx companies have been founded by Lorin K. Johnson, PhD, a successful American biotech entrepreneur with strong family ties to the Isle of Man. As a part-time resident on the Isle of Man, he has worked closely with the Manx Biomed Cluster for the past five years, and saw it as the ideal home for his latest venture.

Glycyx will focus on acquiring and developing undervalued pharmaceutical assets in the fields of oncology, gastrointestinal conditions and neuroscience. Typically, these are drugs whose current owners – ranging from university spin-outs to multinational healthcare companies – see limited potential, but where the Glycyx team can see greater opportunity, by changing the development strategy, the formulation, or pursuing entirely new indications in a 'repurposing' of the drug.

It was using this repurposing strategy that enabled Dr Johnson to grow the previous company he founded, Salix Pharmaceuticals, Inc., into a global leader in the in-licensing, development and commercialisation of treatments for gastroenterology disorders, and to reach the point where it was acquired for $15.8bn by Valeant Pharmaceuticals International, Inc.

"Glycyx is going to have a significant impact on the Isle of Man biomed sector which has already been enjoying a growth rate of 13% per annum," says Manx-born Dave Taggart, a former international consultant in health and life sciences who returned recently to the Isle of Man. He has joined the executive team of Glycyx, and recently completed a strategic review of the healthcare and life sciences sector for the Isle of Man Government.

"Initially we will have senior management functions and clinical/commercial strategy setting activities on the Island, but if the business areas take off the way we expect, then there could be a much broader ecosystem of investor, CRO, and commercial and business development functions in place. This will also match the goals of the Isle of Man Government for the sector, where the aspiration is for a moderate number of high value-added jobs to be created over the coming five years."

The strong support of the Manx Government is expected to be a key driver of growth in the Manx biomed community. In addition to commissioning and acting upon the recent strategic review, the government is establishing strong linkages between the Department of Health and Social Care, the Department of Economic Development and the private sector to explore opportunities in the healthcare and life sciences sector.

Joint advance in cancer care

The first major success for Glycyx came earlier this week with the announcement of the signing of an exclusive development partnership with Valeant to develop the drug Relistor for a variety of oncology indications, including pancreatic and colon cancer.

Dr Lorin K Johnson noted that "Relistor may impact survival rates in cancer patients as well as someday provide a potential new treatment option for those who suffer with the disease."

Whereas details of the deal remained sketchy at the time of going to press, it is known that Relistor is currently marketed in 35 countries for the treatment of opioid-induced constipation – a side effect of the widespread use of opioids to treat chronic pain in cancer patients. However, a recently published study co-authored by Dr Johnson, and clinicians at MD Anderson and the University of Chicago, showed that treatment with Relistor is associated with increased survival in patients with a variety of advanced cancers.

Dave Taggart of Glycyx commented: "Glycyx has initial seed money committed for the development of Relistor and the next 4-5 development assets (yet to be disclosed). We will be actively seeking both further undervalued assets and funding to continue their development in the coming months."

For further details, contact ***david.taggart@glycyx.com***

Small workforce that has major global standing

SINCE THE 1980S THE ISLE OF Man has been home to a range of world-class biomed companies involved in: device manufacture, clinical trials, regulatory affairs, compliance and data capture.

While what is known as the ManxBioMed Cluster may only account for less than 1% of the island's workforce, it punches way above its weight in the global healthcare sector. The current Cluster members include:

Mannin Regulatory
Mannin Regulatory specialises in providing both strategic and practical support in regulatory affairs. Current projects are focused on pharmaceuticals, medical devices and cosmetics. The broad range of support offered includes strategic planning, medical writing, clinical evaluation reports for medical devices, cosmetics safety assessments, pharmaceutical regulatory affairs, preparation of dossiers in CTD (Common Technical Document), NeeS (Non-eCTD electronic submissions) and eCTD formats, and general management. *manninregulatory.co.uk*

Safe-T
The company offers automatic needle retraction and safety system for blood retraction.

As such it helps protect patients, nursing staff, and all handlers of contaminated medical materials from injury caused by used needles Blood collection preparation and process using Safe-T happens in the same way as with standard Vacutainer®-style blood sampling. *safe-t.co.uk*

Bodystat
Bodystat researches and manufactures a range of products which analyse body composition by using Bioelectrical-Impedance Analysis (BIA). Non-invasive, fast and relatively inexpensive, BIA is an accurate and portable technique for fat and fat-free mass measurements. Major clients are BUPA, hospitals and health screening centres. It is used in clinical trials for new drugs designed to combat obesity or cancer. *bodystat.com*

SEQ Ltd
SEQ are experts in pharmaceutical advice, regulatory strategy and regulatory affairs and is an established recognised service provider operating for close to 30 years. With the EU introducing new/complicated regulation requirements throughout the 1990s and 2000s, SEQ's expertise has been a welcome support to their European clients. They have achieved more than 500 new product approvals across Europe. The company operates worldwide in the pharmaceutical, device, herbal, food and cosmetic industries. *seq.co.im*

Clinical Accelerator
The company offers a range of clinical research services to worldwide clients in the pharmaceutical, biotechnology and medical device industries.
Its services extend from protocol development and regulatory affairs through clinical conduct to data management, biostatistics and study reporting. It claims to offer the best of both worlds in that its operation extends to Eastern Europe where clinical trials are most cost effective. *clinicalaccelerator.com*

Nasaleze
Nasaleze is a patented product and is classified as a medical device around the world. It is a completely natural cellulose powder from organic plant extract. Rather than being a cure or medicine, it prevents allergic reactions by acting as an unnoticeable gel barrier to nasal irritants. Likened to an invisible pollen mask, it traps impurities effectively, and helps allergy sufferers. It is sold by Boots in the UK and distributed by Nasaleze in 22 other counties.
nasaleze.com

ProMetic Biosciences
ProMetic's proprietary processes enable the superior extraction and recovery capabilities in the fields of therapeutic plasma proteins, biomanufacturing and the treatment of diseases such as fibrosis, anaemia, neutropenia (abnormally low number of white blood cells), cancer, autoimmune disease and certain nephropathies (kidney damage or disease). Due to the nature of the processes, some of the rarest and most valuable proteins can be accessed at unprecedented levels.
prometic.com

Nimbus Medical
Nimbus Medical is the future in the care of the elderly and chronically ill, increasing their support while decreasing costs. To achieve this Nimbus has developed InterCare™, the world's most sophisticated internet based home care system. Simple to use but powerful in its ability to provide multi way video communication, vital sign tracking, rehabilitation training and personal management.
nimbusmedical.co.uk

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