Generics Bulletin
Pharma Intelligence

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Five Things Facing Teva's New CEO Richard Francis

Former Sandoz Head To Take Charge At Teva On 1 January 2023

by Dean Rudge

With Teva clearing up early who will replace outgoing president and CEO Kåre Schultz, *Generics Bulletin* looks at five issues that await his replacement, the former Sandoz head Richard Francis.

A new year is on the horizon, bringing a new, recognizable face to the top job at *Teva*. Four years after departing from rival Sandoz, Richard Francis is once again to take the CEO role at one of the generics and biosimilars industry's leading players.

Francis will swap gene therapy for generics when he officially takes up the mantle at Teva on 1 January – some ten months ahead of incumbent Kåre Schultz's current contract expiring, with Schultz now set to step down at the end of 2022. (Also see "*Teva Names Former Sandoz CEO Francis To Replace Schultz Within Weeks*" - Generics Bulletin, 22 Nov, 2022.)

When Francis joins Teva he will do so on the other side of what his predecessor insisted was a trough year for the company, one which has seen the company drop its full-year revenues guidance from $15.6bn-$16.2bn to $14.8bn-$15.4bn amid severe sustained foreign exchange headwinds and other challenges.

"Teva may be frail on the top line, but the company is built like a tank in the middle. Management again managed to deliver largely in line expectations via a seemingly perpetual grind lower in opex trends," Raymond James pithily observed earlier this month.

"This is the right time for a transition," Schultz commented, five years after joining Teva from Lundbeck, "and Richard's proven track record in the industry makes him the right person to serve as Teva's next CEO."

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With more than two and a half decades of experience, including on the other side of the aisle working as senior vice-president of Biogen's US commercial operations, Francis indeed seems a good fit to direct and galvanize Teva following the Schultz era of stability.

Quick Out Of The Blocks Or Slow And Steady?

Teva is now a different beast to the one Schultz joined in the back end of 2017. With Teva groaning under the weight of its $35bn debt pile and unattractive 4.7x leverage ratio, and bloated with manufacturing factories the world over, Schultz quickly took the scalpel to the company, in a dedicated effort to significantly reduce its cost base, simplify its organization, and improve performance, profitability, cash-flow generation, and productivity.

Within weeks of his appointment, Schultz unveiled a comprehensive two-year restructuring plan to pare back costs, with facilities to be closed or sold and portfolios rationalized in order to chip away billions in annual costs from the Teva base. (Also see "*Drastic action by Schultz aims to right Teva's ship*" - Generics Bulletin, 22 Dec, 2017.)

Meanwhile, he overhauled the company's structure, abandoning the traditional separation of generics and specialty units in favour of a single commercial organization.

Five years later, Schultz observed recently, Teva's annual spend base had fallen nearly $5bn, allowing for around $18bn to be repaid to bondholders in debt and interest. As Schultz directed, Teva managed this in part by cutting the firm's global manufacturing footprint from 80 sites to a little over 50 – with Schultz revealing back in July plans to shutter "around 10 [more] over the coming years."

Taking the reins in January, Francis must decide whether his impact will be as marked so early on, albeit under different circumstances than those facing Schultz; or whether he will pause and take greater stock, given the business now has a much sturdier footing.

Stepping down from Sandoz early in 2019, Francis said that he could not commit to a new multi-year journey instigated by its parent Novartis wanting greater autonomy for its generics and biosimilars unit. His decision to join Teva now, after much surgery under Schultz's leadership, suggests a willingness to commit to a project, however long it takes to unveil.

Rebuilding The US Generics Sector

Teva has prided itself in previous years on delivering $1bn in revenues every quarter from its North America generics segment, which includes biosimilars and a small offering in Canada.

However, in the final quarterly earnings before Francis takes charge, a continued drought of low-competition, high-margin generic launches in the US dragged down sales by 6% in the third quarter to $806m – well below the benchmark, amounting to $2.7bn in revenues year-to-date.

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(Also see "*Blocked Pipeline Leads Teva's US Generics To Fall Well Below $1bn Floor*" - Generics Bulletin, 4 Nov, 2022.)

Management moved to reassure investors that big-ticket products were on the horizon, insisting: "This will only improve in 2023," while acknowledging a continued shortfall in the remainder of the year.

"In the second half of 2022, we do not have any significant additional launches," Teva's North America commercial vice-president, Sven Dethlefs acknowledged, in the wake of Teva rolling out the first generic version of Revlimid (lenalidomide) in March.

He underlined the company's "commitment to the development of complex generics, among them...Forteo (teriparatide), Restasis (cyclosporine) and so forth," with the former previously earmarked by Teva as "one which would be a significant contributor to our sales in 2022." (Also see "*Teva Identifies Teriparatide Importance Amid US Launch Drought*" - Generics Bulletin, 4 May, 2022.)

Teva Eyes '80% Of Off-Patent Opportunities' For Generics And Biosimilars

By Dean Rudge

29 Jul 2022
Teva's president and CEO Kåre Schultz provided fresh long-term financial targets for the company in the wake of the firm agreeing in principle to settle opioid-related claims in the US – but will the architect of Teva's restructuring remain beyond his current November 2023 contract?

Read the full article here

Overall, the result of Teva's efforts to launch complex generics stands in stark contrast to its ambitions. The company had stated last year that it had between 10 and 12 complex ANDA products it could introduce potentially in 2021, with an acknowledgement that Teva could not achieve them all.

Last year, Teva management told *Generics Bulletin* that "more can be done to improve patient outcomes and access by addressing the inefficiencies with the current FDA approval process for complex generics. Current inefficiencies delay patient access or even keep complex generics off the market entirely."

Also on the slate is the complete response letter Teva received recently for the 505(b)(2) risperidone long-acting injectable in partnership with MedinCell – although noises from the company suggest confidence in a quick remedy. (Also see "*Teva Targets Risperidone LAI In H1 2023 Following Earlier FDA Snub*" - Generics Bulletin, 7 Nov, 2022.)

While failing to move big-ticket items to commercialization has harmed the company's prospects in the US, the company's massive US base has faced up to the cumulative pressures of pricing turmoil – up to 10% in 2021 – and distributor consolidation.

"We are not independent of the macro environment in the US with price deflation," management observed in May.

A Return To M&A? Or More Licensing?

During his tenure, Schultz was crystal clear on one aspect of Teva's strategy: no M&A until the lenders get their money back.

"We are not looking to buy companies. We don't have the money for it. We don't have the appetite for it. But we are looking to find products that will fit nicely with our commercial footprint already," Schultz reiterated earlier this month.

"Of course, it will be nice to do some interesting M&A," he acknowledged, speaking in May this year, "but you must look at our balance sheet. We don't really have any cash or significant debt capacity, so that's not really going to happen in terms of any major transactions for the next several years."

"We will be working to further optimize, further increase the gross margin, the operating margin, and building a stronger and stronger foundation.

"And then we will, as a consequence of the debt reduction and the margin improvement, free up more and more cash to do [acquisitions]," he said during a July earnings call, picking back up the theme.

By 2027, according to Schultz's final long-term financial vision for the firm, Teva aims to strengthen its foundations by delivering a non-GAAP operating margin of 30%, up from its current figure of around 28%, as well as a net-debt-to-EBITDA ratio of 2.0x, significantly down from the current 4.16x ratio.

Teva Likes Biosimilar Licensing Deals As It Cuts Full-Year Sales Guidance

By Dean Rudge

30 Jul 2021

Teva is keeping a keen eye out for opportunities like its US biosimilars agreement with Alvotech and more recent deal with Bioeq for biosimilar Lucentis as it attempts to maintain revenues in the coming years, following a cut to full-year sales guidance for 2021.

Read the full article here

How will Teva's new CEO approach M&A, a long-time tool to boost earnings and swell pipelines

and portfolios? Raymond James envisions a less stringent adherence to the current 2027 leverage target of under 2.0x, with potentially a "more liberal but acceptable target of 2.5x-3.0x."

In lieu of M&A, Schultz targeted licensing deals, leveraging the company's massive global commercial presence to partner with the likes of Celltrion, Alvotech and Bioeq in launching biosimilars.

"We are looking for these kinds of opportunities where our commercial footprint in Europe and North America can be used by companies who have a good product, but don't have that commercial infrastructure," Schultz said in July last year.

"And I'm marginally optimistic that we'll find some more products. They will not be huge blockbusters because then people tend to do it on their own. But I think we can supplement our revenues with these kind of deals over the coming years."

Massive Ex-US Presence – What About It?

The US may be the world's largest market, but Teva remains deeply enmeshed outside, with a massive presence in Europe and a not insignificant one beyond.

In the first nine months of the year, Europe returned $3.4bn in revenues, including $2.5bn from generics, resulting in a $1.13bn segment profit excluding amortization and other items.

Meanwhile, the bulk of the company's $1.4bn International Markets unit revenues in the nine months to 30 September came from generic products, at $1.2bn.

"We have a stable business outside the US, which will have single-digit positive growth," noted Schultz. "So that's Europe. That's International Markets," Schultz had told investors during his final earnings call.

"As you know, the pricing there is quite stable. We are in the top three in all the European markets and doing well in international markets. So, that piece is sort of growing, you could say, low single-digit and that's very stable."

What will Francis do with Teva's sprawling non-US operations? Schultz left his mark to some degree, divesting a significant chunk of its joint business generics venture with Takeda in Japan to Nichi-Iko, while overseeing biosimilar launches in the EU and UK. (Also see "*Bioeq's Lucentis Biosimilar Is Given EU Go-Ahead*" - Generics Bulletin, 31 Aug, 2022.)

In his penultimate quarterly earnings call, Schultz had remarked, "I am 100% confident that we will stay the world leader in generics going forward."

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Steering Through The Legal Overhang

Just 24 hours after Francis was announced as Teva's CEO, the company finalized documentation addressing long-running opioids litigation in the US through a nationwide agreement in principle worth $4.35bn – following a series of individual state-level settlements.

However, the process is not quite over, as the milestone of the finalized deal serves to kick off a sign-on process that will see individual US states, subdivisions and special districts elect to participate in the agreement.

The bottom line resulting from Teva's settlement: $2bn of legal settlements and loss contingencies on its nine-month income statement, driving a $1.24bn operating loss year-to-date.

Worse still, Teva earlier this month agreed to pay a $313.3m premium to the US state of New York after reaching an agreement with the Attorney General settling the state's and its subdivisions' opioid-related claims.

The proposed deal takes the Israeli firm's total potential liability in New York to $523m, considering the $210.5m in damages it has already agreed to pay as part of the firm's recent $4.35bn nationwide agreement in principle. (Also see "*Teva's New York Opioid Liability Climbs To $523m With Settlement Deal*" - Generics Bulletin, 4 Nov, 2022.)

While the opioids deal removes one potential headache for Francis, the company continues to be mired in a in a suite of state lawsuits and federal investigations over alleged generics price-fixing, dating back before Schultz's tenure to late 2016.

To date, the company has settled price-fixing claims with four US states, most recently with Arkansas for just shy of $1m. (Also see "*Teva Agrees $931,000 For Arkansas To Dismiss Price-Fixing Claims*" - Generics Bulletin, 24 Oct, 2022.)

Teva was itself previously front and center in the controversy, with the Connecticut attorney general describing Teva as a "consistent participant in the conspiracies," which amounted to "possibly the largest cartel case in the history of the US." (Also see "*Unsealed US Price-Fixing Complaint Reveals 'Diary Of Collusion'*" - Generics Bulletin, 9 Feb, 2021.)

Schultz had last year forecasted that it would be a "significant period of time" before both criminal and civil proceedings move to trial – while in typically outspoken fashion remarking that only the "worst cartel in history" would be responsible for generic drug prices in the US being lower than in Europe, per the findings of a RAND Corporation report.

"It's interesting, when we are being accused of rigging and doing a cartel on generic pricing in

the US," he said in reference to the report.