



ALKEM

ALKEM LABORATORIES LTD.

Regd. Office : "ALKEM HOUSE", Senapati Bapat Marg,
Lower Parel, MUMBAI 400 013. Phone : 3982 9999, Fax : 022 - 2495 2955
Email : contact@alkem.com Website : www.alkemlabs.com
CIN :- L00305MH1973PLC174201



Press Release

Alkem reports Q2FY19 and H1FY19 Results

Mumbai, November 2, 2018: Alkem Laboratories Ltd (Alkem) today announced its standalone and consolidated financial results for the second quarter & six months ending September 30, 2018. These results were taken on record by the Board of Directors at a meeting held in Mumbai today.

Key financial highlights of H1FY19

- Revenue from Operations was Rs.35,780 million, year-on-year growth of 12.9%
 - India sales were Rs.24,091 million, year-on-year growth of 6.0%
 - International sales were Rs.11,288 million, year-on-year growth of 33.7%
- Earnings before Interest, Tax, Depreciation and Amortization (EBITDA) was Rs.5,680 million, resulting in EBITDA margin of 15.9% vs. 17.2% in H1FY18. EBITDA grew by 4.1% YoY
- R&D expenses for H1FY19 was Rs.2,035 million, or 5.7% of Revenue from Operations compared to Rs.1,602 million in H1FY18 at 5.1% of Revenue from Operations
- Profit before tax (PBT) was Rs.4,978 million compared to Rs.5,127 million in H1FY18
- Net Profit (after Minority Interest) was Rs.3,906 million compared to Rs.3,922 million in H1FY18

Key financial highlights of Q2FY19

- Revenue from Operations was Rs.19,189 million, year-on-year growth of 3.2%
 - India sales were Rs.13,184 million, year-on-year decline of 6.2% on the high base of Q2FY18 on account of GST led inventory restocking
 - International sales were Rs.5,809 million, year-on-year growth of 32.5%
- Earnings before Interest, Tax, Depreciation and Amortization (EBITDA) was Rs.3,642 million, resulting in EBITDA margin of 19.0% vs. 24.4% in Q2FY18
- R&D expenses for the quarter was Rs.1,049 million, or 5.5% of Revenue from Operations compared to Rs.901 million in Q2FY18 at 4.8% of Revenue from Operations
- Profit before tax (PBT) was Rs.3,260 million compared to Rs.4,321 million in Q2FY18
- Net Profit (after Minority Interest) was Rs.2,545 million compared to Rs.3,207 million in Q2FY18

At the start of FY19, in order to streamline its distribution process, the Company has made changes in its distribution policy which has led to shifting of some of its India sales between the quarters and this will eventually normalise on the full year basis. Adjusting for this change in distribution policy, the India sales in H1FY19 would have reported higher growth, leading to higher growth in the revenue from operations and better EBITDA margin.

Commenting on the results, Sandeep Singh, Managing Director, Alkem said, "We have seen a steady progress in the first half of the financial year. Adjusting for the change in distribution policy and GST impact, our India business delivered a double digit growth in H1FY19, while our US business grew at close to 50% YoY. In terms of regulatory compliance, our formulation facility at Baddi and API facility at California successfully cleared the US FDA inspection without any observation. We look to build upon this momentum for the remaining half of the year, and close the financial year on a stronger note."

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Operational Highlights

India Business

In Q2FY19, the Company's India sales was Rs.13,184 million compared to Rs.14,056 million in Q2FY18 – YoY decline of 6.2%. For H1FY19, the Company's India sales was Rs.24,091 million compared to Rs.22,731 million in H1FY18 – YoY growth of 6.0%. Adjusting for the GST impact and change in distribution policy, the YoY growth in H1FY19 was in double digit.

As per IQVIA MAT September 2018, during the quarter, the Company's secondary sales registered value growth of 18.2% YoY, outperforming the Indian Pharmaceutical Market (IPM) growth of 13.3% YoY. Also for the six months ended September 2018, the Company's secondary sales growth was 16.4% YoY – higher than IPM growth of 12.1% YoY in the corresponding period. In most of the large therapy segments like anti-infectives, vitamins / minerals / nutrients, neuro / CNS, derma, cardiac and anti-diabetes, the Company outperformed the segment growth rate, thereby gaining market share and improving its market ranking. While the Company continues to feature amongst the top three companies in the acute segments of anti-infectives, gastro-intestinal and pain management, it is also building upon its base in the fast growing chronic segments of neuro / CNS, derma, cardiac and anti-diabetes.

The performance highlights in the key therapeutic segments in Q2FY19 and H1FY19 is as shown below:

Key Therapy segment	Q2FY19				H1FY19			
	Alkem Rank	YoY change in Rank*	YoY growth (Alkem)	YoY growth (IPM)	Alkem Rank	YoY change in Rank*	YoY growth (Alkem)	YoY growth (IPM)
Anti-infectives	1	Unchanged	18.9%	9.7%	1	Unchanged	17.3%	8.3%
Gastro Intestinal	3	Unchanged	21.2%	11.5%	3	Unchanged	18.7%	9.9%
Pain / Analgesics	3	Unchanged	5.6%	10.7%	3	Unchanged	4.9%	9.2%
Vitamins / Minerals / Nutrients	4	Unchanged	15.4%	14.9%	4	+1	15.7%	13.4%
Neuro / CNS	8	+1	18.9%	13.4%	8	+1	17.8%	10.7%
Derma	14	+4	26.7%	17.7%	16	+2	22.4%	16.4%
Cardiac	26	+2	32.0%	14.0%	26	+2	26.8%	12.2%
Anti-Diabetic	22	+3	37.7%	15.3%	22	+3	34.7%	14.6%
Total	5	Unchanged	18.2%	13.3%	6	Unchanged	16.4%	12.1%

*Positive change in rank reflects improvement over same period previous year

Source: IQVIA MAT September 2018

International Business

In Q2FY19, the Company's International sales grew by 32.5% YoY, recording sales of Rs.5,809 million as compared to Rs.4,384 million in Q2FY18. For H1FY19, the Company's International sales grew by 33.7% to Rs.11,288 million compared to Rs.8,441 million in H1FY18.



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- **US sales** for the quarter was Rs.4,725 million, recording a year-on-year growth of 55.3%. For H1FY19, the US sales was Rs.8,962 million, up 49.3% compared to H1FY18.
- **Other International Markets sales** for the quarter was Rs.1,084 million, recording a year-on-year decline of 19.3%. For H1FY19, Other International Markets sales was Rs.2,326 million, a decline of 4.6% compared to H1FY18.

R&D Investments

Company's revenue R&D expenses for the quarter was Rs.1,049 million, or 5.5% of revenue from operations. Similarly for H1FY19, Company's revenue R&D expenses was Rs.2,035 million, or 5.7% of total revenue from operations.

During the quarter, the Company filed 7 abbreviated new drug applications (ANDAs) with the US FDA and received 2 approvals (including 1 tentative approval). For H1FY18, the Company filed 11 ANDAs with the US FDA and received 4 approvals (including 2 tentative approval).

As on September 30, 2018, the Company has filed a total of 117 ANDAs and 1 new drug application (NDA) with the US FDA of which 52 are Para IV filings including first-to-files (FTFs). Of these, it has received approvals for 52 ANDAs (including 7 tentative approvals) and 1 NDA.

Update on the US FDA inspection

Facility	Capability	Inspection Date	Update
Daman (India)	Formulations	March 2018	EIR received in July 2018
Baddi (India)	Formulations	August 2018	Successfully closed the inspection with zero observations
Ankleshwar (India)	API	December 2016	EIR received in March 2017
Mandva (India)	API	September 2015	EIR received in March 2016
St. Louis (USA)	Formulations	March 2018	Received one observation – CAPA filed with the US FDA
California (USA)	API	August 2018	Successfully closed the inspection with zero observations



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Q2FY19 and H1FY19 Conference Call at 5:00pm IST, November 2, 2018

Alkem Laboratories Ltd. will organize a conference call for investors and analysts on Friday, November 2, 2018 from 5:00 pm to 6:00 pm IST to discuss its Q2FY19 and H1FY19 financial results.

Alkem Laboratories Ltd. will be represented on the call by Mr. Sandeep Singh, Managing Director and the senior management team.

Motilal Oswal Securities will host the call.

Details of the conference call are as under:

Time: 5:00 pm to 6:00 pm IST (GMT + 5:30) on Friday, November 2, 2018.

Dial in Details:

India : +91 22 6280 1149 / +91 22 7115 8050

International Toll Free

USA : 1 866 746 2133
UK : 0 808 101 1573
Singapore : 800 101 2045
Hong Kong : 800 964 448

You are requested to dial in 10 mins ahead of the scheduled start time. A transcript of this conference call will also be available on our website www.alkemlabs.com

About Alkem Laboratories Ltd.

Established in 1973 and headquartered in Mumbai, Alkem (NSE: ALKEM, BSE: 539523, Bloomberg: ALKEM.IN, Reuters: ALKE.NS) is a leading Indian pharmaceutical company with global operations, engaged in the development, manufacture and sale of pharmaceutical and nutraceutical products. The Company produces branded generics, generic drugs, active pharmaceutical ingredients (APIs) and nutraceuticals, which it markets in India and International markets. With a portfolio of more than 750 brands in India, Alkem is ranked the sixth largest pharmaceutical company in India in terms of domestic sales (Source: IMS TSA MAT March 2018). The Company also has presence in more than 50 international markets, with the United States being its key focus market.

For more information on Alkem Laboratories Ltd., please visit www.alkemlabs.com

For further information or queries please contact

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Investor Relations – Alkem Laboratories Ltd.

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ALKEM LABORATORIES LIMITED

Investor Presentation Q2FY19 – November 2, 2018

Safe Harbor Statement

This presentation contains forward-looking statements and information that involve risks, uncertainties and assumptions. Forward-looking statements are all statements that concern plans, objectives, goals, strategies, future events or performance and underlying assumptions and other statements that are other than statements of historical fact, including, but not limited to, those that are identified by the use of words such as “anticipates”, “believes”, “estimates”, “expects”, “intends”, “plans”, “predicts”, “projects” and similar expressions. Risks and uncertainties that could affect us include, without limitation:

- General economic and business conditions in India and other key global markets in which we operate;
- The ability to successfully implement our strategy, our research and development efforts, growth & expansion plans and technological changes;
- Changes in the value of the Rupee and other currency changes;
- Changes in the Indian and international interest rates;
- Allocations of funds by the Governments in our key global markets;
- Changes in laws and regulations that apply to our customers, suppliers, and the pharmaceutical industry;
- Increasing competition in and the conditions of our customers, suppliers and the pharmaceutical industry; and
- Changes in political conditions in India and in our key global markets.

Should one or more of such risks and uncertainties materialize, or should any underlying assumption prove incorrect, actual outcomes may vary materially from those indicated in the applicable forward-looking statements.

Any forward-looking statement or information contained in this presentation speaks only as of the date of the statement. We are not required to update any such statement or information to either reflect events or circumstances that occur after the date the statement or information is made or to account for unanticipated events, unless it is required by Law.

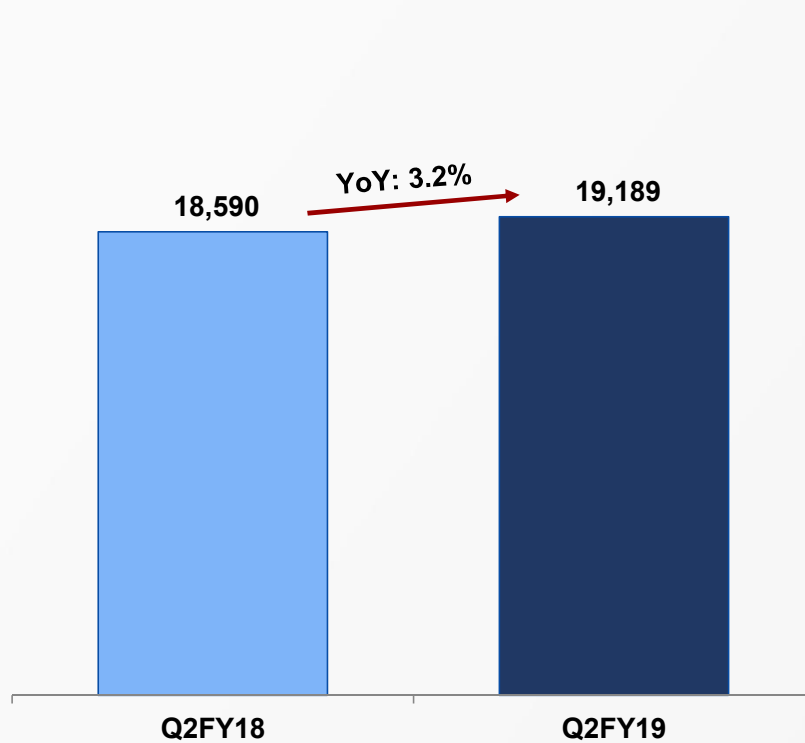
Key Highlights of Q2FY19 and H1FY19

- **India Business:** Adjusted for the change in the distribution policy and GST impact, the India business grew in double digit YoY in H1FY19
 - Company's secondary sales in H1FY19 grew by 16.4% - higher than IPM growth of 12.1% (Source: IQVIA MAT Sep. 2018)
- **International Business:** Company's International Business comprising of the US and select international markets registered a robust growth of 33.7% YoY in H1FY19
- **US Business** grew by 55.3% YoY in Q2FY19 and 49.3% YoY in H1FY19, largely driven by new product launches and market share gain in existing products
- **R&D** – R&D expenses in H1FY19 increased by 27.0% YoY and was at 5.7% of revenue from operations.
- **ANDA filings:** The Company filed 11 ANDAs and received 4 ANDA approvals (including 2 tentative) from the US FDA during H1FY19
- **Update on the US FDA inspections :**
 - July 2018 - Received an EIR from the US FDA for its Daman facility, thereby successfully closing the inspection
 - August 2018 – Inspection at Baddi formulation facility, received zero Form 483
 - August 2018 - Inspection at California (USA) API facility, received zero Form 483

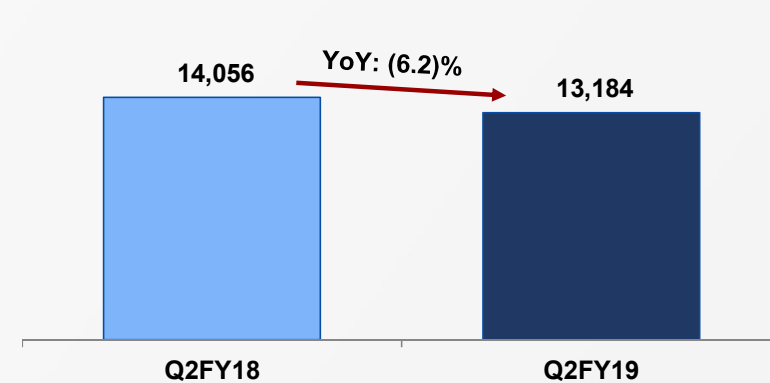
Key Financial Highlights – Q2FY19 (Consolidated)

All figures in Rs mn

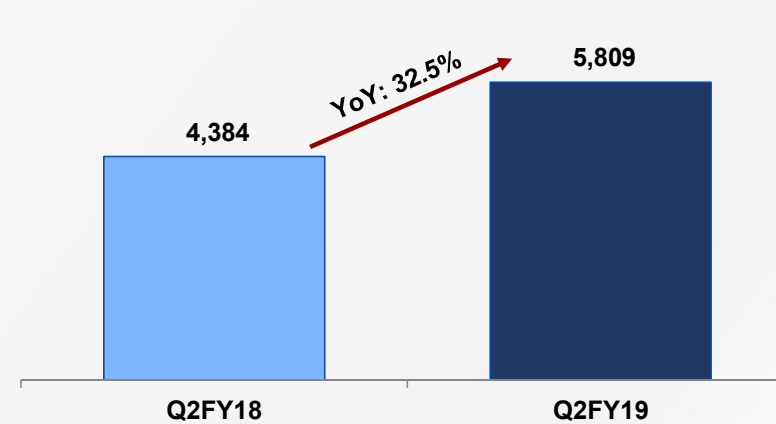
Revenue from Operations



India sales*



International sales

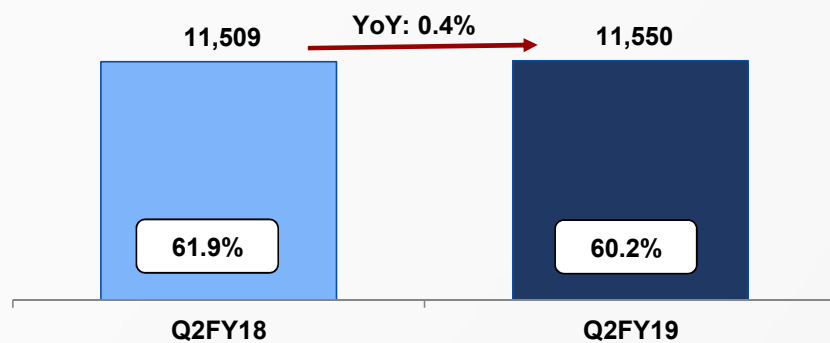


* YoY growth in India sales impacted by high base of Q2FY18 on account of inventory restocking post GST implementation

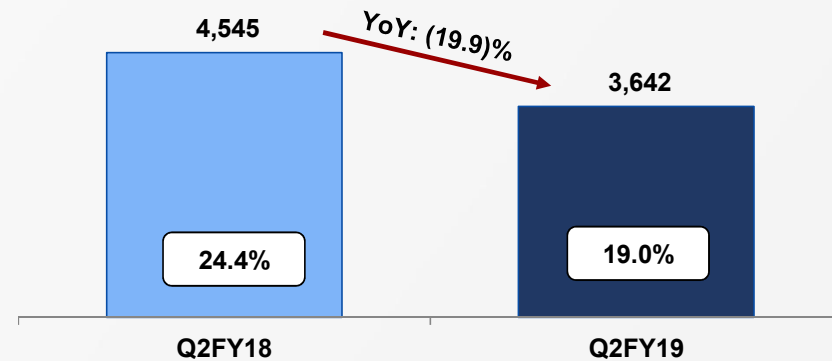
Key Financial Highlights – Q2FY19 (Consolidated)

All figures in Rs mn

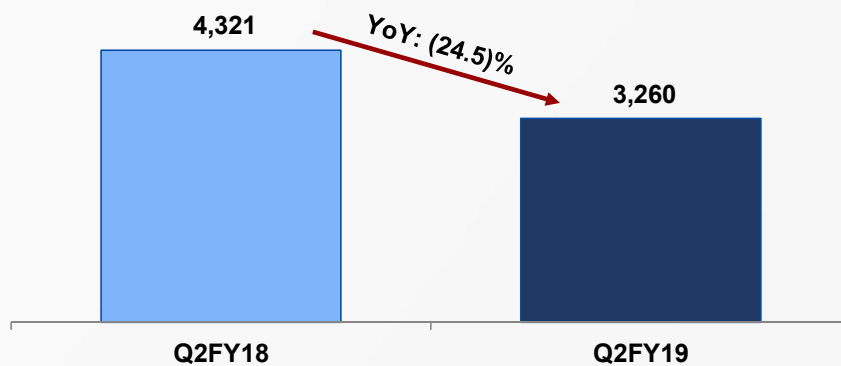
Gross Profit and Gross Margin



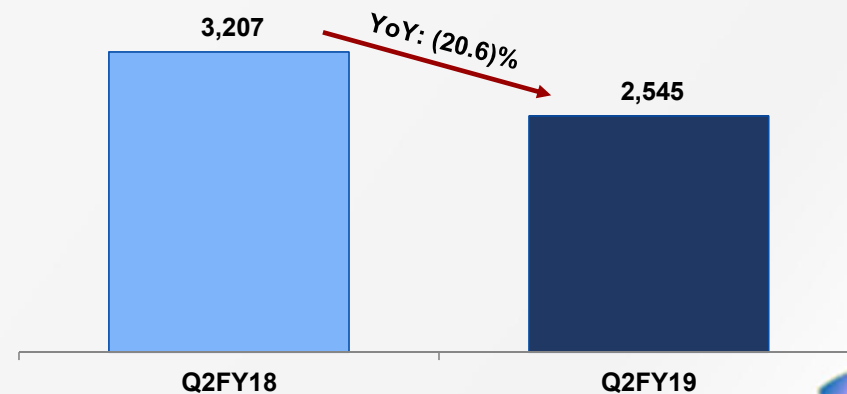
EBITDA and EBITDA Margin



PBT (before Minority Interest)



PAT (after Minority Interest)



Key Financial Highlights – H1FY19 (Consolidated)

Particulars (Rs mn)	H1FY19	H1FY18	YoY growth
Revenue from Operations	35,780	31,680	12.9%
Gross Profit	21,479	18,975	13.2%
Gross Profit margin	60.0%	59.9%	
EBITDA	5,680	5,454	4.1%
EBITDA margin	15.9%	17.2%	
PBT	4,978	5,127	(2.9)%
PBT margin	13.9%	16.2%	
PAT (After Minority Interest)	3,906	3,922	(0.4)%
PAT margin	10.9%	12.4%	
EPS (Rs / share)	32.67	32.80	

Adjusting for the change in distribution policy and GST impact, the underlying growth in India sales in H1FY19 was in double digits implying a higher than reported underlying YoY growth in the overall Revenue from Operations, EBITDA margin and PAT (after minority interest) in H1FY19.

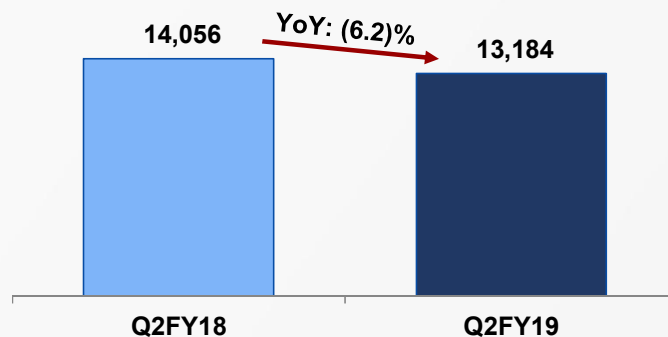
Notes: Post implementation of GST with effect from July 1, 2017 and as per Ind AS 18, revenue from operations is disclosed net of GST. Revenue from operations for earlier periods includes excise duty. Accordingly, revenue from operations for the six months ended September 30, 2018 is not strictly comparable with that of six month ended September 30, 2017.

India Business

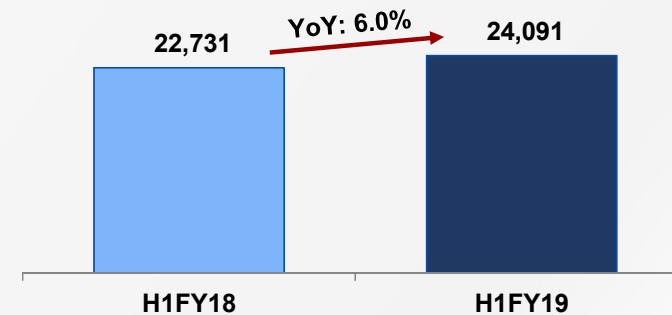
India Business: Q2FY19 Sales of Rs.13,184 million (6.2% YoY decline)

- YoY growth in India sales was impacted by high base of Q2FY18 on account of inventory restocking post GST implementation
- India sales contributed 69.4% to total sales in Q2FY19
- In Q2FY19 and H1FY19, Company's secondary sales growth outperformed the IPM growth by more than 400 bps (Source: IQVIA data)
- The Company continues to consolidate its position amongst the top 5 companies in the acute therapy areas of Anti-infectives, Gastro-intestinal, Pain / Analgesic and Vitamins / Minerals / Nutrients (Source: IQVIA data)
- The Company continues to grow significantly ahead of the segment growth rate in the chronic therapy areas of Cardiac, Anti-diabetes, Neuro / CNS and Derma, thereby improving its market share and rankings. The Company currently ranks as the 8th largest company in the CNS / Neuro segment for the six months ended September 2018 (Source: IQVIA data)

Q2FY19 – India Sales (Rs mn)



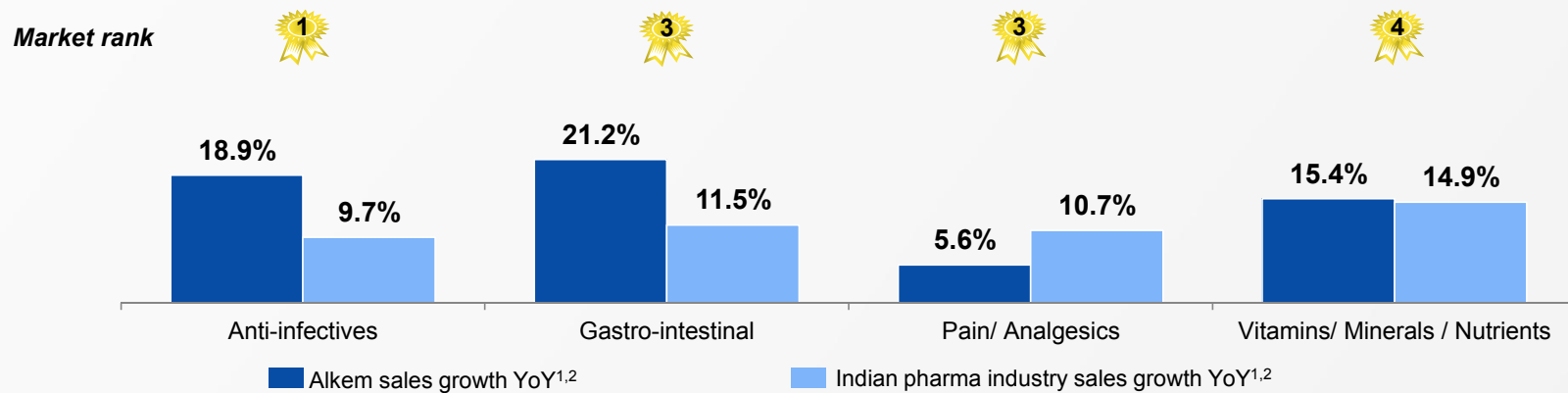
H1FY19 – India Sales (Rs mn)



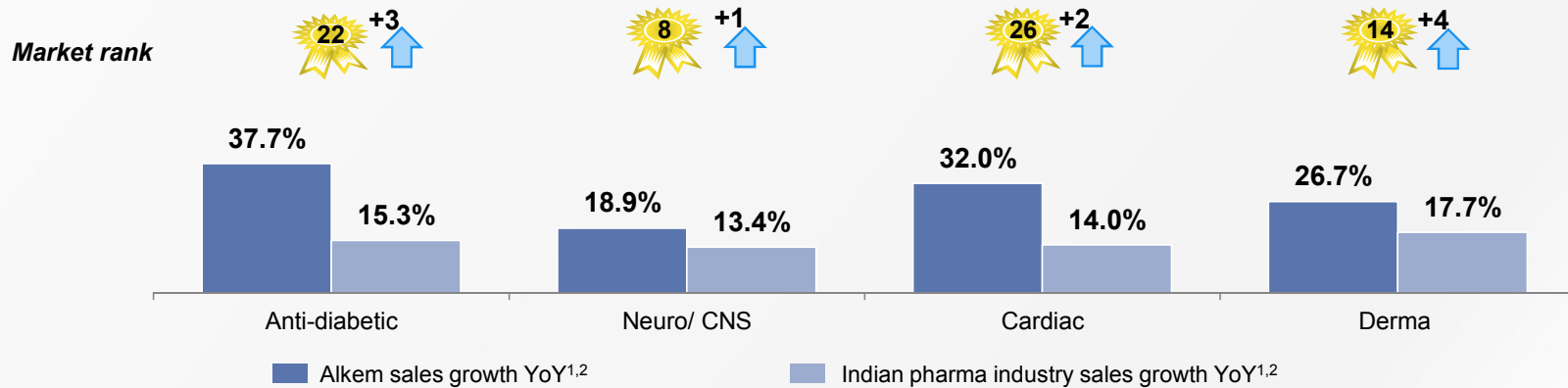
India Business – Secondary Sales Performance

Outperformance across most of the major therapeutic areas in Q2FY19

Established therapeutic areas of Alkem



Emerging therapeutic areas of Alkem



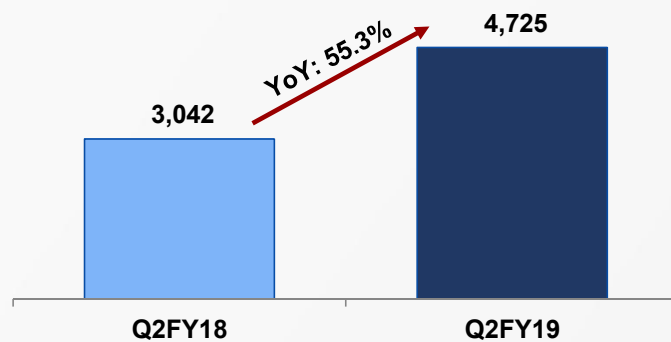
Source: IQVIA TSA data ¹ Domestic formulations sales; ² For 3 months ended September 30, 2018

US Business

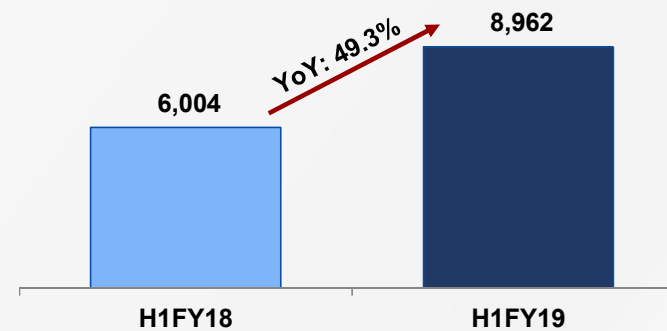
US Business: Q2FY19 Sales of Rs.4,725 million (55.3% growth YoY)

- US sales contributed 24.9% to total sales in Q2FY19
- Growth in the US business was driven by combination of new product launches and market share gains in the existing products. Depreciation of INR against USD also helped the YoY growth during Q2FY19 and H1FY19
- In Q2FY19, the Company filed 7 ANDAs with the US FDA and received 2 approvals (including 1 tentative approval)
- As on September 30, 2018, the Company has filed a total of 118 ANDAs (including 1 NDA) with the US FDA and has received 53 approvals (including 7 tentative approvals and 1 NDA)

Q2FY19 – US Sales (Rs mn)

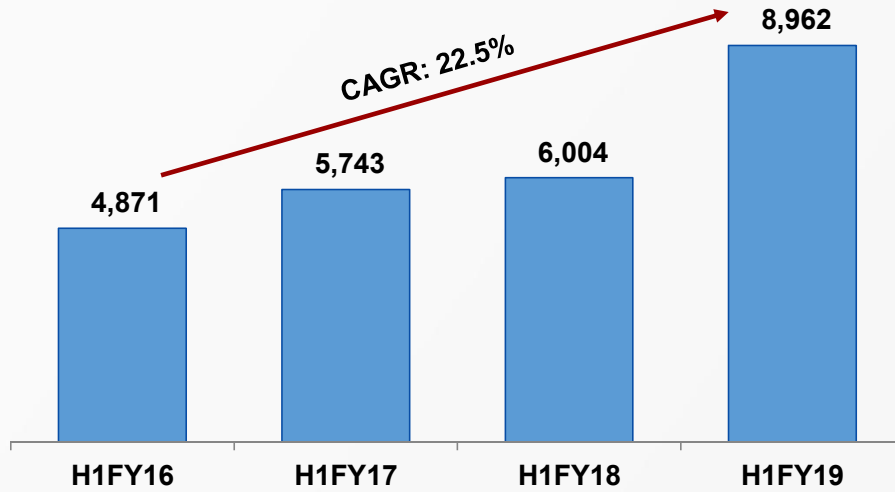


H1FY19 – US Sales (Rs mn)

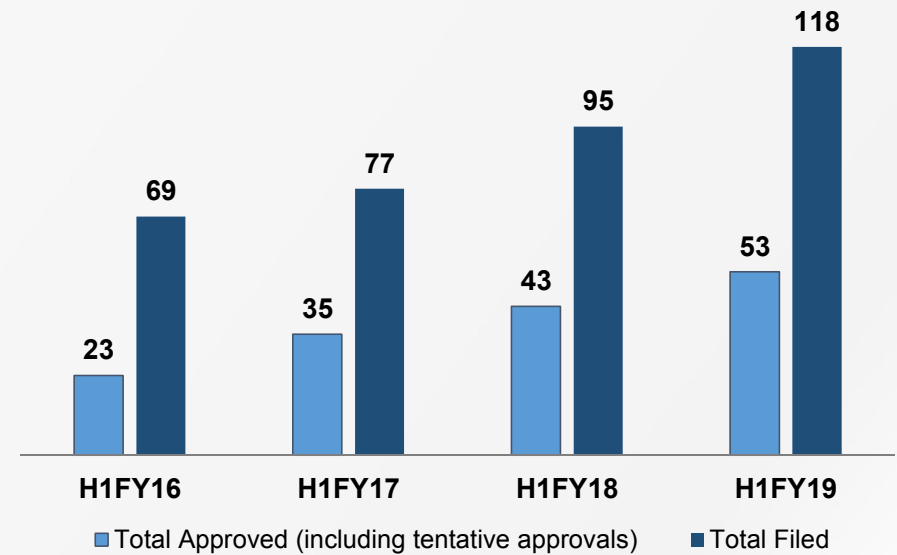


Steady progress in the US Business

US Sales (Rs mn)



Cumulative ANDA filings and approvals



Update on US FDA inspection

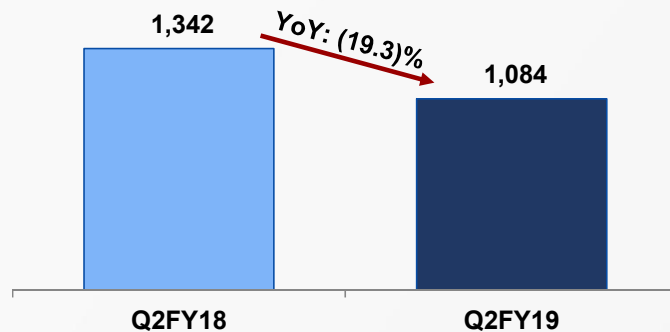
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Other International Business

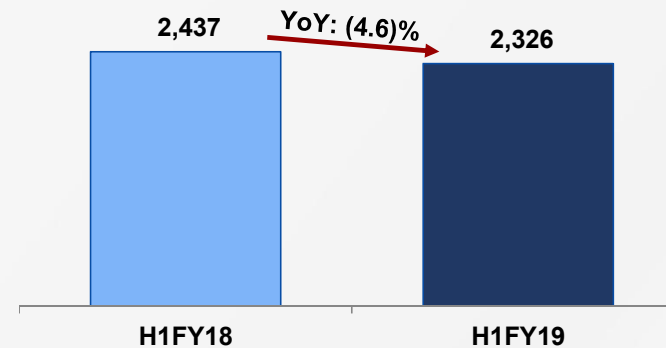
Other International Business: Q2FY19 Sales of Rs.1,084 million (19.3% YoY decline)

- Other International Market sales contributed 5.7% to total sales in Q2FY19
- The Company has presence in Australia, Europe, South East Asia, Latin America, Africa and CIS with key markets being Australia, Chile, Philippines, UK and Kazakhstan

**Q2FY19 – Other International Sales
(Rs mn)**

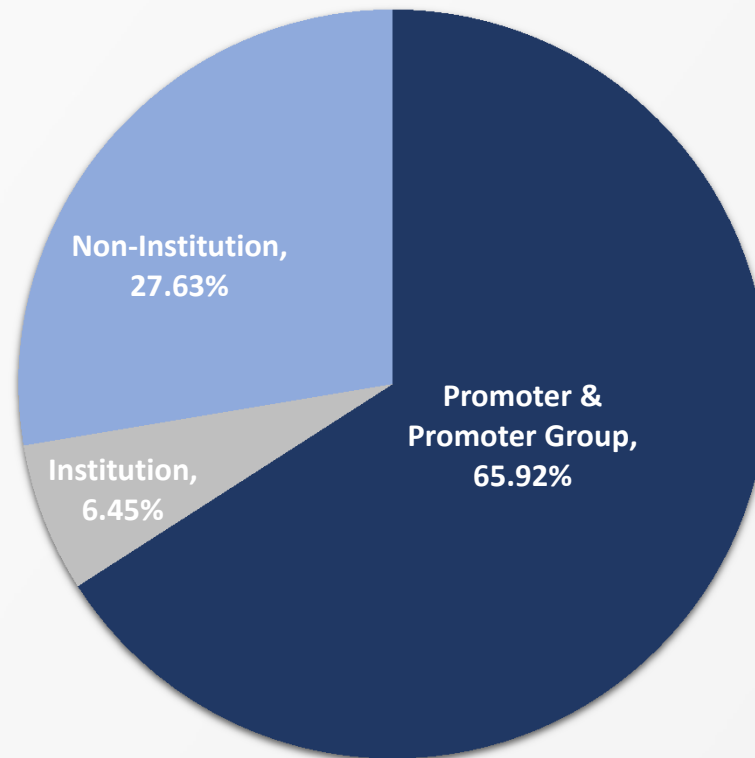


**H1FY19 – Other International Sales
(Rs mn)**



Latest Shareholding Pattern

Shareholding pattern as on September 30, 2018



Institution – Mutual Funds, Alternate Investment Funds, Foreign Portfolio Investors, Financial Institutions / Banks

Non-Institution – Public, Other Bodies Corporates, Clearing Members, Non Resident Indians, Hindu Undivided Family and Trusts

Thank You