Accord acts differently to plot a path towards further growth

Having built a strong European presence in hospital and retail generics, Accord Healthcare is seeking further growth through added-value products, including biosimilars. EMENA head James Burt and vice-president of Specialty Brands Paul Tredwell told Aidan Fry their plans.

James Burt

Paul Tredwell

Just over 10 years ago, privately-owned Indian pharma company Intas made its first sale in Europe under the Accord brand. A decade on, Accord Healthcare is one the continent's largest and fastest-growing generics and biosimilars players, with an annual turnover in its Europe, Middle East and North Africa (EMENA) region of over half a billion euros.

And in that decade, Accord has filed more than 10,000 individual marketing authorisation applications (MAAs) in Europe, around 9,500 of which have already been approved.

That rapid EMENA expansion, coupled with the growth of the Accord brand in North America, emerging markets and the Indian group's progress in its domestic market, has seen Intas more than double its group turnover in its past four financial years, notably having increased sales by 30% to Rs109 billion (US$1.49 billion) in the 12 months ended March 2018 (see Figure 1).

Speaking exclusively to **Generics *bulletin***, Accord's EMENA head, James Burt, noted that this was a long way from Accord's first trading year in Europe which contributed only around £10,000 (US$13,000) to the group's turnover.

"Back when I joined the company in 2010, it really felt like a start-up with around 35 staff in the Europe region," Burt recalled. "Today, we have over 1,300 employees, and we are keen to attract further talent to our appealing story."

"Our compound annual growth rate (CAGR) since I joined is over 50% on the top line, and we are still looking to grow," Burt stated. Following its £603 million acquisition of Actavis' operations in the UK and Ireland at the start of 2017, Accord posted EMENA growth of about 70% in its most recent financial year, and is targeting a further 20% rise in its current year.

From its humble beginnings in the UK, Accord has rapidly expanded its reach, such that its own commercial platform now serves around 93% of patients within the European Union (EU), while the other 7% are covered by local distribution partners. And to capitalise on that sales and marketing platform, as well as its regulatory, quality and supply-chain expertise, the company positions itself as a 'one-stop-shop' for companies in regions such as North America and Asia that are developing generics, added-value products (AVPs), biosimilars, and even new chemical entities (NCEs) looking to access European patients. "We are getting a lot of traction, because developers see us as a route to service half a billion people in some of the wealthiest markets in the world," Burt asserted.

Building from its starting point in oncology injectables, Burt explained, Accord has been pursuing a "trifecta strategy". Firstly, he said, the firm had used a "total oncology" concept – developing and launching a comprehensive cancer-care portfolio that enabled it to drive efficiencies of scale – as a "spear-tip" from which to become a broader hospital injectables player in therapeutic classes such as anti-infectives. "We built up both a strong pipeline and platform, and we kept feeding the beast," he remarked.

Secondly, Accord then moved into retail generics markets, concentrating first on low-barrier and tender-driven markets. "Over time," Burt pointed out, "we have built out and are increasingly adding fieldforces for branded generics markets, learning skills such as clinical detailing and medical marketing." In total, he said, Accord now offered around 600 different international non-proprietary names (INNs) in selected European markets, with between 50 and 70 more scheduled for rolling out each year. "In the three years starting from 1 April 2018," he revealed, "we have 4,000 stock-keeping units (SKUs) planned for launch."

The push into more brand-driven markets is informing the third pillar of Accord's trifecta strategy, a push into AVPs, including biosimilars and, eventually, novel NCEs. And the company has just achieved a major milestone in this area by launching its first-to-market Pelgraz (pegfilgrastim) biosimilar in Europe immediately upon receipt of a marketing authorisation from the European Commission (see page 18).

Pelgraz, Burt highlighted, was "the first time an Indian firm has commercialised a first-to-market, in-house developed biosimilar in Europe". "It puts us in a very select group of companies that have developed, manufactured and commercialised a first-to-market biosimilar."

As it builds out its specialty AVP and biosimilars offering, Burt is keen to ensure that Accord does not try to chase every opportunity. "We are not going to go and do every biosimilar, but rather focus on our core areas of strength," he stated. "We are trying to focus on categories where we have credible lead candidates and novel developments."

Playing in the OTC arena was, he believed, "OK as a tactic, but not as a strategy" given the need for mass-market advertising to build consumer healthcare brands. "It is all down to Ricardo's theory of comparative advantage," he said. "Do what you are relatively best at."

To that end, Accord is focusing on five core therapeutic categories: oncology; autoimmune diseases, such as rheumatoid arthritis; critical care; central nervous system (CNS); and fertility. However, Burt clarified, the company's country management teams were permitted a significant degree of latitude to identify local opportunities, such as building a differentiated transplantology offering in Poland. Similarly, he noted, while Accord did not regard pain-management as a core therapeutic franchise, analgesics could fit well with both its oncology and autoimmune disease portfolios.

"We like to give a fair degree of autonomy to the country management, and say 'pick from this buffet to suit your market'," Burt explained. "But let's try to

stay on the buffet menu and not go á la carte!"

"We give employees much more scope and progression within Accord than in more traditional pharma companies," he claimed, adding that the whole team shared dedication to "push forward and not to be satisfied".

In the oncology franchise, the recent market launch of Pelgraz builds not only on Accord's previous success with its short-acting granulocyte-colony stimulating factor (G-CSF), Accofil (filgrastim), but also on the roster of around 35 cancer molecules that the firm currently has on the market. Accord expects that figure to increase to around 40 by the end of this year, and then to 50 within the next 18 to 24 months.

Paul Tredwell, Accord's vice-president of Specialty Brands, pointed out that the firm currently averaged market share of about a third for the oncology molecules that it had marketed in Europe. "We are already quite well known in the oncology space, but perhaps less so by oncology physicians," he recognised.

Independent research commissioned by the company found that, among hospital pharmacists in France, Spain and the UK, Accord was the most spontaneously recalled name of companies offering hospital generics. The company is now investing in building stronger relationships with the medical oncology community, with a sizeable number of around 400 in its commercial operations.

Describing Pelgraz as "a gateway product" to the company's pipeline of differentiated drugs, such as its proprietary liposomal products, Tredwell said the firm expected to launch Pelgraz "across all major territories within six months of approval". While the timing of the roll-out in individual countries would depend largely on local pricing and reimbursement clearance, he insisted that supply constraints would not be a problem. "The launch stock is made and everything is ready," he stated.

The Intas group already has significant fermentation capacity at its long-established biologics plant in Moraiya, the first biopharmaceuticals plant in India to obtain good manufacturing practice (GMP) approval from the European Medicines Agency (EMA). To support its extensive biosimilar product pipeline, the firm is currently installing thousands of additional litres to become one of the largest domestic manufacturers of therapeutic recombinant proteins.

"We have already planned in extra capacity for the Pelgraz launch," he continued, revealing that extra capacity was coming online in the near future. With Neupeg/Pegasta (pegfilgrastim) already on the market in India, and Accofil well established in Europe with approaching a 20% market share despite having been sixth to market, Accord would, he said, be able to maximise yields and realise economies of scale. "We have built experience and supply-chain reliability by launching in less regulated markets ahead of Europe," he noted.

Speaking to **Generics *bulletin*** shortly before three other companies – Cinfa, Mylan and Sandoz – received positive opinions from the committee for human medicinal products (CHMP) within the European Medicines Agency (EMA) for pegfilgrastim (**Generics *bulletin***, 28 September 2018, page 15), Tredwell forecasted that pegfilgrastim would be "a very competitive market" in Europe. The company's sales and marketing team was well prepared to make best use of Accord's first-mover advantage, he insisted, pointing out how the firm had used differentiating utility features such as a longer shelf life out of the fridge to gain share for Accofil despite having entered a crowded arena. Accofil, he added, had an immaculate safety record.

Tredwell – who joined Accord at the start of this year, having previously spent more than four years leading Sandoz' fledgling Biopharmaceuticals business in the UK – argued that pegfilgrastim conferred a distinct patient advantage over standard filgrastim. "There is much less chance of administraton errors which could lead to the delay of a chemotherapy cycle," he claimed.

While competition would inevitably drive down pegfilgrastim prices, the market was poised to expand, especially as large countries such as the UK did not currently reimburse the drug. "As time goes on, we might see a rebalancing between short-acting and long-acting G-CSF," he predicted. "Offering both versions

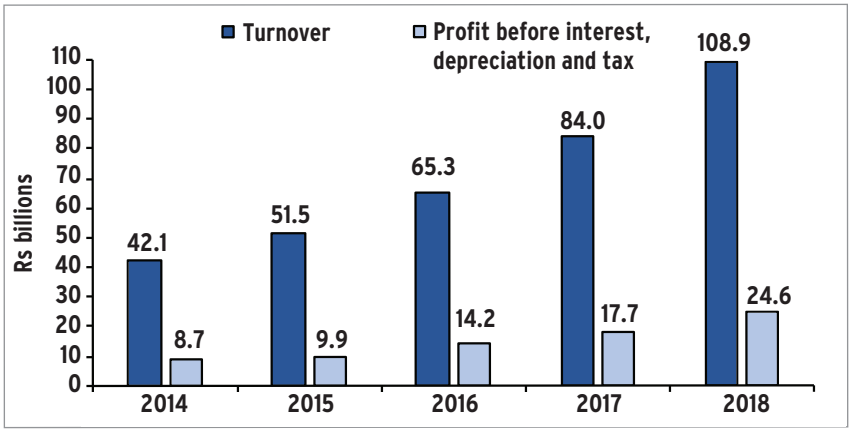

Figure 1: Intas has recorded rapid growth in both turnover and profits before interest, tax and depreciation in its financial years ended 31 March 2014 to 2018 (Source – Intas)

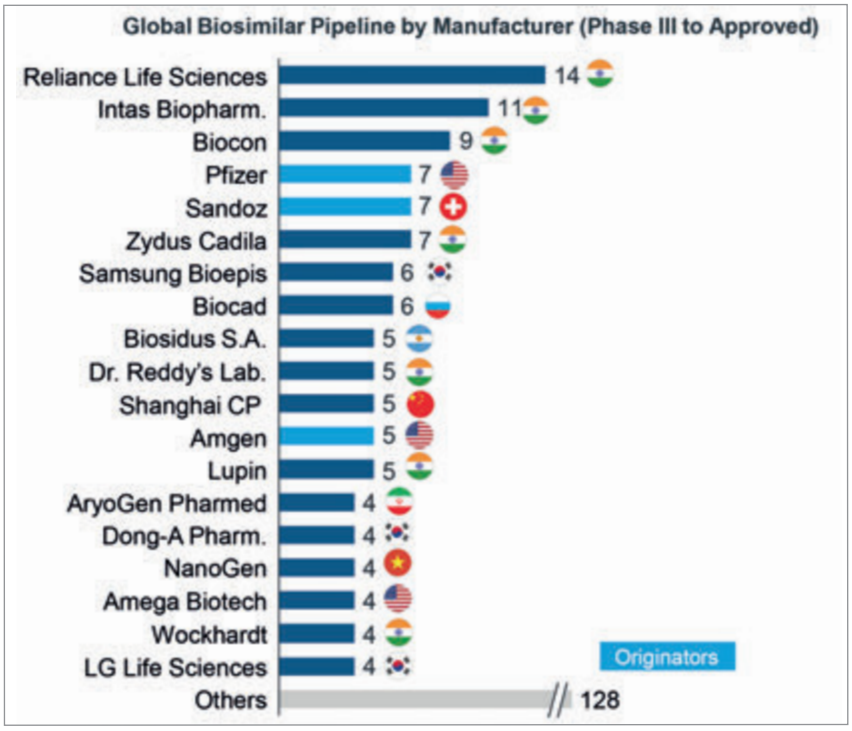

Figure 2: The number of biosimilar development candidates at Phase III clinical stage or beyond that leading companies have in their global pipelines (Source – Iqvia)

will be an advantage."

Uptake would vary by local market dynamics, with some countries favouring tender models, and others like France and Germany tending more towards retail sales. Through its heritage in both tender-driven hospital and retail-led pharmacy markets, Accord was well placed to compete on all commercial fronts.

To augment its in-house biosimilars pipeline, the group recently struck a deal with China's Shanghai Henlius Biotech for another monoclonal antibody, trastuzumab, in more than 70 countries around the world (**Generics *bulletin***, 6 July 2018, page 1). Burt noted how licensing deals could offer synergies to maximise the efficiency of Accord's sales and marketing network.

Tredwell highlighted recent IQVIA research that suggested that, with 11 biosimilars in its global pipeline at Phase III clinical stage or beyond, Intas was well ahead of almost all its peers (see Figure 2). "Most people had no idea we would be that big a player," he remarked.

The advent of biosimilar competition, Tredwell observed, had spurred investment into improved formulations, delivery devices and patient packages. "I think product enhancements will resonate as well with pegfilgrastim," he predicted, adding that this tallied with Accord's mantra to "think differently" and to innovate rather than replicate. "Just because an originator stopped investing in a molecule, that does not mean we cannot bring better stability, presentations and packaging."

"As a company, we are aligned at looking for niche areas where we can add patient value and a differentiating factor," Tredwell continued. "And while we might not always be first into a market, we aim to be last out – to be the last man standing is a key goal for us."

Tredwell stressed that biosimilars should not be viewed in isolation, but rather as a key element of Accord's drive into speciality, added-value products. "We do not have a biosimilars division," he pointed out. Rather, biosimilars form part of a broader offering that ranges within the firm's core therapeutic franchises from generics, through AVPs or 'supergenerics' to novel drugs. "In this way," he explained, "when we send a sales team out, we can maximise efficiencies. And if somebody offers us a product as a partner, we can add that to the basket without a huge incremental cost to our commercial platform."

"Our strategy is a franchise and AVP roll-out, not solely a biosimilars play," Tredwell clarified.

While adding value to biosimilars through utility features is a key element of the AVP strategy, Accord is applying similar principles to its small-molecule portfolio as it seeks to add value for both patients and healthcare professionals.

As an example, Tredwell cited the methotrexate self-dose auto-injector device that Accord recently launched in the UK as a lead market within Europe. Noting that this built upon the market position that the company had already established in Europe for the rheumatoid arthritis drug with its pre-filled syringes, he said the unique device included a large bulb that was easy for arthritis patients to hold, with a smooth, hidden needle application. The device, he added, was designed such that it fitted onto the leg without wobbling, enabling the patient to control the whole process of delivering the dose.

"If you look at the way that methotrexate market is moving, the auto-injector or pen device is taking more share across Europe. We have invested a lot of time and effort in the device, testing it in human-factor studies which demonstrated how patients highly rated its ease of administration," Tredwell elucidated.

"The device was designed specifically for the arthritis patient group, but that does not mean we cannot use the device in other disease areas as we move forward through our launch portfolio," Tredwell remarked. Offering patient benefits without driving up prices substantially was core to Accord's AVP strategy, he said, noting that this could include improvements not only to drug delivery, but also to drug formulation and routes of administration.

Commenting on whether companies could reap any economic reward for such patient-friendly innovations, Burt hailed the health-economic studies being undertaken by industry association Medicines for Europe. In the case of methotrexate, he pointed out, improving patient compliance by spending a few euros on an effective device could save thousands by deferring the use of far more expensive treatments.

Supported by Intas' vast team of developers in India, Accord currently has a pipeline of around 35 AVPs slated for launch over the next seven years.

"It is all about thinking differently around how to solve the problem, not has it been done before and then copy it. As an industry, we have to get away from that vanilla generic attitude," Burt contended. He noted that the industry had, historically, been so concerned about being perceived as different to the reference brand that it had failed to explain why its products represented improvements, thereby exposing companies purely to competition on price. "Something as simple as a smaller pack taking up less fridge space should be reflected in the price and value of a product," he argued.

As it rolls out this extensive pipeline in the EMENA region, Accord is balancing large-scale efficient manufacturing with an ability to react rapidly to market requirements. The group is now shipping "a significant number of products" to Europe from its solid-dose facility in Dehradun, India, that was recently approved by the UK's Medicines and Healthcare products Regulatory Agency (MHRA), while it is also building a "state-of-the-art facility" in a special economic zone (SEZ) in Ahmedabad, India.

Within Europe, Accord has complemented its highly-efficient former Actavis facility in Barnstaple, UK, by renovating and equipping an ex-Sanofi site in Fawdon near Newcastle, UK, that already employs more than 100 people and is ramping up towards an annual production and packing capacity of up to 5-6 billion units, becoming "a centre of excellence for European late-stage differentiation". The Barnstaple plant is also supporting Accord's growing presence in the Middle East, where the company now has around 60 granted marketing authorisations.

"We are effectively doubling capacity within the space of a year," Burt observed. "And that is really going against the direction of travel in the industry as other companies cut capacity and portfolios."

With the company also constructing a large-scale warehousing and logistics centre in Didcot, Oxfordshire, Burt acknowledged that Accord was unusual in investing in infrastructure not only in Europe, but

also in the UK with the country's 'Brexit' departure from the European Union (EU) looming. The aim, he explained, was to balance the cost effectiveness of large-scale production in India for large, stable volumes whilst being able to react quickly and locally to shifts in demand in Europe.

Burt said he believed it was in the interests of all stakeholders for the UK to reach a regulatory agreement with EU bodies, especially given the prevailing trend towards international alignment of standards. However, he said, Accord had made contingency plans, including bolstering its own network of test-and-release laboratories in Europe and identifying a small number of strategic partners to support batch release.

And at the same time that the firm was preparing from any Brexit fall-out, it was also working hard on issues such as artwork variations and installing printers so as to be ready ahead of time for the EU's implementation deadline for the Falsified Medicines Directive in February next year.

With Accord confident that its pipeline will deliver solid growth for the foreseeable future, Burt said Accord continued to be very selective in the acquisitions it considered and was only looking to deals that fitted with its core strategy, particularly for AVPs. "We are still looking, but we have learned lessons from others over-paying," he commented. With private-equity investors often looking to healthcare as a relatively secure home for investments, he queried whether some of the valuations being made currently were sustainable.

However, he said Accord's own 'Argentum' acquisition of Actavis' UK and Ireland operations had been a game-changer, making the company the leading generics player in the UK and giving the company scale to leverage across Europe. "It has certainly positively affected our relationships with key integrated healthcare companies," Burt stated.

Accord Healthcare intends to make a former Sanofi facility in Fawdon, UK, a production and packaging 'centre of excellence for European late-stage differentiation'

Acknowledging that Accord had previously operated "slightly in stealth mode", Burt said the privately-owned firm was starting to tell its story more openly. "At the company, we feel strongly that our best is yet to come and that we are delivering on our commitment to improve access to high-quality, affordable medicines and delivering innovation by thinking differently," he concluded.