GENERICS BULLETIN
CITELINE COMMERCIAL

27 Sep 2021 | **News**

Hikma Buys Injectables Specialist Custopharm In $400m+ Deal

Deal To Acquire California-Based Firm Will Bolster Hikma's US Injectables Business

by David Wallace

Hikma has agreed to acquire US sterile injectables specialist Custopharm in a deal that includes a $375m upfront purchase price and a further $50m in milestone payments. The transaction is set to bolster Hikma's near-$1bn injectables business that currently accounts for around two-fifths of turnover.

Hikma is to acquire US sterile injectables specialist Custopharm from Water Street Healthcare Partners in a deal worth up to $425m, with the transaction set to expand Hikma's US injectables portfolio and bolster an injectables segment that already accounts for around two-fifths of the firm's total turnover and is on track to become a billion-dollar division in 2021.

Announcing the deal – which is subject to US Federal Trade Commission approval – Hikma said it would "pay an initial cash consideration of $375m on a debt and cash-free basis," funded "from Hikma's existing cash resources."

On top of this, the firm said there would be "a further $50m in contingent consideration payable upon the achievement of certain commercial milestones," highlighting Custopharm's "differentiated product portfolio and R&D pipeline."

Hikma CEO Siggi Olafsson has previously indicated to *Generics Bulletin* that the firm's healthy balance sheet puts it in a favorable financial position to act on the right deal opportunities. (Also see "*Hikma Enjoys Luxury Of M&A Opportunism*" - Generics Bulletin, 16 Apr, 2020.)

Insisting that the acquisition "strengthens Hikma's platform for future growth," the company

GENERICS BULLETIN
CITELINE COMMERCIAL

said "Custopharm is a growing business and Hikma expects it to generate full year 2021 revenue in excess of $80m and for the acquisition to be accretive to Hikma's injectables operating margin."

As of 31 December 2020, gross assets of Custopharm were $43m, while the firm recorded a pre-tax loss in 2020 of $7.5m.

California-based Custopharm – which currently markets its injectables through commercial arm Leucadia Pharmaceuticals – will add 13 approved products and further pipeline projects to Hikma's portfolio. The 13 products approved since Custopharm partnered with Water Street in 2015 include four first-to-market abbreviated new drug applications, one of which also has a competitive generic therapy designation, along with a novel 505(b)(2) hybrid medicine.

"Custopharm has consistently obtained regulatory approval for new products," Hikma emphasized, "with four first-to-market US Food and Drug Administration ANDA approvals, including one CGT exclusivity for calcitonin salmon, which was launched in May 2021."

Hikma also pointed to the enhanced R&D capabilities that it would gain as a result of the acquisition, with the deal "adding an experienced scientific team of dedicated R&D professionals with a proven ability to develop and commercialize complex sterile injectable products and a state-of-the-art R&D laboratory in California."

Deal Takes Hikma's US Portfolio To Nearly 130 Injectables

Olafsson summarized that the acquisition "provides Hikma with an attractive opportunity to further strengthen our US injectables business, by adding an attractive and profitable portfolio of marketed products and an exciting pipeline of future opportunities."

"Custopharm is an accomplished operator in the US injectables market," Olafsson commented, "with a first-class scientific team and a strong regulatory track record. This acquisition is highly complementary to our existing business and adds high-quality and differentiated growth potential."

Meanwhike, Riad Mishlawi, president of Hikma's injectables business, noted that "with this acquisition, Hikma will have a differentiated US portfolio of close to 130 injectable medicines – a more than fivefold increase over the last decade. Through this broad portfolio and by combining Custopharm's strong R&D capabilities with our high-quality and extensive manufacturing footprint, we will be in an excellent position to better serve the growing needs of hospitals, doctors and patients."

"I look forward to welcoming the team at Custopharm and Leucadia to Hikma," Mishlawi said, "as we continue to grow and strengthen our injectables business."

GENERICS BULLETIN
CITELINE COMMERCIAL

Custopharm and Leucadia CEO William Larkins said the firm was "excited to become part of Hikma, a global leader that shares our deep commitment to bringing generic products to market and into the hands of patients who need them," while acknowledging that "Water Street has been an outstanding partner in working with us to build an exemplary portfolio of complex generic products. We're looking forward to building on this success."

Prior to joining Custopharm and creating Leucadia, Larkins was vice president and general manager of Bedford Laboratories – which was acquired by Hikma in 2014 (Also see "*Hikma to buy Ben Venue's Bedford Labs for up to $300m*" - Scrip, 29 May, 2014.) – where he oversaw a portfolio of more than 100 generic injectables.

US Injectables Down In First Half For Hikma

In the first six months of 2021, Hikma reported US injectables sales that slipped by 8% to $318m, "reflecting reduced demand for COVID-19 related products, increased competition on certain other products and the slow return of elective surgeries, which were only partially offset by the contribution from recent product launches."

But while the US accounted for a significant portion of Hikma's $492m total injectables sales in the first half, the segment still grew overall, by just over 1%, thanks to a 54% increase in European injectables sales to $97m, "reflecting an exceptionally strong contribution from contract manufacturing and good demand across our portfolio of own products, including new launches."

And in the Middle East and North Africa region, injectables sales grew by 3% to $77m.

> ***Hikma Raises Expectations For 2021 After A Host Of Launches***
>
> By David Wallace
>
> 12 Aug 2021
> On the back of a string of launches in 2021 – including the full introduction to the US market of its generic rival to Advair – Hikma has raised its full-year forecast for its generics business in anticipation of a healthy second half.
>
> *Read the full article here*

Overall, however the injectables segment's core gross profit and margin declined in the first half "reflecting the shift in product mix in the US," with the unit's operating profit dropping by 9% as reported to $175m.

Following injectables sales of $977m in 2020, Hikma said that in 2021 "we continue to expect our injectables business to deliver revenue growth in the mid-single digits and core operating margin to be in the range of 37% to 38%."

"The US market continues to face some volatility," Hikma acknowledged, but the firm said that "we continue to expect to deliver growth in US injectables for the full year." While the return to normal levels of elective surgeries against the backdrop of the COVID-19 pandemic had been a little slower than expected, Olafsson said "we are hopeful this will improve," indicating that "by the end of the year, we should be at a normal level."

Olafsson also highlighted "the nine new launches we had" in the US in the first half, as well as "a little bit of a sketchy supply issue by our competitors" – including Fresenius and Pfizer – as potential tailwinds for the second half of the year (*see sidebar*).