Pharmaceuticals

YES SECURITIES
INSTITUTIONAL EQUITIES

US concerns persist

Opinion on US generics remains divided

Pharma earnings season turned out to be a divergent pack with mixed commentaries from managements. In this report, we have collated the key takeaways from the conference calls of companies under coverage and highlight some of the common threads running across US, India and ROW markets. While Sun alluded to no change in underlying US generics operating environment, some of the key competitors like Lupin and Dr Reddys' remained optimist on the US market on back of turn in lead indicators like decline in ANDA submissions and high product discontinuations. Importantly, Teva, a bell weather for US generics, indicated that it is seeing stability in US generics as its revenue has been stable for five quarters in a row.

Need for specialty pipeline has fully sunk in

Importantly, managements of all frontline pharma companies with US$500mn plus US sales reiterated a pressing need to build a specialty portfolio to mitigate the persistent erosion in base business. Moreover, Glenmark and Taro, key players in the US derma market, echoed similar commentary of challenging growth environment characterized by persistent price erosion in dermatology. Limited period opportunities due to withdrawal of large players or supply disruptions like Valsartan played a meaningful role in supporting US business; indeed, AmerisourceBergen, a large US generics distributor, also highlighted such quick volume openings for most of the companies; albeit such opportunities cannot be relied upon for sustained growth. On a contrasting note, Aurobindo management remained confident of growth on a sizable base business on back of solid injectables growth in FY19 which is likely to sustain in the current fiscal.

India: weak anti infective season impacts acute-focused companies

In the domestic market, generic-generic may be causing a dent on IPM especially at the lower end. Separately Alembic Pharma management flagged a surprising slow-down in Q4 which needs a close watch. In another common refrain, companies indicated that trade channels have definitely pared inventory with average holding down to around 40 days from pre-GST norm of 45-50 days. FY19 also saw a weak anti-infective season which impacted predominantly acute focus companies like Alkem; management believes 1 in 3 years would be bad for acute business which, given the moderate growth in past 2 years, offers better prognosis in FY20. Europe implemented serialization of drug supply chains which dampened YoY growth for most companies in H2 FY19 though the issue would be resolved in the current quarter. Institutional business in Africa was impacted to due to sharp pull back in global funding and price erosion which lowered anti-malarial sales; expect funding to remain depressed which precludes recovery in sales.

No V-shape recovery expected in US

Sun Pharma guided to mid-teens revenue growth on FY19 reported base which translates in to 11% growth as Q4 was devoid of ~Rs11bn due to restructuring of Aditya Medisales. Barring Aurobindo, most managements remained circumspect about US business as despite semblance of stability in price erosion, product opportunities in base business are vulnerable to commodity type pressures; at the same time, specialty basket will take time to offset the base erosion. We retain our negative stance on the sector with Sell on Sun, DRRD and Lupin; retain preference for non-US plays like IPCA Labs.

Research Analyst: Bhavesh Gandhi ✉ bhavesh.gandhi@ysil.in
Head of Research: Amar Ambani ✉ amar.ambani@ysil.in

ALEMBIC PHARMA: ADD

Domestic commentary

- ✓ Surprised by flat sales in domestic business; possible reason is primary not doing well as trade channel may not want to load up on inventory so as to block more capital; 35-38 days of inventory in trade
- ✓ **Generic-generic may be causing some dent across companies**; if not back on track in Q1 then slowdown will entail a deeper study of underlying factors
- ✓ Expectation is for India growth of 13-14% and would look closely at Q1 FY20 sales to gauge the trend

US business

- ✓ Valsartan contributed to large chunk in Q2 and some bit in Q3; though there is still some disruption it is not as large a product as earlier
- ✓ Management believes would be tough to grow US revenue over FY19 base
- ✓ Will launch 15-20 products in US in FY20; Aleor JV will commercialize from June 2019;
- ✓ Aspire to grow US business to US$500mn in 3-4 years

Chinese JV

- ✓ Chinese JV is for products where the JV partner does not have a presence; no capex planned as of now and products would be manufactured in India and shipped to China. JV commercial launch is couple of years away
- ✓ 85% of purchasing is by hospitals in China; even with reduced pricing it is still an attractive market

ROW markets

- ✓ ROW sales down qoq as Europe as moved to serialization and implementation has led to lower available capacities; Q2 FY20 should see normalization of sales in Europe
- ✓ ROW had one off opportunities like Valsartan so loss to that extent but can be offset by new product launches; ROW will grow steady 15-20% growth in FY20

API business

- ✓ API disruptions in China due to pollution-led local capacity shutdown has led to good API business in FY19

ALKEM LABS: ADD

Domestic business

- ✓ FY19 a mixed year with robust growth in US but weak anti-infective season and FDC ban in India took its toll
- ✓ India growth delivered 13% adjusted for change in distribution policy in Q4; added MRs which would increase productivity even as hiring will continue with additional 1,000 MRs this year to touch 10k strength
- ✓ 13-14% growth in domestic market assumes a better acute season in India after tepid anti-infective performance in FY19
- ✓ To market 2 exclusive in-license products in domestic market including a gliptin for diabetes
- ✓ Added 30% MR in chronic and 70% in acute largely to declutter some of the larger brands
- ✓ OTC portfolio is less than Rs1bn and winding it down
- ✓ Stick to 5-6% R&D guidance; capex for FY19 Rs5.3bn and Rs4bn in FY20

US business

- ✓ Valsartan to be Q1 product opportunity; supply situation has stabilized and it is not as attractive an opportunity as it was 2 quarters earlier
- ✓ **Mycophenolate**: erosion on expected lines; US growth to be driven by double digit launches and market share gains

Margin performance

- ✓ Higher API prices and revenue mix had an impact on EBIDTA margin; expect improvement in gross margin due to some easing in API prices
- ✓ **Margin to improve 100-125bps in FY20**; working with **60% gross margin**; 18% margin looks achievable in FY21 with 150bps rise in each year
- ✓ Small growth in non-US markets with focus on few key markets of Australia, Chile and some markets in Europe

AUROBINDO: ADD

US business

- ✓ Management indicated **fair degree of optimism on US growth** in FY20 with **significant injectable launches** despite a sizable base business. Injectables grew 30% in FY19
- ✓ Acquired businesses of Spectrum oncology portfolio and Apotex contributed US$8mn and Rs1.4bn to US and European revenues respectively
- ✓ **Sandoz portfolio** acquisition approval is in its last leg and would take 8-12 weeks; acquisition to add 300 products plus under development pipeline
- ✓ R&D at 5% of sales in FY20 on the expanded business as biosimilars enter clinical trials in current fiscal; US$200mn capex in FY20
- ✓ Engaging with the agency on the OAI status which is specifically related to sartans; have submitted CAPA on work done at the API unit. All the players in Valsartan market have to undertake a CBE30 to update their respective process and methodologies.

Europe/Other highlights

- ✓ Europe: Margin of acquired Apotex business will definitely improve and turn the corner
- ✓ Gross margin: One off cost related to products, recall related to Valsartan pulled down gross margin by US$10mn

BIOCON: SELL

Q4 highlights

- ✓ Booked forex loss of Rs70mn vs gain of Rs420mn and is reflected in other expenses
- ✓ Margin has increased despite higher R&D and forex loss; gained market share in previously launched Rosuvastatin
- ✓ Biosimilars: despite launches in emerging markets and Europe, sales have been flat due to lumpiness and tender business which leads to quarterly variations
- ✓ Small molecules: Majority of growth from volumes and little contribution from forex

Biosimilars update

- ✓ Global biosimilar program for Bevacizumab and Insulin Aspart are progressing well; Insulin Aspart filing in Q3 or Q4 CY19 in Europe and US in mid CY20
- ✓ Global trial for **Bevacizumab** is on track and would submit for **US in CY19** and Europe in Q1 CY20
- ✓ Continue to ramp up insulin in emerging markets and expect the process to continue over 1-2 years; **would look to Glargine approval in US which would drive Malaysia plant volumes and sales**
- ✓ Expect continued growth in Neulasta over next few quarters despite challenges mounted by innovator
- ✓ Malaysia plant is at a breakeven stage and would start generating profit; other capacities like biologics would be capitalized over next few quarters
- ✓ Seen some stability in US pricing compared to year ago and do not expect any significant changes
- ✓ Large investment has been initiated on anti-body facility at Bangaluru for US$200mn apart from Malaysia capex

Guidance & Outlook

- ✓ **Growth momentum led by biosimilars will continue** with core EBIDTA margin (ex-R&D, forex) to sustain at FY19 level; R&D expenses across business segments as well as depreciation will rise significantly; staff costs to rise to create organization supporting Biocon Biologics
- ✓ R&D to be 15% of sales ex-Syngene on a gross basis; to cover biosimilar, novel programs and ANDA filings
- ✓ Gross margin increase will be seen in FY21 as US launches gather steam next fiscal
- ✓ **Reduced capitalization and higher R&D** will offset the incremental revenue from biologics in emerging and developed markets which will leave **core margin unchanged from FY19**
- ✓ Tax rate to rise to between 22-25% depending on quantum of R&D spending

DR REDDYS': SELL

Q4 highlights

- ✓ One offs in manufacturing overheads, higher share of PSAI and adverse forex movement impacted gross margin
- ✓ India is affected by weak seasonality in 4Q and see **healthy growth in domestic business**

US business

- ✓ **Generic pricing** has been much more **stable in 4Q** compared to prior quarters
- ✓ **Copaxone** received additional queries and in the process of responding to the same; launch unlikely in current fiscal
- ✓ Xenoport asset: in the planning phase and would go to FDA for guidance
- ✓ Remain in litigation for Revlimid in US; slow off take on Suboxone as there are four other players but confident on the asset on higher conversion from innovator to generic volumes
- ✓ **Nuvaring**: Continue to engage with agency and hope to launch in next 9 months
- ✓ R&D spend of US$250-300mn in FY20; focus on reduction of COGS and sales and marketing productivity after rationalizing SG&A in the previous fiscal
- ✓ **Change in Chinese regulations** with focus on generics now widens the opportunity; longer term, Chinese business can transition towards the tender model

GLENMARK PHARMA: HOLD

US business

- ✓ Generics environment remains challenging especially with price erosion persistent in dermatology; generics is a mid-single digit business and most companies will find it hard to grow beyond 5-10%
- ✓ US will grow in mid-single digit; other geographies would report better traction
- ✓ Had a stock out situation in Mupirocin which impacted US sales; **see competition in Q4 FY20 or FY21 emerging in the key product**
- ✓ **Ryaltris, Otiprio and derma** launches will **drive 10-15% US growth** in FY21; Otiprio will complement Ryaltris and would be sold by Ryaltris sales force
- ✓ Goa is the largest plant servicing US market and received EIR in March
- ✓ Major spends incurred on Ryaltris in FY19 which would not be repeated in FY20

India

- ✓ Consumer care business grew 35% in Q4 and FY19 secondary sales at 29%; all three brands are leaders in respective categories
- ✓ If Remogliflozin does well, Glenmark will have a very good year in domestic business; so far, offtake has been good
- ✓ Capex includes Rs5bn in tangibles and Rs3bn on in-licensing products mostly for Europe
- ✓ One off expense of Rs350mn related to Remogliflozin in Q4 and one off Rs250mn in setting up of API subsidiary; other income includes Rs380mn forex gain in Q4
- ✓ API is a profitable business with 61% gross margin and 30% EBIDTA margin

Corporate restructuring

- ✓ Invested US$113mn in the newly constituted innovation company and would incur similar amount in FY20
- ✓ Assets outside of core therapeutic areas of respiratory, oncology and dermatology will be divested; minority investor in Glenmark Life Sciences (API) and sale of non-core assets should take care of debt

IPCA LABS: BUY

FDA status

- ✓ Status quo as of now maintained across all 3 units since no communication from FDA; would submit Ratlam dossier within few days

FY20 guidance

- ✓ **Guidance of 12-14% growth with 200bps improvement in margin** in FY20; 13% growth in domestic market expected in current fiscal
- ✓ Capex of Rs2.2bn mostly for maintenance purpose and on APIs like Losartan, Valsartan in FY20

India business

- ✓ Anti-malarial is only 6% of the domestic business; Non-steroidal anti-inflammatory drugs now contribute 46% to domestic revenues
- ✓ As part of domestic strategy, do not launch many products in a year and between 14 divisions, will not launch more than 3-5 new products; focus is on building brands and higher doctor penetration.
- ✓ **Ramdev Chemicals is a FDA inspected facility** and has filed dossiers in Europe; would augment API supply through site transfer if Ratlam resolution gets further delayed

Institutional business

- ✓ Expected anti-malarial institutional business of Rs2.5bn while branded and generic businesses to clock 13% and 10% growth respectively
- ✓ R&D focus is on developing products for EU, ROW and other markets

Others

- ✓ UK revenues declined 10% yoy due to issue at distributor's end while ex-UK grew 24%; overall Europe grew 4% in FY19
- ✓ API growth to continue for next two years as prices remain strong

Key subsidiaries performance

- ✓ **Bayshore could contribute US$17-18mn** in revenues and FY20 guidance does not include Bayshore; Bayshore slipped in to loss in Q4 but recovery expected by Q2 FY20
- ✓ Onyx Scientific contributed Rs170mn profit in FY19
- ✓ **Piscah Labs**: 3 products under development and contributed Rs120mn loss in FY19 since business consists of mainly technology transfer; albeit loss would be lower in FY20

LUPIN: SELL

Q4 highlights

- ✓ Seen an encouraging trend in multiple indicators like ANDA submissions and higher product discontinuations that imply US generics market is stabilizing
- ✓ Top 3 IPM segments of diabetes, cardio and respiratory are also the top 3 therapies for Lupin which account for 55% of revenues
- ✓ Emphasis on cost rationalization with focus on US and India; optimize R&D productivity with large impact seen in FY21

US business

- ✓ Key pipeline products: Albuterol (gProAir) under FDA review and H2 FY20 launch; Tiotropium DPI (gSpiriva) filed, FTF confirmed with best case launch in 2022; gBrovana filed in US
- ✓ 6 biosimilars in development-notably Pegfilgrastim in clinic for US to be filed next year
- ✓ Etanercept under review in EU for H2 FY20 launch; Bridging studies underway for Etanercept in US
- ✓ 4 injectables products with 1 approved and launch in H1 FY20
- ✓ In NCEs, MALT1 out licensed to AbbVie for total US$947mn potential milestone payment with US$430mn upfront payment, one of the highest for preclinical deals

EU/Japan

- ✓ Japan is a pain point as volumes are growing but offset by pricing pressure which is likely to persist
- ✓ Namuscla is a smaller but profitable opportunity in Europe and launched in UK and Germany; H2 should see Namuscla launch in major European markets. Solosec ramp up in US has been slower than expected

NATCO PHARMA: BUY

Guidance & Outlook

- ✓ **Revenues up 7-8% and profit up 9-10% in current fiscal**; key assumptions include improved Copaxone performance based on demand projected by Mylan coupled with robust ROW - India, Brazil and Canada. Guidance does not include any meaningful contribution from Tamiflu
- ✓ India to grow 12-15%, while Brazil should also outperform local market; Canada will see some settlements and these three markets should grow 40% in FY20 revenues
- ✓ Company believes **profit will double from FY20 level of ~Rs7bn** driven by settlement and new launches and this includes expected moderation in Copaxone sales

US business

- ✓ Copaxone: initial payments were linked to milestones and now linked to market share and hence **more consistent revenues** seen from current fiscal
- ✓ **Alvogen has settled on Revlimid** but the launch date is much after Natco so do not expect loss of market on that count
- ✓ Imbruvica-90% of market has been moved to tablets from capsules where multiple filers are present; Natco is only one in tablet and could be the next Revlimid in management view

Agrochemicals foray

- ✓ Agro-chemicals plans on track with Rs1bn investments, facility should be ready by Oct 2019; segment would be 10-15% of revenues in 3 years with a similar sort of EBIDTA though tough to forecast at current juncture. Do not look at this space as a commodity business and would do only value-added products

ROW & usage of cash

- ✓ Intend to keep cash to make high risk investments which has been the forte of Natco or may be acquisitions down the line
- ✓ Overall ROW product mix is biased towards oncology which carries better gross margin

SUN PHARMA: SELL

Q4 highlights

- ✓ Higher expenses in specialty led to higher other expenses
- ✓ Aditya Medisales impact of Rs11bn otherwise consolidated sales up 21% yoy

US business

- ✓ US sales boosted by a 6-month generic supply to a customer but otherwise seen no improvement in underlying generics business
- ✓ Started DTC promotions in Q4 and will continue and will be a material cost in FY20; satisfied with formulary coverage for Ilumya
- ✓ Have put patients on early access program on Ilumya as company negotiates with payors and delayed revenue recognition has dampened revenues since the product is free to patients and funded by company
- ✓ 1,200 doctors out of 8k possible prescribers of biologics for Ilumya but of these only 2,000 are heavy prescribers of biologics; targeted docs would cover all decile of users
- ✓ Investment phase in specialty business would continue; Ilumya peak sales seen within next 4-5 years though breakeven would depend on additional costs incurred for new indications
- ✓ Once current with all approvals, should get a meaningful business from new launches
- ✓ **Xelpros:** In the market for 3 months but will not be a huge product in the overall scheme of things. Over 10% market share in Odomzo

FY20 Guidance

- ✓ Mid-teens growth in FY20 on reported base, capex of US$200mn and R&D at 9% of sales

Taro Q4 FY19 highlights

- ✓ Volumes up 7% and third year of volume growth; have 26 pending approvals
- ✓ Competition has increased with more players getting derma approvals and no respite is seen as players try to grab market share
- ✓ No product concentration in US and well diversified portfolio
- ✓ Overall market has seen no dramatic volume growth

SYNGENE: ADD

Q4 highlights

- ✓ Underlying sales growth is 20% in FY19 excluding 6% currency impact and 2% one offs; FY20 growth to be higher
- ✓ Revenue from top 10 clients at 66% vs 71% in FY15 as a result of diversification
- ✓ Have put up new capacities in discovery services and development; discovery services performing well
- ✓ Other expenses included higher consulting fees related to safety and compliance initiatives
- ✓ Revenue mix remains balanced with roughly equal share of discovery (biology, chemistry), development (with small manufacturing base) and dedicated centres

Outlook

- ✓ Expect momentum in discovery services and specifically biologics to continue; sales growth similar or notch higher than FY19
- ✓ Investment in safety and compliance which will lead to **slight compression in margin** which will reverse over time
- ✓ Much too early to read anything in to BMS merger with Celgene; BMS remains a flagship relationship
- ✓ Company is 18 months away from being a small-scale biologics manufacturer; will be adding 2 more lines in Bangalore which will be operationalized next fiscal
- ✓ Capex of US$200mn over 2 years till FY21; about US$75mn to be spent on Mangalore facility
- ✓ FY21 would be a startup year for Mangalore unit; although conversations are happening for building a funnel, clients would not commit until the unit is ready and qualified

RECOMMENDATION PARAMETERS FOR FUNDAMENTAL REPORTS

Analysts assign ratings to the stocks according to the expected upside/downside relative to the current market price and the estimated target price. Depending on the expected returns, the recommendations are categorized as mentioned below. The performance horizon is 12 to 18 months unless specified and the target price is defined as the analysts' valuation for a stock. No benchmark is applicable to the ratings mentioned in this report.

BUY > 15%

ADD 5% to 15%

HOLD -15% to +5%

SELL > - 15%

NOT RATED

UNDER REVIEW

POSITIVE: Positive is rating given to stocks we like but yet to be formally included in our coverage universe.

NEGATIVE: Negative is rating given to stocks yet to be formally included in our coverage universe, but we find valuations expensive vis-a-vis fundamentals.

NEUTRAL: Neutral rating is given to stocks that are not under our formal coverage yet, but we find current valuation fairly representing fundamentals.

ABOUT YES SECURITIES (INDIA) LIMITED

YES SECURITIES (INDIA) LIMITED (''YSL'') was incorporated on 14th March 2013 as a wholly owned subsidiary of YES BANK LIMITED. YSL does not have any other associates. YSL is a SEBI registered stock broker holding membership of NSE and BSE. YSL is also a SEBI registered Category I Merchant Banker, Investment Adviser and a Research Analyst. YSL offers, inter alia, trading/investment in equity and other financial products along with various value added services. We hereby declare that there are no disciplinary actions taken against YSL by SEBI/Stock Exchanges.

DISCLAIMER

Investments in securities market are subject to market risks, read all the related documents carefully before investing.

The information and opinions in this report have been prepared by YSL and are subject to change without any notice. The report and information contained herein are strictly confidential and meant solely for the intended recipient and may not be altered in any way, transmitted to, copied or redistributed, in part or in whole, to any other person or to the media or reproduced in any form, without prior written consent of YSL.

The information and opinions contained in the research report have been compiled or arrived at from sources believed to be reliable and have not been independently verified and no guarantee, representation of warranty, express or implied, is made as to their accuracy, completeness, authenticity or validity. No information or opinions expressed constitute an offer, or an invitation to make an offer, to buy or sell any securities or any derivative instruments related to such securities. Investments in securities are subject to market risk. The value and return on investment may vary because of changes in interest rates, foreign exchange rates or any other reason. Investors should note that each security's price or value may rise or fall and, accordingly, investors may even receive amounts which are less than originally invested. The investor is advised to take into consideration all risk factors including their own financial condition, suitability to risk return profile and the like, and take independent professional and/or tax advice before investing. Opinions expressed are our current opinions as of the date appearing on this report. Investor should understand that statements regarding future prospects may not materialize and are of general nature which may not be specifically suitable to any particular investor. Past performance may not necessarily be an indicator of future performance. Actual results may differ materially from those set forth in projections.

Technical Analysis reports focus on studying the price movement and trading turnover charts of securities or its derivatives, as opposed to focussing on a company's fundamentals and opinions, as such, may not match with reports published on a company's fundamentals.

YSL, its research analysts, directors, officers, employees and associates accept no liabilities for any loss or damage of any kind arising out of the use of this report. This report is not directed or intended for distribution to, or use by, any person or entity who is a citizen or resident of or located in any locality, state, country or other jurisdiction, where such distribution, publication, availability or use would be contrary to law, regulation or which would subject YSL and associates to any registration or licensing requirement within such jurisdiction. The securities described herein may or may not be eligible for sale in all jurisdictions or to certain category of investors. Persons in whose possession this document may come are required to inform themselves of and to observe such restriction.

DISCLOSURE OF INTEREST

Name of the Research Analyst : Bhavesh Gandhi

The analyst hereby certifies that opinion expressed in this research report accurately reflect his or her personal opinion about the subject securities and no part of his or her compensation was, is or will be directly or indirectly related to the specific recommendation and opinion expressed in this research report.

Sr. No.	Particulars	Yes/No
1	Research Analyst or his/her relative's financial interest in the subject company(ies)	No
2	Research Analyst or his/her relative or YSL's actual/beneficial ownership of 1% or more securities of the subject company(ies) at the end of the month immediately preceding the date of publication of the Research Report	No
3	Research Analyst or his/her relative or YSL has any other material conflict of interest at the time of publication of the Research Report	No
4	Research Analyst has served as an officer, director or employee of the subject company(ies)	No
5	YSL has received compensation or other benefits from the subject company(ies) or third party in connection with this research report	No
6	Broking/Investment Banking/Merchant Banking relationship with the subject company at the time of publication of Research Report	No
7	YSL has managed or co-managed public offering of securities for the subject company in the past twelve months	No
8	Research Analyst or YSL has been engaged in market making activity for the subject company(ies)	No

Since YSL and its associates are engaged in various businesses in the financial services industry, they may have financial interest or may have received compensation for investment banking or merchant banking or brokerage services or for any other product or services of whatsoever nature from the subject company(ies) in the past twelve months or associates of YSL may have managed or co-managed public offering of securities in the past twelve months of the subject company(ies) whose securities are discussed herein.

Associates of YSL may have actual/beneficial ownership of 1% or more and/or other material conflict of interest in the securities discussed herein.

YES SECURITIES (INDIA) LIMITED
Registered Office: Unit No. 602 A, 6th Floor, Tower 1 & 2, Indiabulls Finance Centre, Senapati Bapat Marg, Elphinstone Road, Mumbai – 400013, Maharashtra, India.
Tel: +91-22-71123123 | **Email:** research@ysil.in | **Website:** www.yesinvest.in

CIN: U74992MH2013PLC240971 | SEBI Single Registration No.: NSE, BSE & MCX: INZ000185632 | MERCHANT BANKER: INM000012227 | RESEARCH ANALYST: INH000002376 | INVESTMENT ADVISER: INA000007331 | AMFI ARN Code – 94338 |
Details of Compliance Officer: Name: Vaibhav Purohit,
Email id: compliance@ysil.in, Contact No-+91-22-33479208