

10 Aug 2022 | Interviews

Hikma Will Push Harder To Make M&A Happen

Executive Chairman And CEO Said Darwazah Talks Strategy Following Fall In Guidance

by **David Wallace**

Following a challenging first half for Hikma, executive chairman and CEO Said Darwazah talks to *Generics Bulletin* about how the firm is planning to be more active in making deals happen, as well as how it plans to address pressures on its Generics division that led to two consecutive downgrades in guidance this year.

Speaking to *Hikma* executive chairman and CEO Said Darwazah immediately after the company reported flat half-year sales and revised down its generics forecasts for the second time this year, the chief executive made clear that the company has a strategy in place to return the company to growth across all three of its business units, including Generics.

Not only that, but Darwazah also set out a bullish approach to deals and M&A, suggesting the firm was ready to be more pushy than it had been in the past to make acquisitions happen.

At the start of August, Hikma cut its full-year Generics sales guidance to \$650m-\$675m – with a core operating margin expected to come in at 15%-16% – as the segment saw a first-half turnover decline of 18% to \$330m.

The Generics division's operating profit plummeted by 73% to \$36m while "core" operating profit was down by 42% at \$58m, although strength in the firm's Injectables and Branded divisions helped to offset the Generics decline (*see sidebar*).

Conceding that 2022 had so far been a "rather challenging year," Darwazah nevertheless told

Generics Bulletin that “for the first six months the company delivered sales of \$1.2bn and the core operating profit was \$296m,” with “24% EBIT margins and 17% net margins. So even in a challenging year, we are delivering very strong results.”

“Generics are down on last year and they are down on the plan,” he acknowledged, “but luckily the other two divisions, the injectables and the branded, have done extremely well.”

Asked whether there had been any impact on the strategic direction of the company stemming from the departure of CEO

Siggi Olafsson earlier this year (Also see "[Hikma Searches For New CEO As Olafsson Resigns](#)" - *Generics Bulletin*, 24 May, 2022.) – with Olafsson recently taking up a new leadership role at Mallinckrodt (Also see "[Who's Hired? Former Hikma Chief Olafsson Takes Lead At Mallinckrodt](#)" - *Generics Bulletin*, 4 Jul, 2022.) – Darwazah explained that Hikma was still moving in the same direction.

“The strategy that Siggi picked up when he came to the company was to leave the same team in charge and try to get the business to become more focused and more profitable – and I think he did a great job with that,” Darwazah described.

“So we are still the same team – the same team leaders and even the second tier of management is still the same. A rather mature team that has been together for quite some time and works very well together. And we are happy with the additions that we have made in Siggi’s time, in terms of management. And we are happy that even in a challenging year we have 17% margins.”

“So we will continue in the same direction. We have done a little bit of cost-cutting in the Generics business, obviously because it didn’t do so well. But besides that, we are moving more or less in the same direction that the company has been moving for quite some time.”

Time To Be More Aggressive On Acquisitions

One likely change highlighted by Darwazah, however, was that going forward Hikma would “try to be more acquisitive.”

“This company has a strong history of acquisitions and that’s how we built this company,” he

Hikma Eyes Return To Growth After Further Cutting Generics Forecasts

By [David Wallace](#)

04 Aug 2022

Hikma has once again downgraded its expectations for its generics business in 2022 as it revealed a first-half drop of 18% in sales for the unit. However, injectables and branded increases helped to offset the decline, while the company maintained that generics growth was on the horizon in 2023.

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explained. “The last three or four years have been a little bit quieter, but I think now we will be a little bit more acquisitive moving forward.”

Asked whether this relatively quiet period had been due to cautiousness on the part of management or a lack of M&A opportunities, Darwazah noted that “Siggi, when he came in, said we can be more profitable, and he focused on that. Also, not enough opportunities presented themselves.”

“But I think in this business, if you want [acquisitions] you have to be more active – you have to go to CEO meetings, meet people, and sometimes you might have to push for one. It might not be available but you might have to make it available, go talk to the owners and try to convince them. As we did with Roxane [acquired by Hikma in 2016] at the time through our good connections with them.”

Asked whether there were any specific areas in which Hikma was looking for acquisitions or deals, Darwazah highlighted various potential opportunities.

On US biosimilars – where Hikma has already struck licensing deals with Bio-Thera for ustekinumab and with Gedeon Richter for denosumab (Also see "[Hikma Highlights Long-Term Importance Of Biosimilars](#)" - Generics Bulletin, 24 Jan, 2022.) – Darwazah said it would be “more of a partnership [model] so not too much upfront money. We are looking for strong partners – so far our partners are very strong and have a history of being very strong technical manufacturers with low costs so we can be competitive.”

“We will capitalize on our knowledge in the Middle East and North Africa, where we have been [marketing] biosimilars for quite some time, the last five years, very successfully,” he indicated. “So that is very helpful and we can learn from that moving forward.”

On the subject of the MENA biosimilars partnership with Celltrion – to which Hikma recently added two further products (Also see "[Hikma Adds Remsima SC To Celltrion MENA Collaboration](#)" - Generics Bulletin, 9 Feb, 2022.) (Also see "[Hikma Strikes Deal For Celltrion's Yuflyma](#)" - Generics Bulletin, 20 Jul, 2022.) – Darwazah said “I think we have a very strong relationship, they know us very well and we know them very well.”

“In MENA they are very committed to Hikma and Hikma is very committed to them – we are trying to convince them to work with us in other places, but right now the main focus is in MENA. We have been very successful with their products, we’ve done a very good job and we are very happy with the relationship and will continue to nurture and try and grow and improve that relationship.”

“We still have firepower of about \$1bn that we can use to strengthen the business going forward.”

Meanwhile, the firm had been going through a “very intense investment year” in Injectables, with the recent acquisitions of Custopharm in the US (Also see "[Hikma's Injectables Business Expands As It Completes Custopharm Acquisition](#)" - Generics Bulletin, 22 Apr, 2022.) and Teligent in Canada. (Also see "[Hikma Buys Teligent Assets To Expand Into Canada](#)" - Generics Bulletin, 17 Jan, 2022.)

“With the injectables, we see that anything we make we can sell – there is more demand than we can supply,” Darwazah observed, adding that the company was also “building manufacturing facilities for injectables in four different sites in MENA, to give relief to Europe and the US and to sell more in Europe and the US.”

Hikma had also made “a lot of investments in upgrading manufacturing capacity and facilities in injectables, building new plants, changing the machinery,” he commented.

And referring to the 503B sterile injectable compounding business that Hikma launched at the start of the year (Also see "[Hikma Seeks To Meet Demand For 503B Compounding In US](#)" - Generics Bulletin, 25 Jan, 2022.), Darwazah said “we have invested in building a new compounding facility – there is a lot of regulation work that has to be done this year, which we hope that we can get done this year so that next year we can start kicking off.”

“We are also looking at adding products for the branded generics business in the US, to see if we can acquire one or two of them to add to the portfolio. Because once you have a team, anything you add becomes very lucrative to that.”

“We will continue to look at possible acquisitions in any of the businesses,” he summarized, “whether it’s the injectables where we just did the Custopharm acquisition, or smaller acquisitions in MENA, we continue to look at product acquisitions, manufacturing facilities and so on.”

“We have strong cash flow and a very good balance sheet,” he highlighted, “so even after the buyback” – a share buyback program of up to \$300m was announced in February – “we still have firepower of about \$1bn that we can use to strengthen the business going forward.”

FDA Approvals Drive Generics Downturn

Moving on to discuss Hikma's recent difficulties in the Generics segment, Darwazah was asked whether the decline was due to industry-wide pricing pressures, factors more specific to Hikma – such as the delay to the launch of an authorized generic version of Xyrem (sodium oxybate) and fresh rivals to Advair Diskus (fluticasone/salmeterol) and Vascepa (icosapent ethyl) recently entering the US market – of a combination of these aspects.

“It's a combination,” he said. “Some things are specific to Hikma, but I think it's really more driven by the US Food and Drug Administration approving so many versions of the same product.”

“What happens then is that suddenly you have six or seven manufacturers that have already manufactured their batches – they need to do the validation batches – and so they flood the market, it kills the price, eventually they pull out and the price recovers.”

Making another prediction for how the market could change in the near future, Darwazah said “I think that the FDA will be doing more inspections, more foreign inspections – and once they do that I think there will be more Form 483s and warning letters coming out. So I think there will be more regulatory pressure on manufacturers to tighten up their compliance,” he said, whereas Hikma was already operating at these standards.

Asked specifically about the extent to which price erosion had affected the US market, Darwazah said “I think a lot of companies, many of them have inventory that they have to sell or it will expire, so they push the prices down too much – but I think many of them will get out [of the market].”

“We have cut down on many of our products,” he said, based on them becoming no longer profitable, “and I think a lot of the bigger guys have done that. So once there is the shake-up, there will be less product in the market.”

On the question of whether there would be some improvement in the pricing environment, he said “I think most of the industry will just be happy if there is no erosion. Then at least everybody knows where they stand.”

“And then you have to launch more products. Our nasal, our inhalers where we are more specialized, we need to concentrate on that. And you need to feed the specialty business,” with the upcoming commercialization of partner Glenmark's Ryaltris (olopatadine hydrochloride/mometasone furoate) 665mcg/25mcg nasal spray acknowledged as a significant launch. (Also see "[Hikma Set For Ryaltris Take Off As Glenmark Wins USFDA Nod](#)" - Generics Bulletin, 14 Jan, 2022.)

Injectables Benefit From Surgery Returning To Normal Levels

Turning to Hikma's Injectables business – which saw its first-half sales grow by 9% as reported and 11% at constant currencies to \$538m, generating an operating profit that was ahead by 2% to \$178m and a “core operating profit” that was up by 12% to \$209m – Darwazah said the business was “in very good condition,” adding that “as the new lines get put in and they start manufacturing we'll be seeing significant growth for that business.”

Talking about how the environment for injectables was emerging from the limitations of the COVID-19 pandemic, he said “obviously there are more operations happening now so more of the normal products are in demand, not just the products that were in demand during the COVID period. Everyday surgeries are returning to normal numbers, and I think there is a lot of backlog there. So I think that will benefit us also as we move forward.”

Asked about the integration of the Custopharm and Teligent businesses, Darwazah said “Custopharm provides a nice platform for future R&D as well as the products that we have, and Teligent is a nice platform to enter the Canadian market. We are working on adding products to that from our portfolio as well as acquiring products from other companies. There are huge shortages of injectables in Canada, so it could be a nice business for us, not as big as the US but a nice business.”

Meanwhile, “Custopharm have been very successful in doing R&D and differentiated products, so we will be able to enhance our R&D in terms of adding more products in future.”

Finally, asked to identify milestones on the horizon for Hikma in terms of key growth drivers for the near future, Darwazah again highlighted the 503B compounding business in the US.

“I think once we get over the compounding regulatory issues – registering and getting the licensing – I think we have a very unique product that's very differentiated. Most compounders out there right now are having regulatory problems, they don't know how to do it properly.”

“We are looking at it from a very different angle. The FDA have never seen something like what we've built, it took them some time to take it in. So I think we will have a very unique compounding product. Once we get the registrations, the approvals, once we get the hospitals online, this could be a very, very nice business for us in the next three or four years.”