

Actavis aims to become global player in diabetes

Actavis will build an international diabetes franchise around analogue insulins, the firm's chief executive Claudio Albrecht told Aidan Fry.



Claudio Albrecht

Rising rates of diabetes throughout the developed and developing world are increasingly turning the spotlight onto generic insulins. Such is the potential of this multi-billion dollar market – there are an estimated 230 million diabetes patients worldwide – that even the world's largest pharmaceuticals company, Pfizer, is seeking a piece of the action through the supply deal for four insulin and analogue insulin products it struck with India's Biocon last year.

Actavis' chief executive officer Claudio Albrecht is equally determined not to miss out on the opportunity that biosimilar insulin offers. Albrecht is currently negotiating an agreement with Poland's Bioton that would give Actavis the global sales and marketing rights to the Polish firm's insulin products, including analogue insulins (*Generics bulletin*, 3 December 2010, page 1).

"The commercial terms are more or less agreed with Bioton," Albrecht told *Generics bulletin* in an exclusive interview. "We are just checking the scientific profiles of the products," he added, noting that his primary focus was on analogue insulins.

Albrecht declined to comment on how much Actavis would pay. However, Bioton has communicated a maximum transaction price of PIZ500 million (US\$176 million) under the terms of the deal.

Noting that Pfizer would make an upfront payment of US\$200 million to Biocon – plus milestones of up to US\$150 million and royalties on sales (*Generics bulletin*, 1 November 2010, page 13) – Albrecht insisted the planned collaboration with Bioton would bring tremendous value to Actavis.

"We have exclusive sales rights for Europe, the US and Japan, as well as other countries that we will negotiate individually," Albrecht explained. "The analogue insulins alone should add around €900 million (US\$1.4 billion) to our enterprise value," he forecasted.

"We are ahead of the game on analogue insulins, and I don't believe Pfizer and Biocon will be able to match our timelines," Albrecht commented, adding that he anticipated approval from the European Medicines Agency (EMA) towards the end of 2013 for Bioton's dossier. Bioton's recently-announced alliance with GlaxoSmithKline for its existing Gensulin and GensuPen insulin brands would have no effect on Actavis' position, he added (*Generics bulletin*, 14 January 2011, page 9).

Albrecht said Actavis had reserved the right to choose between a delivery device that Bioton was developing or an alternative device from an established third-party manufacturer.

"We are well aware that the insulins battle can be won in the device arena," he acknowledged.

For Albrecht, the potential development, sales and marketing deal with Poland's Bioton represents a more fundamental strategic concept.

"The diabetes idea for us is a much wider one than just natural insulin and the two analogue insulin lead substances," he stated. Highlighting the extensive range of generic type-2 oral diabetes drugs that the firm

already offers, Albrecht said treatments for the condition played a big part in the company's pipeline. "In the near future, we will see patent expiries for pioglitazone, including fixed combinations with metformin, and for repaglinide," he observed. Actavis' pipeline also included high-value 'gliptin' products, he added.

"We are the only company that can offer such a broad diabetes portfolio," he asserted. Even if Pfizer came to market with Biocon's insulin, the brand firm would lack Actavis' breadth of oral generics, Albrecht pointed out, adding that heavyweights in the insulins arena such as Eli Lilly, Novo Nordisk and Sanofi-Aventis were in a similar position to Pfizer.

"With long-acting and short-acting analogue insulins as lead substances, it will make us a 'one-stop-shop' for diabetes," Albrecht continued. "We can tell insurers and payers that we cover the whole diabetes segment for a cost that is probably considerably less than they have been paying so far."

Aims to sell insulin from 2014

"We think we are a step ahead, and we need to maintain that momentum," Albrecht insisted. "The idea is to start selling our insulin in 2014, but we need to prepare the ground."

Albrecht's plan is to go beyond direct treatment for diabetes by pushing into adjacent categories and services, such as devices and test strips to measure blood-sugar levels. "We will not develop these products ourselves. We will look for a partner that has the devices, but lacks the reach into the prescriber arena," he outlined.

Noting that diabetics often suffered from associated conditions such as eyesight problems and poor circulation to hands and feet, Albrecht said there was great potential for Actavis to leverage its extensive prescription and OTC portfolios and pipelines. "The opportunity is considerable, but not too complicated for a generics player," he insisted, adding that Actavis would develop a full-service concept within a Diabetes Care unit. This would operate as a separate entity under the corporate banner.

By building on its existing salesforces that visit doctors in markets such as Germany and Spain – as well as throughout central and eastern Europe – Actavis would promote a broad basket of diabetes products not only to healthcare opinion leaders, but also to insurance funds and patients' organisations, Albrecht said. "We can provide from one source the products and services that patients need for a better quality of life – training, scientific information, whatever they want," he stated.

Albrecht is also keen to employ a similar strategy for women's health products, although he admits that any such project is still in its infancy. "Nevertheless, we still believe this concept makes a lot of sense for us," he remarked.

A third therapeutic category in which Albrecht has big plans is oncology drugs. He revealed that Actavis

was exploring deals for monoclonal antibodies such as cetuximab and rituximab “with two or three developers”, but was proceeding cautiously in light of the sizeable investment required.

Meanwhile, Actavis had been enjoying notable success with small-molecule cancer treatments. “We’ve just had a great launch with docetaxel, not only through our own organisation, but also through attractive contracts negotiated by our Medis third-party business,” Albrecht said (*Generics bulletin*, 3 December 2010, page 15). “We are really struggling to satisfy all the demand,” he added.

“The next compound we’re going to launch in the US is topotecan,” Albrecht stated, adding that the firm’s US operation was also “in the starting gates” to introduce gemcitabine after the 180-day exclusivity period that Teva had effectively licensed to APP (see page 17). At the start of this year, Actavis also obtained a pan-European centralised marketing authorisation for topotecan.

Oncology drugs are also a key component of Albrecht’s plans to expand in its three ‘growth initiative’ regions: southern Europe, the Middle East and North Africa (MENA region) and Japan (*Generics bulletin*, 15 October 2010, page 20). Portfolio and salesforce expansion – as well as a new management team – is to fuel rapid growth in southern European markets such as Italy and Spain, while Albrecht is evaluating plans to set up a local cytotoxics facility in North Africa. And in Japan, filings for molecules such as docetaxel and gemcitabine are to spearhead a concerted push into the country’s hospitals arena (see box entitled ‘Actavis seeks stronger position in Japan’).

The next 12 to 18 months would see major brands losing protection in western Europe’s top five markets, with molecules such as atorvastatin, escitalopram, olanzapine, valsartan and valsartan/hydrochlorothiazide becoming subject to competition, Albrecht observed.

“We have the approvals. We are just sitting and waiting until we can go,” he stated, stressing that Actavis had an opportunity to improve its standing in markets where it had never been strong, such as Germany and in southern Europe. “In Germany,” Albrecht added, “we rank eighth or ninth overall, but we are in the number four position with pramipexole following a great launch (*Generics bulletin*, 14 January 2011, page 17).”

“We are in the process of signing up a new general manager in Italy,” Albrecht revealed, adding that his

Polfa Warszawa would be Polish base

Four rival bidders stand between Actavis and a takeover of Polfa Warszawa, a move that would see the company become a major player in Poland. To win a privatisation process – and make Poland its third-biggest market behind the US and the UK – Actavis will have to outbid local firms Adamed and Polpharma, as well as China’s Harbin Gloria and Ukraine’s Arterium.

“Clearly this is a key priority for us in the first quarter and we don’t know if we will manage to win it,” Actavis chief executive officer Claudio Albrecht told *Generics bulletin*. “We will undertake due diligence over the next few weeks and appraise another offer,” he said, arguing that Actavis could offer sustainable employment to the Polish firm’s workforce.

Albrecht said Polfa Warszawa would not only strengthen Actavis’ position in the strategically important Polish market, it would also offer synergies with the group’s existing operation in Russia.

Furthermore, the Polish company would give Actavis a plant for producing ampoules, turning Polfa Warszawa into a global technology centre from which the group could export products into other markets. **G**

former Ratiopharm colleague, Rodrigo Roman, had come in to head Actavis’ operation in Spain. Roman’s experience, he insisted, would be invaluable in tackling the disparate healthcare policies and regulations among Spain’s autonomous healthcare regions (see page 12). “We have a steep sales acceleration planned, so Spain should be the first country to show an improvement,” Albrecht commented.

“In Spain, we have nearly finished adding around 100 people to our salesforce, and in France we have added 30 representatives,” Albrecht continued. Once the new general manager was in place, Italy would follow suit “as a kind of start-up”, focusing particularly on the injectables market, he added. “We have this great oncology plant in Nerviano, near Milan, allowing us to approach the Italian market through the hospitals sector,” Albrecht explained.

Seeking far larger share in France

Actavis’ French management team was also aware of the need to build up the firm’s presence. “We’re doing alright in France, but we need a much bigger market share than we have at the moment,” Albrecht asserted.

Highlighting Actavis’ positions of strength in Bulgaria, Scandinavia, Serbia and the UK – as well as its successful focus on high-profit niches in the US – Albrecht admitted that “France, Italy, Spain and Poland

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Actavis seeks stronger position in Japan

Obtaining a larger stake in its joint venture with Aska is crucial to Actavis’ progress in Japan, according to chief executive officer Claudio Albrecht. “If we can take a majority holding, I am ready to go full speed ahead, especially with product development and sales,” he told *Generics bulletin*.

Under Actavis’ previous management team, the company had taken a 45% stake in the Actavis Aska joint venture as a route into the Japanese generics market (*Generics bulletin*, 14 November 2008, page 1). Albrecht’s proposal to take control – a move that would allow Actavis to consolidate Japanese sales – is to be discussed during a meeting with Aska this month.

“I need to have an Actavis presence in Japan, and at the moment we are more or less a supplier. We want to be able to control the pace and the level of investment,” Albrecht explained.

Noting that Actavis held some Japanese approvals of cytotoxics such as topotecan – and had filed for other oncology drugs including docetaxel and gemcitabine – Albrecht said his preference was to market them in collaboration with Aska. “If that is not possible, we will find a different way for Actavis on a standalone basis, possibly through a local partner or an acquisition,” he said. **G**

are problem areas we want to attack”.

In Poland, Albrecht intends to expand inorganically by acquiring local firm Polfa Warszawa through a privatisation tender (see box entitled ‘Polfa Warszawa would be Polish base’). If successful in the bidding process, Actavis would not only become a significant player in the Polish branded generics market, it would also acquire an ampoules production plant that it could use to export products to other central and eastern European countries.

Salesforce expansion is underway in the Czech Republic, where Albrecht has installed another former Ratiopharm colleague.

And in Serbia – where Actavis says it ranks third by generics turnover – the company is awaiting the outcome of a privatisation process for its local rival, Galenika. “Serbia is an interesting market, but not the healthiest at the moment,” Albrecht observed, noting that Actavis was working to limit its exposure to bad debts and poor liquidity among distributors that had afflicted rivals such as Stada’s Hemofarm (**Generics bulletin**, 15 October 2010, page 5).

Albrecht maintained that Actavis’ market-leading position in Bulgaria had not been diminished by divesting its wholesaling unit, Higia. The company’s successful Bulgarian model could be exported to other markets, he believed. Furthermore, he said, the group was assessing its production assets in Bulgaria, Russia and Serbia to optimise cost of goods and utilisation levels.

In Russia – where Albrecht is considering his options regarding local manufacturing (see box entitled ‘Actavis is ready for Russian expansion’) – Actavis intends to use its array of marketing authorisations for cytotoxic drugs to strengthen its position in the hospitals market. Russia is also the base from which the company

manages its ‘cluster’ of operations in the Commonwealth of Independent States (CIS).

“Ukraine and Kazakhstan are quite important markets for us already, and I think Uzbekistan is highly interesting. It is a relatively rich country of more than 20 million people, but is underdeveloped in terms of medical services,” Albrecht observed. “Belarus is another big market, but it hasn’t really taken off yet,” he added.

However, Albrecht’s main focus in the region is centred on expanding in Poland, Russia and Turkey.

“We have big plans in oncology in Turkey,”

Albrecht stated, pointing out that the firm’s cytotoxics facility in Romania had been inspected by the relevant Turkish authorities. “This inspection will help us enormously,” he stated.

On the solid-dose side of the business, Actavis has handed back its former Fako facility in downtown Istanbul to a Turkish developer, which will redevelop the site as an office complex. Actavis is negotiating product licences and supply deals with local firms, and has restructured its Turkish salesforce to focus on niche areas, such as dermatology.

Turkey is to act as the northernmost point of a triangle of key markets for Actavis in the MENA region, along with Algeria in the west and Egypt in the east.

Considering Algerian oncology plant

“In Algeria, we are currently considering a proposal to build an oncology site with a partner which has already obtained the necessary licences. We have a memorandum of understanding in place and people assigned to the project, but we need to see how the Algerian government will support us,” Albrecht revealed, adding that the facility would be designed to have sufficient capacity to act as an export base for other North African markets.

“We are still looking around for targets in Egypt,” Albrecht said, admitting that the prices being sought for major local players were hard to justify. “If we can find a platform in Egypt, including a joint venture, that makes sense and delivers synergies, we are very interested in pursuing it,” he stated.

Actavis is using third-party consignment warehouses to improve its product availability in Middle Eastern markets including Iran, Iraq and Saudi Arabia.

Albrecht described the South African market as “tempting given its potential”, but said several strong local and Indian players meant it would not be a priority for the resources Actavis has available.

Admitting that Actavis had historically spread itself fairly thin in terms of both markets and technologies, Albrecht said he was determined to focus the company on “four or five key areas”. A stable senior management team was now in place, and the firm was about to move into new corporate offices in Zug, Switzerland, he pointed out.

“Preliminary figures suggest we exceeded our targets in 2010 with a turnover of around €1.8 billion,” Albrecht commented, adding that the company was well placed to achieve its ambitious goals for this year. After several years of uncertainty while the firm’s ownership had been discussed among banks, it was vital that Actavis built up its credibility, Albrecht believed. “We have to integrate successfully anything we buy, and ‘walk the talk’,” he insisted.

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Actavis is ready for Russian expansion

Actavis’ ambitious growth plans in Russia have led the firm’s chief executive officer Claudio Albrecht to consider investing in a large-scale production plant that could be used for exports to surrounding countries, as well as to serve the local market. At present, Actavis owns a 51% stake in a tablets facility in Podolsk, near Moscow, but the plant will be running close to full capacity once all the planned product transfers are completed, and there are limited opportunities for expansion.

“We believe long-term it’s the right move to have a manufacturing site in Russia,” Albrecht told **Generics bulletin**, highlighting the need to press tablets locally to avoid heavy import duties. The question, he added, was whether to sell Actavis’ stake in the Podolsk plant and invest the proceeds in buying a larger site.

“Russia is now close to a €120 million (US\$165 million) market for us, and we envision growing strongly in the future,” Albrecht commented.

Six plants supply local markets

Podolsk is currently one of six Actavis plants that supplies local markets, along with sites in China, Indonesia, Serbia, the UK and the US. The firm also has factories in Iceland and Malta at which it can stockpile for ‘day one’ launches, as well as semi-solids plants in Troyan, Bulgaria and Lincoln, US; and cytotoxics sites in Nerviano, Italy, and Bucharest, Romania. High-volume solid-dose facilities are located in Dupnitsa, Bulgaria and Elizabeth, US; and will be in future in Alathur, India, where work is underway to expand the capacity of the plant near Chennai from less than one billion to five billion oral-solid doses per year.

Albrecht said Actavis was partway through optimising its manufacturing network, which currently comprised 14 manufacturing sites in 12 countries. However, he stressed that he had no intention of making Actavis into a major player in the area of active pharmaceutical ingredients (APIs).