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Viatris CEO Talks Integration, Roadmap And Interchangeable Biosimilars

Michael Goettler Sets Out Vision For Viatris On Anniversary Of Mylan-Upjohn Merger

by David Wallace

As CEO Michael Goettler provides an update on the progress made by Viatris in its first year as a combined company, he also offers Generics Bulletin hints as to the detailed strategy that will be unveiled at the firm's upcoming investor day and explains how biosimilars – including interchangeable Semglee (insulin glargine) – and complex generics are important components of the firm's future growth plans.

Speaking to Viatris CEO Michael Goettler on the first anniversary of the merger between Mylan and Upjohn, his enthusiasm for the firm's achievements over the past 12 months is immediately obvious.

"It feels good to reflect a little bit on all that we have accomplished in the first year, because it's been a fantastic year really," he said in an exclusive interview. "I could not be prouder of everything that our 38,000 colleagues around the world have accomplished in our first year."

Viatris Plots 'Significant' Restructuring As Mylan-Upjohn Merger Completes

By Dean Rudge

16 Nov 2020

In merging Mylan and Upjohn, Goettler explained, "we started with a vision to create not only a new healthcare company but a new kind of healthcare company, one that empowers patients around the world to live healthily at every stage of life, one that is really passionate about access and making sure that the medicines that patients need actually reach the patients; high-quality medicines and affordable

medicines."

"And we have also created a really sustainable business model here," he added. "We think this is really a healthcare company for the future."

Nearly 16 months after it was first announced, the $12bn merger of Mylan and Pfizer's Upjohn has completed, with the resulting company Viatris preparing to unveil restructuring plans by the end of 2020.

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Invited to comment on the company's financial performance to date, Goettler said "I think the results of the first year really speak for themselves. We now have three strong quarters of meeting and beating expectations – our own expectations and the street expectations – for three consecutive quarters, so that feels strong."

After raising its full-year guidance earlier in 2021, the firm once again did so as it recently reported third-quarter results.

In terms of the firm's financial priorities, Goettler highlighted that "we have a very clear commitment in our capital allocation priorities and financial commitments that we made that includes paying down our debt. We committed to a $6.5bn debt paydown in the first three years, [and after the] first three quarters we are already at $1.9bn, so we are on track to deliver that."

Meanwhile, in terms of the financial benefits that Viatris would reap from the combination of Mylan and Upjohn, Goettler intimated that "we are on track to achieve our cost synergies. Integration is going very well," he indicated, noting that "we are on track to deliver $500m synergies for this year and $1bn by 2023."

"So on the business side, it's very, very strong and we're very pleased with the progress we're making."

Moreover, Viatris was "also being recognized for the impact that we are making," Goettler pointed out. "We were listed by Fortune magazine on their 'change the world' list, we were one of the top five companies to have a positive impact on the world – that was specifically for the work we did on HIV/AIDS, but you can apply that to many other areas. And we were named by Forbes magazine as one of the world's best employers. It's really going great."

"It's not only about integrating two companies, putting one and one

> *together and making it work. It's also about creating a stronger company."*

Asked specifically about the progress made so far on integration, Goettler acknowledged that there was still "clearly more work to do, but I think we're fully on track with what we set out to do. Not only in terms of the cost synergies but also how the companies come together, how we work, how we transition people into a common HR system, we start exiting some of the transitional services agreement that we set up with Pfizer, etc."

Talking further about the approach taken in combining Mylan and Upjohn, he said "it's not only about integrating two companies, putting one and one together and making it work. It's also about creating a stronger company, and I think that's where it really comes in well for us."

"We have an internal roadmap as well, to make us a stronger company, simplify processes, simplify systems, increase transparency, build the right culture going forward, and I think it's all playing out very nicely."

January Investor Day Will Lay Out Two-Phase Plan

Analysts and investors waiting for a detailed look at Viatris' longer-term plans recently learned that the company would on 7 January 2022 "discuss more details of the company's two-phase strategic roadmap" at an investor event.

"On January 7 we're going to lay out what we see as a two-phase plan," Goettler elaborated. "Phase one being the years 2021, 2022 and 2023, where we have very clear commitments in terms of debt pay-down, dividend initiation, cashflow generation etc. for those first three years. We're going to give specific guidance for 2022 and targets for 2023 and show you how we plan to deliver on those commitments."

"But then it's also about phase two, and phase two is about returning to growth, it's about what are the catalysts for our growth, and we're going to show the ingredients for that. That includes what our capital allocation priorities are for that period, including returning value to shareholders but also share repurchases, that's on the table."

The roadmap would include "how we see organic opportunities," Goettler said, suggesting that "our pipeline, I think, is one of the most under-appreciated assets that we have." And it would also cover "what our priorities are for business development. So all of that we're going to lay out on 7 January."

Pressed for more detail on aspects such as the "inorganic business development priorities" that the firm had alluded to when it announced the investor event, Goettler was reluctant to disclose more at this stage. "On the inorganic [opportunities], I think wait for the investor day, what we are going to do there is to give you more on the priorities that we have [and] the areas that we want to focus on," he indicated.

> *"For a company like Viatris that has as broad a portfolio as we have, a market like China is always going to be a great opportunity."*

Similarly, when asked about how the global infrastructure that Viatris now possessed as a result of combining Mylan and Upjohn could be used to move more generics and biosimilars into geographies such as China, Goettler again said "I think tune in to the January 7 event, [when] we are going to lay out the China strategy in more detail."

"But at a high level," he offered, "we are very pleased with the performance we have in China, we see China as an important market."

"We have already identified more than two dozen products that we want to move to China and register in China," Goettler said. "I think several of them are going to be registered before the end of the year, some of them we already have."

"So there is momentum there," he observed, "and I think that for a company like Viatris that has as broad a portfolio as we have, a market like China is always going to be a great opportunity."

"There is so much growth that's possible – [when] you look at the population trends, the ageing trends, you look at the growth of the middle class, you look at the government policy of extending health access to all citizens, all 1.4 billion of them, there is significant opportunity for us as a company."

Interchangeable Semglee Launch Will Broaden Access

Turning to the recent groundbreaking launch by Viatris of the first US interchangeable biosimilar, Semglee (insulin glargine-yfgn), Goettler said "we're obviously very excited about the launch, we think it's an important milestone and it's a good day for patients."

"As you know, we are launching it in both branded and unbranded forms," as both Semglee and

Insulin Glargine, Goettler underlined. "Both the vial and pen are available in both of these forms."

"And that's really meant to make sure that the drug reaches as many patients as possible, regardless of their financial circumstances, whether they are insured or not insured, regardless of the channel."

In terms of pricing, Viatris said that the unbranded version of the product was being offered at a wholesale acquisition cost of $147.98 for a pack of five 3ml pens and $98.65 per 10ml vial, with this cost representing a 65% discount to the list price of the Lantus reference brand and giving the unbranded biosimilar "the lowest WAC for any insulin glargine pen on the market to date."

Meanwhile, the WAC for the branded Semglee version would be higher at $404.04 per pack of five 3ml pens and $269.38 per 10ml vial.

"We also have patient assistance programs, copay programs, all the bells and whistles that you would expect around an important launch like this," Goettler pointed out.

"We want to make sure that the product reaches the maximum number of patients," he emphasized. "And I think the recent wins that we had with the Express Scripts national formulary and the Prime Therapeutics national formulary are testament to that."

"We're quite excited about that, these are very big formularies and there are a lot of patients in those," he commented.

Asked whether the approach of launching an unbranded biosimilar was linked closely to the interchangeability designation, Goettler said "I think it makes sense for Semglee, and again it's important for Semglee because we want to make sure that the patients can get it. By having these two versions out there we can ensure that to a greater degree than we could otherwise."

And on interchangeability more generally – including the question of whether the firm would pursue the designation for other biosimilars – he said "I see it as case by case."

First Interchangeable Biosimilar Launched In US

By David Wallace

16 Nov 2021

Viatris and Biocon have introduced their interchangeable Semglee insulin glargine biosimilar in the US, along with an unbranded interchangeable version, marking the first ever launch of an interchangeable biosimilar. The non-interchangeable version is expected to be phased out rapidly.

Read the full article here

"It depends on a variety of factors," he suggested. "Is it a chronic disease or an acute disease? I think [that] makes a difference. Is it a pharmacy product or a specialty pharmacy product, or is it physician-administered? I think you have to look at it case by case, what the market formation is, the circumstances of the disease that is being treated, and what the competition looks like."

Still Waiting For Action On Bevacizumab

Touching on other biosimilars in the firm's pipeline, Goettler was invited to comment on whether delays experienced by Viatris and other biosimilars developers as a result of the US Food and Drug Administration's inability to conduct facility inspections during the COVID-19 pandemic could be expected to continue to affect the firm's filings.

"I don't want to speculate," he said, "because it depends on a variety of factors. It depends on how COVID evolves, it depends on to what extent the FDA uses the tools that Congress has given it in terms of remote inspections, virtual inspections and other tools like that."

Late last year, Viatris and partner Biocon saw their application for a biosimilar version of Avastin (bevacizumab) knocked back by the FDA, explaining that due to pandemic travel restrictions, the agency was unable to conduct a necessary inspection.

Had it been approved by the end of 2020, Mylan and Biocon's bevacizumab candidate would have become the third US biosimilar to Avastin, after Amgen's Mvasi (bevacizumab-awwb) and Pfizer's Zirabev (bevacizumab-bvzr). But almost a year on, these two products remain the only FDA-approved bevacizumab biosimilars.

"For Avastin specifically, I think we are very clear that there is a delay because of the delay in the overseas pre-approval inspections that impacts us," Goettler confirmed, noting that the FDA had no other questions on the application. "So for Avastin that is really the only outstanding issue that we have, and we'll bring it to market as soon as we get it."

> *"Just like biosimilars, the complex generics space is an important growth area for us."*

Finally, touching on Viatris' interests in complex generics, Goettler attested that "just like biosimilars, the complex generics space is an important growth area for us…and it is important for patients. Because it is so complex, because it is difficult to develop generics in this space, there is a lack of access."

Historically, the firm has also broken ground in this area, with Mylan having in early 2019 introduced the first US generic rival to GlaxoSmithKline's Advair Diskus (fluticasone/salmeterol) in the form of its Wixela Inhub version.

"You look at products like Wixela, our generic Advair, and others, you look at how long it took to get them to the market," he noted, emphasizing the firm's commitment to this area.

"Just this year we have a couple more trailblazers," he pointed out. "We were the first to file paliperidone, a very important schizophrenia medication." And "we have tentative approval for [a generic rival to AstraZeneca's] Symbicort (budesonide/formoterol fumarate dihydrate), another asthma/COPD [treatment]."

"So we continue to break barriers and we see this, together with biosimilars, as a growth opportunity," he said, observing that "75% of our pipeline is now in biosimilars and complex generics."

"We are all about access," he concluded, "we are about breaking down barriers, whether scientific barriers, regulatory barriers, legal barriers, market barriers. Whatever it is, we want to break down those barriers and provide access for patients."