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A Year Of Change: Looking Back At Francis' First Year At Teva

Teva's CEO, In Charge For A Year, Has Laid Clear Its More Innovative Ambitions

by Dean Rudge

As part of a *Generics Bulletin* series focusing on some of the industry's biggest players, we look at the changing landscape at Teva in 2023, spearheaded by the appointment of its CEO Richard Francis.

"Does there come a point where the company has to think differently? Maybe thinking about investment levels differently or how to run the business differently?" <u>Teva's</u> CEO Richard Francis was asked in January, just ten days after the former Biogen and Sandoz exec took up the role.

Teva's struggles to increase its revenues since 2017 are well documented. The Israeli giant endeavoured to make up for the loss of exclusivity for its key Copaxone (glatiramer acetate) brand through an expensive acquisition spree that continues to weigh down the company's balance sheet with debt while falling short of expectations.

Francis' predecessor, Kåre Schultz, came on board the same year, with a reputation for corporate turnarounds. He spent his five years at Teva chiselling away at the firm's debt pile, shutting and offloading sites across the world while keeping a firm eye on expenses.

"We have stabilized the business and undergone a significant operational transformation across our international footprint," Teva said. But then came time for fresh leadership. (Also see "*Teva Names Former Sandoz CEO Francis To*

A Year Of Change: Sandoz Completes A Transformational 2023

<u>Replace Schultz Within Weeks</u>" - Generics Bulletin, 22 Nov, 2022.)

Making clear that he would implement change in the coming months, Francis spelled out jut days into his appointment that it would be no revolution. "Even in the short term, there's an allocation of resources that can be decided upon pretty quickly," he said. (Also see "<u>Teva's New</u> <u>CEO Francis: No Revolution, But New</u> <u>Strategy Will Not Be Marginal</u>" - Generics Bulletin, 12 Jan, 2023.)

By David Wallace

21 Dec 2023 An eventful 2023 for Sandoz saw multiple major deals and key launches, with the year culminating in the firm's long-awaited spinoff from parent company Novartis in October.

Read the full article here

"First and foremost, we've got to make some choices about what we want to invest in. And that means [thinking about] what we're going to have to stop investing in," Francis reasoned, "because I do think we need to keep control of costs to make sure we can keep servicing the debt in the way we are and have been."

Investors waited eagerly for his new strategic blueprint. Among key questions to answer, had Francis thought about how capital would be funnelled to biosimilar assets vs. the company's innovative pipeline? The initial message, at least, was that the strategy could not be half-hearted or piecemeal.

"What are we trying to do long term?" he pondered. "Based on that, every function and every dollar should follow that strategy."

As the market awaited the big day for Teva's new path forward – set for 18 May – it reacted badly to the company's financial guidance for 2023, on the back of fourth quarter results that Raymond James said "fell relatively within expectations as a result of yet another underperformance in North American generics."

"Though Teva's growth struggles are nothing new, realization that diminished headwinds for the industry as a whole won't enable sufficient lift to deliver positive year-on-year comparisons without more kick from new complex generic approvals – which have been few and far between the past two years – is likely to render shares relatively rudderless headed into the new management's strategic update mid-year," the investor warned. (Also see "*Complex Generics Drought Could Make Teva Stock 'Relatively Rudderless'*" - Generics Bulletin, 13 Feb, 2023.)

Teva Looks To Novartis For US Strategy

Titled 'Pivot to Growth,' Teva's strategy arrived in May with a few major changes for the Israeli

firm's direction.

Delivering growth, stepping up innovation, sustaining the company's generics 'powerhouse' status and focusing on growth drivers were unveiled as its four broad pillars. (Also see "*Teva Establishes Four Pillars To Prop Up Its Return-To-Growth Strategy*" - Scrip, 18 May, 2023.)

The last of these envisions Teva directing its investments toward commercializing brands with room for growth, such as Austedo (deutetrabenazine) for tardive dyskinesia and Huntington's disease, as well as the long-acting antipsychotic Uzedy (risperidone), a 505(b)(2) hybrid asset containing the same active ingredient as Johnson & Johnson's well-established Risperdal Consta (risperidone) brand.

Another long-acting antipsychotic in partnership with MedinCell has also caught Francis' eye in 2023. "When I came in," Francis told attendees to the Morgan Stanley Global Healthcare Conference on 11 September, ten months into his appointment as CEO, "obviously I looked at our TL1A, our anti-PD1-IL2, our IL15, all the sexy stuff. And I sort of overlooked the olanzapine."

"Then, I came back and looked at olanzapine again. And the product profile, once again, is really exciting based on this technology we have through our partnership with MedinCell." (Also see "<u>Teva's Francis: I Looked At All The Sexy</u> <u>Stuff And Overlooked Olanzapine</u>" -Generics Bulletin, 12 Sep, 2023.)

With the US so important to Teva's growth prospects, the company announced in late September that Christine Fox, an executive with plenty of experience in the branded sector – most recently serving global president of gene therapies at Novartis – would take over as the new head of Teva's US commercial business – evidence enough that a shift in focus would take place.

A Year Of Change: Viatris Ploughs Ahead With Brand Ambitions

By Chloe Kent

21 Dec 2023

In 2024, Viatris will initiate the second phase of its long-term business plan, which will see it step away from the perceived volatility of the generics space and begin to move toward innovative and high-growth products. The past year has seen it lay the groundwork for this pivot, shedding surplus business units and making significant hires from the branded space.

<u>Read the full article here</u>

Fox replaced Sven Dethlefs, who stepped down from his position as executive vice-president for North America commercial and left the company on 17 November, after a 15-year tenure with the firm. (Also see "*Teva Looks To Novartis To Replace Departing Dethlefs*" - Generics Bulletin, 29

Sep, 2023.)

"Chris is a heralded pharmaceutical executive with extensive experience growing and overseeing complex business units and regional operations throughout the world. I have every confidence that Chris will bring great strength to Teva and be pivotal to our success," Francis said of her appointment.

In particular, Teva cited her "deep understanding of issues affecting the pharmaceutical and biotech sectors, as well as expertise across a range of therapy areas."

In one of Francis' major cash outlays this year, Teva in early October drafted in Sanofi to help challenge the frontrunners in the race to develop the next blockbuster treatment for inflammatory bowel disease, signing a deal worth up to \$1.5bn for the Israeli firm. (Also see "*Teva Shows Its Big Pharma Clout With \$1.5bn Sanofi Deal*" - Generics Bulletin, 4 Dec, 2023.)

The asset, Teva's TEV'574, is a TL1A inhibitor currently in a Phase IIb study for ulcerative colitis and Crohn's disease. Sanofi has paid a hefty \$500m upfront to co-develop and co-commercialize the asset, with a further \$1bn in development and launch milestones on the table for Teva.

Biosimilars For The Long Term

While promoting a more brand-focused Teva, Francis underlined the continued importance of biosimilars to Teva's story in the years ahead. Taking a more global approach to biosimilars while leveraging the company's vast capabilities and manufacturing scale to build out a sizeable portfolio, with a continued focus on partnerships and business development, would be key, he said.

"People have asked me whether biosimilars are really a growth driver for the long term: Absolutely," Francis underlined during the one hour forty-five-minute call with investors in May. (Also see "*Teva: Our Biosimilars Strategy Has Been Fragmented, We Want To Be Global*" - Generics Bulletin, 22 May, 2023.)

While there were "some conditions to that," in the short term, "there are \$40bn of brands coming off patent, which we are targeting with our pipeline [of five late-stage assets]. And longer term, we have 13 assets which we want to bring to the market."

"So, we see significant opportunity to drive growth short, medium and long term across this Pivot to Growth strategy."

Meanwhile, with \$300bn-\$400bn of biologics set to lose exclusivity in the 2030s and 2040s, Teva has ambitions to broaden its nascent biosimilar portfolio and presence in the EU, Francis outlined.

"We're looking at doing that a bit more thoughtfully with our biosimilars," he noted. "I think our biosimilars [strategy] has been slightly fragmented in how we have approached that geographically. We want to do it globally. So, we will be doing that more going forward."

Alvotech Setback, And Commitment

Teva's good intentions in the space have ultimately led to frustration this year, however. The firm has pledged to help to resolve manufacturing issues at its US biosimilars partner Alvotech and also hinted at new biosimilars deals on the horizon in the near future, while acknowledging that the "bumpy" US market was still carrying a degree of uncertainty that was leading it to allocate capital accordingly. (Also see "*US Biosimilars 'Bumpy' For Teva As It Prepares For Alvotech Inspection*" - Generics Bulletin, 9 Nov, 2023.)

Ahead of a key facility reinspection for Alvotech next month, the five-year-old partnership has so far failed to deliver any US Food and Drug Administration approvals, leading Teva to trail behind the foundation of the biosimilar Humira (adalimumab) market in 2023.

Demonstrating its continued confidence in the Icelandic firm, Teva has this year expanded its collaboration agreement with Alvotech to cover two further products, while agreeing to get more involved in Alvotech's quality oversight and making a \$40m investment. (Also see "*Teva Doubles Down On Alvotech Biosimilars Partnership*" - Generics Bulletin, 24 Jul, 2023.)

"With regard to Alvotech and the partnership, the relationship is actually very good," Francis commented. "Alvotech is very good when it comes to developing biosimilars. [With] their R&D capability I think we will have the best product in the market if we launch [biosimilar] Humira, both from a device point of view and from a product profile, interchangeability, they are very good at that."

Complex Generics Vital As Off-Patent Target Shrinks

What about generics then, Teva's bread and butter for so many years? In a shakeup to Teva's old strategy, Francis outlined in that vital May call that Teva will drop from 80% to 60% its targeted proportion of drugs going off patent each year, with "the majority of the value within the 60%."

"The incremental value for that extra 20% is marginal," he pointed out. "But what is not marginal is the amount of work that [takes out of] the organization and the amount of complexity it adds. We want to focus on less to get more."

"Now, our core business, our generics business, I think is obviously a global leader," Francis commented.

"And that business throws off a significant amount of cash, which in the short term allows us to pay down on debt but in the longer term allows us to invest in some of these growth drivers and

some of this innovation."

"From a company that had a core generics business, we are going to create a more sustainable business. But we have a significant portion of our business now, over 20%, that is going to be innovative."

"And that has different margins...different levels of profitability and different multiples, as does biosimilars. And I think that is something to consider," Francis implored analysts, "as you evaluate the company going forward."

Against its renewed focus on high-value generics, particularly complex generics, such as drugdevice combination products and long-acting injectables that take advantage of Teva's capabilities, Teva has struggled to get certain complex product approvals over the line, as Raymond James highlighted.

One analyst joked at the beginning of the year that Teva had been "talking about [generic Forteo] teriparatide and [generic Restasis] cyclosporine for three presidential administrations."

Teva did, however, become the first firm to garner approval for a substitutable generic rival to Eli Lilly's Forteo (teriparatide) injection in the US. The November approval "showcases Teva's proven strengths in complex generic formulations development and device engineering," Teva said, after being knocked back by complete response letters. (Also see "*Teva Delivers First US Forteo Equivalent*" - Generics Bulletin, 20 Nov, 2023.)

Meanwhile, Teva has fallen behind Viatris in the race to gain US approval for a generic version of AstraZeneca's Symbicort (budesonide/formoterol) – with the FDA's "high hurdles to get drug-device combination products approved" given as the reason.

Before departing Teva in November, Dethlefs told *Generics Bulletin* as part of an exclusive interview, "I don't believe that complex technologies are the only answer for the generics industry, because you still drive tremendous value in simple [generics]." (Also see "*<u>Hitting A</u> <u>Moving Target: Teva's Dethlefs Discusses US Complex Generics*" - Generics Bulletin, 16 Mar, 2023.)</u>

"This market has not gone away, it's still very attractive," he underlined. "The advantage is that the approval timelines are very predictable. You can develop the product easily, there's no complexity linked to it. You don't have to work with changing FDA guidance. For that reason, I think every generics company is staying in oral solid-dose drugs."

What Will 2024 Hold For Francis And Teva?

As the clock ticks over into 2024, Teva can at least be a little pleased that it was able to raise the guidance that so disappointed investors at the start of the year.

Buoyed by rising generics sales across all three of its geographical regions as well as higher turnover from Austedo and its other major brand, Ajovy (fremanezumab), Teva has hiked its full-year revenues forecast by \$100m to a range of \$15.1bn-\$15.5bn.

"We've grown our generics business across all of our regions, US included," highlighted Francis as the company delivered its third-quarter results, citing "strong growth in the US of 15%, solid growth in Europe and good growth in emerging markets in local currencies of 17%."

Meanwhile, it was a year in which the company managed finally to find an answer to a significant legal overhang that had weighed on its stock: "fully resolving" a nationwide US settlement over its long-running opioids litigation by agreeing terms with "all 50 states and 99% of litigating subdivisions." (Also see "*Teva Wraps Up Nationwide US Opioids Settlement*" - Generics Bulletin, 9 Jun, 2023.)

Alvotech resolving its manufacturing deficiencies with the FDA in order for Teva to begin growing its biosimilar footprint in the US is naturally a huge objective for 2024. But with the appointment of Fox in the US, and the cash deal with Sanofi rounding out 2023, it looks highly likely that the company will capitalize on further branded opportunities in the new year.

Such ambitions in the branded space are of course dependent to some extent on how much Teva is able to put its hand in its pocket amid its creaking balance sheet. Barclays, for one, expects Teva to continue to make progress towards its longer-term financial targets, including 2.0x or lower net debt/ EBITDA ratio, "setting the company up for greater flexibility around business development as cash flow improves."