

# Watson is authorised to expand rapidly in 2011

**Watson believes that its 2011 generics growth will come primarily from its US authorised-generic launches, as Mike Rice reports.**

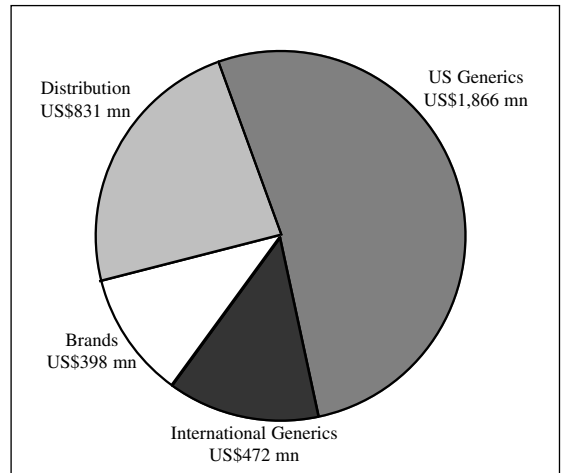
**U**S atorvastatin sales will make a US\$100 million contribution to Watson's gross profit in just one month at the end of this year. Revealing the US firm's 2011 expectations, chief financial officer Todd Joyce said the pre-tax profit forecast assumed an authorised-generic launch by Watson at the end of November 2011 with just one generic competitor. He added, however, that about 85% of the 2011 after-tax gross profit contribution would be paid to former Arrow shareholders in 2012. It was Arrow that had negotiated the Lipitor authorised-generic deal with Pfizer before its US\$1.75 billion takeover by Watson in December 2009.

President and chief executive officer Paul Bisaro commented that after Ranbaxy's 180-day generic exclusivity expired, Watson only expected "maybe two or three" rather than seven or eight atorvastatin players to enter the market. "Pfizer is suing on patents running to 2018, there are 30-month stays and no tentative approvals have been granted to date," he said. "Think of the fentanyl patch market when price decline was gradual."

Asked why there had been no tentative approvals to date, Bisaro said he had no explanation. "Sometimes the [Food and Drug Administration (FDA)] doesn't grant tentatives. They just wait till the end and grant final approvals," he said, adding that "we believe we'll have plenty of capacity and plenty of product to be able to supply the entire market, if need be, in November".

Before then, Watson will be launching on 1 May its authorised generic of Concerta (extended-release methylphenidate) under a deal with Johnson & Johnson (*Generics bulletin*, 12 November 2010, page 19). The agreement over the drug for attention-deficit hyperactivity disorder (ADHD) runs until the end of 2014, after which time Watson will be able to launch its own generic, provided it has final FDA approval. In the meantime, however, Watson expects there to be a two-player market, with Ortho-McNeil-Janssen continuing to market the brand for which Johnson & Johnson reported US sales down by 5.8% to US\$929 million in 2010.

Global Generics head, Siggí Olafsson, noted the brand originator had recently imposed a double-digit price increase, adding there would be price erosion, but Watson and McNeil would have the market to themselves "for some time". McNeil settled its Concerta patent litigation with Impax four years ago (*Generics bulletin*, 20 October 2006, page 13), and the generics



**Figure 2: Breakdown by business of Watson's group turnover up by 28% to US\$3.57 billion in 2010 (Source – Watson)**

firm still expects to launch upon FDA approval.

Watson won its court battle last year, but it is still awaiting FDA approval for its extended-release product. Bisaro commented that he was not certain the FDA had concluded yet what it wanted to do. McNeil has called for additional bioequivalence metrics in a citizen petition, but Bisaro thought the agency was in no hurry to resolve the issues because "there's only one other filer and that filer is pretty early in the process". "It's hard to predict how long it's going to take them," commented Bisaro.

Watson is forecasting that extended-release products, including its Concerta authorised generic from 1 May, will contribute US\$230 million to its pre-tax gross profit in the first half of this year (see Figure 1). This will increase to US\$290 million in the second half, when its Concerta product will have contributed a full six months instead of just two.

Joyce pointed out that Watson's earnings growth this year would be driven by product launches, and primarily those of its Lipitor and Concerta authorised generics in the US. Price erosion, he added, would be "modest" and consistent with that in 2010. Additional competition, however, would impact key franchises, such as Watson's extended-release metoprolol generic equivalent of Toprol XL, its extended-release potassium chloride capsules offering an alternative to KV Pharmaceutical's Micro-K, and its oral contraceptives.

Business segment	Fourth-quarter sales (US\$ millions)	Change (%)	Operating margin (%)
Generics	646	+38.2	38.1
Brands	103	-14.6	2.0
Distribution	203	+3.0	5.3
<b>Watson</b>	<b>953</b>	<b>+21.2</b>	<b>5.8*</b>

\* includes unallocated corporate expenses totalling US\$204 million

**Figure 3: Breakdown by business segment of Watson Pharmaceuticals' turnover and operating margin in the fourth quarter of 2010 (Source – Watson)**

Business segment	Annual sales (US\$ millions)	Change (%)	Operating margin (%)
Generics	2,338	+40.2	35.6
Brands	398	-13.7	17.6
Distribution	831	+25.1	5.9
<b>Watson</b>	<b>3,567</b>	<b>+27.7</b>	<b>8.6*</b>

\* includes unallocated corporate expenses totalling US\$647 million

**Figure 4: Breakdown by business segment of Watson Pharmaceuticals' turnover and operating margin in 2010 (Source – Watson)**

Oral contraceptive sales had increased by 3% year-on-year to US\$97.9 million in the fourth quarter of 2010, Joyce noted, while net revenues from outside the US had reached US\$149 million, although this included US\$25 million from a third-party development agreement.

Total global generics sales for the year as a whole had been 40.2% higher at US\$2.34 billion, of which international generics sales outside of the US accounted for US\$472 million (see Figure 2). “In our global generics business, we filed 34 abbreviated new drug applications (ANDAs) in the US and made over 145 applications around the world,” commented Bisaro. “We also launched seven products in the US and disclosed 17 new patent challenges,” he added.

Selling more extended-release US products towards the end of the year was behind a nearly four percentage-point rise in global generics’ adjusted fourth-quarter gross margin to 50.6%. “Sales of extended-release products increased by 53% to US\$191 million,” Joyce noted.

The gross margin would have been higher, he added, but for lower gross margins in the international business. Global fourth-quarter generics turnover improved by 38.2% to US\$646 million (see Figure 3), driven by adding Arrow’s international business and new products, including extended-release diltiazem and metoprolol, as well as Zarah, Watson’s generic version of Bayer’s Yasmin oral contraceptive. “Our focus on making Watson one of the most profitable pharmaceutical companies in the industry translated into a very strong year,” said Bisaro, who pointed out the firm’s total turnover had grown by 27.7% during 2010 (see Figure 4).

**Rapid rise in expenses**

Adjusted earnings before interest, taxes, depreciation and amortisation (EBITDA) was 22% higher at US\$838 million, noted Bisaro, although operating income as reported was a fifth lower at US\$305 million. Amortisation expenses nearly doubled to US\$180 million; while selling, general and administrative expenses, as well as research and development costs, were both about 50% higher at US\$756 million and US\$296 million, respectively.

“In our global brands business, we launched three new US products, completed the phase III study with Columbia Labs on Prochieve 8% for preventing pre-term birth in women with a short cervix, and announced an alliance with Gedeon Richter to develop Esmya for treating uterine fibroids,” recalled Bisaro.

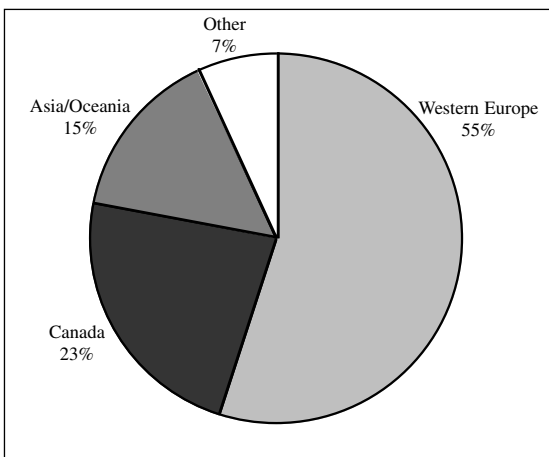


Figure 5: Breakdown of Watson's international generic sales worth US\$472 million in 2010 (Source – Watson)

	1st half 2011 (US\$ millions)	2nd half 2011 (US\$ millions)	Total 2011 (US\$ millions)
Extended release*	230	290	520
Oral contraceptives	130	110	240
Atorvastatin**	–	100	100
Others (incl. international)	210	230	440
<b>Generics</b>	<b>570</b>	<b>730</b>	<b>1,300</b>

\* includes May 2011 launch of Concerta generic  
\*\* assumes late November 2011 launch with one other competitor

Figure 1: Forecast gross profit contributions to Watson's global generics total in 2011 (Source – Watson)

Joyce pointed out that Watson ended the year with over US\$290 million in cash and marketable securities, as well as US\$500 million of undrawn capacity within its revolving credit facility. “Strong cash flow from operations of over US\$570 million,” said Bisaro, “enabled us to reduce our debt-to-adjusted EBITDA ratio to approximately 1.2-times, which provides us with the flexibility to capitalise on future opportunities to grow the company. We have a balance sheet that’s capable and ready to take on additional work, and we’re going to put that money to work as quickly as we can.”

Bisaro told *Generics bulletin* he wanted to make Watson stronger in the international markets in which it was already present and to enter new markets, possibly in “creative ways”. “Emerging market multiples have skyrocketed to the point that it’s not even appropriate for us to participate in some of those opportunities,” he said. He cited the unusual deal with Brazil’s Moksha8, in which Watson has taken a significant minority share for US\$30 million (*Generics bulletin*, 15 October 2010, page 3). “It will take time, but we’ll probably end up owning Moksha8,” commented Bisaro, who noted that this was preferable to paying profit multiples of 20-times or 30-times at the outset.

Moksha8 demonstrated Watson’s commitment to expand its global footprint and maximise the potential of its current portfolio, Bisaro said, noting that more than half Watson’s international generics business was in western Europe (see Figure 5). However, Bisaro wants to take Watson’s existing products and use them to build sales in North and South America as well as in Asia and the Pacific Rim countries. This includes evaluating the best way for Watson to enter the Japanese market, where it does not have a presence currently. Europe, however, is seen for the time-being as a

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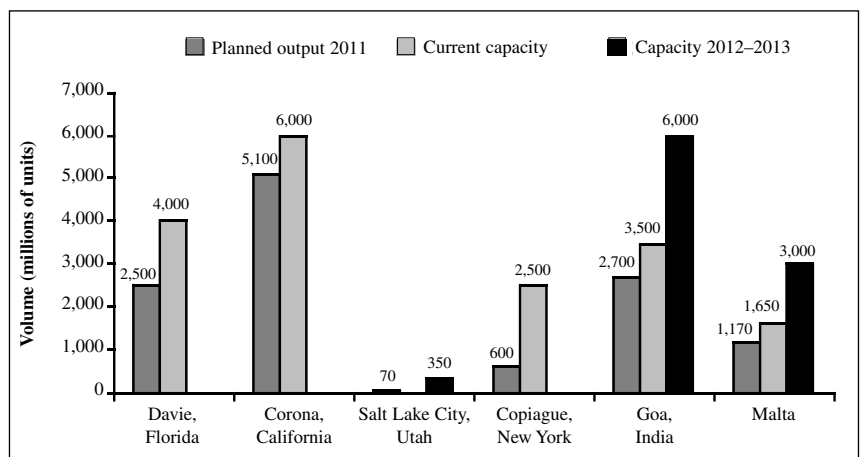


Figure 7: Planned expansion of Watson's global manufacturing network showing planned output in 2011, and current capacity and 2012-13 capacity. Volumes are shown in millions of units (Source – Watson)

“licensing opportunity” for Watson’s US products.

In Australia, where 97% of Watson’s business was through Spirit and Sigma – now part of South Africa’s Aspen – the firm planned to build a Watson sales channel, commented Olafsson. Noting that a significant pipeline had already been established, Olafsson added that there was an opportunity to introduce Watson’s US portfolio and pipeline in the country.

When asked about Watson’s plans to develop its European business, Bisaro commented: “We’re in the big markets of Europe to stay.” As Figure 6 shows, Watson is currently ranked in fifth place in the UK market and sixth in France. It also has presences in Germany, Poland and the Nordic countries. This is some way short, however, of Bisaro’s market aspirations. “We’ve got to be a top five company,” he remarks, “so that we’re relevant, and customers have to pay attention to us.”

Through Arrow’s Cobalt subsidiary, Watson is already sixth in Canada, where Bisaro says Watson has “critical mass”. Indeed, during 2010, the Canadian operation had the highest growth rate in the number of prescriptions dispensed of any player, racking up a 59% increase, according to Olafsson. Six new launches were instrumental, but the gains were achieved against a background of double-digit price erosion as a result of provincial government intervention.

In Brazil, Watson would be targeting both branded generics and branded on-patent drugs through Moksha8, according to Olafsson, who said the initial focus would be on specific therapeutic categories such as central nervous system, pain and urology. Brazil also offered a platform for entering the Mexican market, he added.

Watson’s existing operation was already competing in tender markets for unbranded generics, he said, and via various partners in branded generics. He noted that half of Brazil’s US\$17 billion pharma market comprised unbranded and branded generics as well as ‘*similares*’ that had not demonstrated bioequivalency. Unbranded generics represented US\$2.5 billion he added.

Watson was registering its US products in Europe, Olafsson said, where it also had joint ventures in Ireland, Spain and Switzerland. In total, 350 products had been commercialised in Europe in 920 stock-keeping units. A total of 115 product approvals had been received last year and 127 submissions had been made, Olafsson said.

Noting Watson was not present in Belgium, Italy and the Netherlands, Olafsson said Watson wanted to expand strategically in Europe “and not enter too many markets at once”. Turkey, however, was an attractive market where it was “ready to run commercially”.

“In Europe, our growth priorities are to improve our market share position in key markets like France and the UK; and to grow our portfolio,” he said. We aim to launch 35-40 products across France and the UK in 2011, and another 25-30 products across other markets.”

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	Revenue (US\$ millions)	Growth (%)	Adjusted gross margin (%)
Generics	2,800 – 3,000	+20 – +28	~43 – 46
Brands	470 – 490	+18 – +23	~73 – 76
Distribution	820 – 840	-1 – +1	~14 – 16
<b>Watson</b>	<b>4,090 – 4,330</b>	<b>+15 – +21</b>	<b>-</b>

Figure 8: Watson’s forecasted segmental revenue in 2011 (Source – Watson)

Country	National ranking
New Zealand	Second
US	Third
UK	Fifth
Canada	Sixth
France	Sixth
South Africa	Ninth
Australia	-
Brazil	-
China	-
Germany	-
Nordic countries	-
Poland	-
Turkey	-

Figure 6: Geographical spread of Watson’s business today, showing local market rankings where appropriate (Source – Watson)

priorities was to improve cost-of-goods by transferring manufacturing to Watson facilities. Referring to the firm’s “operational excellence initiative”, Bisaro pointed out that Watson had continued to strengthen its global supply chain in 2010. “We initiated the closure of our Australian research and development facility and our Toronto, Canada manufacturing facility,” Bisaro said, “and we closed our Carmel, New York facility on schedule at the end of the year. More recently,” he added, “we announced plans to phase out and ultimately end generic research and development activities at our Corona, California facility.”

In addition to three active pharmaceutical ingredient (API) facilities in Jiangsu in China, Amernath in India and Coleraine in Ireland, Watson has 11 manufacturing sites worldwide. Three in particular would be expanded significantly, according to Bob Stewart, head of Watson’s global operations. These would be Arrow’s plant in Malta, the Indian facility at Goa and the Salt Lake City research centre, which would focus on patches and hydrogels (see Figure 7).

**First biologic development candidate**

Watson announced its first biologic development candidate during the year from its deal with Itero Biopharma for recombinant FSH for infertility, Most of the technology had now been transferred to Watson’s Eden facility in Liverpool, UK, Bisaro said, adding that a clinical programme had been established “which will result in registrations for this product around the world”.

Pointing out that the biosimilars opportunity was five to 10 years away, Bisaro said most monoclonal antibodies were well within the time horizon for Watson to catch up and become a first marketer. “We’re talking to potential players,” he told *Generics bulletin*, noting that Eden had a strong track record in the biologics arena.

“Watson is beginning 2011 with extraordinary momentum to grow across all of our businesses,” Bisaro said, underscoring the firm’s 2011 forecast (see Figure 8). Further forward, his vision for Watson is that of a global, integrated pharmaceutical company existing in a world where the various pharma business models have “morphed together”.

“We shall be vertically-integrated and have offerings in generics, brands and ultimately biologics,” he said. “Our research and development capabilities will be accelerating our global pipeline growth and we shall be expanding profitably in a number of key markets.” **G**