THIRD-QUARTER RESULTS

Mylan's Fulphila has secured an 8% share

Mylan has declared itself "very happy" with the progress of its Fulphila (pegfilgrastim-jmdb) rival to Neulasta, after revealing that the biosimilar – co-developed with India's Biocon – has captured just over 8% of the pegfilgrastim pre-filled syringe market in the US.

Noting that the pre-filled syringe market represented "almost 50% of the entire Neulasta marketplace" in the US, the company said its penetration into community oncology clinicals and hospital-based outpatient clinics was "continuing to grow". Production capacity is also proceeding "exactly as planned and as we had anticipated this launch", following Fulphila's approval in early June (**Generics *bulletin***, 8 June 2018, page 1).

Acknowledging Coherus' recent pegfilgrastim approval in the US (see front page), Mylan chief financial officer Ken Parks said, "this is a US$4 billion product in oncology, the largest biologic product available in the oncology therapeutic world. So I think there is [an] opportunity for more."

Separately, Mylan is still working on securing US Food and Drug Administration (FDA) approval for its proposed Wixela Inhub (fluticasone/salmeterol) rival to Advair, having previously received a goal date of mid-October. Mylan president Rajiv Malik indicated

Region	Third-Quarter Sales (US$ millions)	Change (%)	Operating Margin (%)
Europe	1,041.3	+-0	29.8
North America	1,012.3	-14	44.1
Rest of World	773.7	+4	25.2
Other	35.1	+14	--
Mylan	2,862.4	-4	11.8[1]

[1] includes US$612.9 million of unallocated corporate expenses

Figure 1: Breakdown by region of Mylan's sales and operating margin in the third quarter of 2018 (Source - Mylan)

that "we are in continuous and ongoing discussions with the FDA regarding the progress of the review", adding that "based on our latest updates from the agency, they are in the final stages of labelling review". "We continue to believe that the FDA will be able to resolve any outstanding issues very soon," Malik stated.

In the third quarter of 2018, Europe overtook North America to become Mylan's largest region by sales, after North American sales tumbled by 14% to US$1.01 billion. European sales, meanwhile, remained flat at US$1.04 billion, but grew by 2% at constant currencies. Sales in Mylan's Rest of World segment grew by 4% as reported and by 11% at constant currencies to US$774 million.

Attributing the North American decline in part to restructuring and remediation issues at Mylan's Morgantown facility, Malik indicated that the affected products were high-volume but relatively low-value, including only one of its top 10 and eight of its top 50 gross margin generating products for North America. "It's more a qualitative issue for us," he suggested. "Our reputation as a reliable supplier is where we feel the pain."

"As we work to reduce the complexity of this facility, we have proactively discontinued a number of products, while also transferring some to other sites," Malik said. "While we are executing on our commitment to the FDA, the plant continues to supply products for the US market." Related expenses of US$48.9 million were registered in the third quarter.

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THIRD-QUARTER RESULTS

More cuts to come as Teva targets US$3bn

Teva is on track to achieve its targeted US$3 billion spending reduction by the end of 2019, according to president and chief executive officer Kåre Schultz. Ridding the firm of a number of its facilities and cutting staff by more than 9,000 has already produced efficiencies of US$1.8 billion in 2018.

Speaking as the firm reported its third-quarter results – and a year since taking the helm at Teva – Schultz insisted that "no matter what happens we will take costs down from US$16.3 billion to US$13.3 billion". However, he admitted, this "doesn't come easy", acknowledging that the reduction of 9,100 full-time equivalents (FTEs) achieved so far represented just under two-thirds of the 14,000 job cuts that Teva had initially targeted when it revealed its restructuring plans at the end of 2017 (**Generics *bulletin***, 22 December 2017, page 1).

Meanwhile, Schultz indicated, Teva was seeing signs of stabilisation in the US generics market, especially after withdrawing from certain unprofitable product lines, which he said the firm was happy to leave to open to competitors. "We wish them good luck, but it's not a market we want to be in," he affirmed. North American generics sales slumped by 25% to US$922 million during the quarter (see Figure 1). Meanwhile, European generics sales slid by just 3% to US$845 million – with price reductions partly offset by new launches – while declines in Japan and Russia led International generics turnover to drop by more than a fifth to US$498 million.

"Copaxone (glatiramer acetate) continues to maintain its market share," Schultz observed, claiming that Teva had retained the "lion's share" of the glatiramer market despite global sales dropping by more than a third to US$601 million. In the US, Copaxone was averaging around 9,000 weekly prescriptions compared to around 2,000 for Mylan's version and 1,000 for Sandoz' Glatopa, the Israeli firm indicated.

In the third quarter, Teva also enjoyed inflated sales for its Austedo (deutetrabenazine) tardive dyskinesia treatment that was approved in the US at the end of August 2017, and recently launched its Ajovy (fremanezumab-vfrm) migraine drug following US Food and Drug Administration (FDA) approval in mid-September.

After accounting for respiratory brands, distribution and the bendamustine brands Treanda and Bendeka, other sales – including Teva's contract-manufacturing business and third-party API sales that were flat at US$171 million – came to US$723 million.

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Region	Third-Quarter Sales (US$ millions)	Change (%)	Proportion of Total (%)
North America	922	-25	*20*
Europe	845	-3	*19*
International	498	-21	*11*
Generics	2,265	-17	50
Copaxone	601	-39	13
Distribution	482	+10	11
Respiratory	236	-28	5
Treanda/Bendeka	161	-10	4
Austedo	62	+870	1
Other	723	-23	16
Teva	4,529	-19	100

Figure 1: Breakdown by region and business of Teva's sales in the third quarter of 2018 (Source - Teva)

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Coherus matches Mylan on pegfilgrastim price

Coherus BioSciences will match the US list-price discount offered by Mylan for biosimilar pegfilgrastim versus the reference brand when it begins shipping the firm's Udenyca (pegfilgrastim-cbqv) on 3 January 2019. Like Biocon's Fulphila (pegfilgrastim-jmdb) that partner Mylan launched earlier this year, Udenyca will be priced at US$4,175 per pre-filled syringe, a 33% discount to Neulasta's wholesale acquisition cost (WAC). "Beyond list price, we also have contracting plans that we believe will deliver additional value to payers, providers and patients in the long term, facilitating uptake," Coherus revealed.

Speaking during the company's third-quarter earnings call, Coherus' management indicated strongly that the company was, for now, prioritising pegfilgrastim efforts in the US over the European Union (EU). This is despite Coherus being among the first companies to obtain a pan-European marketing authorisation approval from the European Commission, and the first to obtain approval from both the US Food and Drug Administration (FDA) and EU regulator.

"We haven't had too much to say about partnering in Europe, for the time being," company head Denny Lanfear said. "We have been approached by some parties in Europe; we continue to chat with some folks. But I think that the company's best focus is in the US market."

With a freshly-hired US team of more than 70 sales representatives and other commercial personnel behind it in preparation for Udenyca's launch, Coherus has revealed ambitions to target the entire US Neulasta market, including the originator's Onpro Kit on-body injector. Senior vice-president of sales Chris Thompson said that the company believed, "through our economic value proposition, as well as the services that we're going to provide to patients," Coherus' pre-filled syringe product would be able to compete with the Neulasta Onpro Kit device.

Coherus was also confident in its ability to supply the market, the company said, "and we are prepared to meet our highest expected demand for an extended period of time." As a mark of quality, Coherus revealed that it had recently received and successfully completed two FDA inspections at Udenyca's production and testing sites.

Hikma to reduce global footprint

Hikma intends to reduce its geographic footprint from its current presence in around 50 countries worldwide, especially by focusing resources on only the most promising markets in the Middle East and North Africa (MENA) region, under a corporate strategy presented by Siggi Olafsson, who became chief executive officer around nine months ago. Olafsson also wants to treble the group's return on research and development investment within the next five years.

Stressing Hikma's differentiating factor of being "the only global local player" in the MENA region, Olafsson said the firm was "de-emphasising the number of countries we operate in". "I would be OK to be in a little bit fewer countries, but be able to grow faster in those markets," he stated. To that end, the group has identified Algeria, Egypt and Saudi Arabia as 'Tier 1' priority MENA markets in which it already has a significant presence, while it will put "minimal investment" and potentially outsource to agents and other third parties in countries such as Morocco, Libya, Tunisia and Sudan.

While Olafsson intends to maintain research and development spending at its current level of 6-7% of group turnover, he wants the sales contribution from new launches to roughly treble from 3% in 2017 and about 10% within five years. To do this, Hikma will, he says, both increase its total number of "shots on goal" and target more complex products. Developing Hikma's pipeline and leveraging partnerships and acquisitions, in part to add products and technologies, form two of three central strategic pillars, alongside driving efficiencies and cutting costs.