

# Mylan plans to play at scale as it aims for 13% growth

**Injectables, respiratory drugs, biologics and geographic expansion are all key elements in Mylan's plan to achieve 13% annual sales growth up to 2018. Aidan Fry reviews the group's strategy.**

Even in the often uncompromising world of generics, it is rare for senior executives to comment directly on the strategies of their competitors. But Mylan's executive chairman, Robert Coury, had no reservations as he sought to differentiate his company from its publicly-listed peers: Teva, Valeant and Actavis.

Reviewing the spectrum of Mylan's competitors, Coury observed that the past 18 months had seen industry consolidation continue at a rapid pace. "It seems that a lot of our competitors are redefining themselves," he told a recent investors' day. "They are taking a look at themselves and saying: 'Maybe I need to look different, because maybe I don't have what it takes to continue sustainable growth'."

Examining those publicly-listed peers he considered to be Mylan's closest competitors, Coury said Teva had made it "abundantly clear" that it was becoming a company focused on drug development. "We all know the risk profile with a straight development company."

Turning to Valeant, Coury contended that the Canada-based group had little development capacity, but was focusing rather on "buying anything it can sell". "And the risk profile of that is you can't keep doing it forever," he added.

"Actavis, as it redefines itself over and over again, keeps changing things around and keeps figuring out what it wants to be when it grows up," Coury continued. "What they have in development will not sustain the kind of growth they need to have to deliver to shareholders. That has its own risk profile, notwithstanding the fact that they have not matured yet. They are still integrating, and there is still execution risk."

While Coury remained open to bolt-on acquisitions and deals to add scale in specific therapeutic categories or product technologies – such as dermatology and ophthalmology – he ruled out making large-scale deals. "We will not be doing anything transformational," he stated. Moreover, Mylan would not pursue deals driven by economic, rather than strategic, rationale, such as to reduce its corporate tax rate. "We are not going to do transactions for financial engineers," he assured investors.

Coury insisted Mylan's risk profile was unique,

due to how the company had matured following its transformational acquisitions in 2007 of Merck Generics and Matrix. "We have come a long way with de-risking and taking the volatility out of our business model," he maintained. "And now that we have got differentiation with our customers, with patients and with doctors, it is time to get that differentiation with our investors."

To display its confidence, Mylan has set ambitious financial goals for the period up to 2018. At the midpoint of its current forecast, group turnover should reach around US\$7.20 billion this year, with single-digit Generics growth in North America – excluding the effect of last year's shared exclusivity for escitalopram – and double-digit advances in the Europe, Middle East and Africa (EMEA) and Asia-Pacific regions. If the company achieves its goal of a 13% compound annual growth rate (CAGR), sales should exceed US\$10 billion in 2016 and reach around US\$13.3 billion in 2018.

Over the same period, Mylan is targeting a 16% CAGR for its adjusted, diluted earnings per share (EPS). This would see Mylan more than double its projected EPS this year of around US\$2.85 to US\$6.00 by 2018.

In the first half of this year, Mylan's turnover edged up by 2% to US\$3.33 billion. The group said that equated to a 12% sales rise, excluding the impact of currency shifts and US\$264 million of escitalopram proceeds from shared exclusivity in the first half of 2012.

Global Generics turnover stalled at US\$2.86 billion as the prior-year exclusivity period for escitalopram caused sales in North America to fall by almost a tenth to US\$1.45 billion. The North American decline was all but offset by a 12.5% EMEA sales rise to US\$745 million on double-digit growth in France, as well as by Asia-Pacific turnover that grew by 9.3% to US\$663 million.

According to chief executive officer Heather Bresch, Mylan's first-half results showed the benefits of having a diversified product pipeline and portfolio, vertical integration through its former Matrix active pharmaceutical ingredients (APIs) operation, and a global marketing platform that gave the group opportunities to operate on a large scale. Mylan plans to launch around 600 products per year through to 2018.

"Today we produce 80% of what we sell," Bresch pointed out, noting that the Merck Generics business that Mylan acquired in 2007 had licensed-in around 70% of its portfolio. "Being in control of our own destiny is a critical differentiator for us," she stated.

Bresch said Mylan intended to be first in, and last out, in all major markets, operating at a scale that made it an attractive partner for customers that were growing larger through consolidation. This, she said, would allow Mylan to capitalise on rising rates of generic penetration, both in southern European countries, as well as in other major markets, including Australia and Japan.

The pending takeover of Strides Arcolab's Agila division would give the group "critical mass in injectables", with over 800 injectable drugs slated for launch by 2018, including 150 in the US. Mylan, she pledged, would use the cash generated by its current

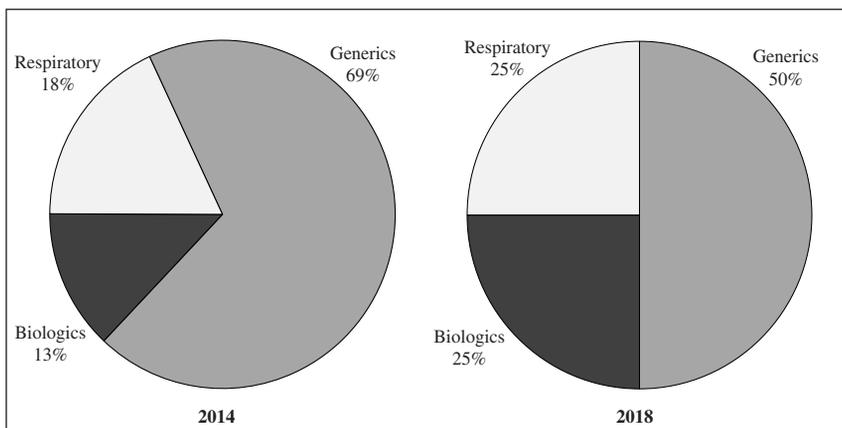


Figure 1: Breakdown by product type of Mylan's anticipated research and development investment in 2014 and 2018 (Source – Mylan)

operations to invest in a pipeline that included respiratory drugs and biosimilars.

To ensure its global marketing platforms are well-stocked through an extensive pipeline, Mylan has a network of nine research and development sites, two of which – in Hyderabad, India and Morgantown, US – are global centres. The other seven sites focus on specific technologies, including three for respiratory drugs in the UK and Ireland. Of around 2,600 scientists and regulatory experts across the nine centres, 150 are working on respiratory projects, 90 on transdermal patches and 470 on APIs. Once the Agila deal is completed (**Generics bulletin**, 8 March 2013, page 1), Mylan will have more than 400 researchers dedicated to injectables development, while a further 265 are working on biologic projects – including analogue insulins – through the firm’s alliance with India’s Biocon.

Over the next five years, Mylan anticipates cumulative research and development spending of around US\$2.8 billion. Next year, 18% of that budget is earmarked for respiratory projects, and 13% for biological drugs (see Figure 1). By 2018, each product group will account for a quarter of Mylan’s investment.

Once the Agila deal closes, Mylan will have more than 1,200 products in its global pipeline, with almost 2,200 submissions pending approval around the world. In the US, the company believes 38 of its 325 pending abbreviated new drug applications (ANDAs) are potential first-to-file opportunities.

Mylan’s president, Rajiv Mailk, noted that in 2007 – when Mylan completed the Merck Generics and Matrix transactions – the group had been primarily an oral solid-dose player. But as of 30 July 2013 – and including Agila on a pro forma basis – only 571, or 47%, of 1,218 development projects were oral solid-dose drugs. Another third, or 410, were injectables. The firm had 54 topical drugs and 39 ophthalmics in development, with between 20 and 30 projects each in patches, soft-gel capsules, inhalants, nasal sprays and solutions and suspensions.

And with Agila on board, approaching half – or 965 – of Mylan’s 2,167 global pending submissions would be for injectables.

Chief operating officer Hal Korman observed that by 2016, Mylan would have a commercial presence or products in development in 19 of the world’s 20 leading therapeutic classes, as measured by IMS Health. The only exception would be vaccines, he noted.

Looking at Mylan’s US Generics operation, Malik said the firm’s marketed portfolio covered products with an annual brand value of US\$54 billion (see Figure 2). On the same basis, its submitted dossiers targetted US\$83 billion of brand sales, while its development portfolio was targetting US\$110 billion of annual value. This left US\$80 billion of brand sales still to aim for.

As can be seen from Figure 3, North America plays a fairly minor part in Mylan’s global launch schedule, which it anticipates ramping up from fewer than 800 this year to more than 1,300 in 2016.

Having 18 months ago pledged to double its manufacturing capacity to meet anticipated global demand as a large-scale generics supplier (**Generics bulletin**, 23 March 2012, page 22), Mylan has been investing heavily in its global supply chain. “Over the past year, we have added almost 500 kilolitres to our APIs capacity,” Malik highlighted.

“Being one of the largest API manufacturers in the

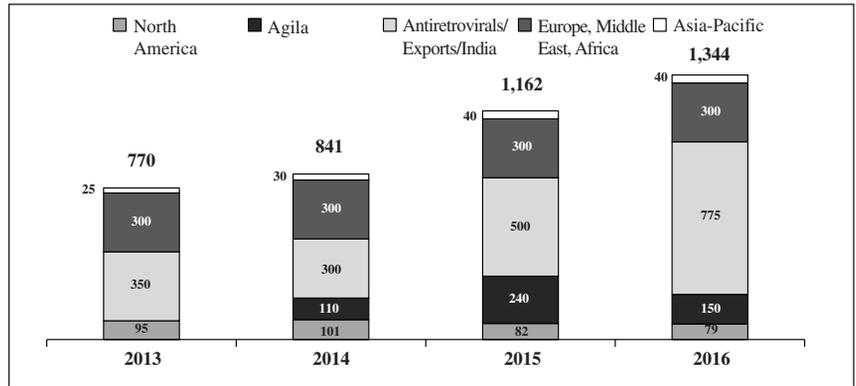


Figure 3: Breakdown by region and product type of Mylan’s global launch schedule, by numbers of products, between 2013 and 2016 (Source – Mylan)

world enables vertical integration,” he maintained. The group’s 10 bulk-drug facilities currently produced 3,500 kilolitres of API across 230 molecules, he said, adding that the firm held 173 US drug master files (DMFs) in the US and 186 comparable approvals in Europe. “Approximately 50% of our global pipeline, and 25% of our commercial portfolio, is vertically integrated,” he revealed.

By controlling its cost of goods, Malik continued, Mylan could ensure its portfolio was durable. “More than 50% of our generics gross profit in the US comes from products that have been on the market for four or more years,” he pointed out.

In the oral solid-dose sector, Mylan plans to raise its current output of 54 billion units to 82 billion by 2016 as the group capitalises on growing generic utilisation.

“We have more than doubled our patch capacity from 105 to 260 million packs,” Malik said, noting that Mylan’s pipeline included products such as a rival to Endo’s Lidoderm (lidocaine) analgesic. Mylan had also doubled its semi-solids and aerosols capacity over the past year or so (see Figure 4), while Agila would vastly increase the relatively small injectables capacity that it had gained by acquiring Bioniche’s plant in Galway, Ireland (**Generics bulletin**, 17 September 2010, page 9).

Once Agila adds sites in Brazil, India, Poland and Singapore, 13 of Mylan’s 28 finished-dosage form facilities will be for injectables. An expected annual output of 650 million units in 2016 would create an “injectables manufacturing powerhouse”, Malik claimed.

Agila will double the size of Mylan’s injectables operation to around US\$600 million next year. As Figure 5 shows, it will have more than 1,250 injectables approved around the world, and almost another 1,000 dossiers pending approval. The group will have more than 400 injectable drugs in development.

Korman pointed out that Agila would strengthen Mylan’s presence in both developed and developing countries. In North America, it would double the former Bioniche portfolio in the US and add to the group’s current fifth-placed ranking in Canada. The US\$1.85 billion deal would diversify

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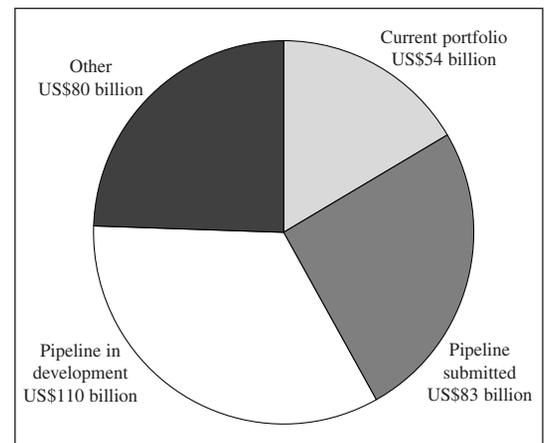


Figure 2: Breakdown by brand value of Mylan’s US generics portfolio and pipeline (Source – Mylan)

Mylan's customer base and add scale in Australia, he said, and would give the group "the ability to go pan-European" in the injectables arena.

"Agila's presence in Brazil provides a launching pad for Mylan's entry into a key growth market," Korman continued. Building on the firm's penems and penicillins facilities in Campos, Brazil – as well as its limited local presence in APIs and antiretrovirals – Mylan would explore opportunities to roll out other dosage forms and therapeutic classes in Brazil and neighbouring countries.

In India, Agila's injectables would allow Mylan to expand its commercial presence beyond antiretrovirals and women's health products (**Generics bulletin**, 12 July 2013, page 11). Korman said the acquired injectables business would also provide a platform from which to expand in other emerging markets, such as in Africa, the Middle East and in south-east Asia. In several countries, he added, Mylan already had a significant operation through its portfolio of 14 antiretroviral molecules offered in 43 formulations.

While Agila will not give Mylan a way into China's finished-dose market, the US-based group is currently exploring strategic collaborations that would move it beyond its existing small presence in the APIs sector. A strategic alliance with Pfizer is already proving valuable in Japan. Having launched its first product, tacrolimus, under a joint Pfizer/Mylan label in June this year, Mylan said the combined salesforce of around 800 representatives had "more than doubled our market share in Japan". "I think [the Pfizer alliance] is a model to roll out in some other emerging markets," Coury stated.

Across all emerging markets, Mylan regards launching its pipeline of respiratory and biologic drugs – including insulin analogues – as a "future opportunity".

The group is currently building capacity for dry-powder inhalers at a purpose-built facility in Dublin, Ireland, as it works towards filing for a generic version of GlaxoSmithKline's Advair/Seretide (fluticasone/salmeterol) brand in both the US and Europe. In the US, a pivotal clinical study is scheduled to start during the second half of this year, ahead of a planned ANDA filing for a fully-substitutable generic in the first half of 2015. A US launch of an inhaler offering "the same size, shape and patient experience" as the Advair device is expected in the second half of 2016.

In the European Union (EU), Mylan expects to launch a fluticasone/salmeterol dry-powder inhaler in the second half of 2015, as "definitive pharmacokinetic trials" get underway this year. A planned dry-powder filing in the second half of 2014 will come about a year

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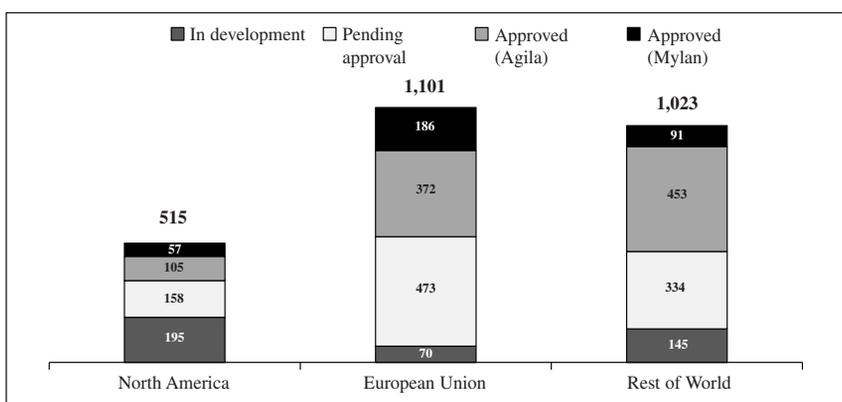


Figure 5: Mylan's current injectables portfolio and pipeline by numbers of products (Source – Mylan)

	2012 (Units mns)	2013 (Units mns)	2016 (Units mns)
API (reactor capacities in kiloliters)	3,000	3,500	5,700
Oral solid dose	45,000	54,000	82,000
Transdermal patches	105	260	290
Semi-solids and aerosols	15	32	42
Injectables*	11	350	650
Dry-powder inhalation	–	0.5	25

\* post Agila close

Figure 4: Mylan's current and forecasted manufacturing capacity (Source – Mylan)

later than the firm's expected submission for a pressured metered-dose inhaler (pMDI) version of Seretide, thanks to the deal Mylan recently struck with 3M (**Generics bulletin**, 9 August 2013, page 23).

An alliance with India's Biocon is spearheading Mylan's drive into the biosimilars arena. Global development programmes are underway for biosimilar versions of five immunology and oncology products. The alliance recently started enrolling patients for a Phase III trial for a rival to Herceptin (trastuzumab) in Europe (**Generics bulletin**, 7 June 2013, page 22), while alternatives to Neulasta (pegfilgrastim) and Humira (adalimumab) should enter clinical trials during the next 12 months. Rivals to Avastin (bevacizumab) and Enbrel (etanercept) are at the pre-clinical stage.

Meanwhile, Mylan has set up its own biosimilars development laboratory that is working on cell-line development for three undisclosed monoclonal antibodies.

Earlier this year, Mylan extended its collaboration with Biocon to cover three insulin analogues that the Indian firm had previously licensed to Pfizer (**Generics bulletin**, 8 March 2013, page 19). The most advanced of the three diabetes candidates is a rival to Sanofi's Lantus (glargine) that is set to enter Phase III trials in first half of 2014, ahead of a planned filing in regulated markets in the first half of 2016. Alternatives to Lilly's Humalog (lispro) and Novo Nordisk's NovoLog (aspart) are at the process-scale-up phase.

The US group is confident of launching a generic version of Teva's Copaxone (glatiramer acetate) multiple-sclerosis blockbuster in May next year, following its recent US Court of Appeals victory on patents expiring in 2015 (**Generics bulletin**, 9 August 2013, page 1).

Mylan's 13% turnover CAGR through to 2018 assumes that it will record no biosimilars sales in the US before that date. Biosimilars in other markets and the firm's generic respiratory portfolio are each expected to contribute no more than 5% of group sales in 2018, while the group's Specialty respiratory brand EpiPen should add a similar amount. The company expects a substitutable generic to enter the US market in 2015. But the group believes its injectables business will be approaching an annual turnover of US\$2 billion by 2018. More than 3,000 cumulative launches will contribute a similar sum to turnover, which will also be swelled by geographic and portfolio expansion.