

## HDFC sec Investor Forum

### Mid-cap Pharmaceuticals Investor Forum: Key takeaways

26-SEP-2017

<b>PARTICIPATING CORPORATES</b>	<b>MCap (Rs bn)</b>
Alkem Laboratories	222.73
Jubilant Life Sciences	104.22
Ajanta Pharma	101.39
Sun Pharma Advanced Research Company	95.50
Indoco Remedies	19.39

<b>PARTICIPATING EXPERTS</b>
Vivek Padgaonkar, Ex-Director – OPPI
Ameesh Masurekar, Director – AIOCD AWACS
Vijaya Shinde, Director – Sai Pharmaceutical Consultants

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**Amey Chalke**  
amey.chalke@hdfcsec.com  
+91-22-6171-7321

**Siddhant Mansukhani**  
siddhant.mansukhani@hdfcsec.com  
+91-22-6639-2476

# Alkem Laboratories *(CMP Rs 1,842, MCap Rs 223bn, BUY)*

## Compounding story

Alkem Labs (ALKEM) was represented by Gagan Borana (DGM-Investor relations) at our Investor Forum. Our view that Alkem Labs provides an opportunity to partake in another compounding story unveiling from the Indian pharma market was re-iterated. Below are the key takeaways:

- **Domestic market:** ALKEM is making concerted efforts to recoup sales lost during the transition to GST. July and August witnessed very good traction and YoY growth.
- Should the entire lost sales be recouped, the domestic business could grow 10-12% in FY18. Only time will tell if channel inventory will recover to pre-GST levels.
- ALKEM has broken-even at the EBITDA level in its chronic business, and is starting to witness an increasing number of prescriptions being written by doctors. This implies that the company is now being recognised as a serious player in this segment. Chronic portfolio growth is 25%+.
- **OTC venture:** ALKEM has big plans in the Indian OTC market, and is confident of succeeding in this segment, owing to its strong brand re-call and wide distribution reach. The current portfolio comprises of six to seven products, with more new launches planned.
- The potential in this segment is huge. Though marketing costs are high (Rs 10-12cr/product), these are one-time expenses. Successful products in this space could earn as much as Rs 30-40cr annually, implying a high ROI.

- **US business:** ALKEM has planned 12 to 15 filings and 8 to 10 launches annually in the US market. This should help the company achieve significant growth over the next two to three years, likely around 20% CAGR in US dollar terms.
- **EBITDA margin:** The EBITDA margin is expected to be under pressure in FY18, owing to the GST disruption and NLEM impact. However, over a period of 2-3 years, ALKEM expects margins to move up to 20%+, with a ramp-up in the US business and increasing profitability in the chronic segment being enough to offset increasing marketing and R&D costs.
- **HDFC sec view:** While earnings will be under pressure in the near-term owing to higher tax outgo, we believe that Alkem will deliver strong earnings growth FY19 onwards, led by continued outperformance in the domestic market and operating leverage from the US business. Foresee 14.2%/14% revenue/earnings CAGR over FY17-20E. The stock currently trades at 20.5x FY19E.

YE March (Rs mn)	FY16	FY17	FY18E	FY19E	FY20E
Net Revenues	50,479	58,525	63,134	74,564	87,208
EBITDA	8,533	9,990	10,421	13,895	16,857
APAT	7,416	8,920	8,027	10,728	13,208
Diluted EPS (Rs)	62.0	74.6	67.1	89.7	110.5
P/E (x)	29.7	24.7	27.4	20.5	16.7
RoE (%)	20.7	21.9	16.8	19.5	20.5

Source : Company, HDFC sec Inst Research

# Jubilant Life Sciences *(CMP Rs 655, MCap Rs 104bn, NOT RATED)*

## Poised for growth

Jubilant Life Sciences (JLS) was represented by Ravi Agarwal (Head – Investor Relations) and Anupam Jain (Senior Manager – Investor Relations) at our Investor Forum. Below are the key takeaways:

- **Pharmaceuticals business:** This business is divided into 4 sub-segments, i.e. (1) Radio pharmaceuticals, (2) Generic formulations, (3) CMO business and (4) Allergy products, and contributes 55% of the top-line and 68% of EBITDA.
- **Radio pharma:** Contributing 14% of sales, this segment is expected to be a key growth driver for JLS going forward. Ruby-Fill especially could provide a huge upside, considering the size of the untapped market, and the shift from the older SPECT technology to the newer PET technology (where Ruby-Fill is used). Ruby-Fill's addressable market size could be ~USD 250mn in 3-4 years from USD 60-70mn currently.
- **Triad acquisition:** The acquisition of Triad (second largest radio pharmacy network in the US) will enable JLS to leverage its distribution network for its radio pharma business, and achieve higher penetration. While initially margin dilutive, JLS is confident of gaining significant synergies from the deal.
- **US Generics:** JLS will continue to file Para III-type products and focus on achieving significant scale from its strong supply chain and backward integration. Expect mid-teen growth.
- **CMO business:** The segment accounts for 10% of sales, and the current order book is healthy and growing. Margins are likely to increase, as the regulatory troubles faced 2-3 years

ago are over, and capacity utilisation scales upwards.

- **Allergy products (US):** While this segment is small (4% of sales), it is growing at a brisk pace and competition is limited. The market is dominated by 2 players (90% share), JLS being the third largest. JLS hopes to leverage its current product basket to gain market share. There are no plans to add MRs.
- **LSI business:** 45% of JLS' sales and 32% of the EBITDA come from this vertical, which is the legacy business of the company. It is divided into (1) Life sciences chemicals, and (2) specialty ingredients and nutrients. While growth has tapered off in this segment, JLS is confident of a revival led by several product launches in crop sciences, better pricing in vitamins and improving traction in ethyl acetate.
- **Margins:** JLS believes that with the improving business mix, revival in the LSI segment, growth in radio pharma and operating leverage from the CMO business, the EBITDA margin trajectory is likely to remain upwards.

YE March (Rs mn)	FY14	FY15	FY16	FY17
Net Sales	58,034	58,262	57,491	58,614
EBITDA	10,076	6,893	12,470	13,453
APAT	1,090	(578)	3,918	5,736
Diluted EPS (Rs)	7.1	(3.6)	25.2	37.0
P/E (x)	92.8	N/A	26.0	17.7
RoE (%)	4.3	(2.3)	14.5	18.0

Source : Company, HDFC sec Inst Research

# Ajanta Pharma *(CMP Rs 1,152, MCap Rs 101bn, NOT RATED)*

## Growth to bounce back in FY19

Arvind Agrawal (CFO) and Rajeev Agarwal (AGM, Finance), represented Ajanta Pharma (AJP) at our Investor Forum. Below are the key takeaways:

- **Domestic business:** GST recovery has commenced, with 2Q expected to be a good quarter. However, channel inventory in AJP's case has only recovered to 20-21 days. Domestic business growth in FY18 is expected to be in high single-digits owing to nearly one month of lost sales.
- Growth rates of ~25% are unlikely to be seen again, due to a higher base and increasing competition. However, AJP will continue to outperform the market comfortably, and also the segments in which it is present. See 15-20 launches annually, with 50% being first to market. The Guwahati plant will come onstream in Mar-18, reducing dependence on loan-licensing.
- **US business:** AJP currently has 17 ANDAs pending approval. Of the approved, 13 are commercialised. Two are pending launch owing to commercial viability issues, and 2 to 3 products are expected to be launched in the near-term. AJP hopes to achieve USD 100mn in sales in the US by FY21.
- **African branded generics:** Expect flat to 3-4% growth in this business in FY18. Volumes are growing in high single-digits, but the currency impact is nullifying this to an extent.
- **Institutional business:** This business is likely to witness a significant decline in FY18 owing to lower tender allocation (~80% of FY17). Going forward too, IPCA's re-entry into the Global Fund tender will likely see AJP lose share worth Rs 50-

75cr. This is not considering the impact of IPCA's likely aggressiveness in pricing, which could also force AJP to lower prices in order to retain as much market share as possible.

- **Asia and other markets:** AJP is seeing low-teen growth in South Asian markets like the Philippines. The decline in West Asian markets will halt in FY18, with growth resuming from FY19. Despite exiting various markets, CIS remains a question mark going forward. Volume off-take is expected to be in the region of 10-12%, with currency movements impacting growth in rupee terms. Stability in oil prices is crucial.
- **EBITDA margin:** Likely to be below 30% this year, with the institutional business trending lower and the GST impact in the domestic business. Expect 30%+ starting FY19.
- **Draft pharma policy:** AJP believes that the proposed pharma policy is positive for the industry as a whole. AJP would be ready for demands such as BA/BE studies and CGMP compliance (including outsourced production).

YE March (Rs mn)	FY14	FY15	FY16	FY17
Net Sales	12,160	14,852	17,429	20,020
EBITDA	3,764	5,169	5,961	6,994
APAT	2,415	3,273	4,168	5,168
Diluted EPS (Rs)	27.3	37.0	47.1	58.4
P/E (x)	42.2	31.1	24.5	19.7
RoE (%)	49.0	45.6	41.4	37.7

Source : Company, HDFC sec Inst Research

# Sun Pharma Advanced Research Company *(CMP Rs 387, MCap Rs 96bn, NOT RATED)*

## R&D play

Sun Pharma Advanced Research Company (SPARC) was represented by Anil Raghavan (CEO), Chetan Rajpara (CFO) and Narendra Lakkad (VP - Business Development) at our Investor Forum. Below are some insights and key takeaways:

- **Xelpros™ and Elepsia™ XR:** The management is still hopeful of launching these products through Halol. While site-transfer has been initiated, it will take at least one year for the process to be completed.
- **Salmeterol-Fluticasone DPI:** Discussions with the EU regulator are scheduled to discuss the path forward. Mgt believes that the product is approvable in higher doses. A way to bridge the higher and lower (where PK study resulted in BE criteria not being satisfied) dose is also being explored.
- **Baclofen GRS:** The once-a-day dosing of Baclofen GRS provides a significant convenience factor over IR Baclofen (requires to administering 3-4 times a day). Estimated peak sales are USD 100mn. SPARC does not intend to pursue additional indications as of now. Phase III data should be available in 3QFY18, with an NDA filing planned for 1QFY19.
- **Taclantis™:** Currently recruiting for the pivotal BE programme. This study is expected to be completed in 1QFY19. No significant hypersensitivity reactions in the multiple clinical studies conducted with Taclantis so far represents a significant differentiation offered over Cremophor-based paclitaxel formulations. This opportunity could provide short-term cash flows, should the clinical data be favourable.
- **Brimonidine OD:** Brimonidine is currently used as the second-line of treatment for Glaucoma. While currently available Brimonidine is dosed thrice a day, SPARC is developing a novel once-a-day formulation. Proof of concept was established in a Phase II study with 140 patients. Will meet the US FDA to discuss Phase III trial design before proceeding. Expect to launch a study in 4QFY18.
- **SUN – K0706:** There is a high unmet need for treatment-resistant CML, and doctors are not satisfied with the current 3<sup>rd</sup> and 4<sup>th</sup> line treatments. SPARC believes that K0706 could fulfill this need. The safety and efficacy profile of the drug could lead to a significant market opportunity as the third-line of treatment. Expect to initiate the pivotal efficacy study by 2QFY19. Parkinson's disease is also being explored as an indication, and SPARC is undertaking a dose range finding study for the same.
- **Funding:** As of now, do not foresee any further funding requirements till next year. Launches of Xelpros™ and Elepsia™ XR are expected to ease cash flow issues.

YE March (Rs mn)	FY14	FY15	FY16	FY17
Revenue	1,670	1,557	1,613	1,810
EBITDA	338	(348)	(628)	(1,230)
APAT	273	(397)	(699)	(1,203)
Diluted EPS (Rs)	1.1	(1.7)	(3.0)	(4.9)
P/E (x)	338.1	N/A	N/A	N/A
RoE (%)	24.5	(33.1)	(106.4)	(125.6)

Source : Company, HDFC sec Inst Research

# Indoco Remedies *(CMP Rs 210, MCap Rs 19bn, NOT RATED)*

## *Momentum halted, for now*

Indoco Remedies (INDR) was represented by Sundeep Bambolkar (CFO) and Vilas Nagare (President - Corporate Affairs and M&A) at our Investor Forum. Below are some insights and key takeaways:

- **Domestic business:** July and August were very strong months, and early signs are that September will be similar. Indoco expects a strong 2QFY18. Channel inventory has recovered to 32-33 days. However, with the market normalizing and the season tapering off, 45 days of channel inventory may not be seen.
- Considering the strong recovery post GST, INDR believes FY18 growth in the domestic business would be in the high single-digit range. 8-10 launches are planned annually. INDR is also on the lookout for inorganic growth opportunities to bolster its chronic portfolio.
- **US business:** Remediation at the Goa plant is complete and the company has sent 2 updates to the US FDA post warning letter, the latest on August 20, 2017. A shipment study has also been conducted for the specific products which were having issues while being transported. INDR expects a re-inspection at any time.
- INDR had voluntarily suspended manufacture of certain products, and it is soon going to restart production. Teva's products would be the first to be resumed, and batch documents have been submitted to them. There is no

requirement to inform the FDA w.r.t the resumption of manufacturing. As per the agreement, Teva will suspend its own manufacturing and procure the respective products from INDR. This is expected to start in 3QFY18.

- **Europe:** INDR has currently filed seven dossiers under their own name, and will continue to build this portfolio. However, this will be a slow process. Targeting 15-20% growth in this business.
- **Draft Pharma policy comments:** Government signals are confusing with respect to price control. Taking powers away from the NPPA is contradictory to what is being said. One company, one brand policy could be extremely disruptive to the sector, with the possible shutdown of 3,000 manufacturing units and resulting loss of employment a possible consequence.

YE March (Rs mn)	FY14	FY15	FY16	FY17
Revenue	7,223	8,522	9,766	10,694
EBITDA	1,204	1,655	1,707	1,565
APAT	580	828	830	771
Diluted EPS (Rs)	6.3	9.0	9.0	8.4
P/E (x)	33.4	23.4	23.3	25.1
RoE (%)	13.3	17.0	15.0	12.5

Source : Company, HDFC sec Inst Research

# Vivek Padgaonkar

*Ex-Director: Project and Policy*



**Vivek Padgaonkar held an interactive session on the domestic pharma scenario and gave us his insights on the future of the market and government policies and their likely impact. Here are the key takeaways:**

- The scope for the IPM to grow is huge, and its role in India is significant. Pharmaceuticals are the second highest employment generator in the country, and the industry is highly unorganised and fragmented. India is the only country in the world in which 52% of the market is comprised of FDCs. Chronic therapies will be the main source of growth going forward.
- **Price control:** Price control is here to stay, and the NLEM and similar measures are likely to expand going forward. Based on the commonality of the respective indications, companies should be able to predict likely additions to the NLEM, and accordingly adapt their marketing strategies.
- **Industry-government relationship:** Interaction between the industry and government is at an all-time high, with the government taking efforts to understand the industry's pain points. There is an increased sense of co-operation and understanding between the various stakeholders.
- **Jan Aushadhi Scheme (JAS):** The government has increased its efforts w.r.t adding stores. 1,700 stores were added in the last 15 months, with an overall target of 3,000 stores by the end of CY-17 (~2,100 currently), and at least 1 store per tehsil.
- The impact of JAS on the industry is not expected to be significant, owing to the momentous challenges in implementing such an initiative. However, there could be some impact on chronic therapies owing to the higher prices. On the plus side, JAS is expected to increase medicine penetration in the country.
- The various challenges for JAS include an insufficient range of medicines, inadequate CPSUs to meet demand for unbranded generics, commercial viability of the stores, excessive reliance on the state government especially for land, and lack of awareness about the scheme.
- **Quality:** Government initiatives in this area are positive, with only 1,600 companies out of 10,000 being CGMP-compliant. Phasing out of non-compliant loan-licensing arrangements is a key objective. Requiring BA/BE studies when applying for new/renewed licenses, while likely to increase costs, is positive from the perspective of the patients.
- **Other government initiatives:** (1) Generic prescriptions are unlikely to have a significant impact. It also is difficult to implement for doctors, where combination drugs have numerous molecules. It also places significant power in the hands of the pharmacist, (2) One company, one drug, one brand, one price could be a significant disruptor for the market, and would require a re-think of the entire business model for many companies.



## Ameesh Masurekar

### Director



**Ameesh Masurekar provided further insights into the domestic market (IPM) scenario. Below are the key takeaways -**

- The recovery in the IPM post-GST implementation is underway, however it is slower than many expected. Channel inventory may not recover to historical levels of 40-45 days.
- Expect the IPM growth to slow down significantly in the coming years, to 7-8% annually.
- Among therapies, anti-diabetes is growing fastest, followed by derma and vitamins. Cardiac growth is slowing down, especially in older treatments.
- The impact of trade generics on the IPM is increasing, with companies like Cipla, Intas, Alembic Pharma and Abbott effectively utilizing this route. With the market still in a state of flux after GST and demonetisation, the true impact of the trade generics phenomenon is not visible.
- Being the first player to launch a product or enter a particular segment is a significant advantage, and the business often becomes sticky thereafter. For e.g., Glenmark was the first Indian player to launch teneligliptin, and has managed to achieve significant success with this product.
- New combination launches are slowing down, however new brands of existing molecules are being launched regularly.
- Among up-and-coming companies, Boehringer Ingelheim, Corona Remedies, La Renon and Bharat Serums are doing well.

## Vijaya Shinde

### Director



**Vijaya Shinde is a regulatory auditor, and has conducted various US FDA standard audits. She provided us with insights regarding where and why Indian companies are having issues with the US FDA-**

- US FDA standards are not changing regularly, hence that is not a reason for Indian companies to not be compliant.
- While cultural differences may hamper the smoothness of an inspection, the formal communication with the inspectors on-site are in a written format, and hence there is limited scope for miscommunication.
- The US FDA does not have any issues with defective or out-of-specification batches. It only requires that companies then follow the prescribed rules and procedures. Indian companies often do not strictly adhere to requirements like disposal or re-processing of batches, which are cost-intensive measures.
- Indian companies need to move past the culture of 'hiding' issues. A more straightforward approach to inspections would yield quicker resolutions.
- Repeated problems at a company's plant is indicative of a deeper issue with the management and their attitude towards maintaining compliance.



## INSTITUTIONAL RESEARCH

**Disclosure:**

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HDFC securities Limited, I Think Techno Campus, Building - B, "Alpha", Office Floor 8, Near Kanjurmarg Station, Opp. Crompton Greaves, Kanjurmarg (East), Mumbai 400 042 Phone: (022) 3075 3400 Fax: (022) 2496 5066

Compliance Officer: Binkle R. Oza Email: complianceofficer@hdfcsec.com Phone: (022) 3045 3600

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**HDFC securities****Institutional Equities**

Unit No. 1602, 16th Floor, Tower A, Peninsula Business Park, Senapati Bapat Marg, Lower Parel,

Mumbai - 400 013

Board : +91-22-6171 7330

[www.hdfcsec.com](http://www.hdfcsec.com)