

Management Discussion & Analysis for the Third Quarter of FY 2019-20

Revenue Figures for the Consolidated Glenmark Pharmaceuticals Ltd.

(Rs. In Millions)

	Third quarter ended December 31			Nine months ended December 31		
	FY 2019-20	FY 2018-19	Growth (%)	FY 2019-20	FY 2018-19	Growth (%)
India	7888.39	6675.30	18.17%	24374.14	21091.77	15.56%
US	7998.28	8556.75	- 6.53%	23785.46	23696.70	0.37%
Rest of the World (ROW)	3413.74	3401.21	0.37%	9488.97	8906.50	6.54%
Europe	3089.36	3217.39	-3.98%	8368.80	8023.02	4.31%
Latin America	1563.18	1014.33	54.11%	3586.84	2975.46	20.55%
API	2621.56	2392.48	9.58%	7625.38	7005.34	8.85%
Total	26574.51	25257.46	5.21%	77229.59	71698.79	7.71%
Other Revenue	781.10	292.99		1505.21	1321.15	13.93%
Consolidated Revenue	27355.61	25550.45	7.07%	78734.80	73019.94	7.83%

Average conversion rate in 9M FY 2019-20 considered as INR 70.25 /USD 1.00

Average conversion rate in 9M FY 2018-19 considered as INR 69.57 /USD 1.00

USD figures are only indicative

Review of Operations for the quarter ended December 31, 2019

For the third quarter of FY 2019-20, Glenmark's consolidated revenue was at Rs. 27,355.61 Mn (USD 385.64 Mn) as against Rs. 25,550.45 Mn (USD 355.87 Mn) recording an increase of 7.07%.

For the nine months ended December 31, 2019, Glenmark's consolidated revenue was at Rs. 78,734.80 Mn (USD 1,120.78 Mn) as against Rs. 73,019.94 Mn (USD 1,049.59 Mn) recording an increase of 7.83%.

GLENMARK PHARMACEUTICALS LTD. (GPL)

GPL is primarily focused on building a global Generics, Specialty and OTC business in the therapy areas of Dermatology, Respiratory and Oncology. It also has strong regional/country-specific presence in other therapeutic areas like diabetes, cardiovascular and oral contraceptives.

India

Sales from the formulation business in India for the third quarter of FY 2019-20 was at Rs. 7,888.39 Mn (USD 111.08 Mn) as against Rs. 6,675.30 Mn (USD 92.49 Mn) in the previous corresponding quarter, recording a growth of 18.17%.

The India business continued to outperform the industry growth; as per IQVIA Q3 FY 2019-20, Glenmark's India business recorded growth of 13.65% compared to IPM growth of 9.03%. As per IQVIA MAT December 2019, the India business recorded growth of 12.98% compared to IPM growth of 10.10%. Glenmark's India formulation business is ranked 14th, with market share of 2.21%. Glenmark has 9 brands among the 'Top 300 Brands in the IPM'.

In terms of market share, Glenmark's India business further strengthened itself in core therapy areas such as Cardiac and Respiratory. As per IQVIA MAT December 2019, the Cardiac segment market share increased from 4.44% to 4.68%; the Respiratory segment market share rose from 4.73% to 5.02%; the Anti-diabetic segment market share increased from 1.61% to 1.72%; and the Derma segment market share changed from 9.08% to 8.92%. Glenmark is ranked 2nd in the overall Dermatology market, 3rd in the overall Respiratory market and 6th in the cardiology market in India.

In April 2019, Glenmark announced the launch of its novel, patent protected and globally-researched sodium glucose co-transporter-2 (SGLT2) inhibitor Remogliflozin Etabonate (Remogliflozin) in India. Glenmark is the first Company in the world to launch Remogliflozin and the response from KOLs has been extremely positive. As per IQVIA December 2019 data, the sales for Remogliflozin is tracking at Rs. 5 cr per month. Remogliflozin is the most successfully launched SGLT2 inhibitor in the Indian market in the first few months from launch, with Glenmark attaining 6.5% market share in Dec 2019 in terms of value in the overall SGLT2 market in India. Glenmark has also launched the combination of Remogliflozin Etabonate and Metformin Hydrochloride for adults with type 2 diabetes in India. The combination product has also received a good response from the market.

India – Glenmark Consumer Care Business

Glenmark Consumer Care business maintained its strong growth momentum with 14% growth clocking Rs. 377.6 Mn in the quarter. This effort is led by Scalpe Shampoo franchise with 32% growth and VWash Plus with a 28% growth in Q3. The growth was aided through modern trade & e-commerce channels, increasing its contribution to GCC business to 22% in Q3 FY 2019-20 vs 19% in Q3 FY 2018-19. This strong sales performance on brands was also reflected externally in IQVIA, wherein the key brands of VWash and Candid continued to dominate the market share at 53% and 55% respectively and at a value growth of 11% and 12% compared to Q3 FY 2018-19.

USA

Glenmark Pharmaceuticals Inc., USA registered revenue from the sale of finished dosage formulations of Rs. 7998.28 Mn (USD 112.70 Mn) for the quarter ended December 31, 2019 as against revenue of Rs. 8556.75 Mn (USD 119.36 Mn) for the previous corresponding quarter, recording a de-growth of (6.53%).

Generics Business:

In the third quarter of fiscal year 2019-20, Glenmark was granted final approval and launched Adapalene and Benzoyl Peroxide Gel, 0.1%|2.5% and Metformin Hydrochloride Extended-Release Tablets USP [generic to Glumetza® Tablets]. In addition, Glenmark launched the previously approved product Ezetimibe and Simvastatin Tablets. Glenmark reintroduced Theophylline [Anhydrous] Extended-Release Tablets USP, 400 mg and 600 mg. One additional approval was obtained for Abiraterone Acetate Tablets, 250 mg. In the nine months of FY 2019-20, the Company has received 13 ANDA approvals including 11 final approvals and 2 tentative approval. The generic industry continues to be subdued with the overall generic topical dermatology market continuing to witness price erosion of 6-7% on a QoQ basis. On a YTD basis the overall generic topical dermatology market is estimated to have witnessed price erosion of around 17% for the first nine months of this financial year.

During the first nine months of the year, the US business was significantly impacted in terms of sales on account of just three products viz. Mupirocin Cream and also Atomoxetine hydrochloride and Calcipotriene cream. Further the sales in the quarter was also impacted due to Ranitidine.

The Company filed three ANDA applications with the US FDA in the quarter taking the tally to seven for the nine months period, and plans to file an additional five applications in the forthcoming quarter. Glenmark's marketing portfolio through December 31, 2019 consists of 165 generic products authorized for distribution in the US market. The Company currently has 43 applications pending in various stages of the approval process with the US FDA, of which 24 are Paragraph IV applications.

Glenmark has 5 US FDA approved formulation manufacturing facilities (Goa, Indore, Baddi, Aurangabad and Monroe). In Sep 2019, the US FDA inspected the manufacturing facility in Goa, India. We have received an EIR regarding that inspection. In Sep 2019, the US FDA also

inspected the manufacturing facility in Indore, India and we received an EIR regarding that inspection. The Baddi facility was inspected by SUKL (State Institute for Drug control), Czech Republic and was issued a certificate of compliance for the audit in Oct, 2019.

Note: All brand names and trademarks are the property of their respective owners.

Africa, Asia and CIS Region (ROW)

For the third quarter of FY 2019-20, revenue from Africa, Asia and CIS region was Rs. 3413.74 Mn (USD 48.15 Mn) as against Rs. 3401.21 Mn (USD 47.57 Mn) for the previous corresponding quarter, recording an increase of 0.37%.

As per IQVIA data for MAT December 2019, Glenmark Russia recorded growth of 7.7% in value vis-à-vis overall retail market growth of 6.5%; Glenmark's overall rank is 48 in Russian pharmaceutical market. Amongst the companies present in the expectorants market, Glenmark secures a strong position and ranks 4 as per IQVIA MAT December 2019. Amongst other CIS markets, Glenmark Ukraine showed secondary sales growth of 45.5% in value in the third quarter of FY 2019-20. In units, Glenmark Ukraine showed growth of 25.5% compared to relevant market growth of -4.8%.

The Asia region recorded moderate performance in the third quarter of FY 2019-20, with secondary sales growth of 6%. Growth remained subdued across all major Asian markets for Glenmark. The Africa region also recorded moderate growth in the third quarter. The South Africa and the Kenya subsidiary continued to record good growth in the third quarter.

Europe

Glenmark Europe's operations revenue for the third quarter of FY 2019-20 was at Rs. 3089.36 Mn (USD 43.59 Mn) as against Rs. 3217.39 Mn (USD 45.09 Mn) recording a de-growth of (3.98%).

Glenmark Europe operations recorded strong growth in the third quarter of the previous financial year. Thus in the current third quarter, the growth is suppressed to that extent. However we still expect the European business to grow at a steady pace in the coming quarters. The European business however recorded growth quarter-over-quarter. Despite the high base effect, the Central Eastern and the Western European business recorded moderate growth as compared to the previous corresponding quarter.

Further, GSK has concluded a settlement agreement concerning the existing litigation against Glenmark and Celon regarding the shape of their inhalation product containing salmeterol xinafoate and fluticasone propionate, named Salmex (aka Stalpex, Salflutin and Asthmex) in selected European markets. Under the settlement agreement concluded between the parties, Celon and Glenmark are permitted to sell Salmex in certain European markets in an agreed shape of inhaler device, free from intellectual property challenge.

Latin America

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1,563.18 Mn (USD 22.10 Mn) for the third quarter of FY 2019-20, as against Rs. 1,014.33 Mn (USD 14.11 Mn), recording an increase of 54.11%. The Brazil subsidiary continued to record good growth because of the launch of the three respiratory products licensed from Novartis. The Brazil subsidiary recorded growth in excess of 50% in the third quarter on a constant currency. The Mexico subsidiary also recorded in excess of 20% growth in constant currency. The Brazilian subsidiary continues to focus on respiratory which will be the main growth driver for the subsidiary.

GPL Specialty/Innovative R&D Pipeline

Ryaltris™

Ryaltris™ (olopatadine hydrochloride and mometasone furoate) Nasal Spray is the Company's respiratory pipeline asset and is currently under review with the US Food and Drug Administration (FDA) as a treatment for seasonal allergic rhinitis in the USA. The Company is currently in the process of bringing in a partner to commercialize Ryaltris™ in the US market. Additionally, Glenmark is also working to close a partnership deal for Ryaltris™ in various markets including the EU. During the third quarter, we filed an application for Ryaltris™ approval in the European Union. The Company has already completed partnership deals for Ryaltris™ in other markets such as Australia, New Zealand, South Korea and China. The Company will continue evaluating partnership opportunities in various markets and also launch the product in some of our key operating markets.

During the first quarter of FY 2019-20, the US FDA issued a Complete Response Letter (CRL) pertaining to the New Drug Application (NDA) for Ryaltris™. We continue to work with the agency to resolve the issues raised in the CRL. During the third quarter of the financial year, Glenmark announced that its partner Seqirus Pty. Ltd. (Seqirus) has received marketing approval for Ryaltris® from the Therapeutic Goods Administration (TGA), Australia. This paves the way for the launch of Ryaltris® in Australia through Seqirus. Australia will be the first market globally where Ryaltris® will be launched.

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GBR 310

During FY 2018-19, Glenmark announced results from a Phase 1 study that suggest similarity in pharmacokinetic, pharmacodynamic, safety and immunogenicity profiles between GBR 310, and the reference product, omalizumab, marketed in the US under the brand name Xolair®. The Company is in discussions with potential partners and is targeting to conclude a deal before initiating Phase 3 studies.

GRC 39815 (RORyt inhibitor)

GRC 39815 is a NCE currently being evaluated as an inhaled compound for the possible treatment of Chronic Obstructive Pulmonary Disorder (COPD). It is an inhibitor of the Retinoid-related Orphan Receptor gamma t (RORyt). The compound is currently in pre-clinical development and the Company plans to initiate a Phase 1 study in FY 2019-20.

GLENMARK LIFE SCIENCES LTD. (GLS)

Glenmark Life Sciences primarily includes manufacturing and marketing of active pharmaceutical ingredient (API) products across all major markets globally. It also includes captive sales (i.e. use of API by GPL for its own formulations).

For the third quarter of FY 2019-20, external sales for Glenmark Life Sciences was at Rs. 2,621.56 Mn (USD 36.95 Mn) as against Rs. 2,392.48 Mn (USD 33.29 Mn), recording growth of 9.58% over the corresponding period last year.

US and Emerging markets led the growth in the third quarter, with the US growing at excess of 125% over the corresponding quarter in the last financial year and 60% over the previous quarter. The emerging markets sales grew at 25%. In the US market, the growth was led by key products such as Aprepitant.

The organisation continues to look at opportunities in emerging markets and has begun seeding multiple products across the region. The Company has begun filing products in China viz. Milnacipran, Adapalene and Tadalafil. GLS has been working on strengthening the business with the top formulation companies specifically in the EU regions and continues to work with them on new launches. GLS remains on track to file 3-4 products in next quarter.

ICHNOS Sciences

During the first half of FY 2019-20, Glenmark invested Rs. 3,835 Mn (USD 55.02 Mn) in the innovation business. For the third quarter of the financial year, Glenmark has invested Rs. 2,108 Mn (USD 30.01 Mn) totalling to Rs 5,943 Mn (USD 85.03 Mn) for the first nine months of this financial year.

Ichnos Sciences would initiate the process to raise capital in the US starting Q4 FY 2019-20 to fund the development of its pipeline and for future growth plans.

For update on Ichnos Sciences pipeline, refer the Annexure. For more updates on organisation, please log on to www.ichnosciences.com

Disclaimer

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ICHNOS SCIENCES INC.

February 2020 Update

Ichnos Sciences is shifting the way the world thinks about innovation in medicine through its transformative treatments in oncology, autoimmune disease and pain. The Company, with headquarters in Paramus, NJ, and facilities in Switzerland and India, has strong capabilities in the research and development of new biological entities (NBE) and new chemical entities (NCE). Ichnos currently has five molecules in clinical development for multiple indications: two in oncology, one in autoimmune disease and two in pain. With a patented BEAT[®] technology platform¹ for biologic drugs, along with drug pioneering teams across locations, Ichnos Sciences has a mission to provide breakthrough, curative therapies that will hopefully extend and improve lives, writing a new chapter in healthcare.

Ichnos Sciences, which officially launched on 15 October 2019, is in the process of obtaining all the necessary statutory, legal, corporate and regulatory approvals for completion of the spin-off from Glenmark Holding SA, which is expected to occur in the first quarter of calendar year 2020. Ichnos' operations are currently funded through investments by Glenmark, and securing additional investors will be a key initiative in 2020.

Highlights

Over the past quarter, Ichnos has taken numerous steps towards independence, including transitioning colleagues in the United States and Switzerland to Ichnos Sciences. Employees in India remain part of Glenmark due to a delay in getting approval from the local authorities.

¹ Bispecific Engagement by Antibodies based on the T cell receptor

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Update on Ichnos Pipeline of Clinical Stage Drugs

Molecule	Potential Indications	Phase	Status (Dates are in Calendar Year)
Autoimmune Disease			
ISB 830 OX40 Antagonist	Atopic Dermatitis	Phase 2b	Part 1 of this randomized double-blind placebo-controlled Phase 2b study is fully enrolled. Top-line results(Part 1) in first half of 2020. Part 2 is enrolling, and results are expected in second half 2020
	Rheumatoid Arthritis	Phase 2b	To start in 2020
	Systemic Lupus Erythematosus	Phase 2b	Timing of study start to be determined
Pain			
ISC 27864 mPGES-1 Inhibitor	Osteoarthritic Pain	Phase 2b	Complete. Study did not meet primary and secondary endpoints.
ISC 17536 TRPA1 Antagonist	Painful Diabetic Peripheral Neuropathy	Phase 2a	Phase 2a study completed. Additional studies to start in 2020
Oncology			
ISB 1302 HER2xCD3 Bispecific Antibody	Breast Cancer	Phase 1a/1b	Currently enrolling
ISB 1342 CD38xCD3 Bispecific Antibody	Multiple Myeloma	Phase 1a/1b	Currently enrolling

Autoimmune Disease

ISB 830 (OX40 Antagonist)

- Part 1 of the Phase 2b study of ISB 830 (anti-OX40 monoclonal antibody) has been fully enrolled. This is a randomized double-blind study assessing three doses and dosing schedules versus placebo in 312 adult patients with moderate-to-severe atopic dermatitis (AD) across study sites in the US, Canada, Germany, Czech Republic and Poland. Top-line results of Part 1 of the Phase 2b study in AD are expected to be available in the first half of 2020.
- Randomization of an additional cohort of 156 patients is underway into Part 2 of the AD study (high-dose arm vs placebo). Top-line results of Part 2 are expected in the second half of 2020.
- In addition, a Phase 2b study to evaluate the safety and efficacy of ISB 830 for the treatment of adults with Rheumatoid Arthritis is in preparation, with a target start date in the first half of 2020.
- Studies to evaluate the safety and efficacy of ISB 830 in Systemic Lupus Erythematosus and other Autoimmune Diseases are under consideration.

Pain

ISC 27864 (mPGES-1 inhibitor)

- ISC 27864 is a non-opioid, selective, and orally bioavailable inhibitor of microsomal prostaglandin E synthase-1 (mPGES-1).
- A randomized double-blind placebo-controlled Phase 2b study of three doses administered once-daily in 624 osteoarthritis pain patients in India was recently completed. The study did not meet the primary endpoint for reduction in pain compared to placebo.

ISC 17536 (TRPA1 antagonist)

- A Phase 2a proof of concept study of the oral transient receptor potential ankyrin-1 (TRPA1) inhibitor, ISC 17536, was previously completed in Europe and India in adult patients with painful diabetic peripheral neuropathy (DPN).
- Towards the end of 2019, Ichnos successfully addressed questions from the FDA to remove a prior clinical hold and planning is underway for potential future studies.

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Oncology

ISB 1302 (HER2xCD3 bispecific antibody)

- A Phase 1, first-in-human study of ISB 1302 to determine the maximum tolerated dose (MTD) with bi-weekly dosing in patients with HER2-positive cancers completed enrollment in the US and Germany in May 2019.
- A Phase 1 study of ISB 1302 to evaluate a weekly dosing regimen is ongoing.

ISB 1342 (CD38xCD3 bispecific antibody)

- Enrollment in a Phase 1, first-in-human study of ISB 1342 to determine the MTD in a bi-weekly dosing regimen in patients with refractory multiple myeloma is ongoing in the US. Cohorts 1-10 have been completed, and Cohort 11 is fully recruited.
- A Phase 1 dose escalation and expansion study including weekly dosing is ongoing.

Update on Ichnos Pipeline of Preclinical Candidates

Ichnos will continue to leverage its capabilities in NCEs and NBEs, particularly through the BEAT[®] platform, and is planning to advance additional small molecule and biologic candidates, including a MAP4K1 inhibitor, in 2020 and beyond.