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CITELINE COMMERCIAL

31 May 2022 | **Analysis**

Glenmark Chief: Running A Facility In The US Has Been A Struggle

Firm Primes Global Scale In Respiratory Segment

by Anju Ghangurde

Glenmark readies scale up in the respiratory segment, with Ryaltris set for a US debut and a filing for a generic rival to Flovent anticipated. Running a facility in that market, though, is not an easy task, says the firm's leadership.

Glenmark Pharmaceuticals Limited remains upbeat about opportunities in the US, a market where the Indian firm has quite a lot going on and is pivotal to propel its respiratory ambitions, but running manufacturing operations there apparently hasn't been easy.

The company's first US facility in Monroe, North Carolina, designed to manufacture a range of fixed dose formulations and generally seen as the "foundation for future product approvals", hasn't quite taken off the way the Indian company would have liked it to. The site failed to make the compliance cut at a recent inspection by the US Food and Drug Administration and hasn't seen launches since August 2021 following a voluntary recall of products. (Also see "*Monroe Site Commercialization 'Critical' For Glenmark's US Step-Up*" - Scrip, 17 Nov, 2019.)

At the earnings call for the fiscal fourth quarter ended 31 March 2022, Glenn Saldanha, Glenmark's chairman and managing director, indicated that while the company is confident that it will be able to remediate the issues at the Monroe site, running a facility in the US, in general, has been a "struggle" for most Indian manufacturers.

Saldanha pointed out that in the last quarter, some peers had ended up closing down their facilities in the US, but maintained that Glenmark hopes to start supplying products back to the market from Monroe by around the fourth quarter. (Also see "*Lannett To Close And Sell NY*

Liquids Plant As Part Of Restructuring Plans" - Generics Bulletin, 8 Nov, 2021.)

"But it's been a challenge. Running a facility in the US is not an easy task. Even the likes of *Teva Pharmaceutical Industries Ltd.* have recently had to shut down their Irvine facility *(see side box)*. So, it's never easy," Saldanha said in response to an analyst's query but declined to provide specifics around what perhaps hasn't quite worked.

Plant Compliance Woes

Earlier this month the FDA issued a Form 483 with 17 observations after an inspection at Glenmark's Monroe site between 4 April and 19 May. The company has asserted that it will continue to work with the agency and is committed to undertaking "all necessary steps" required to address their observations at the earliest.

"The company is committed to maintaining the highest quality and compliant manufacturing standards at all of its facilities across the globe," it said at the time. A form 483 is a notice of the FDA's inspectional observations that lists deficiencies in the quality system

Saldanha, however, underscored on the earnings call that the company has five formulation facilities that supply the US market and Monroe was one of them.

At peak capacity, the Monroe site is anticipated to produce 300-400 million tablets and capsules, 20-25 million vials and pre-filled syringes and 25-30 million ampoules for inhaled formulations, the company had previously indicated.

The FDA also flagged up compliance deviations at Glenmark's facility at Goa in India. An inspection between 12-20 May

US Plant-Related Actions

Compliance issues and changing market dynamics has seen some companies review US manufacturing plans over the recent past.

In October last year, Teva was reported to have temporarily stopped production at its plant in Irvine, California as "a precautionary measure" and to conduct a thorough review at the site after issues raised by the FDA during an inspection.

Bloomberg, at the time, said that the production halt followed Teva's recall of over 2.5 million vials of drugs in months prior, that may have been contaminated with mold owing to water leaks discovered by FDA inspectors.

Last week, *Torrent Pharmaceuticals Ltd.* pulled the plug on its liquids business in the US; the Indian firm indicated that incremental investments required for taking pipeline products to the market and increased competition intensity made it unviable. (Also see "*Torrent Acquires Chronic Brands From Dr. Reddy's, Folds Up US Liquids Business*" - Scrip, 27 May, 2022.)

Credit Suisse noted that the firm's liquids

resulted in a Form 483 with five observations.

manufacturing facility in Levittown is now discontinued and is expected to result in annual operational cost savings of INR1.35bn.

Respiratory Scale Up Plans

The plant-related struggles notwithstanding, Glenmark remains "excited" about the US business and is gearing towards creating global scale and momentum for its respiratory operations.

In the US, Glenmark expects its rhinitis therapy Ryaltris (olopatadine/mometasone furoate nasal spray) to debut in FY23, which is the 12-months ended 31 March next year. Ryaltris has been launched in several markets including the UK, the Czech Republic, Poland, Italy, with FY23 expected to see the product debut in markets such as Belgium, Ireland and Nordic countries as well, among others. (Also see "*Ryaltris US Debut Plan, Generic Spiriva Fuel Buoyant Glenmark Outlook*" - Scrip, 21 Feb, 2022.)

Hikma Pharmaceuticals plc is the commercialization partner for Rylatris in the US and can also produce the product via its nasal manufacturing capabilities in Columbus, Ohio ; *Menarini* is Glenmark's partner for the product in select EU markets. (Also see "*Hikma Set For Ryaltris Take Off As Glenmark Wins USFDA Nod*" - Generics Bulletin, 14 Jan, 2022.) (Also see "*Glenmark Celebrates European Ryaltris Approvals*" - Generics Bulletin, 30 Sep, 2021.)Regulatory approvals for Ryaltris are also awaited in Brazil, Malayisa, South Korea and Cambodia in FY23.

Glenmark has also completed a pivotal biostudy on Flovent (fluticasone propionate) pressurized metered-dose inhalers (pMDI) and initiated clinical trials with 2,634 patients and expects to make a US filing next year.

"It's hard to predict a launch date. But definitely by 2025, we think this product should be on the market," Saldanha said

Leadership Change

Glenmark is also beginning fiscal 2023 with leadership change, with ex-Teva executive Brendan O'Grady set to take charge as CEO (global formulations business) effective 10 June 2022. Robert Crockart, Glenmark's Chief Commercial Officer, is moving on.

O'Grady will lead the commercial business units for Glenmark and provide strategic leadership for bringing "greater focus and alignment" across all regions and therapeutic areas.

He comes with wide-ranging experience across both the generics and specialty segments, and was previously Chief Growth and Commercial Officer for Amwell, Inc wherein he provided strategic leadership to the telehealth company's global business

in on the earnings call on 30 May.

The company hopes to file at least one more respiratory pMDI next year.

operations. Prior to that, O'Grady was President and CEO, Teva USA and executive vice president, North America Commercial.

In Q4 FY22, Glenmark's North America finished dosage formulations revenues declined by 7.9% year-on-year to INR7.37bn ($98.2m). The quarter saw Glenmark launch bisoprolol fumarate and hydrochlorothiazide tablets, metronidazole vaginal gel, 0.75% and lacosamide tablets in the US, while esomeprazole magnesium delayed-release capsules, which was approved in 2019, also made its debut during the period.

Q4 Results , India Business

Overall, in Q4FY22 Glenmark's consolidated revenue rose 5.6% to INR30.19bn, while profit after tax declined to INR1.72bn versus INR2.34bn in the corresponding quarter of the previous year. Net profit adjusted for one time COVID-19 related inventory provision and exceptional items related to recall and associated remediation cost in the US was at INR2.93bn for the fourth quarter. (Also see "*India FY22 Earnings: Everyone's Talking Of Big Spikes In Input, Logistics Costs*" - Scrip, 27 May, 2022.)

Sales from the formulation business in India stood at INR8.84bn(+7.4%). The company launched seven new products during the quarter, including the once-daily Zita Plus Pio (teneligliptin 20 mg/pioglitazone 15mg) a first of its kind combination for diabetes in India.

The firm's non-COVID base portfolio grew 15.5% as compared to 10.6% growth of the non-COVID portfolio in the Indian pharma market, as per IQVIA data for January -March 2022.

Other than small pockets of endemic COVID-19 incidences, the company doesn't anticipate significant COVID-19 product sales in FY23. "We don't think you're going see it as a pandemic in FY23, particularly in India," Saldanha declared.

Favipiravir Adds Near-Equivalent Of AZ India To Glenmark's Sales

By Anju Ghangurde

27 May 2021

Antiviral favipiravir brings stunning gains to Glenmark, almost equal to the entire India sales of some multinationals, as demand surged amid the ferocious second of COVID-19 in the country. Such brand build-up could have taken five to seven years in pre-pandemic times, experts said.

Read the full article here

This could potentially mean limited traction for products like the *SaNOtize Research and Development Corporation*-partnered Nitric Oxide Nasal Spray (NONS), FabiSpray. Glenmark told *Scrip* that since the COVID-19 case load is low in India, this had "some impact" on FabiSpray sales, but provided no specifics. (Also see "*Watch This Space: Glenmark-SaNOtize's COVID-19 Nasal Spray Debuts In India*" - Scrip, 10 Feb, 2022.)

"Glenmark also has partnership for NONS for some select countries in South East Asia. We have successfully launched it in Hong Kong and Singapore under brand name VirX. We will continue to launch it in other markets in the region during the year," the company added.

Another product, Fabiflu (favipiravir) had made huge gains during the pandemic and in April 2021 emerged as the highest selling drug in the Indian pharma market amongst all therapies. As per IQVIA moving annual total data for December 2021, the product is the sixth largest brand across all brands in India. (Also see "*Glenmark Reaps Favipiravir Gains, Progresses COVID-19 Nasal Spray*" - Scrip, 17 Aug, 2021.)