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Industry Update

This Industry Update covers the period 1–31 March 2014 and is based on information sourced from company press releases, scientific literature, patents and various news websites. This month saw some significant commercial activity with Baxter (IL, USA) announcing a split, Corium an initial public offering and Vectura a major acquisition, which both expands its development pipeline and also gives it access to another inhalation device platform. A number of technologies are under development that enable the transfer of drugs across the blood–brain barrier and MedImmune (MD, USA) continued its interest in the area by announcing a new deal with BiOasis (Vancouver, Canada). In another drug-delivery deal, Caisson (TX, USA) announced an expansion of its HEptune collaboration with Novo Nordisk (Bagsværd, Denmark). Clinical progress was reported by Arrowhead Research Corporation for its RNAi therapeutic for the treatment of chronic hepatitis, which began a Phase IIa study, and Ocular Therapeutix (MA, USA) embarked on its Phase III clinical program to evaluate the safety and efficacy of its dexamethasone formulation. In the regulatory arena, the US FDA approved oral treatment from Celgene (NJ, USA) for psoriatic arthritis and Avanir (CA, USA) announced the FDA has accepted its new drug application for a nasally delivered sumatriptan for the treatment of migraine. A paper in *Nature* described an ‘on-skin’ system that can monitor patients, deliver drugs and communicate data. A paper published by a group from University of Illinois (IL, USA) described a biodegradable battery that could be used to power implanted devices used to deliver drugs.

Business Development

Baxter to split, creating a \$6 billion biotechnology business separate from its US\$9 billion medical products business

Baxter International (IL, USA) has announced its plan to split into two listed healthcare businesses, one focused on medical products and the other on innovative biopharmaceuticals. Some analysts see this as a relatively sudden change of strategy given that only in January CEO Robert Parkinson seemed to be dispelling the suggestion of a split at the JP Morgan Healthcare Conference, although the news appeared to be well received with a strong rise in share price reversing falls over the previous year.

The new, yet unnamed biopharmaceuticals business includes much of the current BioSci-

ence business that has plasma-based treatments for hemophilia, bleeding disorders and various immune disorders, as well as compounds under development in oncology and in the emerging field of biosimilars. It will be led by Ludwig Hantson, president of its BioScience group and it has revenues of around US\$6 billion.

The larger (~\$9 billion) remaining business will retain the Baxter name and includes the dialysis business (recently expanded through the acquisition of Gambro [Stockholm, Sweden]) as well as a portfolio of intravenous fluids and medications and associated delivery systems such as infusion pumps. It will also include a contract pharmaceutical manufacturing business and some biosurgery products that move across from the current BioScience Division. It will continue to be led by Robert Parkinson.

Iain Simpson^{*,1}

& James Blakemore¹

¹Cambridge Consultants, Science Park, Milton Road, Cambridge, CB4 0DW, UK

*Author for correspondence:

Tel.: +44 (0)1223 392215

iain.simpson@cambridgeconsultants.com

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This move seems to be part of a current trend to split healthcare companies: in the past 2 years Abbott (IL, USA) has spun off its innovative biopharmaceuticals division as free-standing AbbVie (IL, USA) and Covidien (Dublin, Ireland) its pharmaceutical business, Mallinckrodt (Dublin, Ireland). Previously, Bristol Myers-Squibb (NY, USA) separated out its nutritional business in 2009 via an initial public offering (IPO) followed by a share sale. The rationale for these decisions is that the separate companies have different market strategies and risk profiles and that the separation of transactions can release shareholder value. Since the Abbott split, AbbVie has increased in value by approximately 50% outstripping its former parent by a factor of 2. Baxter will be hoping that its strategy will pay off in a similar way but similar to AbbVie, the new biopharmaceuticals business needs to see diversification in its product portfolio, which is currently heavily dominated by its hemophilia drugs, Advate® and Feiba™. However, it claims to have a pipeline worth in excess of \$2 billion, led by factor VIII treatment BAX 855, which it hopes to file with the FDA later this year, and Hantson is predicting around ten new products over the next 4 to 5 years.

The transaction is expected to be completed by mid-year 2015, subject to market and regulatory hurdles as well as shareholder and board agreement [1].

Vectura to acquire German respiratory company Activaero for £108 million

Vectura (LSE:VEC.L; Chippenham UK) has announced the acquisition of Activaero GmbH (Gemünden/ Wohra, Germany) for a total consideration of £108 million.

Activaero is a private German pharmaceutical company focused on the development of products for the treatment of respiratory diseases. It has developed proprietary smart nebulizer-based technology (FAVOR-ITE), which allows drug deposition into targeted areas of the lung and is currently utilized in seven clinical and several preclinical stage programmes in the areas of asthma, chronic obstructive pulmonary disease (COPD), cystic fibrosis, idiopathic pulmonary fibrosis and other severe lung diseases.

Vectura's rationale for the acquisition is that it provides a pipeline of respiratory drugs alongside its existing portfolio, as well as nebulizer technology, which complements the dry powder technology that it has developed over the past decade. The acquisition therefore gives Vectura one of the broadest inhalation device platforms that can be utilized both for its own products as well as for partnered deals. Vectura argues that many of the intended markets can be addressed using a relatively small specialist sales force.

The acquisition has had a mixed reception among analysts – some criticize the high price paid for a rela-

tively immature development pipeline, which might explain a recent fall in Vectura's share price since the deal was announced. However, Vectura point out that potential revenues for Activaero's lead product FAVORIR®, tabled for filing in Europe in late 2017 exceed the total acquisition cost. Corium International plans to raise up to \$50 million in an IPO to help with its efforts to develop patches used in drug delivery.

The deal is to be funded through a combination of existing cash and equity [2].

Transdermal company Corium plans \$50 million IPO

Transdermal technology company Corium International, Inc., (CA, USA) has announced its intention to float on the Nasdaq in an IPO, that is set to raise around \$50 million for the business. The company is using its technology to provide improved delivery of previously approved drugs and already has drugs on the market, notably a clonidine patch developed with Teva Pharmaceuticals for the treatment of hypertension and ADHD, and a fentanyl patch developed with Par Pharmaceuticals (NJ, USA) for treatment of chronic pain. It also has three other programmes in registration with unnamed partners.

To date, the company has raised at least \$40 million from venture backers and is now looking to use the funds from the IPO to continue to develop its MicroCor® PTH(1-34) and Corplex Tamsulosin patch technology, which are in early clinical trials. Transdermal patch technology is seen to offer greater convenience over other delivery routes and MicroCor PTH(1-34) is set to compete with Lilly's Forteo®, an injectable treatment for osteoporosis that in 2012 had sales in excess of \$1 billion. In the past Lilly has recognized the potential benefits of a non-injectable form of Forteo, investigations including inhalation (using the Alkermes AIR technology) and active transdermal delivery (using technology from Transpharma), but both of these programmes have ended.

In addition to its transdermal technologies, Corium also has a tooth whitening system with Proctor & Gamble (Surrey, UK) that is on the market.

Corium's revenue rose from \$35.7 million in 2012 to \$37.7 million in 2013. During that time its net loss has more than doubled from \$5.4 million to \$13.9 million, reflecting its investment in the development of its new products [3].

Sanofi appoints Dr Anne C Beal as chief patient officer

In a move seen to be as a first for a top ten biopharmaceutical company, Sanofi (Paris, France) has announced the appointment of Dr Anne C Beal, who

previous was previously deputy executive director at the Patient Centered Outcomes Research Institute, as its first Chief Patient Officer.

According to the announcement, Beal's responsibility will be to further promote the patient within Sanofi to ensure its future healthcare offerings better incorporate the priorities and needs of patients and caregivers in Sanofi's healthcare activities. In striving to meet the need of patients better, the company also presumably intends to strengthen its position in negotiating with payers that its products are more cost effective and have fully considered issues around non-adherence.

The reference to 'healthcare offerings' suggests that Sanofi have ambitions beyond providing drugs. CEO Christopher Viehbacher has previously said he sees the pharmaceutical industry moving away from pay-for-product and toward reimbursements tied to patient outcomes and has been spoken about the use of digital technologies to improve healthcare effectiveness. Within its diabetes business, the company has previously launched glucose meters, including a version connected to an iPhone and has recently announced that it has signed up with Vodacom to provide real-time monitoring of diabetes patients in Africa. Addressing patient outcomes calls for a much better understanding of healthcare delivery than just supplying drugs and we may well see more evidence of service provision from pharmaceutical companies, and it would not be a surprise to see Sanofi take a leading position in this move using some of the digital technologies it has been developing combined with Beal's patient insights.

It is interesting to note that Johnson and Johnson's Janssen division recently appointed a chief design officer to consider how products can be better designed to address common patient problems, such as failing to take medication; a role that does not look too dissimilar to that being filled by Beal [4].

Licensing & Collaboration

MedImmune signs licensing deal with Bioasis for brain drug-delivery platform

AstraZeneca's (London, UK) global biologics R&D arm, MedImmune (MD, USA), has agreed a new deal to evaluate Bioasis Technologies' (Vancouver, Canada) Transcend Platform technology, which is intended to deliver drugs across the blood-brain barrier (BBB). The BBB, which exists to protect the brain and neurological system from infection, presents a challenge for drug delivery particularly for large molecules. In light of this, finding ways to transport drugs from systemic circulation into the brain and CNS is key to developing drugs that can address diseases, such as Parkinson's disease, Alzheimer's disease and other neurodegenerative diseases as well as glioma, other brain cancers and

psychotic disorders. Bioasis has used the technology to investigate potential treatments for neurodegeneration, metastatic cancer and metabolic diseases in the brain. Transcend is one of a number of receptor mediated transport mechanisms under evaluation by several companies. Receptor mediated transport aims to target drugs to specific receptors in the endothelial layer that makes up the BBB, and then use the receptors to transport the drug across the BBB and release it into the brain interstitial regions. By targeting specific receptors the approach is seen to offer more specificity than other transporter technologies in targeting the BBB as opposed to other membranes [5].

Vectura gains VR315 development milestone

Vectura (LSE:VEC.L; Chippenham, UK) has announced that it has triggered a US\$3 million (GBP£1.8 million) milestone payment associated with the development of VR315 (fluticasone plus salmeterol) in the USA. VR315 is an inhalation product for the maintenance treatment of asthma and chronic obstructive pulmonary disease which has already received approval in several European countries for licensee Sandoz (Holzkirchen, Germany). In 2010, Sandoz and Vectura modified their agreement for the drug, with Vectura regaining the US rights. Then in August 2011, Vectura signed a licence agreement for the development, manufacturing and commercialization of VR315 in the USA with the US division of an undisclosed international pharmaceutical company. Vectura is eligible to receive up to a further \$29 million upon achievement of future predetermined development milestones plus royalties from all VR315 US sales once the product is approved. The likely approval date for VR315 in the USA is still not clear but following recent FDA guidance, it is now clearer what is required to demonstrate equivalence to Glaxo-SmithKline's (London, UK) Advair®/Seretide®, which achieved global sales of \$8.25 billion in 2013 [6].

GlaxoSmithKline & Theravance announce study results showing improved outcomes for ANORO™ ELLIPTA™ compared with SERETIDE DISKUS for COPD

GlaxoSmithKline (LSE: GSK.L) and Theravance (NASDAQ: THRX; CA, USA) have reported positive results from three Phase III studies that compared the efficacy and safety of Anoro™ Ellipta (umeclidinium plus vilanterol [UMEC/VI]) with Advair® Diskus (fluticasone plus salmeterol [FSC 250/50]) and Seretide Diskus (FSC 500/50) in patients with COPD and no history of moderate-to-severe COPD exacerbations. In each of the studies UMEC/VI achieved a statistically significant improvement in lung function,

measured as weighted mean forced expiratory volume in one second (wm FEV₁) over 0–24 hours at the end of the 12 week study (day 84), compared with either dose of FSC.

These results are significant for GSK as they may support the switch away from FSC to their new combination product, as generic versions of the drug beginning to enter the market in Europe and the USA. Late last year Sandoz announced approval of their version of FSC (developed with Vectura) in Denmark which has been followed by approvals in some other European countries. Although approval of similar generics has been help up in the USA, mainly due to a lack of clarity about approval pathway, this has now been addressed by the FDA and several companies including Sandoz are planning to enter that market. Annual Advair/Sertide sales have been in excess of \$8 billion globally for GSK [7].

Caisson expands drug-delivery deal with Novo Nordisk bringing up to \$167 million in milestone payments plus royalties for Caisson

Caisson Biotech (TX, USA), has expanded the scope of its existing HEPtune drug delivery deal with Novo Nordisk (Bagsværd, Denmark). The new agreement give Novo exclusive rights to the technology for inulin as well as nonexclusive rights to use it on other diabetes treatments as well in a much wider list of therapeutic areas. Caisson could receive up to \$167 million in milestone payments upon achievement of certain predefined clinical, regulatory and commercial objectives as well as long-term royalties for approved drugs using the technology.

HEPtune is composed of heparosan, a natural polysaccharide with the structure related to heparin and, similar to PEG can improve the circulating half-life of drugs. However, compared with PEG it offers lower immunogenicity and in studies performed by Caisson, heparosan-modified drugs have been shown to be either more potent or have equal biological potency than similarly sized PEGylated versions.

The deal with Novo gives Caisson the finances to progress the technology into new clinical studies as well as a powerful endorsement of the technology by Novo given their decision to expand the original 2012 deal [8].

Development & clinical trials

Link Technologies

On 27 March 2014, Link Technologies (Scotland, UK), a molecular biology tools company, announced expansion of its range of lipophilic modifiers for the delivery of oligonucleotides into cells. Link's collection of lipophilic oligo modification reagents now

also includes 5'-palmitate-C6-CE phosphoramidite. According to Link, palmitic acid in the cell is known to conjugate to proteins via cysteine residues and, in doing so, is believed to aid the movement of proteins between intracellular compartments. It is also known that improved cell delivery is achieved when an oligonucleotide is modified with palmitic acid, and that modification at the 5'-end results in more efficient uptake than modification at the 3'-end. When incorporated during oligo synthesis, the use of this novel palmitate modifier potentially results in more efficient uptake of the oligonucleotide by the cell, therefore offering important value particularly for therapeutic applications [9].

Arrowhead Research Corporation

Arrowhead Research Corporation (CA, USA) announced on 24 March 2014 that patient dosing had begun in a Phase IIa clinical trial of ARC-520, its RNAi therapeutic for the treatment of chronic hepatitis B virus (HBV) infection. The study, by the RNAi therapeutics-focused biopharmaceutical company, is designed to evaluate the depth and duration of hepatitis B surface antigen decline, among other measures, in response to a single dose of ARC-520. Arrowhead's RNAi-based candidate ARC-520 is designed to treat chronic HBV infection by reducing the expression and release of new viral particles and key viral proteins. The goal is to achieve a functional cure, which is an immune clearant state characterized by hepatitis B surface antigen-negative serum with or without seroconversion. Approximately 350 million people worldwide are chronically infected with the HBV. Chronic HBV infection can lead to cirrhosis of the liver and is responsible for 80% of primary liver cancers globally. Arrowhead anticipates planned enrollment to be complete in the second quarter of 2014 and expects top line results to be released in the third quarter [10].

Ocular Therapeutix

US-based Ocular Therapeutix (MA, USA) announced on 17 March 2014 the start of its Phase III clinical program to evaluate the safety and efficacy of its sustained release dexamethasone for the treatment of post-operative inflammation and pain following cataract surgery. The ophthalmic therapeutics company's formulation is administered as a one-time, bioabsorbable intracanalicular plug for release of the steroid to the ocular surface for up to 30 days. The technology is designed to release drugs in a sustained fashion over a specified period of time depending on the drug and its corresponding therapeutic need. At the end of the treatment period, the plug is designed to absorb, and exit the nasolacrimal system without need for removal by the physician [11].

Nasal spray for depression offers minimally invasive treatment option

Study data published by researchers at the Canada-based Center for Addiction and Mental Health (Toronto, Canada) that a nasal spray could offer a new route by which to administer a peptide used to treat depression. Dr Liu from the Center announced the development of a protein peptide that provided a highly targeted approach to treating depression and which it was hoped would have minimal side effects. However, the drug could not be taken orally and required injection directly into the brain which is seen to be an unattractive approach. The new delivery technology comes from US company Impel NeuroPharma, and was shown to deliver the peptide to the right part of the brain. It also relieved depression-like symptoms in animals [12].

Synthon

Synthon (Nijmegen, The Netherlands), a specialty pharmaceutical company, announced on 27 March 2014 that its glatiramer acetate formulation met the main endpoint of a late-stage study in patients with relapsing remitting multiple sclerosis. The Phase III clinical trial has demonstrated an equivalent efficacy and safety profile for Synthon's glatiramer acetate compared with Copaxone®, the top-selling multiple sclerosis drug of 2013. Synthon reported that its study is the only Phase III trial conducted to date with a generic version of Copaxone that has been found to have an equivalent efficacy and safety profile to Teva's drug. This result may have significant impact upon Teva's forecast revenues depending upon physician uptake of a new generic version [13].

Regulatory news & approvals

Celgene

Celgene (NJ, USA) announced on the 21 March 2014 that FDA had approved Otezla® (apremilast), its oral, selective inhibitor of PDE-IV, for the treatment of adult patients with active psoriatic arthritis. Otezla is the first FDA-approved oral treatment for psoriatic arthritis. The drug is an oral small-molecule inhibitor of PDE4 specific for cyclic adenosine monophosphate. PDE4 inhibition results in increased intracellular cAMP levels. More than 75% of patients were previously treated with DMARDs only and 22% of patients were previously treated with biologics. Psoriatic arthritis is a painful, chronic inflammatory disease characterized by pain, stiffness, swelling and tenderness of the joints, inflammation of specific ligaments and tendons, and decrease in physical functioning. It is estimated that nearly 38 million people worldwide have psoriatic arthritis. Psoriatic arthritis can impact

day-to-day activities and has been reported to increase work disability. Common signs and symptoms of psoriatic arthritis include pain, stiffness and swelling in joints [14].

Avanir moves closer to inhaled migraine therapy approval as FDA accepts new drug application

Avanir Pharmaceuticals, Inc. (CA, USA), a biopharmaceutical company focused on acquiring, developing and commercializing novel therapeutic products for the treatment of CNS disorders announced that the FDA has accepted its new drug application for AVP-825, a form of sumatriptan delivered intranasally for the treatment of migraine. The combination product uses a dry powder drug formulation with a breath-actuated nasal device licensed from Optinose (PA, USA), which reduces the loss of drug from the nasal cavity into the throat and lung which is an issue for most current nasal devices. Sumatriptan is most commonly delivered orally but like for many oral drugs has a much slower onset time (30–60 min) than for other administrations including those injected or nasally delivered, both of which have already been approved. However, Optinose have published data showing that a 20% lower dose of sumatriptan delivered in their device resulted in 60% higher levels of the drug in the bloodstream after 15 min compared to the Imitrex spray, marketed by GSK.

Avanir and Optinose signed a deal to commercialise the product in July 2013, for the 2013 announcement of the agreement between Optinose and Avanir [15,16].

AstraZeneca looks to pen injector approval to turn Bydureon® diabetes sales around

AstraZeneca gained US approval of its pen for the Bydureon®, a once per week formulation of exenatide, a GLP-1 agonist used in the treatment of Type 2 diabetes. The drug was acquired by AstraZeneca via Bristol-Myers Squibb when the two companies ended their diabetes alliance in late 2013, having been developed by Amylin (CA, USA). Sales of Bydureon have been disappointing due to a lack of differentiation from the market leader, Novo Nordisk's (Bagsvaerd, Denmark) Victoza, and concerns over pancreatitis arising from use of GLP-1 agonist class. The pen variant is first-in-class and so may provide a much needed advantage over Victoza and other GLP-1s that are entering the market [17].

Patents & novel technology

biOasis Technologies

biOasis Technologies Inc (Vancouver, Canada), announced on 27 March 2014 that it received notices

of allowance from the European and Canadian patent offices for its patent application titled, “Use of P97 as an enzyme delivery system for the delivery of therapeutic lysosomal enzymes”. The claims of the patent cover methods of using biOasis’ brain penetrating drug-delivery vector, Transcend, coupled with a lysosomal storage disease enzyme for the treatment of lysosomal storage diseases (LSD). Specifically, the Transcend-coupled enzymes claimed in the patent allowance include those that are used clinically as enzyme replacement therapies to treat LSDs, such as Hunter syndrome, Hurler syndrome and so forth. According to the biopharmaceutical company, Transcend offers the creation of a new class of drugs that can cross the BBB to address unmet medical needs in the treatment of brain metastatic cancer and other brain disorders, such as neurodegeneration and metabolic diseases, including LSDs. The BBB represents the single greatest challenge in treating diseases and other disorders within the brain. Diseases, such as cancer and LSDs, are readily treated in many areas of the body, but drugs designed to treat them simply cannot penetrate the BBB. LSDs are inherited metabolic disorders caused by a deficiency in lysosomal enzymes, of which approximately 50 have been described to date. These diseases usually affect children, many of whom die within several years of birth and some following years of dealing with symptoms of the disease that may include developmental delay, movement disorders, seizures, dementia, deafness and blindness. The most effective therapeutic strategy used is replacement of the missing enzyme. However, no currently approved therapeutic enzyme is able to effectively treat the effects of these diseases on the CNS [18].

Seoul National University & University of Texas

Researchers at Seoul National University (Seoul, South Korea) and University of Texas (TX, USA) published a paper in *Nature Nanotechnology* on 30th March 2014 describing materials, mechanics and designs for a multifunctional, wearable-on-the-skin system. The aim of such systems is to store and transmit data about a person’s movements, receive diagnostic information and release drugs into the skin. Similar flexible ‘electronic skin’ patch efforts have fallen by the wayside in recent

times. This is due to key technical challenges associated with the fabrication of high-performance, energy-efficient sensors, memory modules that require intimate mechanical contact with soft tissues and controllable delivery of therapeutic agents. The researchers address these technical challenges through the integration of nano-membranes, nanoparticles and stretchable electronics on a tissue-like polymeric substrate. Further development and validation of the system is required, particularly wireless connectivity considerations. Nonetheless it is hoped that the technology could potentially aid patients with Parkinson’s disease or epilepsy [19].

Small, drug-releasing battery could dissolve completely over time

A paper published in *Advanced Materials* describes a biodegradable new battery invented by a team at University of Illinois (IL, USA), which will completely dissolve in the body. The battery consists of anodes of magnesium foil and cathodes of iron, molybdenum or tungsten with phosphate-buffered saline solution as an electrolyte in polymer structure. All these components and the ions formed during degradation of the metals are harmless in low concentrations. It is envisaged that the battery to deliver drugs in a controlled manner possibly using radio control from outside the body. At present, the battery can work for around a day but the researchers expect to be able to increase its lifetime and also power output [20].

Financial & competing interests disclosure

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