



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 no.:- L00305MH1973PLC174201

VISION

To achieve value driven leadership in
Indian Health Care Industry and beyond...
Through
Quality that is infinite
Service that cares
Hardwork that endures

8th February, 2019

The Corporate Relationship Department BSE Limited Phiroze Jeejeebhoy Towers, Dalal Street, Mumbai 400 001. <i>Scrip Code: 539523</i>	National Stock Exchange of India Limited Exchange Plaza, Bandra Kurla Complex, Bandra East, Mumbai 400 051. <i>Scrip Symbol: ALKEM</i>
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Dear Sirs,

Sub: Press Release and Analyst Presentation on Q3FY19 and 9MFY19 Results

With reference to relevant provisions of SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015, we enclose herewith press release and analyst presentation on Q3FY19 and 9MFY19 earnings and business updates and the same will be uploaded on the website of the Company.

Kindly take note of the same.

Sincerely,
For **Alkem Laboratories Limited**


Manish Narang
President - Legal, Company Secretary & Compliance Officer

Encl.: a/a



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Press Release

Alkem reports Q3FY19 and 9MFY19 Results

Mumbai, February 8, 2019: Alkem Laboratories Ltd (Alkem) today announced its standalone and consolidated financial results for the third quarter and nine months ending December 31, 2018. These results were taken on record by the Board of Directors at a meeting held in Mumbai today.

Key financial highlights of Q3FY19

- Revenue from Operations was Rs.19,250 million, year-on-year growth of 10.6%
 - India sales were Rs.12,475 million, year-on-year decline of 0.7%
 - International sales were Rs.6,532 million, year-on-year growth of 40.2%
- Earnings before Interest, Tax, Depreciation and Amortization (EBITDA) was Rs.3,118 million, resulting in EBITDA margin of 16.2% vs. 20.7% in Q3FY18. EBITDA declined by 13.5% YoY
- R&D expenses for the quarter was Rs.1,195 million, or 6.2% of Revenue from Operations compared to Rs.927 million in Q3FY18 at 5.3% of Revenue from Operations
- Profit before tax (PBT) was Rs.2,581 million compared to Rs.3,324 million in Q3FY18
- Net Profit (after Minority Interest) was Rs.2,025 million, year-on-year growth of 18.0%

Key financial highlights of 9MFY19

- Revenue from Operations was Rs.55,030 million, year-on-year growth of 12.1%
 - India sales were Rs.36,566 million, year-on-year growth of 3.6%
 - International sales were Rs.17,820 million, year-on-year growth of 36.0%
- Earnings before Interest, Tax, Depreciation and Amortization (EBITDA) was Rs.8,798 million, resulting in EBITDA margin of 16.0% vs. 18.5% in 9MFY18. EBITDA declined by 2.9% YoY
- R&D expenses for 9MFY19 was Rs.3,230 million, or 5.9% of Revenue from Operations compared to Rs.2,529 million in 9MFY18 at 5.2% of Revenue from Operations
- Profit before tax (PBT) was Rs.7,559 million compared to Rs.8,451 million in 9MFY18
- Net Profit (after Minority Interest) was Rs.5,932 million, year-on-year growth of 5.2%

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 for 9MFY19 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, "Q3FY19 was a mixed quarter for the Company. While our International business, mainly led by the US business, continued its strong growth momentum with more than 40% YoY growth, our India business faced challenges on account of ban on select FDC products, de-growth in our trade generic business due to tightening of credit terms and relatively weak anti-infective season. This along with higher API prices adversely affected our profit margins. With significant investments in people and infrastructure over the last couple of years, we are hopeful of delivering a better performance over the coming quarters."

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**Operational Highlights****India Business**

In Q3FY19, the Company's India sales declined by 0.7% YoY, recording a sales of Rs.12,475 million as compared to Rs.12,567 million in Q3FY18. For 9MFY19, the Company's India sales grew by 3.6% to Rs.36,566 million compared to Rs.35,298 million in 9MFY18.

As per IQVIA MAT December 2018, during the quarter, the Company registered value growth of 10.1% YoY, which was largely in-line with the Indian Pharmaceutical Market (IPM) growth of 10.2% YoY. For the nine months ending December 2018, the Company outperformed the IPM with YoY growth of 14.2% compared to IPM growth of 11.5%. During this period, the Company grew faster than the IPM in most of the large therapy segments like Anti-Infectives, Gastro Intestinal, Vitamins / Minerals / Nutrients, Neuro / CNS, Cardiac and Anti-Diabetes, thereby gaining market share and improving its market ranking. Company's emerging therapy segments in the chronic space, like Anti-Diabetic, Cardiac, Derma and Neuro / CNS also delivered strong growth.

The performance highlights in the key therapeutic segments in Q3FY19 and 9MFY19 is as shown below:

Key Therapy segment	Q3FY19				9MFY19			
	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	8.3%	6.7%	1	Unchanged	13.9%	7.8%
Gastro Intestinal	3	Unchanged	15.9%	7.0%	3	Unchanged	17.8%	9.0%
Pain / Analgesics	3	Unchanged	7.6%	8.6%	3	Unchanged	5.8%	9.1%
Vitamins / Minerals / Nutrients	5	-1	9.1%	12.2%	5	-1	13.8%	13.0%
Neuro / CNS	8	Unchanged	8.5%	10.4%	8	+1	14.5%	10.7%
Derma	16	+1	2.6%	10.5%	17	+1	15.1%	14.4%
Cardiac	26	+2	33.7%	13.0%	26	+2	29.2%	12.5%
Anti-Diabetic	22	+2	32.0%	16.0%	22	+3	33.7%	15.1%
Total	5	Unchanged	10.1%	10.2%	6	Unchanged	14.2%	11.5%

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

Source: IQVIA MAT December 2018

International Business

In Q3FY19, the Company's International sales grew by 40.2% YoY, recording sales of Rs.6,532 million as compared to Rs.4,659 million in Q3FY18. For 9MFY19, the Company's International sales grew by 36.0% to Rs.17,820 million compared to Rs.13,101 million in 9MFY18.

- **US sales** for the quarter was Rs.5,182 million, recording a year-on-year growth of 44.3%. For 9MFY19, US sales was Rs.14,144 million, up 47.4% compared to 9MFY18.



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- **Other International Markets sales** for the quarter was Rs.1,349 million, recording a year-on-year growth of 26.4%. For 9MFY19, Other International Markets sales was Rs.3,675 million, up 4.9% compared to 9MFY18.

R&D Investments

Company’s revenue R&D expenses for the quarter was Rs.1,195 million, or 6.2% of revenue from operations. Similarly for 9MFY19, Company’s revenue R&D expenses was Rs.3,230 million, or 5.9% of total revenue from operations.

During the quarter, the Company filed 3 abbreviated new drug applications (ANDAs) with the US FDA and received 6 approvals (including 1 tentative approval). For 9MFY19, the Company filed 14 ANDAs with the US FDA and received 10 approvals (including 3 tentative approval).

As on December 31, 2018, the Company has filed a total of 119 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 59 ANDAs (including 8 tentative approvals) and 1 NDA.

Update on US FDA Inspections

In the month of January and February 2019, the US FDA conducted inspections at the Company’s formulation manufacturing facilities located at Daman (India) and St. Louis (US). At the end of the inspection, no Form 483 was issued for the Daman facility, while the St. Louis facility received Form 483 with 8 observations.

Facility	Capability	Inspection Date	Update
Daman (India)	Formulations	January 2019	Successfully closed the inspection with no Form 483
Baddi (India)	Formulations	August 2018	Successfully closed the inspection with no Form 483
Ankleshwar (India)	API	December 2016	EIR Report received in March 2017
Mandva (India)	API	September 2015	EIR Report received in March 2016
St. Louis (US)	Formulations	February 2019	Received Form 483 with eight observations
California (US)	API	August 2018	Successfully closed the inspection with no Form 483



Alkem Laboratories Ltd

Investor Presentation Q3FY19 – February 8, 2019

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.

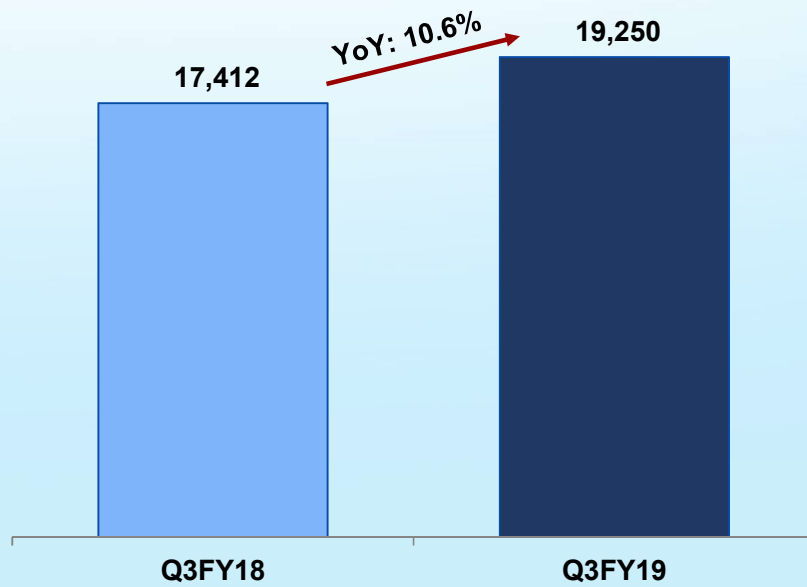
Key Highlights of Q3FY19 and 9MFY19

- **India Business:** Company's India sales registered 0.7% YoY decline in Q3FY19 on account of ban on select FDC products, slower growth in anti-infective and gastro-intestinal market and de-growth in trade generic business due to tightening of credit terms
 - Company's secondary sales in 9MFY19 grew by 14.2% YoY - higher than IPM growth of 11.5% YoY (Source: IQVIA MAT Dec. 2018)
- **International Business:** Company's International Business comprising of the US and select international markets registered a robust growth of 40.2% in Q3FY19 and 36.0% YoY in 9MFY19
- **US Business** grew by 44.3% YoY in Q3FY19 and 47.4% YoY in 9MFY19, largely driven by new product launches and market share gain in existing products
- **R&D** expenses in 9MFY19 increased by 27.7% YoY and was at 5.9% of revenue from operations compared to 5.2% in 9MFY19
- **ANDA filings:** The Company filed 14 ANDAs and received 10 ANDA approvals (including 3 tentative) from the US FDA during 9MFY19
- **Update on the US FDA inspections :**
 - January 2019 – Inspection at Daman formulation facility, received no Form 483
 - January - February 2019 - Inspection at St. Louis (US) formulation facility, received Form 483 with eight observations

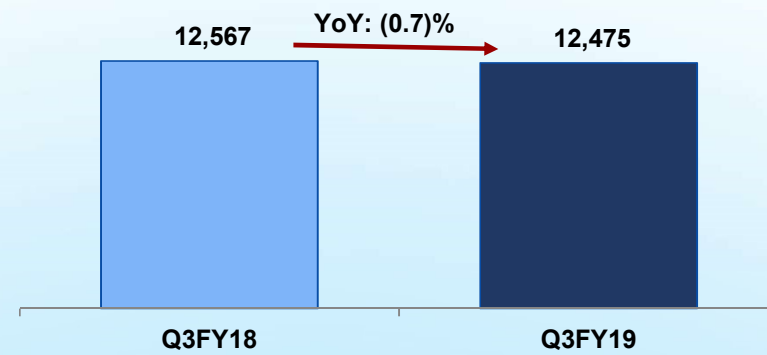
Key Financial Highlights – Q3FY19 (Consolidated)

All figures in Rs mn

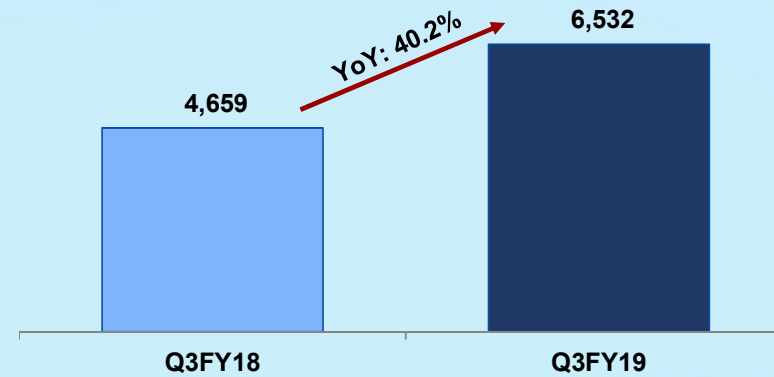
Revenue from Operations



India sales



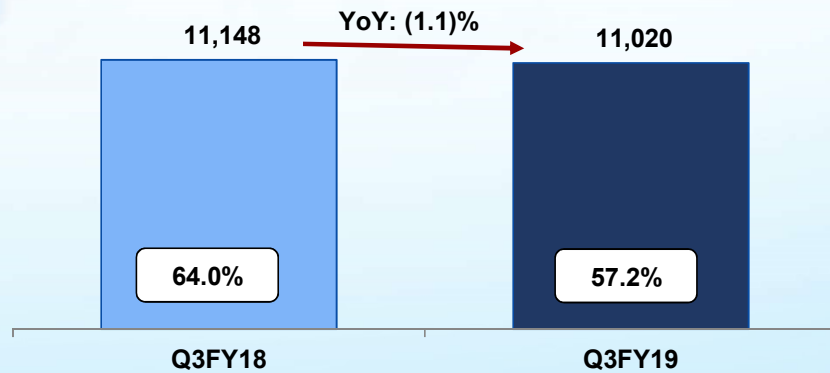
International sales



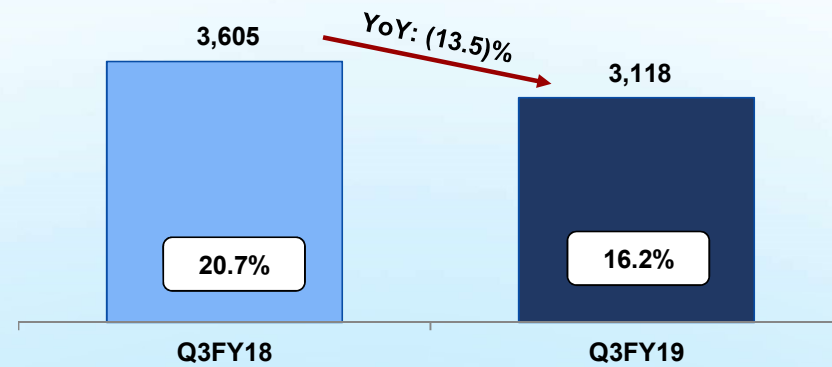
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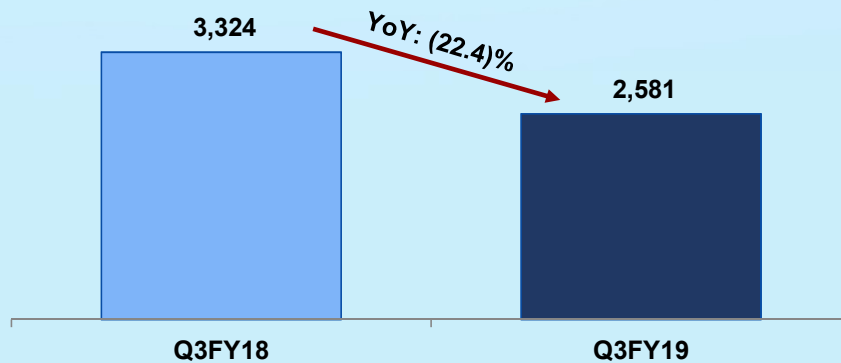
Gross Profit and Gross Margin



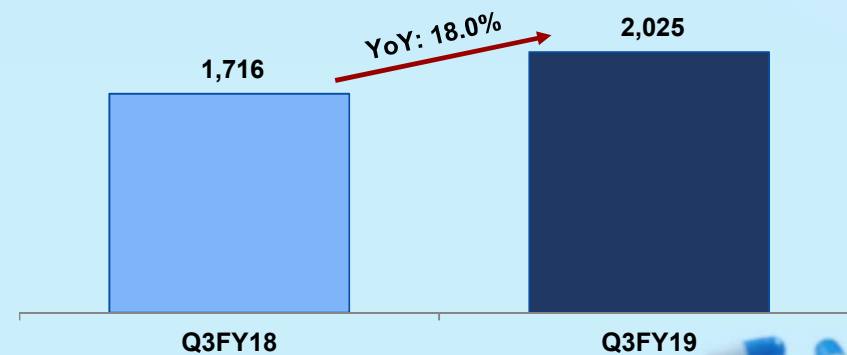
EBITDA and EBITDA Margin



PBT (before Minority Interest)



PAT (after Minority Interest)

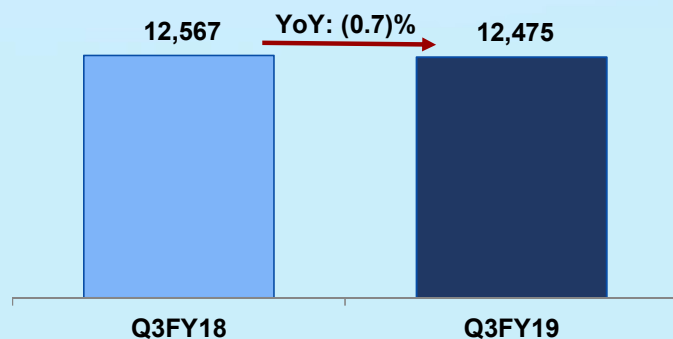


India Business

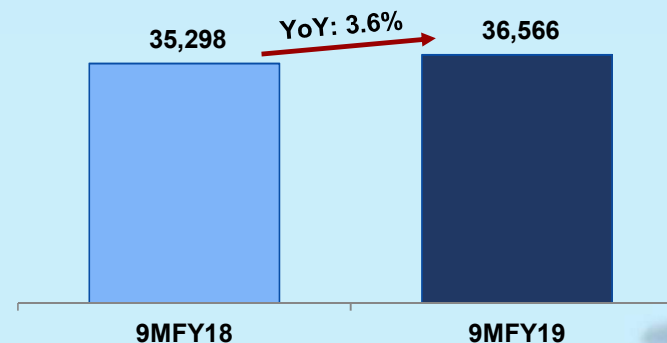
India Business: Q3FY19 Sales of Rs.12,475 million (0.7% YoY decline)

- YoY decline in India sales during Q3FY19 was mainly on account of ban on select FDC products, de-growth in Company's trade generic business due to tightening of credit terms, slower growth in the anti-infective market and high base of Q3FY18 (due to post GST channel inventory normalization)
- India sales contributed 65.6% to total sales in Q3FY19
- For 9MFY19, Company's secondary sales growth outperformed the IPM growth by 270 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 (Source: IQVIA data)

Q3FY19 – India Sales (Rs mn)



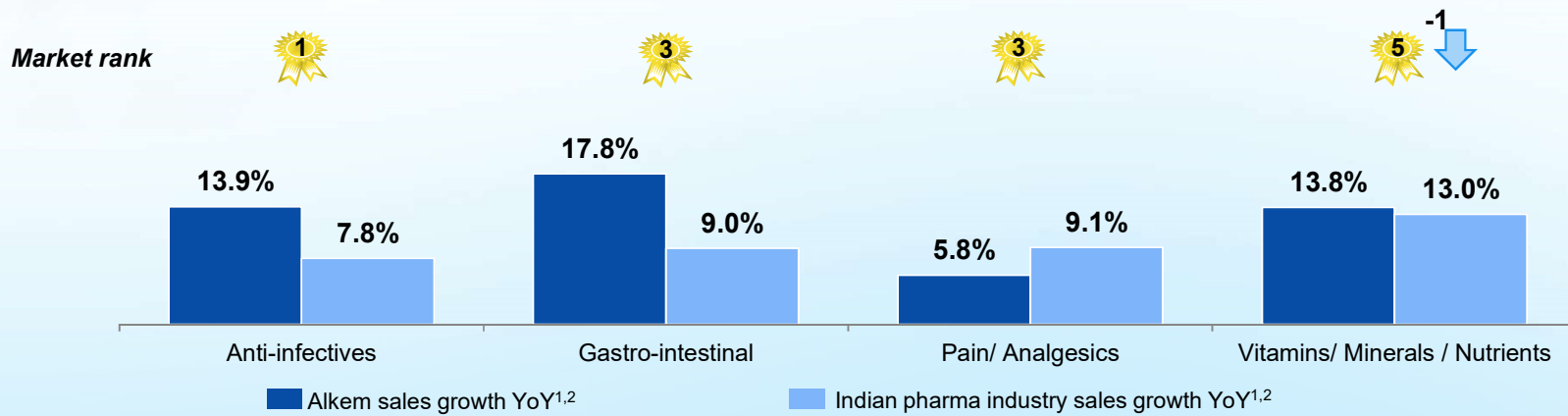
9MFY19 – India Sales (Rs mn)



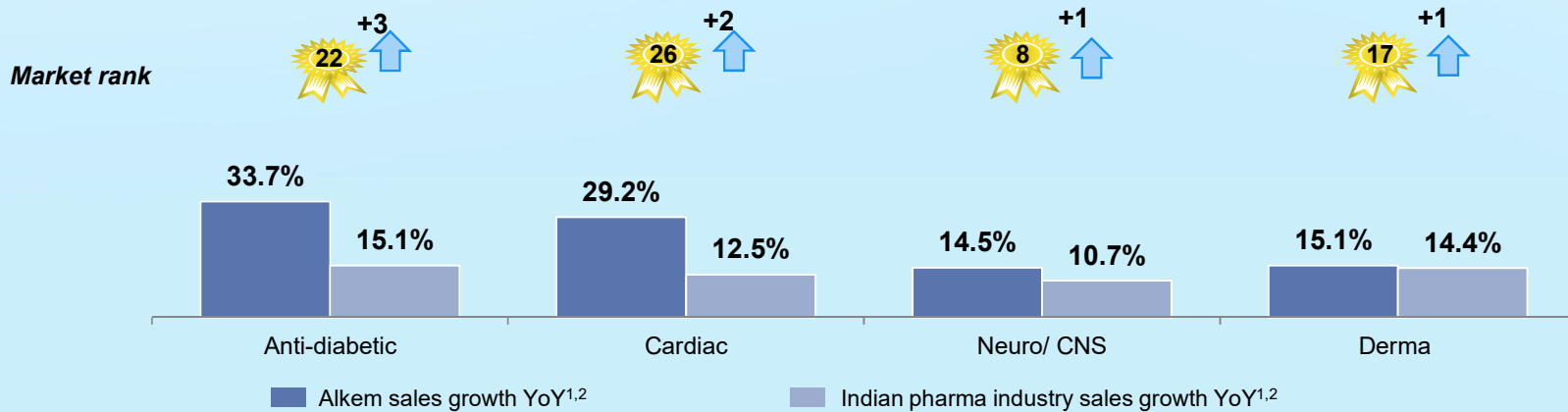
India Business – Secondary Sales Performance

Outperformance across most of the major therapeutic areas in 9MFY19

Established therapeutic areas of Alkem



Emerging therapeutic areas of Alkem



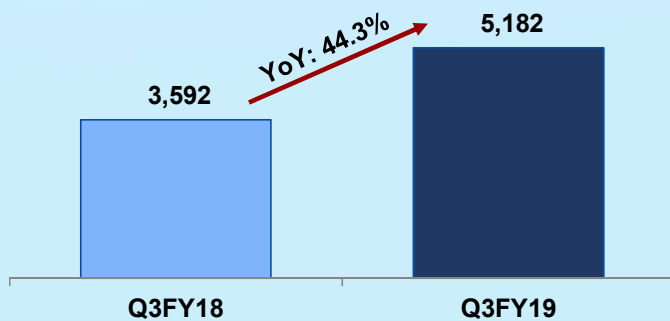
Source: IQVIA TSA data ¹ Domestic formulations sales; ² For 9 months ended December 31, 2018

US Business

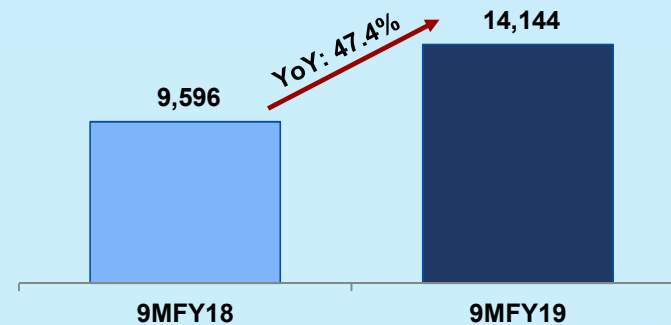
US Business: Q3FY19 Sales of Rs.5,182 million (44.3% growth YoY)

- US sales contributed 27.3% to total sales in Q3FY19
- 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 Q3FY19 and 9MFY19
- In Q3FY19, the Company filed 3 ANDAs with the US FDA and received 6 approvals (including 1 tentative approval)
- As on December 31, 2018, the Company has filed a total of 120 ANDAs (including 1 NDA) with the US FDA and has received 60 approvals (including 8 tentative approvals and 1 NDA)

Q3FY19 – US Sales (Rs mn)



9MFY19 – US Sales (Rs mn)



Update on the US FDA inspection

In the month of January and February 2019, the US FDA conducted inspections at the Company's formulation manufacturing facilities located at Daman (India) and St. Louis (US). At the end of the inspection, no Form 483 was issued for the Daman facility, while the St. Louis facility received Form 483 with 8 observations

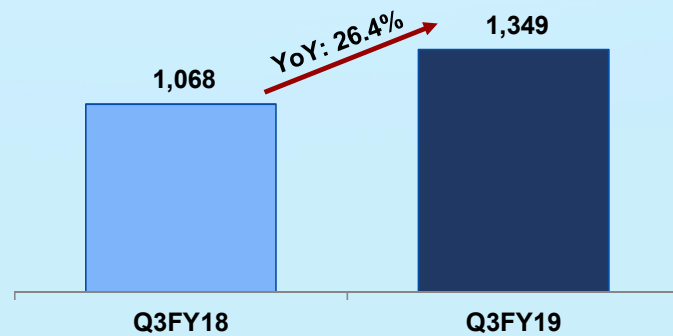
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Other International Business

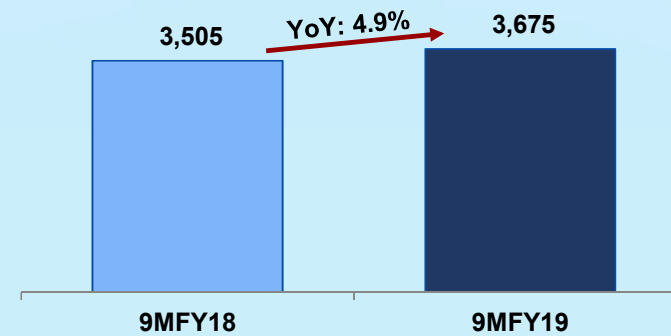
Other International Business: Q3FY19 Sales of Rs.1,349 million (26.4% YoY growth)

- Other International Market sales contributed 7.1% to total sales in Q3FY19
- The Company has presence in Australia, Europe, South East Asia, Latin America, Africa and CIS
- Australia and Chile registered robust growth during the quarter

**Q3FY19 – Other International Sales
(Rs mn)**

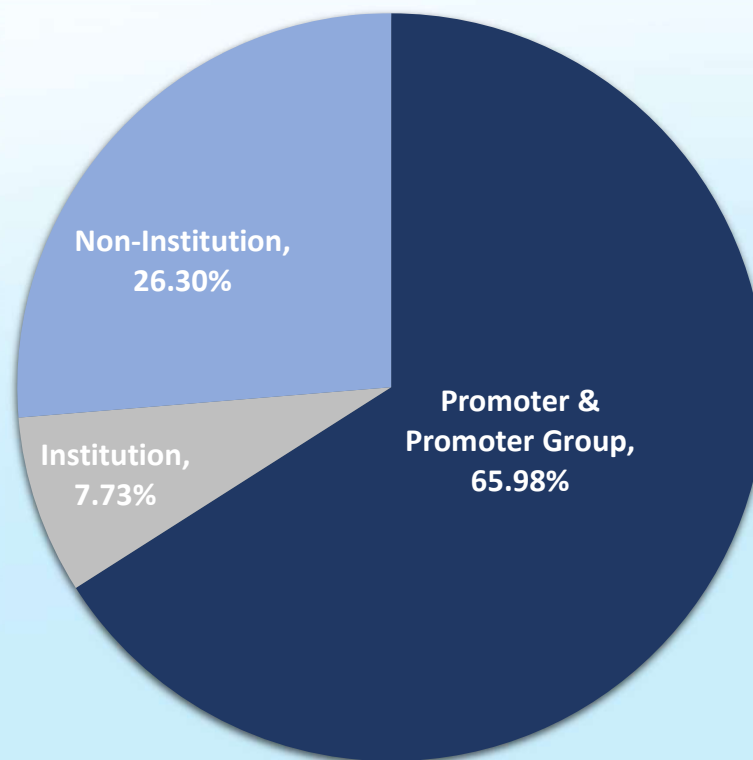


**9MFY19 – Other International Sales
(Rs mn)**



Latest Shareholding Pattern

Shareholding pattern as on December 31, 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

The background of the slide is a light blue gradient. In the top left corner, there is a semi-transparent image of a person wearing a white surgical mask and clear safety goggles. In the bottom right corner, there is a small cluster of white and blue capsules or pills.

Thank You