

Glenmark Pharmaceuticals Limited  
Audited Financial Results for the quarter and year ended 31 March 2015

(Rs. In Millions)

Particulars [ Refer notes below ]	Standalone (Indian GAAP)					Consolidated (IFRS)				
	Quarter ended 31/03/2015 (Audited)	Quarter ended 31/12/2014 (Unaudited)	Quarter ended 31/03/2014 (Audited)	Year ended 31/03/2015 (Audited)	Year ended 31/03/2014 (Audited)	Quarter ended 31/03/2015 (Audited)	Quarter ended 31/12/2014 (Unaudited)	Quarter ended 31/03/2014 (Audited)	Year ended 31/03/2015 (Audited)	Year ended 31/03/2014 (Audited)
1. Income from Operations										
(a) Net Sales / Income from Operations (Net of excise duty)	30,778.79	6,467.95	6,522.35	49,992.10	22,735.57	17,537.92	16,921.12	16,817.41	65,952.57	59,838.52
(b) Other Operating Income	408.42	104.65	219.30	863.92	273.47	220.21	91.95	218.18	495.11	230.82
Total Income from Operations (net)	31,187.21	6,572.60	6,741.65	50,856.02	23,009.04	17,758.13	17,013.07	17,035.59	66,447.68	60,069.34
2. Expenses										
a. Cost of Materials consumed	11,276.72	1,470.23	1,386.33	15,640.26	4,678.86	3,902.06	5,829.08	3,268.63	18,248.42	14,319.78
b. Purchase of Stock-in-trade	541.31	437.98	479.49	1,739.54	1,599.71	1,562.97	30.03	1,361.97	3,647.98	4,687.77
c. Changes in Inventories of finished goods, work-in-progress and stock-in-trade	(470.59)	(38.14)	16.17	(696.53)	(52.30)	(1,647.27)	(299.29)	(191.93)	(2,552.03)	(277.33)
d. Employee benefits expense	2,930.89	1,198.11	1,026.74	6,622.54	3,953.53	2,541.85	3,165.25	2,773.91	12,024.10	10,261.46
e. Depreciation and Amortisation expense	951.47	81.22	84.30	1,194.60	302.00	644.62	654.50	602.96	2,599.80	2,167.95
f. Other expenses	6,062.97	2,191.65	2,073.61	12,900.31	7,869.56	8,584.44	5,631.39	6,006.84	22,832.98	17,977.12
Total expenses	21,292.77	5,341.05	5,066.64	37,400.72	18,351.36	15,888.67	15,010.96	13,822.38	56,801.25	49,136.75
3. Profit from Operations before Other Income, finance costs & exceptional items ( 1-2 )	9,894.44	1,231.55	1,675.01	13,455.30	4,657.68	2,169.46	2,002.11	3,213.21	9,646.43	10,932.59
4. Other Income	390.69	120.37	130.91	849.41	671.34	3.25	21.25	(120.73)	68.79	97.47
5. Profit from ordinary activities before finance costs and exceptional items (3+4)	10,285.13	1,351.92	1,805.92	14,304.71	5,329.02	2,172.71	2,023.36	3,092.48	9,715.22	11,030.06
6. Finance costs	68.54	74.00	72.39	301.89	309.78	396.79	513.26	464.26	1,901.50	1,885.94
7. Profit from ordinary activities after finance costs but before Exceptional Items (5-6)	10,216.59	1,277.92	1,733.53	14,002.82	5,019.24	1,775.92	1,510.10	2,628.22	7,813.72	9,144.12
8. Exceptional items	1,687.37	-	-	1,687.37	-	1,870.89	-	2,175.36	1,870.89	2,175.36
9. Profit/(Loss) from Ordinary Activities before tax ( 7-8 )	8,529.22	1,277.92	1,733.53	12,315.45	5,019.24	(94.97)	1,510.10	452.86	5,942.83	6,968.76
10. Tax Expense	1,824.92	110.62	216.85	2,240.20	681.00	(200.82)	362.50	18.72	1,190.43	1,512.73
11. Net Profit/(Loss) from Ordinary Activities after tax ( 9-10 )	6,704.30	1,167.30	1,516.68	10,075.25	4,338.24	105.85	1,147.60	434.14	4,752.40	5,456.03
12. Extraordinary items	-	-	-	-	-	-	-	-	-	-
13. Net Profit/(Loss) for the period (11-12)	6,704.30	1,167.30	1,516.68	10,075.25	4,338.24	105.85	1,147.60	434.14	4,752.40	5,456.03
14. Share of profit/(loss) of associates	-	-	-	-	-	-	-	-	-	-
15. Minority Interest	-	-	-	-	-	(0.28)	(0.13)	3.48	(0.70)	33.28
16. Net Profit/(Loss) after taxes, minority interest and share of profit/(loss) of associates (13-14-15)	6,704.30	1,167.30	1,516.68	10,075.25	4,338.24	106.13	1,147.73	430.66	4,753.10	5,422.75
17. Paid-up Equity Share Capital (Face value per share Re. 1)	271.29	271.28	271.22	271.29	271.22	271.29	271.28	271.22	271.29	271.22
18. Reserves excluding Revaluation reserves	-	-	-	49,249.22	28,789.00	-	-	-	29,732.05	29,561.58
19.i Earning Per Share (before extraordinary items) (of Re 1/- each) (not annualised)										
Basic Earnings Per Share (in Rupees)	24.71	4.30	5.59	37.14	16.01	0.39	4.23	1.59	17.52	20.01
Diluted Earnings Per Share (in Rupees)	24.70	4.30	5.59	37.13	16.00	0.39	4.23	1.59	17.52	20.00
19.ii Earning Per Share (after extraordinary items) (of Re 1/- each) (not annualised)										
Basic Earnings Per Share (in Rupees)	24.71	4.30	5.59	37.14	16.01	0.39	4.23	1.59	17.52	20.01
Diluted Earnings Per Share (in Rupees)	24.70	4.30	5.59	37.13	16.00	0.39	4.23	1.59	17.52	20.00

**PART II**  
Select information for the quarter and year ended 31 March 2015

Particulars	Quarter ended 31/03/2015	Quarter ended 31/12/2014	Quarter ended 31/03/2014	Year ended 31/03/2015	Year ended 31/03/2014	Quarter ended 31/03/2015	Quarter ended 31/12/2014	Quarter ended 31/03/2014	Year ended 31/03/2015	Year ended 31/03/2014
<b>A Particulars of Shareholding</b>										
1. Public Shareholding										
Number of Shares	140,247,733	140,237,533	140,268,036	140,247,733	140,268,036	140,247,733	140,237,533	140,268,036	140,247,733	140,268,036
Percentage of Shareholding	51.70	51.69	51.72	51.70	51.72	51.70	51.69	51.72	51.70	51.72
2. Promoters and promoter group Shareholding										
a) Pledged/Encumbered										
- Number of shares	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
- Percentage of shares (as a % of the total shareholding of promoter and promoter group)	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
- Percentage of shares (as a % of the total share capital of the company)	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil	Nil
b) Non-encumbered										
- Number of Shares	131,046,820	131,046,820	130,955,617	131,046,820	130,955,617	131,046,820	131,046,820	130,955,617	131,046,820	130,955,617
- Percentage of shares (as a % of the total shareholding of promoter and promoter group)	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00
- Percentage of shares (as a % of the total share capital of the company)	48.30	48.31	48.28	48.30	48.28	48.30	48.31	48.28	48.30	48.28

**Glenmark Pharmaceuticals Ltd.**

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	Particulars	Quarter ended 31/03/2015
<b>B</b>	<b>Investors complaints</b>	
	Pending at the beginning of the quarter	-
	Received during the quarter	9
	Disposed off during the quarter	9
	Remaining unresolved at the end of the quarter	-

- Notes:**
- The above results were reviewed by the Audit Committee and approved at the meeting of the Board of Directors held on May 29, 2015.
  - The Company is exclusively in the Pharmaceuticals business segment.
  - During the quarter ended March 31, 2015, pursuant to Employee Stock Option Scheme 2003, the Company converted 10,200 options into equity shares of Re.1 each. As at March 31, 2015, 164,800 options were outstanding, which upon exercise are convertible into equivalent number of equity shares.
  - Tax expenses is computed after considering MAT credit and other income tax benefits.
  - Diluted EPS has been computed considering the effect of conversion of ESOPs and the Shares proposed to be issued pursuant to the amalgamation (refer note 9 b).
  - The Standalone Financial Statements have been prepared in accordance with accounting principles generally accepted in India including the Accounting Standards notified under the Companies (Accounting Standards) Rules, 2006 (as amended) read with Rule 7 of the Companies (Accounts) Rules, 2014 in respect of Section 133 of the Companies Act, 2013.
  - The Company has voluntarily adopted IFRS (International Financial Reporting Standards) in preparation of the consolidated financial statements which is in compliance with the SEBI circular dated April 5, 2010, accordingly the consolidated results have been prepared in accordance with the recognition and measurement principles as per IFRS and presented in the format as per clause 41 of the listing agreement.
  - In terms of the proviso to Clause 3(i) of Part A of the Schedule II to the Companies Act, 2013 (the Act), the Company has based on a technical evaluation, decided to adopt useful life for various categories of fixed assets, which are in certain cases, different from those prescribed in Schedule II to the Act.
  - a) The Board of Directors (the Board) had approved the Scheme of Amalgamation (the Scheme) of Glenmark Generics Ltd. (GGL) and Glenmark Access Ltd. (GAL) with Glenmark Pharmaceuticals Ltd. (the Company) on January 31, 2014. Pursuant to the Scheme being sanctioned by the Hon'ble High Court of Judicature at Bombay vide its order dated March 20, 2015, all assets and liabilities have been transferred to the Company with effect from April 1, 2014 (the Appointed Date as per the Scheme) and the certified copies of the aforesaid order of the High Court has been filed with the Registrar of Companies on April 10, 2015.  
b) In terms of the Scheme, the Company is required to allot 17,803 equity shares of the face value of Re. 1 each as fully paid up to the public shareholders of GGL in the ratio of 4 equity shares of Re. 1 each of the Company for every 5 equity shares of Rs. 10 each held in GGL. As the amalgamating company GAL is wholly owned subsidiary of the company, no equity shares will be exchanged to effect the amalgamation in respect thereof. The shares held by the company in GGL and GAL is cancelled.  
c) The amalgamation is accounted for under the "Pooling of Interests method" as prescribed under Accounting Standard -14 'Accounting for Amalgamations' and has been effected in the financial statements. Pursuant to the scheme, the difference between the net assets acquired and cost of investments of the Company together with the shares to be issued to the public shareholders of GGL amounting to Rs. 1,975 million has been adjusted in the general reserves.  
d) Consequent to giving effect to the Scheme during the quarter ended March 31, 2015, the standalone figures to this quarter include 12 months' figures of GGL and GAL. Hence, the Standalone results for the current quarter and year ended March 31, 2015 are not comparable with that of the corresponding quarter and year ended March 31, 2014.  
e) These amalgamations with the Company are non-cash transactions.
  - Pursuant to the provisions of Chapter VII of the SEBI (CDR) Regulations and Section 42, 62 and other applicable provisions of the Companies Act, 2013 read with the rules made thereunder, the Company has on May 19, 2015 allotted 1,08,00,000 equity shares of the face value of Re. 1 each at a price of Rs. 875 per equity share on preferential basis to Aranda Investment (Mauritius) Pte Ltd.
  - As disclosed to the Stock Exchanges on April 08, 2015, the exceptional item relates to settlement claim including legal expenses arrived with State of Texas by Glenmark Generics Inc., USA an ultimate subsidiary of Glenmark pharmaceuticals limited.
  - The disclosure of statement of assets and liabilities as per clause 41(v)(h) of the listing agreement are integral part of these results.
  - The Board of Directors recommend a final dividend of 200% i.e. Rs.2 per equity share on the face value of Re. 1 each for F.Y. 2014-2015. The payment is subject to the approval of shareholders in the ensuing Annual General Meeting.
  - Previous period's figures have been re-grouped/re-classified wherever necessary.

For and on behalf of the Board of Directors

Glenn Saldanha  
Chairman & Managing Director

Mumbai, May 29, 2015

**GLENMARK PHARMACEUTICALS LIMITED**  
STATEMENT OF ASSETS AND LIABILITIES

(Rs.in Millions)

Particulars	STANDALONE		CONSOLIDATED	
	Indian GAAP As at 31.03.2015 Audited	Indian GAAP As at 31.03.2014 Audited	IFRS As at 31.03.2015 Audited	IFRS As at 31.03.2014 Audited
<b>A EQUITY AND LIABILITIES</b>				
<b>1 Shareholders' funds</b>				
(a) Share capital	271.29	271.22	271.29	271.22
(b) Merger consideration pending allotment	0.02	-	0.02	-
(c) Reserves and surplus	49,249.22	28,789.00	29,732.05	29,561.58
(d) Money received against share warrants	-	-	-	-
<b>Sub-total - Shareholders' funds</b>	<b>49,520.53</b>	<b>29,060.22</b>	<b>30,003.36</b>	<b>29,832.80</b>
<b>2 Share application money pending allotment</b>	-	-	-	-
<b>3 Minority interest</b>	-	-	(1.87)	132.80
<b>4 Non-current liabilities</b>				
(a) Long-term borrowings	-	-	25,743.80	24,286.61
(b) Deferred tax liabilities (net)	1,323.97	364.17	2,386.99	1,081.10
(c) Other long-term liabilities	1,219.21	518.79	1,219.22	521.34
(d) Long-term provisions	-	-	-	-
<b>Sub-total - Non-current liabilities</b>	<b>2,543.18</b>	<b>882.96</b>	<b>29,350.01</b>	<b>25,889.05</b>
<b>5 Current liabilities</b>				
(a) Short-term borrowings	3,475.99	3,533.16	12,255.52	8,383.11
(b) Trade payables	15,667.86	5,626.82	20,456.67	13,625.84
(c) Other current liabilities	3,786.99	2,236.34	2,887.89	3,914.04
(d) Short-term provisions	1,513.80	956.42	1,512.82	3,568.67
<b>Sub-total - Current liabilities</b>	<b>24,444.64</b>	<b>12,352.74</b>	<b>37,112.90</b>	<b>29,491.66</b>
<b>TOTAL - EQUITY AND LIABILITIES</b>	<b>76,508.35</b>	<b>42,295.92</b>	<b>96,464.40</b>	<b>85,346.31</b>
<b>B ASSETS</b>				
<b>1 Non-current assets</b>				
(a) Fixed assets	15,248.67	5,318.24	32,704.42	30,356.89
(b) Goodwill on consolidation	-	-	579.70	602.04
(c) Non-current investments	16,595.18	14,092.42	171.18	181.18
(d) Deferred tax assets (net)	-	-	5,137.28	2,600.75
(e) Long-term loans and advances	8,546.31	6,705.23	4,376.45	3,771.89
(f) Other non-current assets	138.63	83.90	262.63	206.62
<b>Sub-total - Non-current assets</b>	<b>40,528.79</b>	<b>26,199.79</b>	<b>43,231.66</b>	<b>37,719.37</b>
<b>2 Current assets</b>				
(a) Current investments	-	-	-	-
(b) Inventories	7,366.32	2,104.26	12,690.39	9,328.79
(c) Trade receivables	24,408.31	11,360.44	25,117.65	21,563.40
(d) Cash and bank balances	485.47	1,084.55	7,681.41	8,006.69
(e) Short-term loans and advances	3,563.22	1,514.29	7,585.08	8,622.05
(f) Other current assets	156.24	32.59	158.21	106.01
<b>Sub-total - Current assets</b>	<b>35,979.56</b>	<b>16,096.13</b>	<b>53,232.74</b>	<b>47,626.94</b>
<b>TOTAL - ASSETS</b>	<b>76,508.35</b>	<b>42,295.92</b>	<b>96,464.40</b>	<b>85,346.31</b>

For and on behalf of the Board of Directors



**Glenn Saldanha**  
Chairman & Managing Director

Mumbai, May 29, 2015

**Glenmark Pharmaceuticals Ltd.**

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Press Release

For Immediate Dissemination

**Glenmark's Consolidated Revenue increases by 10.62% to Rs. 66447.68 Mn in FY 14-15****Consolidated Revenue in Q4 FY14-15 was Rs. 17758.13 Mn an increase of 4.24%****Business Highlights**

- India Business grew at 15.03% to Rs. 4405.71 Mn for the quarter and to Rs. 17489.53 Mn for the year
- US Business grew by 7.09% to Rs. 5363.44 Mn for the quarter and to Rs. 20397.66 Mn for the year
- Europe Business grew by 25.93% to Rs. 2433.00 Mn for the quarter and to Rs. 6445.33 Mn for the year
- Latin America Business grew by 70.51% to Rs. 1810.35 Mn for the quarter and to Rs. 7640.00 Mn for the year

**Mumbai, May 29, 2015:** Glenmark Pharmaceuticals Limited, the research-led global integrated pharmaceutical company today announced its results for the fourth quarter and year ended March, 31, 2015.

For the fourth quarter ended March 31, 2015, Glenmark's consolidated revenue was at Rs. 17,758.13 Mn (USD 285.38 Mn) as against Rs. 17035.60 Mn (USD 276.86 Mn). For the year ended March 31, 2015, Glenmark's consolidated revenue was at Rs. 66,447.68 (USD 1086.19 Mn) as against Rs. 60,069.35 (USD 994.09 Mn) recording an increase of 10.62%.

Consolidated Net Profit was at Rs. 106.13 Mn for the Quarter and Rs. 4753.10 Mn for the year ended March, 31, 2015.

*\*The Net Profit is not comparable due to exceptional item of Rs. 1870.89 Mn in the fourth quarter on account of the settlement claim including legal expenses arrived with the State of Texas by Glenmark Generics Inc., USA an ultimate subsidiary of Glenmark Pharmaceuticals Ltd.*

*"We continue to record good growth in our India, LatAm and Europe businesses. Currency devaluation and subdued business environment persisted to impact our Rest of the World, especially Russian operations. We have been also making steady progress in our innovation pipeline with our 3 NCE and 4 NBE molecules in development;"* said **Glenn Saldanha, Chairman & MD, Glenmark Pharmaceuticals Limited.**

The Board of Directors recommend a final dividend of 200 % i.e. Rs. 2 per equity share of the face value of Re. 1 each for FY 2015.

### **India**

Sales for the formulation business in India for the fourth quarter ended March 31, 2015, was at Rs. 4405.71 Mn (USD 70.71 Mn) as against Rs. 3,829.96 Mn (USD 62.05 Mn) in the previous corresponding quarter, recording a growth of 15.03%.

### **USA Formulations**

Glenmark Pharmaceuticals Inc., U.S.A. registered revenue from the sale of finished dosage formulations was at Rs. 5,363.44 Mn (USD 86.16 Mn) for the quarter ended March 31, 2015 against revenue of Rs. 5,008.52 Mn (USD 81.09 Mn) for the previous corresponding quarter, recording an increase of 7.09%.

### **Africa, Asia and CIS Region (ROW)**

For the fourth quarter, revenue from Africa, Asia and CIS region was Rs. 2198.41 Mn (USD 35.34 Mn) as against Rs. 3,425.34 Mn (USD 55.93 Mn) for the previous corresponding quarter.

### **Europe Formulations**

Glenmark Europe's operations revenue for the fourth quarter ended March 31, 2015 was at Rs. 2,433.00 Mn (USD 39.37 Mn) as against Rs. 1,932.00 Mn (USD 31.60 Mn) recording growth of 25.93%.

### **Latin America**

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1,810.35 Mn (USD 29.00 Mn) for the fourth quarter ended March 31, 2015 as against Rs. 1,061.74 Mn (USD 17.22 Mn), recording an increase of 70.51%.

### **Active Pharmaceutical Ingredients (API)**

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 1,547.22 Mn (USD 24.84 Mn), for the quarter ended March 31, 2015 against Rs. 1,530.63 Mn (USD 24.88 Mn) for the previous corresponding quarter.

### **About Glenmark**

Glenmark Pharmaceuticals Ltd. (GPL) is a research-driven, global, integrated pharmaceutical company headquartered at Mumbai, India. It is ranked among the top 80 Pharma & Biotech companies of the world in terms of revenues. (SCRIP 100 Rankings published in the year 2014). Glenmark is a leading player in the discovery of new molecules both NCEs (new chemical entity) and NBEs (new biological entity). Glenmark has several molecules in various stages of clinical development and is primarily focused in the areas of Inflammation [asthma/COPD, rheumatoid arthritis etc.] and Pain [neuropathic pain and inflammatory pain].

The company has a significant presence in branded generics markets across emerging economies including India. GPL along with its subsidiary has 14 manufacturing facilities in four countries and has six R&D centers. The Generics business of Glenmark services the requirements of the US and Western Europe markets. The API business sells its products in over 80 countries, including the US, various countries in the EU, South America and India.

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## Management Discussion and Analysis for the Fourth quarter of FY 2014 – 15

### Revenue Figures – Consolidated

*(Rs. in Millions)*

	Fourth quarter ended March 31, 2015			Twelve months ended March 31, 2015		
	FY 2014 – 15	FY 2013 – 14	Growth	FY 2014 – 15	FY 2013 – 14	Growth
India	4405.71	3829.96	15.03%	17489.53	15104.89	15.79%
US	5363.44	5008.52	7.09%	20397.66	20270.24	0.63%
Rest of the World (ROW)	2198.41	3425.34	-35.82%	8123.29	9869.01	-17.69%
Europe	2433.00	1932.00	25.93%	6445.33	5060.70	27.36%
Latin America	1810.35	1061.74	70.51%	7640.00	4045.54	88.85%
API	1547.22	1530.63	1.08%	6052.82	5353.46	13.06%
<b>Total</b>	17751.30	16788.19	5.74%	66141.80	59703.84	10.78%
Out-Licensing Revenue		247.41		299.05	365.51	
<b>Consolidated Revenue</b>	17758.13	17035.60	4.24%	66447.68	60069.35	10.62%

Average conversion rate in 12M FY 2014 – 15 considered is Rs. 61.17/ USD 1.00

Average conversion rate for 12M FY 2013 – 14 considered is Rs. 60.43/ USD 1.00

USD figures are only indicative

## **Review of Operations for the quarter ended March 31, 2015**

For the fourth quarter ended March 31, 2015, Glenmark's consolidated revenue was at Rs. 17,758.13 Mn (USD 285.38 Mn) as against Rs. 17035.60 Mn (USD 276.86 Mn). For the year ended March 31, 2015, Glenmark's consolidated revenue was at Rs. 66,447.68 (USD 1086.19 Mn) as against Rs. 60,069.35 (USD 994.09 Mn) recording an increase of 10.62%.

### **India**

Sales for the formulation business in India for the fourth quarter ended March 31, 2015, was at Rs. 4405.71 Mn (USD 70.71 Mn) as against Rs. 3,829.96 Mn (USD 62.05 Mn) in the previous corresponding quarter, recording a growth of 15.03%.

As per IMS MAT March 2015, Glenmark Pharmaceuticals Ltd. moved up to 17<sup>th</sup> rank from 19<sup>th</sup> compared to MAT March 2014 with increase in market share by 0.09%, exhibiting value growth of 18% vis-à-vis IPM growth of 13%. For the month March 2015, the business registered growth of 19% vis-a-vis market growth of 16%. Glenmark presently has 8 brands in the Top 300 Brands in the Indian Pharmaceutical Market.

The India business strengthened itself in the following therapeutic segments with significant growth in market share from IMS MAT March 2014 to MAT March 2015 respectively. The Cardiac segment market share increased from 3.69% to 3.80%; the Respiratory segment market share rose from 3.49% to 3.80%; Anti-infective segment market share rose from 1.68% to 1.81%; the Anti-diabetic segment market share rose from 1.64% to 2.07%; and the Derma segment market share changed from 8.07% to 8.04%.

### **USA Formulations**

Glenmark Pharmaceuticals Inc., U.S.A. registered revenue from the sale of finished dosage formulations was at Rs. 5,363.44 Mn (USD 86.16 Mn) for the quarter ended March 31, 2015 against revenue of Rs. 5,008.52 Mn (USD 81.09 Mn) for the previous corresponding quarter, recording an increase of 7.09%.

In the fourth quarter of fiscal year 2015, Glenmark was granted a final approval for Levonorgestrel/Ethinyl Estradiol Tablets, 0.15mg/0.03mg and Ethinyl Estradiol Tablets, 0.01 mg (Seasonique®). During the financial year, Glenmark has filed 18 ANDA applications with the US F.D.A.



As of March 31, 2015 Glenmark's portfolio consists of 95 generic products authorized for distribution in the U.S. market. The Company currently has 70 applications pending in various stages of the approval process with the US FDA, of which 33 are Paragraph IV applications.

## **Africa, Asia and CIS Region (ROW)**

For the fourth quarter, revenue from Africa, Asia and CIS region was Rs. 2198.41 Mn (USD 35.34 Mn) as against Rs. 3,425.34 Mn (USD 55.93 Mn) for the previous corresponding quarter, recording a decrease of 35.82%.

The currency devaluation and subdued business environment continued to impact the Russia business. However, as per IMS MAT March 2015, Glenmark Russia rank improved to 46 from 51 MAT March 2014. The Ukraine business continues to remain challenging due to the unstable economic and political environment. The Asia and Africa region continued to record good secondary sales growth. The good secondary sales growth for Asia and Africa augurs well for FY 2015 – 16.

## **Europe Formulations**

Glenmark Europe's operations revenue for the fourth quarter ended March 31, 2015 was at Rs. 2,433.00 Mn (USD 39.37 Mn) as against Rs. 1,932.00 Mn (USD 31.60 Mn) recording growth of 25.93%.

During the quarter, Glenmark launched 6 products in the European region driven mainly by in-licensed products. Glenmark launched 2 products in Czech and Germany and 1 product each in Romania, Slovak and Poland.

## **Latin America**

Glenmark's revenue from its Latin American and Caribbean operations was at Rs. 1,810.35 Mn (USD 29.00 Mn) for the fourth quarter ended March 31, 2015 as against Rs. 1,061.74 Mn (USD 17.22 Mn), recording an increase of 70.51%.

For the quarter, in local currency, the Mexico and Venezuela unit recorded growth in excess of 100% respectively. The growth in Mexico was backed by the respiratory line of products.

## Active Pharmaceutical Ingredients (API)

Revenue from sale of API to regulated and semi-regulated markets globally was Rs. 1,547.22 Mn (USD 24.84 Mn), for the quarter ended March 31, 2015 against Rs. 1,530.63 Mn (USD 24.88 Mn) for the previous corresponding quarter, recording an increase of 1.08%.

During the quarter Glenmark has filed for 6 US DMFs including 3 targeting FTF molecules. The good growth was bagged by continued strong sales of Amiodarone, Lercanidipine, Adapalene and Perindopril. The Ankleshwar and Dahej manufacturing facilities were successfully inspected by the US FDA during the quarter.

## Research & Development

The company has a pipeline of 3 NCE and 4 NBE molecules in clinical trials or ready to enter clinical trials soon, including the in-licensed molecule “Crofelemer”.

### GRC 17536

GRC 17536, a TRPA1 antagonist, has proven highly efficacious in treating inflammatory and neuropathic pain in animal models. GRC 17536 has showed good safety in the Phase I enabling GLP safety pharmacology and toxicology studies performed. Glenmark has completed Phase 1 study in the Netherlands. Single and multiple ascending doses have been well tolerated with expected pharmacokinetic profile. GRC 17536, has shown positive data in a Phase 2a proof of concept study in patients with painful diabetic neuropathy conducted in Europe and India. Phase 2 enabling toxicology studies have been initiated. Glenmark intends to open an IND in Q2 FY 2015 – 16 for a Phase 2b dose range finding study.

### GRC 27864

Glenmark’s Novel Chemical Entity (NCE) 'GRC 27864' targets Microsomal Prostaglandin E synthase-1 (mPGES-1) as a novel therapeutic target in pain management. Selective mPGES-1 inhibitors are expected to inhibit increased prostaglandin E2 (PGE2) production in the disease state without affecting other prostanoid metabolites and, consequently, may be devoid of the GI (gastrointestinal) and cardiovascular side effects seen with NSAIDs and COX-2 inhibitors, respectively.

Glenmark has completed preclinical studies and Phase I enabling GLP studies for its selected lead molecule, GRC 27864 and has approval for Phase I first-in-human trial from MHRA, UK. A single ascending dose study has been completed with no safety concerns. Multiple ascending dose study is currently on-going.

## **Vatelizumab (GBR 500)**

GBR 500, a monoclonal antibody, is an antagonist of the VLA-2 (alpha2-beta1) integrin. It has the potential to be a broadly applicable anti-inflammatory compound in diseases like Crohn's disease (CD) and Multiple Sclerosis. It is a 'first-in-class' monoclonal antibody therapeutic with this target and has established proof of concept in animals. Phase I studies for GBR 500 have been completed in the US. GBR 500 has been licensed to Sanofi. The Phase II studies which are conducted by Sanofi are currently on-going for Multiple Sclerosis.

## **GBR 900**

Glenmark licensed from Lay Line Genomics, Italy, exclusive intellectual property rights for monoclonal antibodies against the neuronal growth factor receptor TrkA. TrkA is part of the NGF-TrkA axis, a validated and novel pain receptor system for treatment of chronic pain. Pre-clinical research on the GBR 900 project is being carried out at Glenmark's Biologics Research (GBR) centre at La Chaux-de-Fonds, Switzerland and is progressing well. Phase I enabling toxicity studies for GBR 900 have been completed successfully. A Phase I clinical trial has been initiated in the UK. GBR 900 is the first anti-TrkA monoclonal antibody to enter clinical development.

## **GBR 830**

GBR 830, the first anti-OX40 monoclonal antibody was discovered at the Glenmark Biologics Research Centre located in Switzerland. The development of OX40 antagonists has been very challenging and Glenmark has achieved a significant milestone with the successful generation of an antagonistic OX40 monoclonal antibody coupled with generation of data validating the role of OX40 in autoimmune diseases. GBR 830 shows great promise to emerge as a valuable therapeutic option to treat patients suffering from autoimmune diseases. Phase I enabling toxicity studies for GBR 830 have been completed and Phase I study is currently on-going in Netherlands, Europe. Glenmark intends to open an IND in Q2 FY 2015 – 16.

## **GBR 1302**

GBR 1302, a HER2xCD3 bispecific antibody, is the first clinical candidate based on Glenmark's proprietary best in class BEAT® platform and also GBR 1302 is the Glenmark's first clinical candidate targeting oncology indications. The BEAT® antibody technology platform facilitates the efficient development and manufacture of antibodies with dual specificities called bispecific antibodies. Glenmark is currently putting together a submission package for initiating clinical trials for GBR 1302 and expects to obtain approval by Q3 FY 15-16.

## **Crofelemer**

Supported by Salix's U.S. FDA approval of Crofelemer, Glenmark has already filed Crofelemer in the some of the key markets within the 140 Countries where it has exclusive marketing and distribution rights. Glenmark has successfully filed Crofelemer in 13 countries and also received approval in Ecuador, Zimbabwe and Botswana. Fillings are planned in several more countries in this fiscal year. Glenmark is also in discussion to expand the supply of Crofelemer API.

## **Disclaimer**

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