### GENERICS BULLETIN

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# Hikma Manages To Stay Flat In 2022 Despite Generics Pressures

Annual Results See Injectables And Brands Success Offsetting Struggling Generics Unit

by David Wallace

As expected, Hikma's generics business saw a significant slide in 2022 – but contributions from its successful injectables and brands divisions helped to stop an overall sales decline for the firm.

<u>Hikma</u> has made no secret of its lowered expectations for its generics business in 2022. Having downgraded its forecasts multiple times over the course of last year (Also see "<u>Hikma Eyes Return To Growth After Further Cutting Generics Forecasts</u>" - Generics Bulletin, 4 Aug, 2022.), the firm has prepared investors and analysts for a rocky 12-month report.

And now, publishing its annual results, the company has confirmed that it has seen "a tough year for this business, especially when compared with the very good year we had last year," with generics sales falling by 18% to \$672m.

Moreover, the division made an operating loss of \$117m as reported, in part due to "impairment charges related to changes in our longer-term expectations for generic Advair Diskus (fluticasone/salmeterol) and excess respiratory production capacity resulting from the rationalization of our R&D pipeline." And even after adjusting the figure to reflect underlying performance, Hikma said its "core" operating profit for generics nearly halved to \$103m.

Nevertheless, Hikma executive chairman and CEO Said Darwazah – who has replaced former chief Siggi Olafsson until a permanent replacement is found (Also see "*Hikma Searches For New CEO As Olafsson Resigns*" - Generics Bulletin, 24 May, 2022.), now said by Hikma to be just weeks away – said the firm would look to invest in the generics business to drive future growth, while also focusing resources on the successful injectables and branded businesses that together

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managed to mostly offset the generics decline in 2022 and deliver total turnover of \$2.517bn for Hikma that was down 1% as reported but flat at constant currencies.

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Hikma had previously pinpointed a key factor in the generics decline as being a delay to the launch of an authorized generic version of Xyrem (sodium oxybate) that it had been expecting to introduce midway through 2022. (Also see "Hikma Slashes Generics Forecast After Key Product Delay" - Generics Bulletin, 5 May, 2022.)

The firm ultimately delivered on this launch in the first days of 2023. (Also see "Hikma Delivers On Authorized Xyrem In US" - Generics Bulletin, 3 Jan, 2023.) During the results call, Brian Hoffmann, president of the generics division, indicating that further generic filers were not expected to launch until six months later, giving the authorized generic a clear run for the first half of the year.

Meanwhile, in contrast to recent suggestions that Hikma could be thinking about exiting the generics business altogether (Also see "Hikma Could Consider Exit Strategy For Generics Business" -Generics Bulletin, 24 Jan, 2023.), Darwazah emphasized that "importantly, we will continue to invest in this business to put it on a stronger footing for the future."

"We are working on improving our portfolio composition to achieve a better balance between traditional generics and more durable, higher barrier-to-entry products, such as Ryaltris (olopatadine hydrochloride/mometasone furoate) nasal spray" – launched late last year (Also see "Hikma And Glenmark Launch Ryaltris In US" - Generics Bulletin, 31 Aug, 2022.) - "and we are investing in our commercial capabilities to support our specialty products," Darwazah outlined.

"We are confident that Generics will grow again in 2023. The headwinds we saw are cyclical and I am confident that the measures we have taken mean the business is more resilient and on a stronger footing for the future."

#### **Injectables And Branded Segments Continue Growth**

Overall, Hikma said its "diversified business model" underpinned a "resilient core performance" in 2022, with "a good performance from Injectables and Branded, offset by the effect of severe competitive pressures in Generics and foreign exchange headwinds in the Middle East and North Africa."

Citing "continued momentum for the Injectables and Branded segments," the firm noted that Injectables sales growth of 8% had included contributions from recent acquisitions such as Custopharm and Teligent's assets in Canada, along with "a good performance in Europe."

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Meanwhile Branded turnover rising by 3% reflected "a good contribution across most markets which offset foreign exchange headwinds."

As reported, overall operating profit more than halved, falling by 52% to \$282m. However, Hikma said that its "core" operating profit had slid by just 6% to \$596m, with exceptional items for the year including impairment charges totalling \$181m – primarily related to the generic Advair and respiratory aspects already mentioned, as well as reorganization costs of \$14m linked to "a one-off global restructuring to align staffing levels with current business conditions."

Overall, Darwazah summarized, Hikma had delivered "a resilient performance in 2022."

"While our generics business has been impacted by industry-wide competitive pressures, we have focused on controlling our costs, driving efficiencies and building our specialty portfolio, which will support the outlook for this business going forward," he suggested. "Looking ahead, we are confident that we will deliver good growth across all three of our businesses in 2023 as we continue to expand our product portfolio and enhance our manufacturing and commercial footprint."

For 2023, Hikma expects "Injectables revenue growth in the range of 7% to 9%, with core operating margin in the range of 36% to 37%," reflecting the breadth of the firm's injectables portfolio "and flexible manufacturing capabilities across our geographies, supported by new product launches."

Branded sales growth is pitched "in the mid to high-single-digits in constant currency," driven by "our expanding portfolio and focus on chronic medications."

Meanwhile, Generics revenue growth is expected to hit "the low double-digits," with a core operating margin "in the range of 16% to 18%," reflecting a contribution from new launches "supported by our commercial strength."