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Blocked Pipeline Leads Teva's US Generics To Fall Well Below \$1bn Floor

As FX Headwinds Chip Hundreds Of Millions More From Top-Line Guidance

by **Dean Rudge**

Teva's final quarterly earnings call of the year was indicative of its continued need to push valuable pipeline projects in the US to commercialization, as it once again lowered its full-year 2022 revenue guidance.

A continued drought of low-competition, high-margin generic launches in the US dragged down **Teva's** North America Generics sales by 6% in the third quarter to \$806m, as management moved to reassure investors that big-ticket products were on the horizon, insisting: "This will only improve in 2023."

Coupled with the much more significant factor of severe sustained foreign exchange headwinds, the firm once again took the axe to its full-year revenues guidance: a projection of \$14.8bn-\$15.4bn versus a previous \$15.0bn-\$15.6bn range – down \$1.4bn year-to-date at the high end (\$15.6bn-\$16.2bn).

"North America sales came in below our run rate target of \$1bn," noted Teva's North America commercial vice-president, Sven Dethlefs, speaking during the Israeli firm's third-quarter earnings call.

"I think we said in the last quarter that we had a strong first half with the launch of

Teva Lowers Forecast As Q3 Revenues Decline Amid Growing Generic Competition

By **Ayisha Sharma**

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generic Revlimid (lenalidomide), resulting in sales above this run rate.” (Also see ["Teva Pounces On US Revlimid Opportunity With Four Strength-Offering"](#) - Generics Bulletin, 7 Mar, 2022.)

“In the second half of 2022, we do not have any significant additional launches,” Dethlefs acknowledged, underlining the company’s “commitment to the development of complex generics, among them...Forteo (teriparatide), Restasis (cyclosporine) and so forth.”

The Israeli firm’s third-quarter revenues and profits decreased as its product sales dipped due to alternative options and generic competition leading it to lower its full-year guidance, but its opioid crisis financial settlement remains on track.

[Read the full article here](#)

Teva’s proposed generic version of Eli Lilly’s Forteo was described in May as “the most important” potential US generic launch this year, “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.)

“We have quite a number of complex generics [for which] we’ve been waiting for a while to get the US Food and Drug Administration approvals,” commented Teva’s president and CEO, Kåre Schultz, “others are just coming on now.”

Major complete response letters for complex ANDA products were something of a “problem pattern,” Teva told *Generics Bulletin* early in 2021, as the firm fell short of launching potentially between 10 and 12 complex generics that year. (Also see ["Teva Identifies 'Problem Pattern' Of Complex CRLs Ahead Of GDUFA III"](#) - Generics Bulletin, 15 Apr, 2021.)

The Israeli firm was “quite optimistic about getting some of those approvals as well,” Schultz continued. “So, that, of course adds to positive, single-digit growth on generics.”

US Price Erosion Stabilizing Incrementally

Quizzed by Raymond James’ Elliot Wilbur on North America trends and expectations, Dethlefs acknowledged the lack of high-value generic launches but maintained, “Other than this, our biosimilars sales were quite stable in Q3. We have a volume market share in the US business that has stabilized over the last month.”

“Next year, we can mention biosimilar Humira (adalimumab), potentially biosimilar Stelara (ustekinumab),” chipped in Schultz. “And of course, you never know exactly how it plays out. You never know exactly how big a share you get. But we think we’re – if not the best – then one of the best to manage the whole commercial part of a biosimilar launch.”

What about base generic price erosion in the US? “We see some improved rates as compared to what we’ve seen a year ago,” Dethlefs said. (Also see "[Can The Pipeline Soothe A US Generics Pricing Headache?](#)" - Generics Bulletin, 17 Jun, 2022.)

“It is an incremental stabilization across various product categories. We always analyze it by different product categories. And we expect this to continue in 2023. So, we have on the price erosion side, I think, a stable outlook. And on the sales side, as I said, it will improve with more product launches coming into our generics business.”

Reflecting on Teva’s North America Q3, Wilbur summarized: “Absence of new launch activity enabled full erosion of base generics to shine through and key complex generics that were supposed to drive the top line in 2019 or earlier are again on deck for next year.”

“Though the company has continued to prove resistant and resilient in the face of elevated inflationary trends,” he noted, “spending less means investing less and the impact is increasingly noticeable in top line performance, currency impact aside.”

Recovery in US generics “at times seems like a lost cause,” Wilbur suggested, “and a debate over whether \$1.0bn is a sustainable quarterly baseline rate has evolved to will sales fall below \$800m.”

Teva Has No Appetite To Buy Firms, Products Only

Away from North America, Teva remained upbeat about its prospects in Europe, reporting sales that fell by a tenth as reported but improved by 5% in constant currencies to \$803m, “mainly due to higher demand for generic and OTC products, together with higher revenues from generic product launches.”

“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 (\$393m, -5% reported, +3% CC).”

“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.”

In Europe, Teva in late August received approval from the European Commission for the Ranivisio (ranibizumab) biosimilar to Lucentis that it in-licenses from Bioeq. The biosimilar is marketed in the UK under the name Ongavia, according to the firm. (Also see "[Bioeq’s Lucentis Biosimilar Is Given EU Go-Ahead](#)" - Generics Bulletin, 31 Aug, 2022.) (Also see "[UK Lucentis Biosimilar Nod Offers Teva Potential First-Mover Advantage](#)" - Generics Bulletin, 18 May, 2022.)

The Israeli firm would continue to target individual products and projects as part of its business

development strategy, Schultz indicated. “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.”

Raymond James’ Wilbur commented: “Despite the evasiveness of growth, management continues to scrub the balance sheet positioning the company for an eventual return to the acquisition arena.”

Analyst: Teva A Heavyweight On Cost Management

Teva’s total net debt has fallen to \$19.0bn, and the company’s debt-to-EBITDA leverage now sits at 4.0x, “a workable level in terms of thinking about a possible modest step up in business development activity over the next several years though management continues to adhere to an aggressive commitment to drive leverage down to 2.0x EBITDA by 2027.”

Reflecting on the cut in revenue guidance, Wilbur concluded, “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.”

The Israeli firm is reaffirming its full year 2022 guidance range for operating income, EBITDA, earnings per share, and free cash flow, underlined chief financial officer Eli Kalif.

“Although we were able to absorb some of the inflationary pressures this year and partly mitigated certain spend categories,” Kalif said, “we may still face a volatile environment, and as such, we are keeping the broader outlook range for these items.”

“Teva,” Wilbur suggested, “is like a heavyweight fighter that just can’t be knocked off its feet when it comes to cost management and management has consistently relied on its ability to take a top line punch by paring back expenses – or investments – to adhere to profitability targets.”