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Viatis: Watch Out For Potential Complex Injectable Launches In 2023

As Firm Welcomes Generics ‘Momentum We Have Never Seen Before’

by Dean Rudge

Viatis has again lauded the potential of its complex injectables and steriles pipeline, as it looks to build a business generating revenues of up to \$1bn per year within the next five years.

Viatis has guided for certain of its pipeline of complex injectable and sterile products in the US to come to market “if we are optimistic later this year or early next year,” as it continues to aim towards building a franchise worth, it believes, at least \$1bn per year in peak net sales by 2027 or 2028.

The company has eight first-to-market opportunities that are currently under regulatory review from within its complex injectable/steriles pipeline, including a generic version of Novo Nordisk’s GLP-1 receptor agonist Wegovy (semaglutide) treatment for obesity, which has captured headlines around the world in 2023.

Another Novo Nordisk version of semaglutide, Ozempic for type 2 diabetes, is also disclosed as part of Viatis’ FTM complex injectable pipeline.

The remaining opportunities named include Invega Trinza (paliperidone palmitate) once-quarterly injection; Abilify Maintena (aripiprazole) once-monthly injection; Sandostatin LAR (octreotide acetate) depot injection; Injectafer (ferric carboxymaltose) intravenous injectable; and Venofer (iron sucrose) intravenous injectable.

Meanwhile, an asset identified only as MR-204 for the treatment of chronic dry eye is also listed as a FTM opportunity that is under review with the US Food and Drug Administration. Viatis

says one more first-to-market product will be filed in 2023.

Rajiv Malik, Viatri's president, insisted to investors during the company's second quarter earnings call that "not that every product is going to come in 2027," with some possible in 2023 and 2024.

"And then from there onwards, I think every year you're going to see two or three key products getting launched – over, I would say, 2024, 2025 and 2026, leading to a \$1bn franchise in 2027, 2028."

"We have about eight first-to-file, first-to-market opportunities which we have already secured. We have about 37 products in this pipeline, and we are adding more," Malik disclosed.

"From the science point of view, we could not be more pleased," he commented. While he acknowledged potential issues with getting the green light from the FDA – "there's always a little bit, changing and time" – Viatri's has "taken that into consideration while modelling all this."

Rocky Mount Hurricane

Meanwhile, on the issue of sterile injectables, Malik also responded to a question relating to Pfizer's major US sterile injectables facility at Rocky Mount, which was hit by a tornado in July. Fortunately, the company's employees at the site were able to evacuate and emerged safe, Pfizer disclosed.

Speculation over potential shortages and disruptions to product availability have since followed, given the significance of the plant to the US supply chain. (Also see "[Pfizer Rallies To Fix Tornado Damage At Key Injectables Plant](#)" - Generics Bulletin, 24 Jul, 2023.)

"First of all, it was a really unfortunate event. Nobody anticipated it," Malik commented. "We have stayed very close to the market, to our customers, to the FDA. From the drug shortages point of view, we do have some overlap products with Pfizer's portfolio coming out of the Rocky Mount facility," he acknowledged.

"And look, if there's a need, we will step up," he underlined. "We are working very closely with the supply chain to make sure that we are in a position to address the drug shortages as and when, if they come through."

Spiriva Generic

Viatri's next touched on its very recent launch of the company's Breyna (budesonide/formoterol) generic version of AstraZeneca's Symbicort for asthma and chronic obstructive pulmonary disease.

Having several years ago broken new ground in the US generics market by launching the first approved rival to Advair (fluticasone/salmeterol) in early 2019, Viatris in late July announced the launch of Breyna, a product developed in collaboration with inhalation device design specialist Kindeva Drug Delivery. (Also see "[Viatris Debuts US Symbicort Rival](#)" - Generics Bulletin, 31 Jul, 2023.)

"We expect that this launch will [come with] 180 days of first-to-file generic exclusivity, which is subject to the FDA's future determination of the issue, if and when another abbreviated new drug application filer becomes eligible for final approval," Malik noted.

Viatris is currently the only firm to hold an FDA approval for a generic equivalent to Symbicort – although other developers are working on generic versions, including Cipla.

Hitting On All Cylinders

Reporting revenues for the unit that "came in ahead of expectations," moving ahead by 5% as reported and 8% on an operational basis to \$1.33bn in the three months to 30 June, Viatris also spoke at length about trends for its global Generics business, especially in the US.

"The base business – we see momentum we have seen never before; whether it's in emerging markets or China or Europe or North America, it's hitting on all cylinders," Malik commented.

"So, the stability and predictability you have seen, we have never seen before. It's setting up the company exactly how we have planned it and now we are seeing it," Malik said. "And the execution is just bringing with it a whole another level now."

Viatris disclosed that its North America business during Q2 was flat year-on-year on an operational basis and also "performed ahead of expectations. Generics delivered a better than expected performance," led by generic lenalidomide, Wixela Inhub [generic Advair] and Xulane (norelgestromin/ethinyl estradiol) transdermal system.

In the US, Malik observed, "we always knew that the pricing is [based on] two factors in effect: supply and demand, and portfolio mix."

On the former, Malik commented, "yes, the market is seeing some disruption, some hiccups and it may go a little bit further in that direction, before it gets better."

But because of the supply disruptions, "and because of our diversity," he said, "we have seen price stabilization over the last several quarters in North America, which we have not seen for a few years."

On portfolio mix, Viatris had worked "diligently to move away from commodities, into more

diversified, complex products, and that's giving the underlying stability of the mix in the US."

"So, yes," he concluded, "we see the market conditions improving in North America as far as the generics are concerned."

Moving away from the US, Malik pointed out that "even in emerging markets and Europe, Generics had a very solid performance. And in fact, [we saw] 11% or 10% growth in emerging markets driven by the Generics performance."

Advanced Discussions With Buyers

From a broader business standpoint, Viartis affirmed that it is on track to announce all of its planned divestitures in 2023, as the company looks to chart a new path to growth following the merger of Mylan and Upjohn late in 2020, under the stewardship of recently appointed CEO Scott Smith.

Viatris had late last year named four more businesses planned for the auction block under its proposed \$9bn global overhaul, after signing off on the \$3.3bn agreement to offload the firm's global biosimilars unit to Biocon Biologics. (Also see "[*Viatris To Shed OTC, APIs And Women's Health As Biocon Deal Nears Completion*](#)" - Generics Bulletin, 9 Nov, 2022.)

The non-core assets identified for sale at the time were the company's OTC, women's healthcare and active pharmaceutical ingredients businesses, "but retaining some selective development API capabilities."

Meanwhile, it was also looking to sell off "certain geographical markets that were part of the combination with Upjohn's business that are smaller in nature and in which we had no established infrastructure prior to or following the transaction."

Smith underlined to investors during the earnings call that "executing these planned divestitures is a matter of strategic choice, not a necessity. I am extremely pleased," he said, "with where we are in the process. We are currently in advanced stages of discussions with potential buyers and anticipate announcing at least one significant divestiture in the third quarter, possibly more."

During the Q&A session, he added further: "It's important to remember that these divestitures represent a cash bonus that will be coming to us to help us accelerate towards our desired leverage ratios."

"What they do is they really set us up well going into 2024 and beyond. And the critical thing for the future is our ability to deliver on our capital allocation plans in 2024 and beyond, which include capital return to investors through divestitures, and particularly share buybacks, as well as business development, M&A, licensing and partnerships."