

Alembic Pharmaceuticals Limited

BUY

CMP: Rs.605

TARGET PRICE: Rs.751

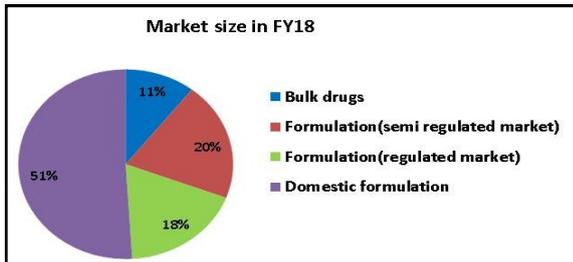
TIME : 12 months

OVERVIEW: Industry – Pharmaceuticals:

Pricing pressure, higher competition, increased regulatory scrutiny by global drug regulators, channel consolidation in the US were all factors that had built a tough business environment for the Pharma Industry as a whole over the past few years. The Indian pharmaceutical sector was valued at USD33bn in 2017, expected to expand at a CAGR of 22.4% over 2015–20 to reach USD55bn. India's pharmaceutical exports stood at USD17.27bn in 2017-18. In 2018-19 these exports are expected to cross USD19bn. (As per IBEF).

The Indian Pharma space was no exception to the above mentioned reasons of drag in the domestic as well as overseas markets with additional factors of price control led by DPCO and NLEM.

Exhibit 1: Indian Market Size across different segments:



Source: Crisil

The Generic Space:

A generic drug is a pharmaceutical drug that has the same chemical substance as the drug that was originally developed, patented and innovated (Wikipedia). The use of generic drugs is preferred by many countries due to increasing prevalence of chronic diseases which is expected to rise by 57% by 2020. (PWC forecast). At the global level, generic drug market accounts to about USD200.2bn in 2015 and is expected to reach approximately USD380.6bn by 2021, growing at a CAGR of ~10.8% between 2016 and 2021. As reported by the UK-based market intelligence firm EvaluatePharma, top selling drugs are expected to go off-patent between 2018-2024 and this could potentially erase sales worth USD251bn of the global Pharma companies.

The US Generics Market:

There has been a significant change seen in the operating environment for generic Pharma companies in the US over the past few years. There has been an increase in the number of players (crowding) entering the space leading to strong pricing pressures.

This is led by factors such as:

- Consolidation in the US Pharma customer base
- Faster approvals from the USFDA
- Increase in competition in the generics market with rising number of players
- Increased emphasis on the regulatory compliance of different manufacturing facilities
- Increased government focus on bringing down healthcare costs
- Diminishing tolerance for price hikes

How are the Indian Players handling it?

India is no exception with regard to its preference to cater the generics market, with ~70% of its revenues coming from the same. With the change in focus from plain vanilla generics to complex generics; the Indian players are all geared and focussed to develop complex generics and speciality offerings that would help them deal with competition and pricing pressures. Also, the Indian Pharma Industry is well prepared to handle any Trump administration's stress regarding getting the overall drug prices down and localising manufacturing through cost leadership and presence of onshore facilities in the US. Overall, we feel that the change in the dynamics of the overall Generic drugs market is well adopted by the Indian players with the inclination going strong.

SNAPSHOT				
52 week H / L	Mcap (INR mn)			
664 / 412	1,14,014			
Face value: 2				
BSE Code	NSE CODE			
533573	APLLTD			
Annual Performance				
(Rs mn)	FY16	FY17	FY18	FY19E
Sales (Net)	31,660	31,346	31,308	35,584
EBITDA	10,067	6,153	6,431	7,793
EBITDA (%)	32	20	21	22
Other Income	73	20	70	22
Interest	54	52	34	86
Depreciation	722	830	1,055	1,272
PBT	9,363	5,291	5,413	6,457
PAT	7,202	4,069	4,209	5,058
Equity (Rs mn)	377	377	377	377
EPS (INR)	38	21	22	26
Quarterly Performance				
Parameters (Rs mn)	Dec-17	Mar-18	Jun-18	Sep-18
Sales (Net)	8,400	8,533	8,625	11,271
EBITDA	1,878	1,732	1,510	3,023
EBITDA (%)	22	20	18	27
Other Income	1	6	1	24
Interest	8	13	16	58
Depreciation	264	316	276	286
PAT	1,309	1,024	904	2,000
Equity (Rs mn)	377	377	377	377
Ratio Analysis				
Parameters (Rs mn)	FY16	FY17	FY18	FY19E
EV/EBITDA (x)	11.0	18.4	18.7	15.8
EV/Net Sales (x)	3.5	3.6	3.8	3.5
M Cap/Sales (x)	3.6	3.6	3.6	3.2
M Cap/EBITDA (x)	11.3	18.5	17.7	14.6
Debt/Equity (x)	0.1	0.1	0.3	0.4
ROCE (%)	69.5	29.1	22.6	21.7
Price/Book Value (x)	7.1	6.0	5.1	4.4
P/E (x)	15.8	28.0	27.1	22.6
Share Holding Pattern as on 30th September, 2018				
Parameters	No of Shares	%		
Promoters	1375,49,073	73		
Institutions	280,52,292	15		
Public	229,14,549	12		
TOTAL	188515914	100		

Source: Annual Report

Note: All the data is calculated as per Market Price on 17th December 2018

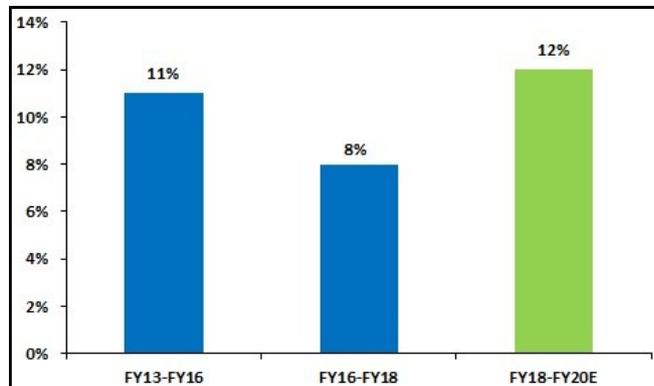
The Domestic Market: Under Focus again:

Domestic Formulations:

They are the end products of the medicine manufacturing process which are ready for consumption. *Formulations are usually composed of two elements namely Active Pharmaceutical Ingredients (APIs), which has the effect causing part of the drug; and excipients, which are basically everything other than the API.*

With the stringency across the export markets, focus of major players is back to the domestic ground. The objective of reducing healthcare costs and improvement in the accessibility by the Indian government has led to implementing price controls and promoting use of generic drugs. This is expected to impact the Indian Pharma players; however, quality issues around generics and strong branding/marketing by larger players will limit the impact. Demonetization and GST is behind us now. We feel that factors like increase in government spends, improving healthcare accessibility; increase in disposable income and

Exhibit 2:Growth across the Domestic Formulations



Source: Crisil

expanding insurance penetration continue to make the Indian Pharma market an attractive structural growth story.

API (Active Pharmaceutical Ingredients): Actively required always:

Drug products are usually composed of several components. *API is the primary ingredient responsible for curative action.* APIs are supplied by Pharmaceutical manufacturers to Formulations players or for own consumption for in-house Formulations. The total API production in India was valued close to around USD11bn in FY16 and is expected to grow at a CAGR of ~9% during the period FY16-22. Of the total domestic consumption; approximately 32% is imported with China accounting for about 57-60% of the total imports while the remaining is procured from countries like Italy, Germany and Malaysia. This proves that there is huge scope for the domestic API market to grow if the manufacturers tap this opportunity prudently and produce the required amount of API rather than importing. (Assocham).

Exhibit 3: Indian Pharma Market (IPM): Growth Prospects and Challenges:

Flavours Going Ahead
<ul style="list-style-type: none"> • Complex drugs would be preferred as plain vanilla generics stand strong competition • Diversified Geographical revenue mix • Biosimilars; the next leg of growth • R&D initiatives to start paying off • Refocus on domestic growth • Improved quality compliance • Rising focus on emerging markets

Challenges Ahead
<ul style="list-style-type: none"> • Elevated pricing pressures • Domestic regulatory uncertainty • Strong Rupee • FDA clampdowns • Policy burdens

Source: Progressive Research

The Indian Pharma Industry has two major scenarios to tackle:

The first being the task to strike a balance across the Healthcare value chain, as governments and insurers take center stage, pressuring pharmaceutical companies to reduce prices and demonstrate greater value from their therapies. Secondly, we believe a swing from treatment to prevention, diagnostics and cure, is growing stronger with time, attracting a host of new entrants from within and outside the sector. (As per KPMG report). How the India Pharma companies strike a balance between the two is the line of interest going forward. Overall, the growing health insurance coverage, increase in lifestyle diseases like diabetes, high blood pressure, etc. (Chronic symptoms) and rising income levels remain the key growth drivers of the Indian Pharma market always.

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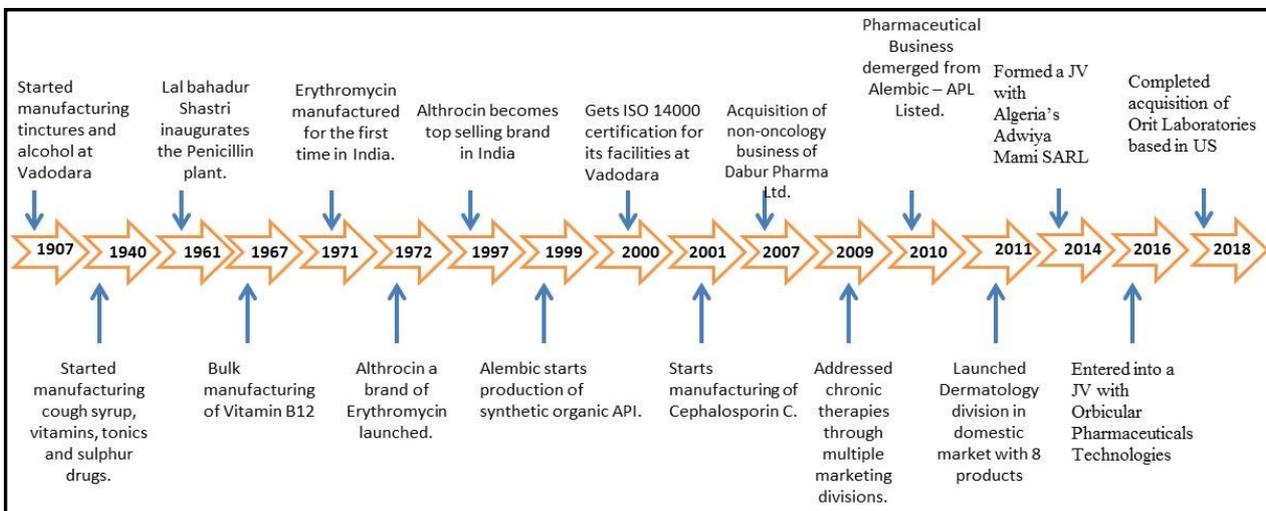
TIME : 12 months

About the Company:

Tracing the history to 1907, Alembic Pharmaceuticals Limited (APL) is a leading player in the Indian pharmaceutical industry. It is the flagship company of the Alembic Group. (In 2011, APL was de-merged from Alembic Ltd to provide more thrust to formulations and insulate this business from the vagaries of commoditised APIs). The Company's competencies include branded formulations, international generics and API. With its diversified product basket; APL is contributing to find solutions for some of the major health challenges being faced. APL is also known as a market leader in macrolides segment of anti-infective drugs in India. It has been extensively active in this space over the years and has been one of the preferred names in the industry with strong brands like Althrocin (Erythromycin), Roxid (Roxithromycin) & Cloff (Clarithromycin) in its kitty. It has manufacturing facilities in Panelav in Gujarat, Karakhadi in Vadodara, Sikkim and R&D centres at Vadodara, Hyderabad and US.

Along with pharmaceuticals, Alembic group has significant presence in various industries such as Glass, Chemicals, Real Estate, Engineering, Education and Healthcare. The current generation-led by Pranav Amin and Shaunaq Amin have transformed the enterprise into a modern maker of generic drugs, with major presence in the US market through its own front-end and inorganic growth. The success is also attributable to its operational improvements with stream lined supply chain ensuring on time product delivery at the right place.

Exhibit 4:History:

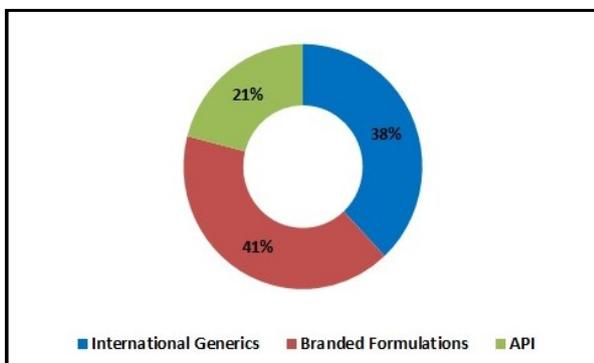


Source: Company

Business Segment:

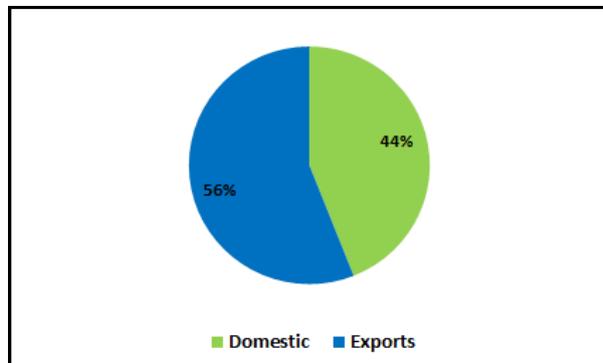
APL's revenues are broadly bifurcated into International Generics (38%), Branded/Domestic Formulations (41%) and API (21%). The exports market has a larger contribution to the revenues of the company. It is well strategized to cater and garner maximum of the opportunities prevailing across each of the segments.

Exhibit 5: Business break-up:



Source: Annual Report

Exhibit 6: Domestic vs. Export:



Source: Annual Report

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INVESTMENT RATIONALE:

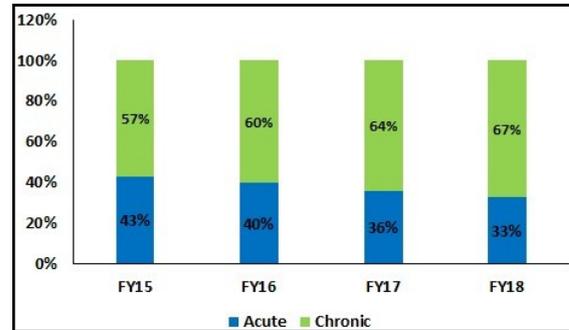
A) Domestic formulations: To Strengthen Again:

The domestic formulation segment contributed around 41% to the overall sales in FY18. The company has a strong field force of ~3,800 medical representatives with the field force productivity of ~Rs3,00,000 per month. It caters to the domestic formulations space through its plant based out of Sikkim. APL's five brands fall under the top 300 formulation brands in India. The prominent brands include Azithral, Rekol, Tellzy, Ulgel, Zeet etc. to mention a few. The company has 17 marketing divisions adding new divisions across gynaecology, cardiology, General injectables, Urology etc.

The anti-infective segment was the face of APL, through its flagship brands Azithral and Althrocin. However, clutches of DPCO and NLEM covered most of the drugs in this segment of the company. This was one of the reasons why APL restricted its focus on the anti-infective and started tilting towards the speciality segment. From then, APL has been constantly restructuring its business portfolio, all for improving the growth and overall operational performance.

The company has made a shift of focus from the always active presence in the acute therapeutic segment to the Chronic side; the speciality segment. This segment now accounts for 67% of revenues garnered through branded formulations business as compared to 64% in FY17. It further expects to maintain the 70:30 ratio for Chronic: Acute blend of therapeutics. APL is constantly ramping up its product basket, comprising of ~170 products (15% products in NLEM) with a strong focus on Cardiology, Anti-Diabetic, Gastrology and Dermatology under this segment which also accounts for about 90% of new launches in the current fiscal.

Exhibit 7: Chronic and Acute contribution:



Source: Company Presentation

Alembic's domestic growth has been severely impacted by the regulatory/policy changes in India such as GST implementation, demonetization, ban on FDCs and extension of products under-pricing control to mention a few. However, the turnaround in the market dynamics with increasing contribution from the high-growth specialty therapies is expected to revert the domestic scenario into positive with double digit growth trajectory.

Further, backed by the aggressive approach of introducing new divisions and launching products across the existing & new therapeutic areas, should help APL on the growth trajectory. 90% of the new launches are in the Speciality segment indicating strongly the focus of the company. Going forward, the company expects its overall domestic formulation business to at least grow in-line with the industry growth rate, before it sees an improvement in the share of the high growth chronic segment. We expect the domestic formulations segment to grow at a CAGR of 15% over the next 2-3 years accompanied with line extension (SKUs) launches at the run rate of 20-25 per year.

B) International Generics: US the focus:

APL took its first step to foray into the world's largest pharmaceutical market by setting up front end marketing at New Jersey in FY15. To add to the success, APL crossed USD100mn sales milestone by growing 69% in FY18 making its way for deeper penetration. After the gAbilify franchise been faded, the US base was reset at USD100-150mn annualised run rate going forward. The formulations business contributed around 30% to the total revenues with majority coming from US and Europe. The company is expected to gradually ramp up in the US backed by the increasing filings (pipeline of 26 ANDAs and 10 DMFs filed in FY18). Despite being a late entrant, the company has done reasonably well with a product basket of 143 ANDAs and received 77 approvals (including 13 tentative approvals). It has also demonstrated the required capabilities by securing limited competition approvals like gAbilify (CNS), gExforge (CVS), gCelebrex (Pain) and gMicardis (CVS). It stands to monetize from Para IV/FTF opportunities such as Multaq, Staxyn, Cialis and Lyrica to mention a few. The increasing contribution of the US front-end having already launched 48 products would further drive operating leverage gains for the company.

The expansions across the Oral Oncology Injectables (Panelav plant), General injectables (Karkhadi) have been completed. The company is undertaking exhibit batches for the same. The oral solids facility in Jarod should be done by 1QFY20. These facilities would support the capacity and capability requirements for a ramp-up in its US operations. Overall, we expect the international formulations business to clock 20% revenue CAGR over the next 3-4 years with 10-15 launches expected every year.

Exhibit 8: Chronic and Acute segment contribution:

Reaching Geographies							
Particulars (FY18)	USA	Canada	Latam	Europe	South Africa	India	Australia
Filings	132	21	14	21	21	0	17
Approvals	70	20	4	19	7	0	14
Product launches	48	12	2	15	2	170	12

Source: Annual Report

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ORIT Laboratories LLC:

Complementing the organic growth, was the inorganic path to expansion where the company had its first cross border acquisition of the US based generic drug maker Orit laboratories LLC in November 2017. Orit's acquisition is to bring synergies in the form of competent R&D team specialising in soft gelatin based oral solids and oral liquids. Orit has seven approved and four pending ANDAs in its kitty along with a manufacturing facility. As rightly said by the management, the 'tuck in acquisition' reflects the company's ambition to grow its US generics business in a measured way.

Joint Ventures:

Aleor Dermaceuticals Limited: Going ahead on the inorganic path to expansion, APL formed a 60:40 JV with Orbicular Pharmaceutical Technologies Limited which is engaged in the business of manufacturing and trading of dermatological products. This alliance is going to aid APL in developing, manufacturing and commercialising dermatology products and increase its global footprints into newer therapies.

Alembic Mami SPA: In 2014, APL through its wholly owned subsidiary Alembic Global Holding SA formed a Joint Venture company with Algeria's Adwiya MAMI SARL called Alembic Mami SPA by acquiring its 49% equity stake. Adwiya Mami owns a large capacity oral drug formulation factory in Algeria. The above arrangement is going to help APL establish its footprints in South African markets by manufacturing drugs through the facility held in Algeria and cater the local markets as import of drugs is one of the major barriers among others.

C) Research & Development:

APL has been constantly improving its R&D spend from Rs1,393mn (6.8% of turnover) in FY15 to Rs4,110mn (13% of turnover) in FY18 and more than 90% of these spend are allocated towards developing products for the US markets. The cash flows generated from gCymbalta and gAbilify sales were prudently invested to expand capacities and improve R&D capabilities to support future growth. APL has majorly routed its R&D spend towards improving its product basket and entering into complex therapeutic segment of Oncology. It has increased the breadth of its pipeline beyond Oral solids and NCEs to include injectables, dermatology (via Aleor), Oncology and Ophthalmology. APL's increasing focus on higher complexity therapies is expected to help ward off growth pressures in the US in the backdrop of increasing competition and pricing pressures, especially in oral solids.

Arrangement with Rhizen (Swiss Subsidiary):

Rhizen Pharmaceuticals is an innovative, clinical-stage biopharmaceutical company focused on the discovery and development of novel therapeutics for the treatment of cancer, immune and metabolic disorders. Since its establishment in 2008, Rhizen has created a diverse pipeline of proprietary drug candidates targeting several cancers and immune associated cellular pathways.

Exhibit 9: Rhizen Pipeline:

PIPELINE DRUGS	
MOLECULE	CURRENT STATUS
ONCOLOGY	
c-Met Kinase inhibitors	Late Pre-Clinical
PI3K δ Inhibitors	Phase 3 (TGR1202)
PI3K δ/γ Inhibitors	Phase 1
IMMUNE THERAPEUTICS	
CRAC Channel Inhibitors	Late Pre-Clinical
PI3K δ/γ Inhibitors	Late Pre-Clinical
VETERINARY THERAPEUTICS	
Canine Lymphoma	Phase-2 clinical in dogs

Source: <http://www.rhizen.com/about.html>

Thus, the in house research activities been undertaken by the company as well as the subsidiaries pipeline clearly indicates that APL has a strong inclination towards innovation and targets better molecule offerings going forward.

D) Focussed Approach:

The management very strongly disseminates the focus it has in terms of therapies to be catered, geographies to be catered and molecules to dart. The leading hands are very clear of the fact that Pharma is the focus with India and US being the key markets. On the regulatory front, APL strongly stands on compliance with regard to manufacturing arms as well as product lines. And to back this all is the 100 years of experience, seen through thick and thin, placing the company at a different level of dedication and focus.

We feel, the clarity in the minds in terms of the business strategies is the key to the gradual inching of growth that the company is garnering in the past few quarters. This should be continued going forward as well.

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Financials:

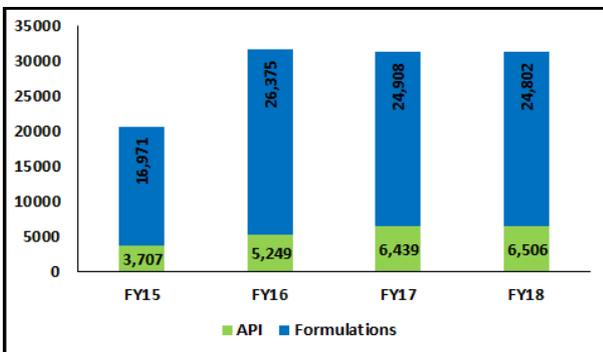
Revenue growth:

In the past 2-3 years, the company has been flat on the revenues front through the blend of formulations and API. However, we feel that going forward with most of the reasons for the slowdown being behind us; optimistically the company should have a decent growth in the domestic as well as exports markets.

Improvement in the operating margins:

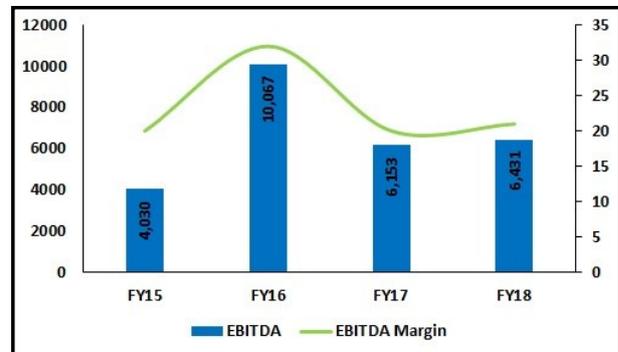
The EBITDA margins in the last two years also have been impacted and stayed flattish. We feel however, that now with a better business mix we should see better margins going forward. There would not be any exponential expansion in margins due to the company being in the investment mode with fruits to be borne only by FY21-22. Till then, the heightened cost structure and absence of lucrative product approvals will keep margin in the range of 20-21%. But at least we would see the company maintaining the current levels going forward.

Exhibit 10: Sales breakup:



Source: Annual Report

Exhibit 11: EBITDA & Margins:

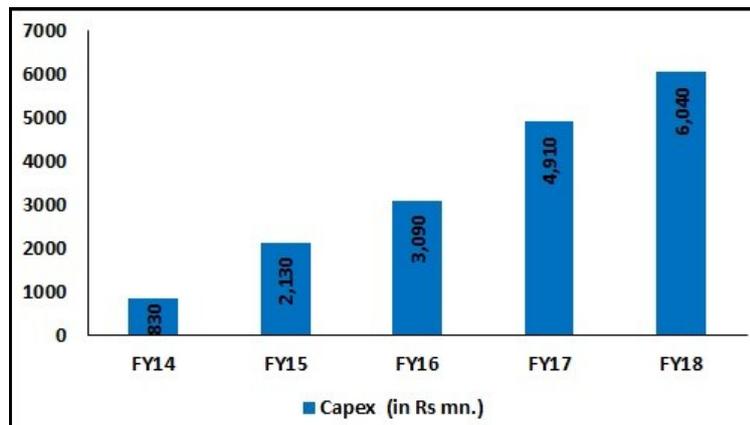


Source: Annual Report

Still in the Investment mode:

APL continues to remain in the investment mode and is likely to spend Rs6bn on capex and Rs5bn on R&D in FY19. Over FY17-18, it has already spent Rs20bn on both capex and R&D. All the benefits from these investments will be realized FY20/21 onwards, with new product approvals to start coming in from these facilities for the US market. For FY20, the management has indicated that there shall be no significant capex except for the maintenance and the spill over from FY19 if any.

Exhibit 12: Sales breakup:



Source: Annual Report

Recent development:

The company has raised Rs350cr through allotment of non-convertible debentures (NCDs) on private placement basis. The NCD committee of Alembic Pharmaceuticals Ltd. has allotted 1,500, 9% rated unsecured listed redeemable non-convertible debentures (NCDs) aggregating to Rs150cr under tranche I. Under Tranche 2, it has also allotted 2,000, 9% rated unsecured listed redeemable NCD aggregating to Rs200cr.

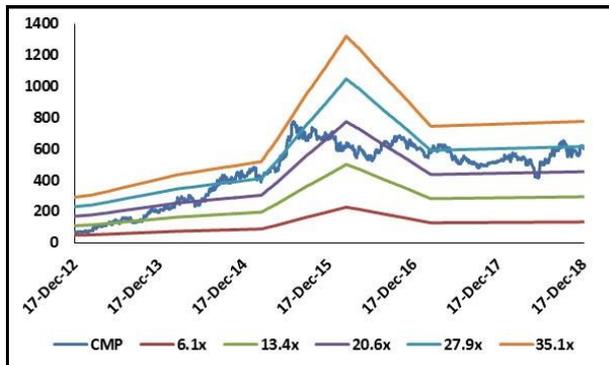
Risks and concerns:

- Any regulatory enforcement actions from the USFDA
- Impact of any new drug policy in India
- Delays in getting ANDA approvals
- Field Force Attrition
- Currency Fluctuations
- Increased coverage of DPCO impacting domestic business (price erosion)

Outlook and Valuations:

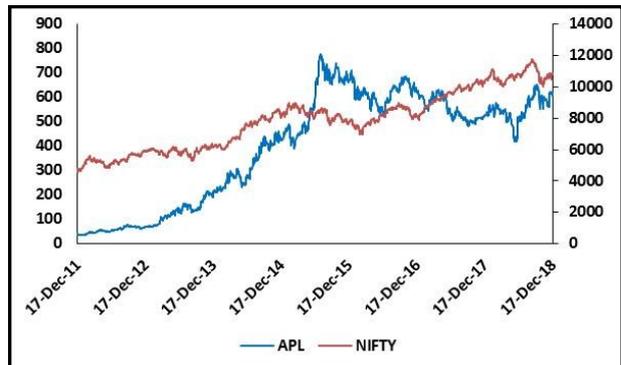
There has been a transformation in the business of the company with renewed efforts from the management towards domestic growth coupled with exports expansions as well. The company is making earnest efforts to improve on the product mix in the domestic markets to favour chronic as that is the key to improving cash flow generation. Ramp up through own front-end operations in US and working on key launches is the requisite being catered. This is all complimented with the R&D efforts and expansions being undertaken by the company. There has been improvement seen in the profitability as well as the return ratio which is here to stay. We feel that the rerating that the stock has been receiving is well justified through the performance of the company. We initiate Buy on the stock with a target of Rs751 over a 12 months horizon.

Exhibit 13: One year forward P/E



Source: ACE Equity

Exhibit 14: Price vs. Nifty



Source: ACE Equity

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