SECTOR: Pharmaceuticals

LUPIN

Growth recovery, a sweet pain relief

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Lupin Ltd.

WAY2WEALTH A COFFEE DAY COMPANY Research Desk

SECTOR: Pharmaceuticals

INITIATING COVERAGE : BUY | **SECTOR: PHARMACEUTICALS** | **27 June, 2019**

Lupin's financial performance has been impacted due to regulatory overhang on Goa and Indore facilities, broadening pricing competition in the US market and overpriced investments not living up to the expectations leading to de-growth of EBITDA /EBITDA margin to 6% and 757bps over FY16-19. We expect most of its concerns to abate going ahead and believe the stocks offer limited downside from the current levels. Key catalysts over FY19-21E are remediation of Goa and Indore facilities, specialty product approvals driving the revenue, and pricing stabilization in the US generic market. We initiate coverage on **Lupin** with a ***BUY* rating.** Lupin is currently trading at 23x FY20E and 18x FY21E P/E vs. its five-year average of 27x P/E.

Our investment thesis is backed by

a) ***Resolution of regulatory hurdles for Goa and Indore facilities,***

b) ***Investment in R&D to fructify through the launch of complex products (inhalers, specialty, injectables and biosimilars) from 2HFY20E***

c) ***US market to bounce back after multiple concerns,***

d) ***Next wave of growth in Japan to be lead by the launch of specialty and biosimilars products, and***

e) ***Indian formulation business to report above market growth rate.***

Key Stock Data	
Rating	**BUY**
CMP	₹764
Market Cap (₹ Crs)	34555
52W High/Low	986 / 697

Shareholding Pattern (%)	
Promoters	46.97%
FIIs	25.87%
Mutual Funds	6.41%
Non Inst	14.96%

Valuation

Lupin has de-rated over the last few years as several challenges emerged in the US market. Lupin has been trading at P/E range of 26-27x on a 1-year forward basis for the past 2 years, while currently it is trading at a discount of 17% vs. its five-year average of 27x P/E and in-line with Nifty Pharma Index on 1-year forward P/E. We believe the current valuation does not reflect the visibility of the near-term pipeline and focus on complex generics. We expect US business to bounce back from regulatory and pricing concerns, and approval of complex products will drive its earnings from 2HFY20E. We expect revenue/EBITDA CAGR of 11%/17% and an uptick in EBITDA margin ~250bps over FY19-FY21E. However, our earnings estimates do not incorporate the risk of adverse outcome from the USFDA for its facilities.

Key Financials (₹ Mn)	FY17	FY18	FY19	FY20E	FY21E
Revenue	174,943	158,041	167,182	185,594	202,169
EBITDA	45996	32978	32462	37191	44466
Net Profit	25575	2512	6066	15070	19333
EPS	57	31	21	33	43
EBITDA Margin in %	26%	21%	19%	20%	22%

Returns (%)

Name	6M	1Y	3Y
Nse Pharma Index	-13	-12	-9
Nifty	4	12	15
Ajanta	-5	-4	-13
Sun Pharma	-15	-30	-19
Cipla	5	-7	6
Dr Reddy's Lab	-7	15	-6
Lupin	**4**	**-15**	**-19**
Cadila	-29	-40	-8
Biocon	-18	-21	29
Aurobindo	-21	2	-4
Glenmark	-30	-24	-16
Divis Labs	-7	54	14
Torrent	-18	7	6
IPCA	1	40	27
ALKEM	-4	-12	8

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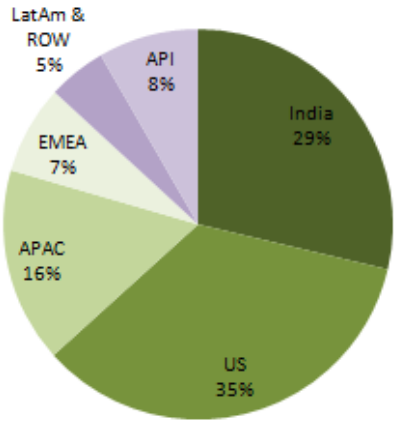
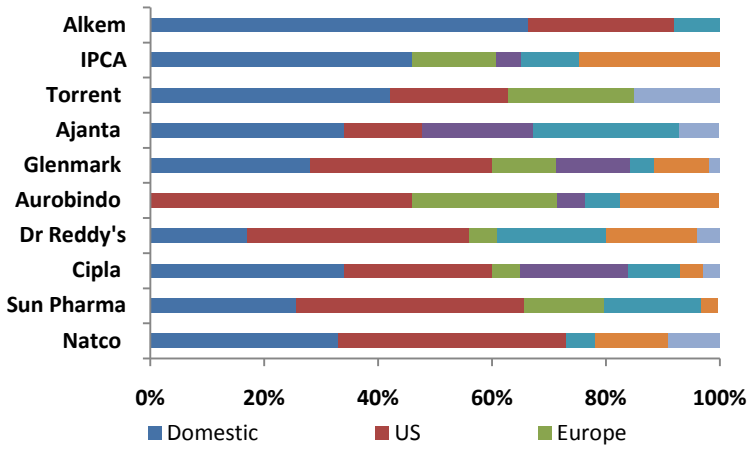
Lupin's FY19 revenue mix region-wise



Source : Company reports

Revenue mix for Indian Pharma Companies

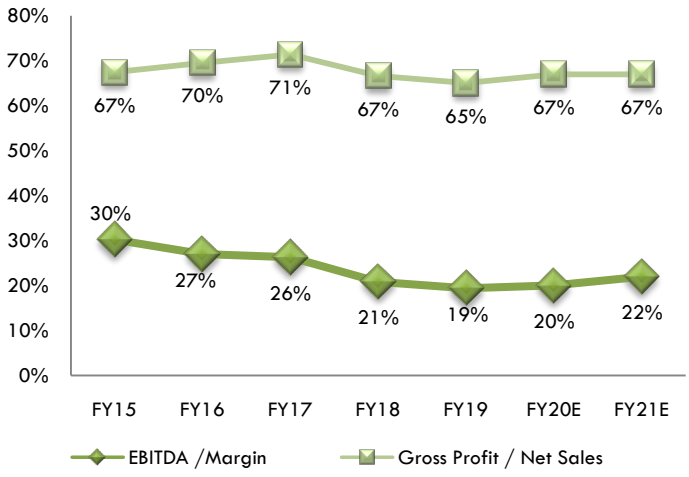


Source : Company reports and Bloomberg

Lupin stock performance from its peak

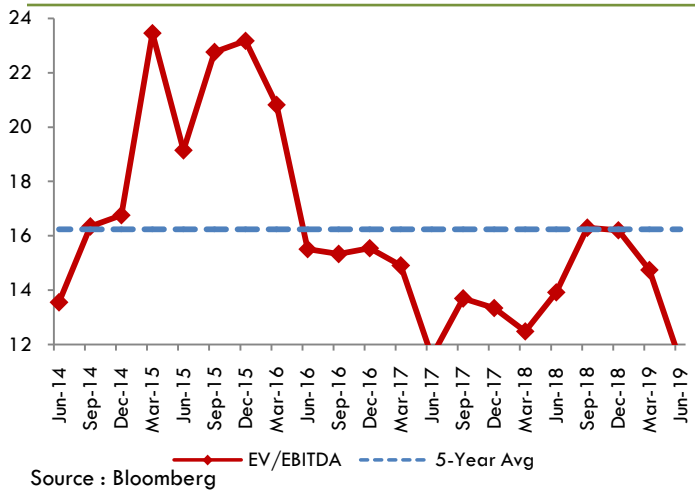
Source : Bloomberg

Margins trend over FY15-FY19

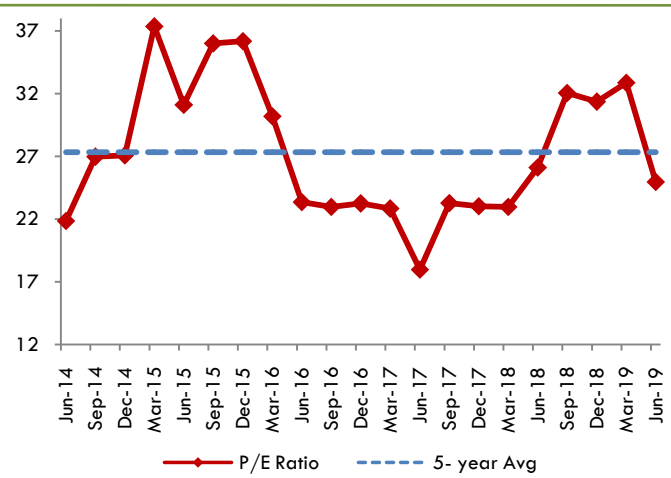


Source : Way2Wealth Research & Company Reports

Lupin has de-rated led by compliance issue, aggressive acquisition approach and pricing concerns



Source : Bloomberg



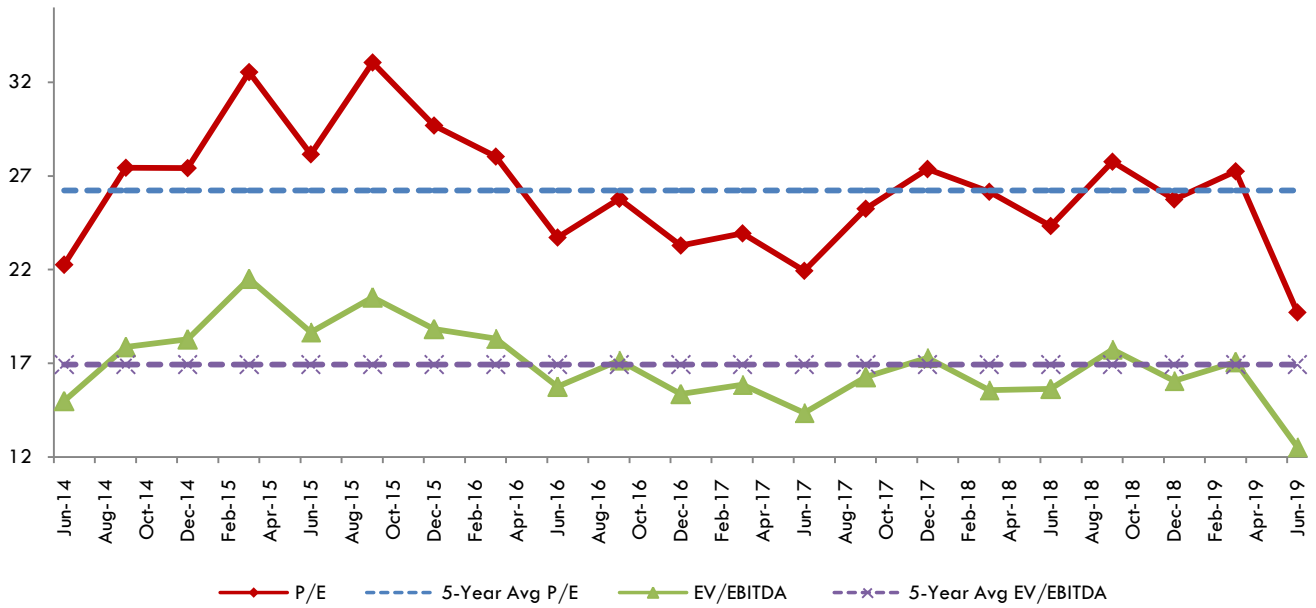
Source : Bloomberg

Pharma Valuation

			Sales CAGR(%)-FY19-21E	EBITDA CAGR(%)-FY19-21E	P/E(x)		EV/EBITDA (x)		EBITDA Margin in %		
Companies	**CMP**	**Mcap in Cr**			**FY20E**	**FY21E**	**FY20E**	**FY21E**	**FY19A**	**FY20E**	**FY21E**
Natco Pharma	530	9786	5%	4%	15	15	11	11	38%	39%	37%
Torrent	1529	26111	10%	13%	29	22	14	12	26%	26%	27%
IPCA	925	11789	13%	22%	21	17	14	11	18%	20%	21%
ALKEM	1682	20290	12%	23%	21	17	15	12	15%	17%	18%
Ajanta	955	8376	13%	15%	20	16	13	11	28%	28%	29%
Sun Pharma	403	95659	12%	18%	21	17	13	11	22%	23%	24%
Cipla	552	44868	12%	15%	24	20	13	11	19%	20%	21%
Dr Reddy's	2563	42831	12%	15%	20	17	12	10	22%	22%	23%
Lupin	764	34555	11%	18%	26	19	12	10	18%	19%	20%
Cadila	238	24391	8%	5%	14	13	10	10	23%	21%	21%
Biocon	248	30222	25%	33%	30	22	16	12	25%	27%	29%
Aurobindo	611	36268	19%	21%	12	11	8	7	21%	21%	21%
Glenmark	449	12768	12%	16%	14	11	8	7	16%	17%	18%

Source : Bloomberg

Nifty Pharma trading at ~25% discount to its 5-year average on P/E and EV/EBITDA



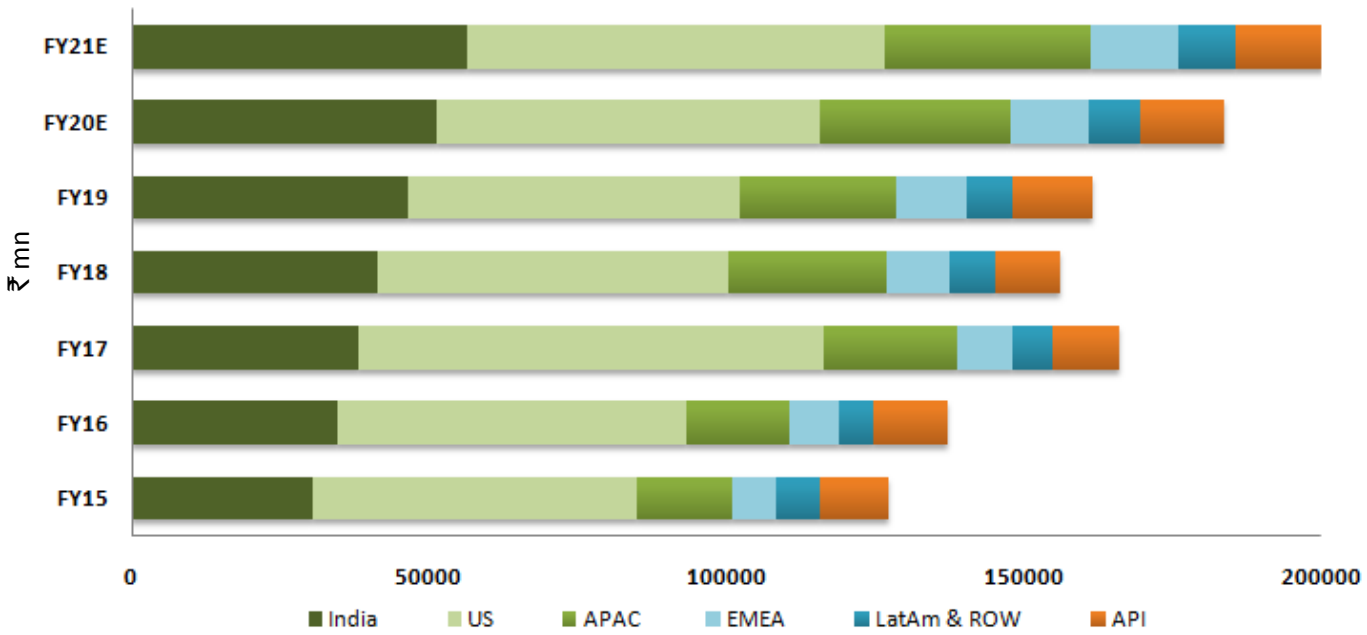
Lupin was founded in the year 1968 by Dr. Desh Bandhu Gupta. Lupin first gained recognition when it became one of the world's largest manufacturers of tuberculosis drugs. The company has always been able to adapt to business evolution. In the past, Lupin has transformed from a pure API to plain oral solids to complex generics player in the last few decades. Over the past years, Lupin has made an investment in expanding its presence globally through acquisitions of companies and brands. .

US and India are the largest markets for Lupin contributing ~64% of the total revenue while other regions like Japan, Brazil, Mexico, Africa, Europe, and Australia contribute to the rest. In the US market, Lupin ranks 5th amongst generic players with a market share of 5.3%. Domestic market growth has been balanced by higher volumes in existing brands and in-licensed product launches. Lupin's domestic business mix is skewed towards chronic therapies at ~70% of total sales which has ensured better visibility on prescriptions and possess higher margins.

Lupin has in-licensed ~27 products for domestic business.

During the year 2008-09, it entered the Japan market through the acquisition of Kyowa Pharmaceutical. In the past decade, Lupin has been able to build a successful business in Japan and has emerged as the only Indian firm to have cracked the market. Lupin stands among the top-10 generic companies in Japan and it has expanded its product offering through receiving approval or acquisition of brands.

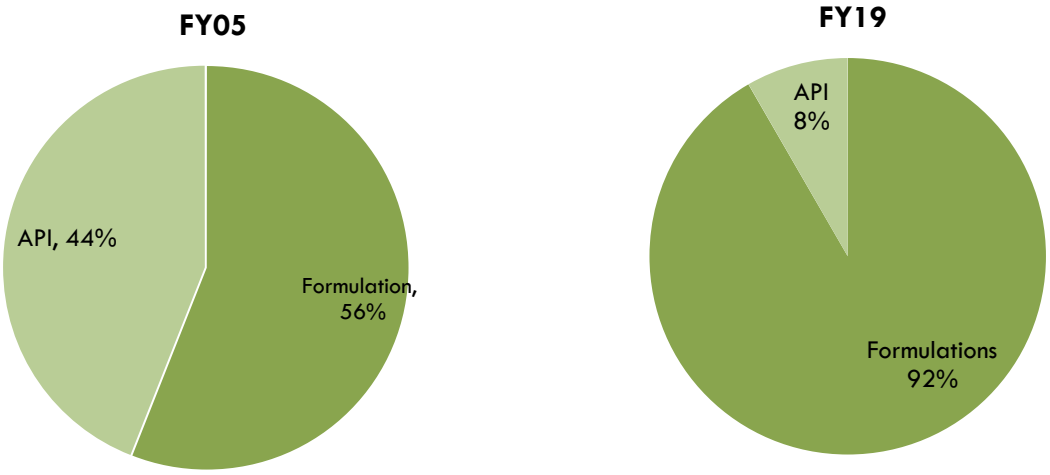
Revenue Details



Source : Company reports & Way2Wealth Research

Lupin has transformed from an API player to an formulation one

Lupin started its business in the year 1968 as an export-oriented API and later the company has scaled up the value chain by successful commercializing complex products globally. The company initially started making an investment in India in the acute portfolio and then moving to the chronic portfolio. Lupin entered the U.S. generic pharmaceutical market in 2003 with the ANDA approval for Cefuroxime Axetil Tablets. Currently, Lupin has become the leader in the US formulation space with a market share of 5.7% and ranks 4th in the generic space. Lupin has 157 ANDAs pending approval with 40 been FTF.



Lupin transformation from an domestic heavy player to a export oriented

The company started out as a domestic heavy player with initial investments in manufacturing antibiotics and anti-Tb drugs in India. The company entered the export market through its API business and later it went to file for its products in the US. Currently, ~74% of the revenue is generated from exports compared to ~48% in FY05. The growth of the export business is primarily due to numerous acquisitions and healthy growth in the US markets.

Source : Company reports & Way2Wealth Research

About the Company

US (35%) – Lupin is the 4th largest pharmaceutical player in the US by prescriptions. Lupin Pharmaceuticals is the marketing arm of the company in the US. The brand business contributes a small-pie of the total US sales .Gavis acquisition in 2016 was the key milestone for Lupin for the US market.

- Generics
- Branded business

India (27%) – India is the 2nd largest market for Lupin by revenue. The Company has built a strong chronic portfolio in the last decade accounting for 58% of the domestic revenues and Lupin ranks 2nd in generating revenues from newly launch products

- Chronic
- Acute

APAC (16%) – Japan stands out to be the key market for Lupin as it contributes 13% of global sales and 83% of the APAC region sales. Lupin has gained exposures in the APAC region mainly through a stream of acquisitions.

- Japan
- Australia
- Philippines

EMEA (7%) – EMEA covers European and Middle East region. The company has a presence in the top 5 European markets. At present, the cumulative filings for Europe stand at 62 with 59 approvals to date while in South Africa Lupin is no. 4 in the prescription generic market.

- Europe
- Africa

LATAM (5%) – Lupin's Brazilian subsidiary, Medquímica and Mexican drug maker Laboratories Grin were acquired in 2015 and 2014 respectively. Grin is the fourth largest pharmaceutical company in Mexico in the eye care segment.

- Brazil
- Mexico

API (8%) – Active Pharma Ingredient is entrenched in the foundation of Lupin and is a backbone to the organization. Lupin started its business as an API player and then moved up the value chain. Most of the APIs are used for captive consumption.

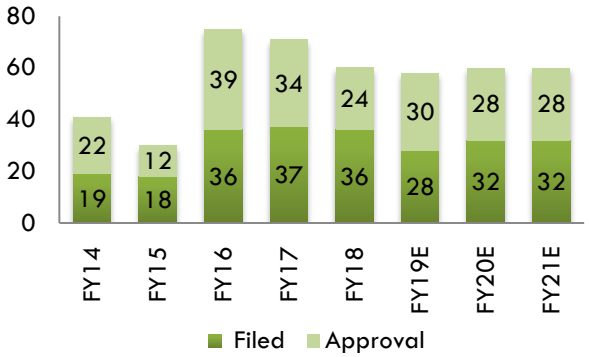
Investment Rationale

US business poised to bounce back after regulatory and pricing concerns.

Lupin's US business can be categorized into branded generics and plain vanilla generics. The latter contributes ~ 90% to the US revenue while the branded generic contributes only ~10%. Lupin's US business has witnessed CAGR of 12% over FY12-FY19 mainly attributed due to the implementation of GDUFA(Generic Drug User Fee Amendments) and ramp-up of branded business. Lupin holds a strong 4th position in the US market and has a market share of 5.7%. The company has been the market leader in 64 products and amongst the top 3 by market share for 111 products. Currently, Lupin has a total of 412 ANDAs filed with the USFDA out of which 154 are pending approval and 41 pending been FTF. The company has always aimed to file at least 20-25 ANDAs per year to maintain its US business momentum.

Recently, Lupin's US business has been adversely affected due to lack of approvals and warning letter status for its Goa and Indore facilities, higher than usual pricing pressure for its key products – Glumetza, Fortamet, and Suprax. In the last 9 quarters, US revenue has decreased ~43%, contribution to the total revenue has declined from 58% to 32% and margins have declined ~700-800 bps.

ANDA Filing and Approval trend in US

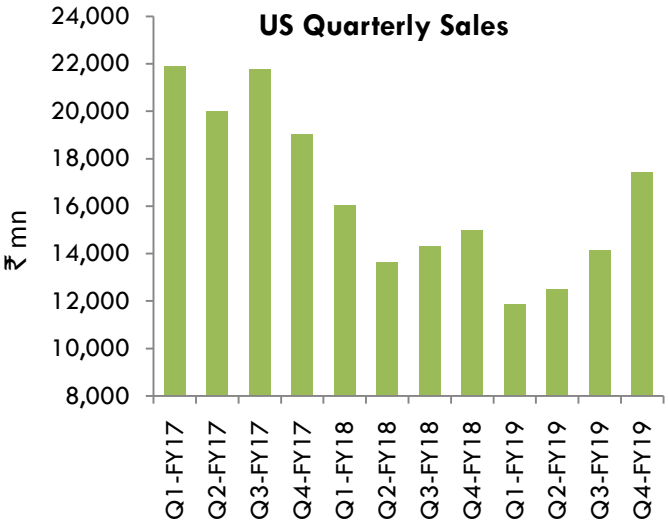


Key Milestone in the US market

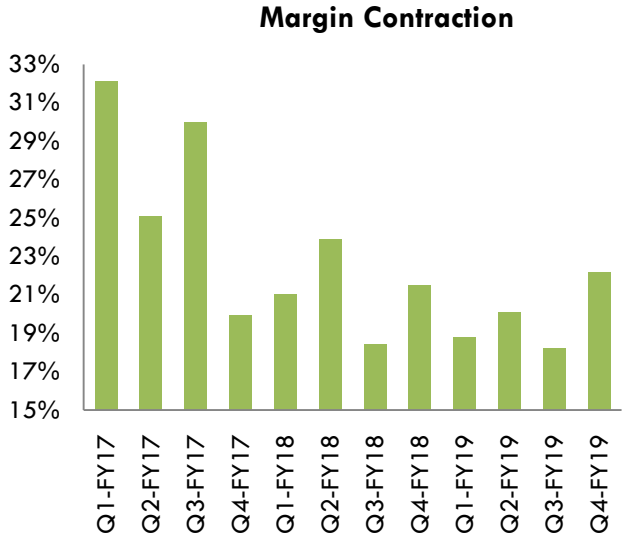
Date	Details
2003	Lupin Pharmaceuticals Inc. USA is formed for trading, marketing and developmental activities in the US
2005	Launches its Generics Business in the US with four products
2016	Acquires Gavis Pharma in New Jersey for $880Mn to expand its US presence. Gavis product pipeline consisted of dermatology, controlled substance products and other high-value and niche generics
2017	Acquires Symbiomix Therapeutics LLC in New Jersey -Lupin acquired Symbiomix for a cash consideration of $150 Mn, in a bid to expand its presence in the women's health segment.

Effect of US business derailment

US Quarterly Sales



Margin Contraction



Source : Company reports & Way2Wealth Research

What went wrong in the US market for Lupin

Warning letter for Goa and Indore Unit II

Lupin received a combined warning letter(WL) for its Goa and Indore (II) in Nov-17. These plants together had ~40-50 pending ANDAs filed with 25-30 launches lined up in FY18-19. These plants contributed ~50% of the U.S. sales and ~20 % of its total sales. The observations were related to quality control procedures that include handling of out-of-specification (OOS) results and conducting hold-time studies. The warning letter was a huge blow to the company as it delayed new approvals and further intensified pressure on the US business. The event not only impacted the growth factors but expenses also inched in the face of remedial cost.

Pricing pressure for key molecules

US is one of the largest markets for Lupin (39% of revenues in FY19). It's US business declined due to the unfavourable pricing environment because of the increase in the approval rate and consolidation in distributors & pharmacies and formation of buying consortiums. The company faced tough competition for its key molecules like Fortamet, Glumetza, Methergine, suprax and base business. The damage was so severe that its contribution from the US business declined to 33% (Q2FY19) of total sales versus 58% (Q1FY17) and its margins declined to 20% (Q2FY19) from 32% (Q1FY17).

Gavis acquisition, didn't not live up to its promise

Lupin acquired US-based Gavis in 2015 for $880Mn to expand its US portfolio, especially pain management drugs (controlled substances) and get a manufacturing base in the US. The payment also included IPs for currently marketed products, ANDAs filed, products under R&D, fixed assets, working capital and goodwill on the acquisition. The acquisition helped Lupin to diversify its product basket but Lupin had made an expensive deal. In FY18, the company took an impairment hit of ₹1464.3 Cr on account of Gavis that is ~25% of its acquisition value in FY18. The impairment was mainly due to.

i. *significant pricing pressure leading to greater price reductions,*
ii. *countermeasures against usage of opioids in the United States and*
iii. *Slow pace of approvals*

Recent acquisition deals

Target	Acquirer	Amount ($Mn)	Deal Date	EV/Sales x
Gavis Pharma	***Lupin***	***880***	***Jul-15***	***9x***
Sandoz	Aurobindo	1000	Sep-18	1x
Actavis	Intas	767	Oct-16	2x
Betapharm	Dr. Reddy	572	Feb-06	2x
Medpro	Cipla	512	Feb-13	2.9x
Invagen	Cipla	550	Feb-16	2.5x
Ranabxy	Sunpharma	3200	Apr-14	2.2x

Factors leading to bounce back in the US market

Regulatory hurdles to ease

Lupin received a combined warning letter in November-2017 for its Goa and Pithampur(II) facility. The warning letter affected approvals of ~25-30 products that were about to be launched in FY18 and FY19 from these facilities. The incident further created a hurdle for the US business, which was already facing pricing pressure in their base business. To limit the potential damage to US sales Lupin identified about a dozen key products for site transfers including the much anticipated generic Ranexa. We believe the situation for Lupin is better as the observations didn't pertain to data integrity or product contamination, which historically were the sole principles by USFDA for issuing warning letters or import alerts. Lupins observation mainly pertained to Out-of-Specification (OOS) results and review of hold time studies were we see a low probability of issues escalating to an import alert. Recently, both the facilities were again inspected and the regulator has again raised concerns. However, we believe the company would be able to resolve the issue by 2HFY20E for both the facilities and get things back on track and start getting approvals.

Lupin had ~ 50 products filed with the US FDA from these two plants and this warning letter impacted approvals of 25-30 products which were expected in FY18 and FY19

Ramping of branded business, Solosec holds the key now

The company began its branded generic business by launching Suprax in 2004. The company has indicated that it is changing its priorities from being a pure generic player to building a branded product portfolio as these products usually command a high margin. After a declining trend of branded business in FY16, Lupin introduced two products from the GAVIS portfolio (Methergine and Methylphenidate) that contributed ~$44mn to the branded business in FY17. Lupin has strengthened its branded business by acquisition of Symbiomix Therapeutics that will help to expand its branded Women's Health specialty business in the U.S by launching key product Solosec. The company is currently in the investment stage for the product and is building on its existing sales force to ramp up its sales. Solosec will hold the key now for the branded portfolio as other products like Methergine and Suprax are facing competition. We believe near term trigger for branded business would be ramping up of Solosec and the company expects peak sales of $100 Mn for the same in the next few years.

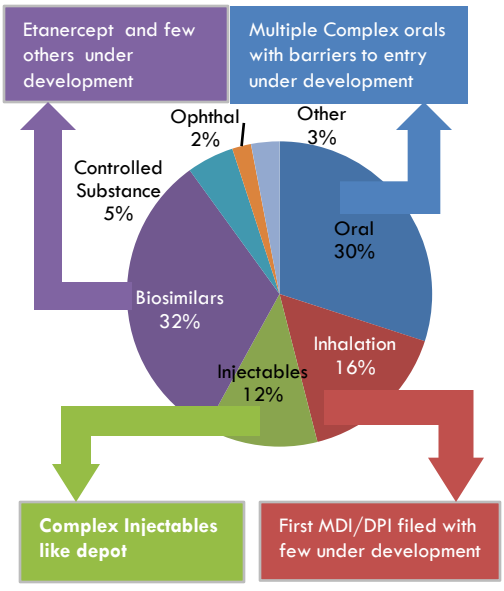
Solosec has been designated a Qualified Infectious Disease Product (QIDP) by the USFDA, which makes it eligible for at least 10 years of exclusivity in the U.S

Key Milestones in US Branded Business

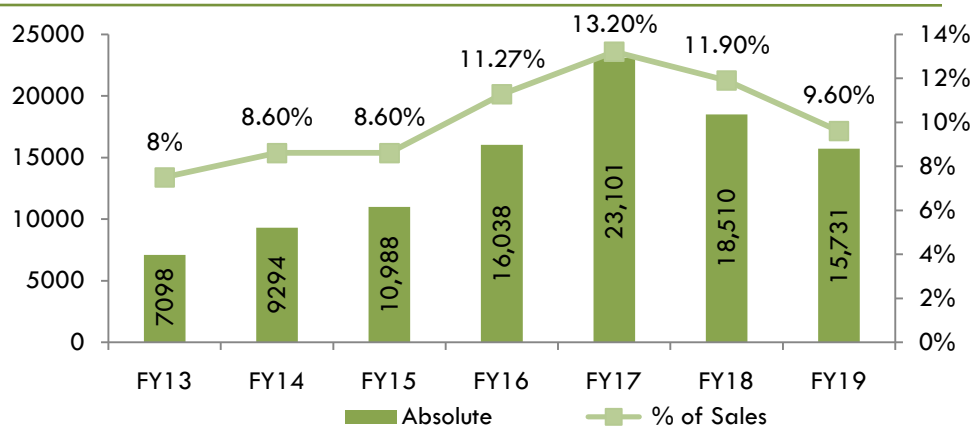
Feb-04	Suprax (Cefixime) – Suprax was the first branded product launched by Lupin in the US market. Lupin acquired Suprax promotion rights in 2004 after it was taken off the market by drug manufacturer Wyeth after its patent expired. Market size for Suprax is USD ~120-130Mn. Aurobindo launched its generic version in the year 2015.
Jun-09	AllerNaze(triamcinolone) – Lupin acquired acquisition of worldwide rights for AllerNaze from Collegium Pharma.It is used for with allergic rhinitis. This was Lupin's first New Drug Application acquisition
Aug-13	Alinia (nitazoxanide) :- Acquired Exclusive US Rights to Alinia® for Oral Suspension from Romark Laboratoriesin Aug 2013.Patent has already expired for the product but no generic players yet.
Oct-13	Antara(fenofibrate) – In 2009, Lupin had bought Antara from Oscient Pharma, which had filed for bankruptcy. It paid about ₹185 Cr for the product.Currently, there are multiple generic players in the market.
Feb-15	Valved Holding Chamber (VHC) – Lupin entered agreement with InspiRX Inc to exclusive rights to promote, distribute and market InspiraChamber VHC in the United States.The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers (pMDIs)
4-Jun-18	Methergine (Methylergonovine Maleate)- Lupin entered an agreement with InspiRX Inc to exclusive rights to promote, distribute and market InspiraChamber VHC in the United States. The device is intended to be used by these patients to administer aerosolized medication from most pressurized Metered Dose Inhalers (pMDIs)
31-May-18	Solosec – Lupin launched Solosec from Symbiomix acquired portfolio. Management expects $100 Mn peak sales in the next four years. Lupin will have 10 years exclusivity. It is the first antibiotic pill in the market in more than a decade to treat bacterial vaginosis (BV) – the most common vaginal infection in the US among women of childbearing age.
FY18	Ritalin-(Methylphenidate) – Lupin launched Ritalin from Gavis acquired portfolio. Ritalin is a highly commoditized product now with multiple generics players already in the market

R&D investments to provide long term sustainability to profit and growth

Lupin has multiple projects in the pipeline that has lead to R & D spends increasing substantially from 7.5% of sales in FY13 to 11.71% in FY18 and 9.6% in FY19. (14% CAGR over FY13-19 on an absolute basis). Lupin is one of the few Indian companies that has invested heavily towards R & D to create a strong product pipeline to maintain growth as the generic business can become overcrowded. The company is in the stage to evolved its product pipeline from an oral solid to a complex generic player. Lupin has invested most of its funds in creating complex products like respiratory, injectables, ophthalmic, dermatology, biosimilars and novel molecules. The company has 10 molecules that are under the development stage from various therapy like oncology, derma and ophthalmology. Recently, the company has out-licensed one its novel Hematological Cancers molecule MALT1 (Mucosa-Associated Lymphoid Tissue Lymphoma Translocation Protein 1) to Abbvie for a US$ 947 million milestone payment and a double-digit royalty fees upon commercialization. Lupin's Product portfolio is poised for a change and investment from these initiatives will aid profit and growth in the long term.



Lupin's R&D spend trend



Source : Company reports

Near term launches , ramping up of existing portfolio, and First-to-File(FTF) pipeline to lead US growth.

In the near term, we expect growth to kick in from 2HFY20E as Lupin is likely to see an uptick in the US business led by key launches like ProAir, and ramp up of Levothyroxine, Ranexa , and Solosec .We believe the company has managed to create a decent pipeline of products where Lupin will be in the first wave of generics and create significant value. We see near term benefit from these launches they will help US business to get back on track.

Few FTF Fillings

Plaintiff	Molecule	Brand name
Keryx Biopharma	Ferric Citrate	AURYXIA
Boehringer Ingelheim	Tiotropium bromid	SPIRIVA
Taro	desoximetasone	Topicort
RENAL PHARMA	sucroferric oxyhydroxide chewable	VELPHORO
MAYNE PHARMA	doxycycline hyclate delayed	DORYX
ENDO PHARMA	cyanocobalamin	Nascobal
ANACOR PHARMA	TAVABOROLE TOPICAL SOLUTION	Kerydin
VALEANT PHARMA	efinaconazole topical solution	Jublia
Lundbeck / Takeda	vortioxetine hydrobromide.	TRINTELLIX
Jazz Pharma	GAMMA HYDROXYBUTYRATE WITH MONOCARBOXYLATE	XYREM
SUNOVION PHARMA	Eslicarbazepine Acetate	APTIOM
Eli Lilly	Tadalafil	Cialis
Sunpharma	bromfenac ophthalmic solution	Bromsite

Source : USFDA

We expect US business to bounce back after reporting muted revenue in FY19 because of several reasons. We pencil in an 12% CAGR over FY19-FY21E for the US business led by the launch of complex limited competition products, and ramping up of the existing portfolio.

Inhalers Pipeline

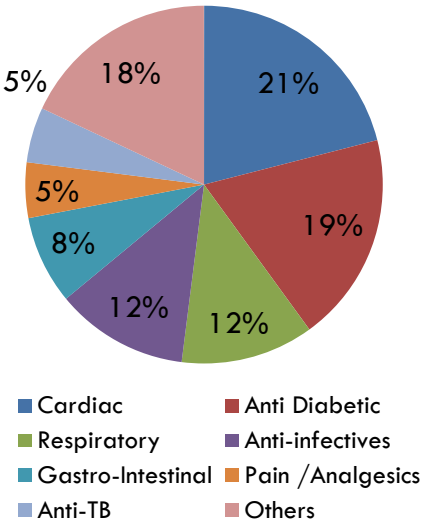
Brand	Market Size in US	Lupin Status & Other Details
Advair(DPI) (fluticasone /salmeterol)	$2.5Bn	Lupin is in early-stage development for this product. Cipla has also initiated the clinical trial for Advair and is expected to file for the product in FY20. Currently, GSK and Mylan have launched a generic version of the drug. With Advair one of the top-selling products in the US, its opportunity remains huge for Lupin if it is able to launch early.
Proair (Albuterol)	$1.2 Bn	Lupin & Cipla both had received CRL for the product and they have responded to it. We expect Lupin & Cipla to launch the product in FY20E. Albuterol is available with a different brand name such as ProAir HFA, ProAir RespiClick, Proventil HFA, Ventolin HFA.
Spiriva (Tiotropium bromide)	$1.9Bn	Lupin had filed for the generic launch of the product but the company has 30-month stay. Lupin will not be able to launch the product before 30 months or unless patent settlement. Lupin is the FTF holder for the product.

Biosimilars Pipeline

Brand	Market Size in US	Lupin Status & Other Details
Etanercept (Enbrel)	$11Bn	Lupin has already received approval Japanese market in March 2019 while approval from European Medicines Agency (EMA)is still awaited. In Europe, Enbrel biosimilars from Sandoz (Erelzi), and Samsung Bioepis (Benepali) are already on the market since Feb '16 while in the US Amgen claims patent to expire in 2029.
Ranibizumab (Lucentis)	US of $1.5Bn	Lupin has started its clinical trial for the product and currently its in Phase 1. The patent is set to expire in the US market in 2020 while 2022 in Europe. Formycon and its commercialization partner bioeq have positioned themselves for the potential launch in 2020
Pegfilgrastim (Neulasta)	US$4.7 Bn in 2016	Lupin is at the early stage of the product development while Mylan/Biocon has already launched the product in the US. Players like Sandoz and Coherus are also in pursuit.

Indian formulation business to report above market growth rate

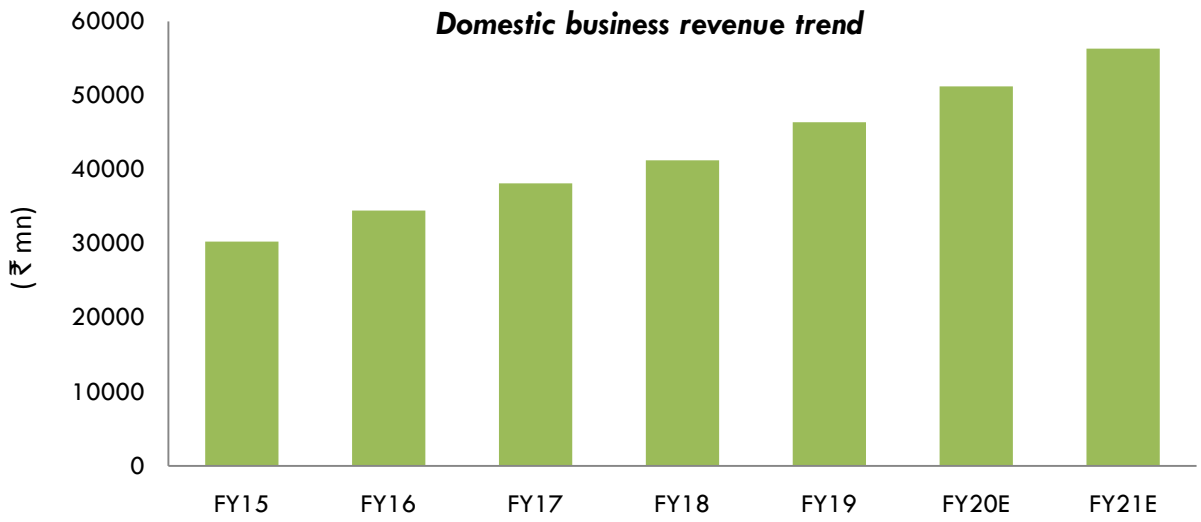
Lupin has a strong position in the domestic market, ranking fifth in terms of sales and has a market share of 3.5 %. The Chronic segment accounts for ~70% of domestic revenue with significant contribution from therapies like Cardiac, Diabetes, CNS, and Respiratory. In FY06, Lupin was an acute heavy portfolio with dependence on the anti-TB portfolio. However, the company changed its strategy and started focusing on the chronic segment which is a high margin and growth driven segment. The Company has successful brands like Gluconorm, Huminsulin, and Budamate. Lupin domestic portfolio is well diversified as only ~21 % of business is generated from the top 10 brands while its peers depend on ~ 25-30% from their top 10 brands..



India is one of the core markets for Lupin with the second highest (40%) contribution to the total revenue. The company's domestic business has witnessed a CAGR of 13.4% over FY12-FY19. The growth was primarily driven by Lupin' transformation from an acute player to a chronic one, the launch of new products and license deals. We believe Lupin's domestic business will continue to outperform IPM and report CAGR of 10% over FY19-21E led by new launches and in-license deals.

Proportion of revenues from Acute and Chronic Therapies		
	Acute Therapies	Chronic Therapies
FY12	34%	66%
FY19	30%	70%

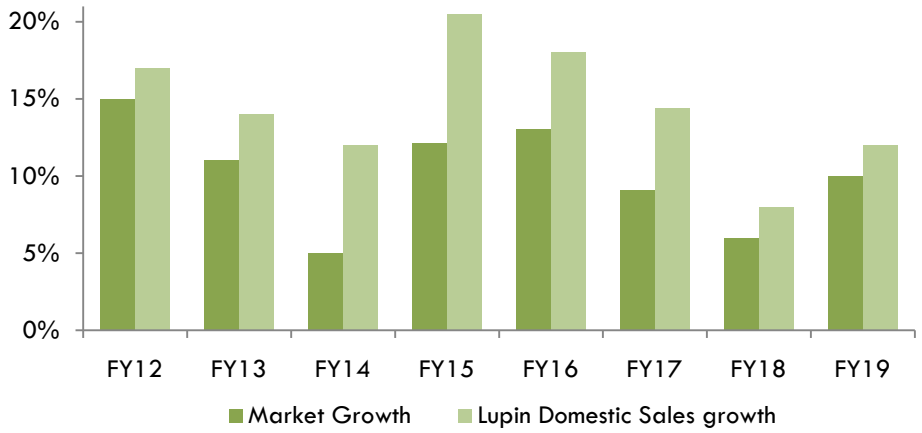
Lupin ranks 2nd in revenues from new product introductions



Chronic focus, new therapy, more license deals to drive domestic growth

Lupin has always grown faster than the market and improved its ranking in the domestic market in the last few years. Lupin's success has mainly been driven due to shifting from acute to chronic and semi-chronic therapy segments, expanding alliances and increasing MR strength.

Lupin's Domestic Business Growth Vs Market Growth



Lupin generates ~17-18% domestic business from in-licensing deals.

We expect Lupin to maintain its growth rate driven by expansion of its product offering through in-licensing agreements and entering into new therapies.

- **Consolidating Chronic segment** – Lupin will continue its focus on the chronic segment as it is a key growth driver in India and offers high margins than an acute segment. It will also focus on the top 3 therapies and try to gain further market share in the chronic segment .
- **Entering new therapy** – The company plans to expand its product portfolio by entering into new therapies like dermatology, Oncology, Ophthalmology etc.
- **More in-licensed deal** – Lupin has the highest number of in-license deals compared to any other company for the Indian market. The in-licensing strategy is crucial for the domestic market where the new product pipeline is drying up and innovation cost may not be covered.

~23% of Lupin's Domestic Portfolio under NLEM

The key risk to domestic market growth will be addition of molecule under NLEM, ban on FDC by the Government and impact of high base.

Lupin's APAC business stood at 16% of Lupin's total sales, and it has stepped up acquisitions over the last decade in the APAC region with a focus on building the international business. The company has a presence in Japan, Australia, and the Philippines with Japan been the most important accounting ~80% for the APAC region. Lupin's APAC region revenue has increased at a CAGR of 13% over the past four years on account of successful brand acquisitions, new approvals and in-license of products. Lupin has been a key beneficiary of the Japanese Government initiative to increase generic penetration.

Japan

Entered Japan in 2005 through a tie-up with Kyowa and later in 2007 went on to acquire the company. Lupin has also expanded its revenue by 10 times from JPY 18 billion to JPY 180 billion in the past 10 years. Japan generates nearly 83% of the APAC region wise.

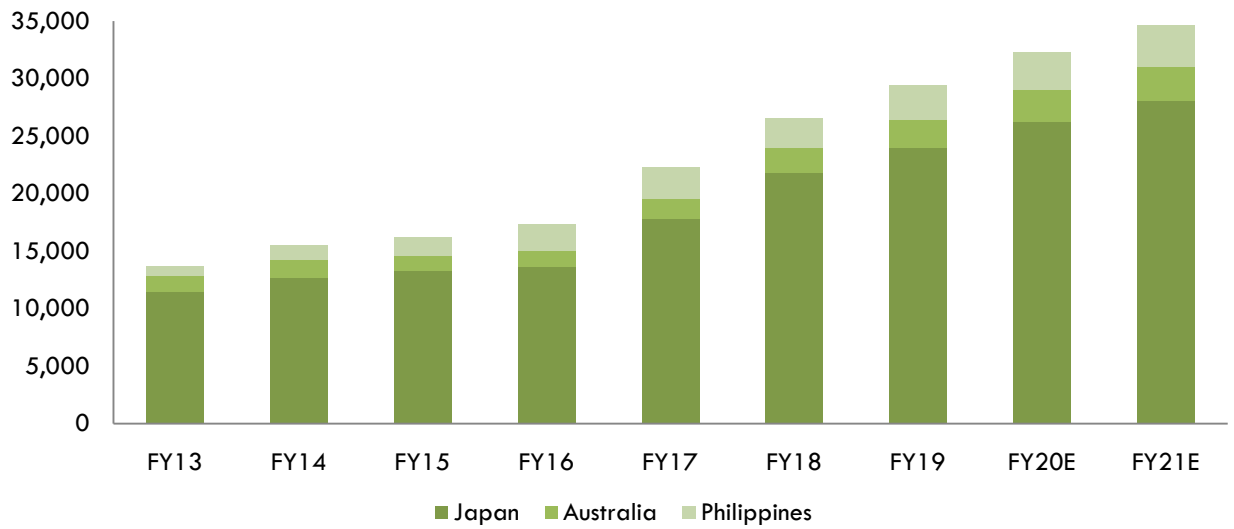
Australia

Lupin secured a strategic investment in Generic Health in 2005,with the aim to break into the Australian market by supplying its range of products to Australia and later in 2010 Lupin acquired majority stake in the company.

Philippines

Lupin acquired stake in MultiCare Pharmaceuticals in 2009. MultiCare is the 19th largest pharmaceutical player in the Philippines and ranks 4th amongst branded generic players .

APAC Region Revenue Trend



Source : Company reports & Way2Wealth Research

Japan is the second–largest pharma market in the world with market size of ~US80Bn. Lupin entered Japan in the year 2005 through a tie-up with Kyowa for product development and manufacturing, but after a few years, Lupin went to acquire Kyowa. Currently, Lupin ranks sixth among generic companies in Japan.

Revenue in the regions has increased at the CAGR of 15% over FY07–FY19 with launch of new products ,licensing deals and brand acquisitions.

In early 2000, Japan has had a weak market share of generic of ~30-33% (72% in the USA, 65% in England, and 63% in Germany).The weak share of generic was mainly because of factors like uncertain quality of the generic drugs, pharmacists were not allowed to substitute generic drugs, and patients were not sensitive to the cost of drugs.

Japan has been known for having the world's oldest population and highest debt-to-GDP ratios. Japan's public budget has been under stress as the ultimate healthcare cost is borne by the Government. The Government in the last decade has taken various measures to reduce the bill by increasing the generic penetration in the country. The government started its initiative of the Economic and Fiscal Reform of 2007 where the government set the goal to double the dispensing rate of generics in volume, pharmacist's discretion in generic substitution, and financial incentives for pharmacies and going ahead pharmaceutical pricing revision process to occur annually instead of biennially.

In 2013, the regulator announced a 5-year plan to expand the use of generic drugs to over 60% by 2018

Key Milestones in Japan

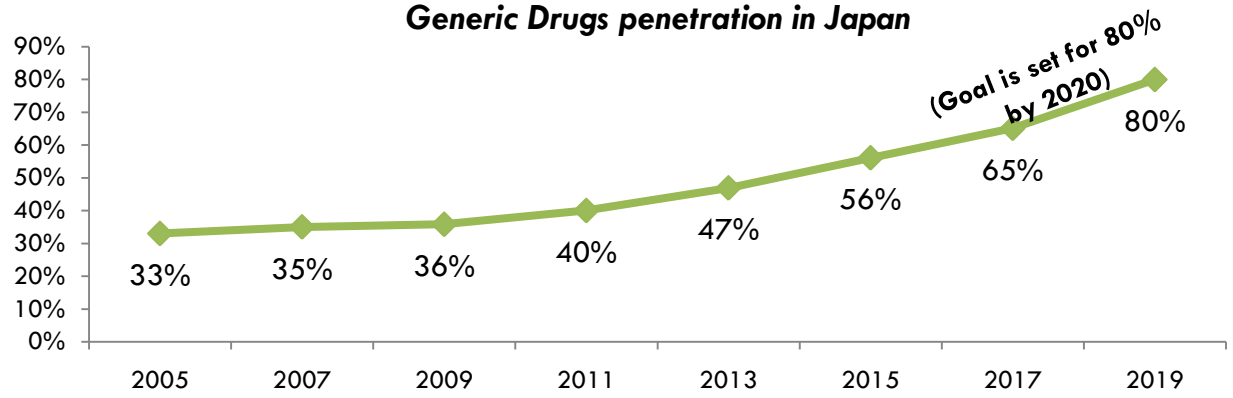
Date	Details
2005	Entered Japan through a tie-up with Kyowa – Lupin undertook product development and manufacture whereas Kyowa was responsible for obtaining regulatory approvals and marketing in Japan.
2007	Acquired Kyowa – Kyowa had a sales of ¥ 7.4 Bn for the year ended and a rich product portfolio in the Psychiatry and Neurological therapeutic categories as well as in cardiovascular, respiratory & allergies, and digestive system.
2011	Acquired Injectables company from Pharmaceutical (IP) – IP is a specialty injectables company. For the fiscal year 2011, IP recorded sales revenues of JPY 5,361 Mn. IP has a significant presence in the DPC(Diagnosis Procedure Combination)hospitals within Japan and Injectable products enjoy a significant usage in the DPC Hospital segment
2014	Formed JV with Yoshindo – Jv was formed for clinical development of biosimilars and handle regulatory filings in Japan
2016	Acquires branded product from Shionogi – Acquired 21 long-listed products. These products cover therapy areas such as CNS, Oncology, Cardiovascular, and Anti-infectives. Sales from these products were JPY 9, 400 Mn (USD 90Mn). This acquisition marked Lupin's foray into the Japanese branded market.
2017	Astellas and Lupin entered into an agreement providing Kyowa the exclusive right to distribute and promote extended-release tablets of quetiapine fumarate in Japan
2019	Received an approval to manufacture and sell their biosimilar Etanercept in Japan.

Next leg of growth in Japan to be lead by specialty and biosimilars

During the last decade, Lupin has benefited from the Government's focus to increase generic penetration in Japan. The company has expanded its portfolio led by approvals and acquisition of brands. We expect generic penetration to settle down and generic makers to face pricing pressure as the government plans to review prices annually from 2020(currently biannual) and this may affect mature products. We expect the next leg of opportunity in Japan that will be lead by specialty and biosimilars products.

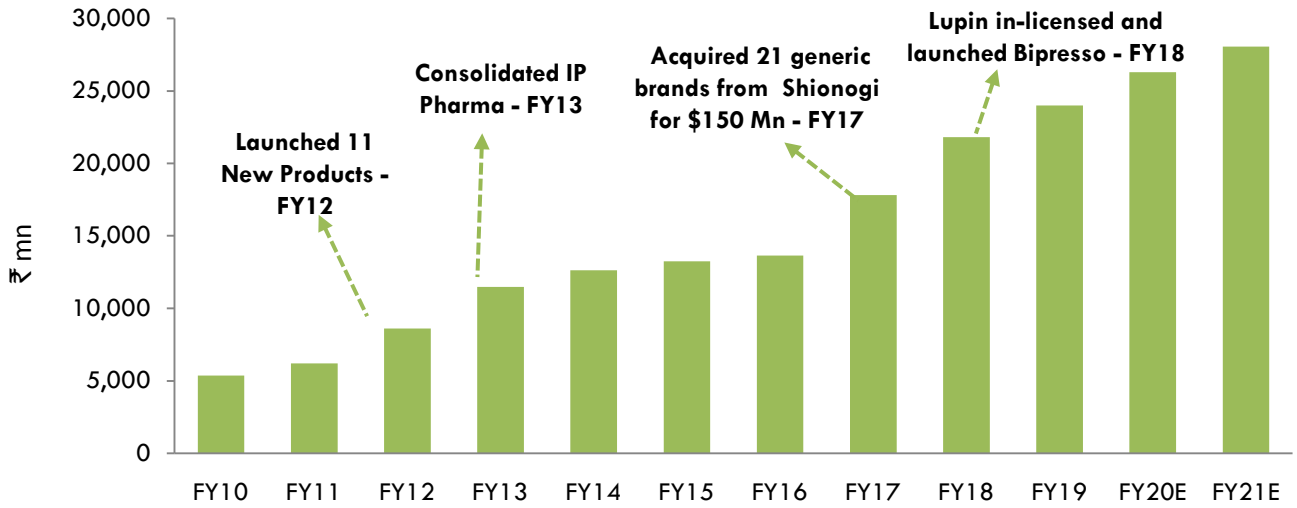
Regulator has a intention to increased the generic penetration to 80%

Generic Drugs penetration in Japan



Lupin has modernized its product offering in Japan frequently. The company's addition of Shionogi brands marked Lupin's foray into the Japanese branded market. With the recent launch of Bipresso and potential launch of the biosimilar, Etanercept lined over the next few months, and Shinogi acquired products would be the key triggers in Japan. We estimate a CAGR of 8% over FY19-FY21E for Japan with the contribution of Etanercept starting from 2HFY20E.

Specialty products to drive Japan going ahead



Source : Company reports & Way2Wealth Research

APAC (EX-Japan)

Lupin entered Australia and the Philippines market through acquisition in the year 2009 and 2010. Its Australian unit(Generic Health) is the 5th largest company by sales in Australia and has witnessed a CAGR of 10% in revenues since acquisition. Lupin has been able to turn around this loss-making unit and it is growing faster than the market.

Australian pharmaceutical market was valued at $13 billion in 2017 with generics accounting for over 30 % of the sales volume

Philippines (Multicare Pharma) division has also witnessed a multifold increase in revenue since acquisition and ranks 4th amongst branded generic players. The company expects its Australian and Philippines business to maintain its growth trajectory and also expand its presence in other regions such as Malaysia, Thailand, Myanmar, and China. Company guides to generate $100 million in sales from non-Japanese APAC markets but we have been a bit conservative in our estimate and penciled in CARG of 10% for APAC(Ex-Japan) over FY19-FY21E as other Indian companies can also enter this region.

MultiCare has a strong presence in Diabetes, Women's Health, Paediatrics, Respiratory, Central Nervous System and Oncology.

EMEA & LATAM

EMEA(Europe & Africa) and LATAM (Brazil & Mexico) combined contributes 12% to the total revenue. The company has made a significant investment in the past years in these regions to expand its footprint. Lupin has mainly acquired companies or brands to expand its business in these regions. The company has been mostly able to turnaround its acquired assets and deliver incremental growth with the only exception being Brazil Unit (Medquimica).In Europe, the growth will be led by launching its biosimilars and Temmler acquired specialty portfolio.

Approved first specialty product NaMuscla in Europe

Currently, Lupin has already filed etanercept in Europe, and also plans to launch in other regions like Australia, New Zealand, LatAm, Africa through its partner Mylan. The company also plans to launch its other biosimilar product Ranibizumab by 2022 in Europe. In the past over FY15-FY19 EMEA and LATAM have reported a CAGR of 12% and 2% on the back of volume growth and new launches. However going ahead, we estimate CAGR of 12% for EMEA and 10% for LATAM over FY19-FY21E.

Investment Risk

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Late entrant in the Biosimilar space

The global biosimilar market is currently valued at ~ USD4-5bn.In the recent past, major Indian companies have invested heavily in this space. However, we remain cautious on biosimilar launch by Indian companies given the fact that they have been late entrants and are way behind global leaders like Pfizer, Sandoz, and Roche. In the biosimilar space, we are given to understand that each of the top 10 molecules is been actively chased by ~7 players, thereby intense rivalry is expected and late entrants could end up with small market share.

Total of 20 biosimilars for 9 different reference products has been approved till date. This includes at least one biosimilar for each of these top selling biological drugs in the US

Delay in resolution of Goa and Indore facilities

The time frame for the resolution of warning letter has been long and can be a challenging task for the companies. It has been seen in the past that the concern related to the WLs are not easy to resolve and it can take a few years. The resolution can result in additional cost such as the hiring of an external consultant. We expect the company to get its resolution for the two facilities till 2HFY20E but the delay in resolution or escalation to import alert can impact earnings negatively.

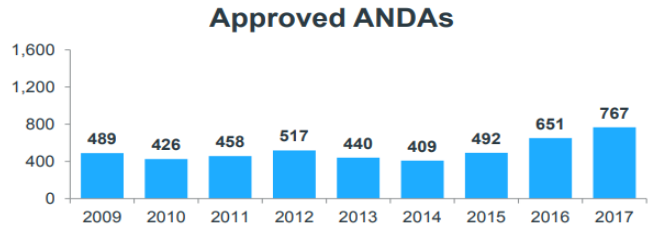
Warning Letter for Goa and Pithampur Unit II facilities clearly pointed there are no data integrity concerns

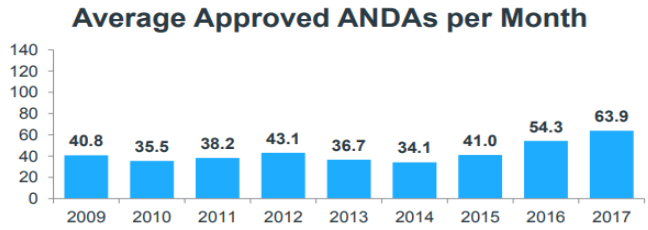
Status of companies which received warning letter in the past

	Date of WL	Days Diff	Status of the Plant
Sunpharma Halaol (Halol Unit)	9-Dec-15	916	WL lifted
Cadila (Moraiya unit)	5-Sep-14	672	WL lifted
Dr. Reddy's Laboratories(Duvvada in Visakhapatnam)	5-Nov-15	1200	WL lifted
Dr. Reddy's Laboratories(API plant located in Srikakulam)	5-Nov-15	1328	Still Not resolved
Lupin Goa & Indore	16-Nov-17	586	Still Not resolved
Mylan Laboratories Limited(Nashik)	8-Jun-15	1162	WL lifted

Greater than expected generic competition

The number of generics approved is a key determinant of generic drug pricing. Implementation of GDUFA and consolidation among buyers has led to an increase in approval rate and pricing pressure. With Donald Trump and FDA still aiming to reduce drug prices and increase the rate of approval, the environment for generic companies can get challenging if the speed of approval increases.





ource: GDUFA Approvals Dec 2017

Domestic Government push towards use of generic names for prescription

Lupin generates 29% of the total revenue from its domestic business. Prime Minister has indicated a few times towards making a law which will require doctors to prescribe medicines by their generic/salt names with an aim to reduce health care expenses significantly. With branded drugs making up to 90% of the Indian market, this move might have some destructive effect on the industry. If implemented branded generic players like Lupin and other domestic players will be significantly impacted as there is a big difference in the pricing of a branded generic and generic.

Delay in monetization of complex products

We believe there could be a material risk to Lupin's US business if there is a delay in the launch of complex products. Some of the complex products are required to conduct full clinical trials to prove bioequivalence. For instance, leading pharma companies Mylan and Teva have received Complete Response letter(CRLs) for Advair which delayed the launch. The timely launch of complex products would be a key trigger for the company when the US business is facing competition and pricing pressure. Any delay in the launch for the same would be a risk to our investment thesis.

Unable to scale up its branded business

Lupin has built its branded business mainly through acquisition route. The branded business has been witnessing immense competition from its competitors for its largest products like Suprax, and Methergine. Acquisition of Symbiomix's Solosec has helped Lupin to expand its product offering but the product is still in its promotional stage and has been not able to meet its own sales expectation. Delay in ramp-up could further negatively impact Lupin's earnings

Adverse currency movement

Lupin earns a significant amount of revenue from export as it has exposure to many countries around the globe. INR appreciation against other markets currency can hamper revenue and profitability in rupee terms. We estimate that the company profits would decline by ~₹360mn for 1% appreciation of the rupee.

Revenue Mix	FY19	CAGR FY15-FY19	CAGR FY19-FY21E	Details
India	46383	11%	10%	Indian business is expected to grow at above domestic market growth rate as witnessed in the past. Focus on chronic segment and in-licensed deals will drive growth.
US	55925	1%	12%	US business to be back on track from FY20E on account of price stabilization and new complex products launches(inhalers, injectables). Pick up in product approvals after the resolution of Indore and goa facilities. Solosec ramp-up will hold the key to drive branded business after its top products (Suprax and Methergine) facing competition.
APAC	26113	13%	15%	APAC region growth will be mainly dependent on the development of Japan's business and launch of Enbrel
EMEA	11906	12%	12%	Performance of NaMuscula and Temmler products are the growth driver for Lupin in this region
LatAm & ROW	7799	2%	10%	ROW business to grow at a healthy rate of 10%
Total Formulations	**148126**	**6%**	**12%**	**Estimate sales to report a CAGR of 12 % over F19-FY21E mainly on account of US business getting back on track and domestic formulation repeating its historical growth rate**
API	13464	4%	5%	API growth to remain subdued ,as most of the APIs are used for its own consumption
Total Revenue from Operations	**161590**	6%	11%	

(₹mn)

Income Statement	FY15	FY16	FY17	FY18	FY19	FY20E	FY21E
Net sales	**127700**	**142250**	**174943**	**158041**	**167182**	**185594**	**202169**
Growth (%)		11%	23%	-10%	6%	11%	9%
Raw Material	41,570	43,326	50,014	52,744	58,458	61,246	66,716
Total Expense	95949	111168	140659	139469	152288	164854	174918
EBITDA	**38,593**	**38,400**	**45,996**	**32,978**	**32,462**	**37,191**	**44,466**
Growth (%)		-1%	20%	-28%	-2%	15%	20%
Depreciation	4,347	4,871	9,122	10,859	10,850	12,182	12,987
EBIT	**34246**	**33528**	**36874**	**22119**	**21612**	**25009**	**31480**
Finance cost	98	595	1,525	2,044	3,078	3,269	3,229
Profit before tax	34148	32983	35431	5467	15172	21740	28251
Tax	9705	10593	9785	2885	9017	6739	9040
Profit / (Loss) for the period	**24443**	**22389**	**25646**	**2583**	**6155**	**15001**	**19211**
EPS	**53.23**	**49.39**	**56.64**	**31.00**	**21.00**	**33.19**	**42.50**

(₹mn)

Balance Sheet	FY15	FY16	FY17	FY18	FY19	FY20E	FY21E
Share capital	**899**	**901**	**903**	**904**	**905**	**905**	**905**
Reserves & surplus	91,074	1,11,053	1,34,418	1,35,267	1,36,986	1,49,603	1,65,806
Shareholders' funds	91,973	1,11,955	1,35,321	1,36,171	1,37,891	1,50,508	1,66,711
Non-current liablities	6,004	63,682	69,546	75,927	80,304	79,804	78,804
Long-term borrowings	1,018	53,739	56,478	64,245	66,417	65,917	64,917
Other non-current liabilities	4,985	9,943	13,068	11,682	13,887	13,887	13,887
Current liabilities	**34,633**	**50,612**	**61,206**	**50,956**	**61,299**	**64,842**	**67,390**
Borrowings	3,692	17,454	23,043	4,518	15,802	15,802	15,802
Trade Payable	17,877	19,888	25,889	25,754	24,982	28,526	31,073
Other Current Liabilities	13,064	13,269	12,274	20,684	20,515	20,515	20,515
Total (Equity and Liabilities)	**1,32,610**	**2,26,249**	**2,66,073**	**2,63,054**	**2,79,494**	**2,95,154**	**3,12,905**
Non-current assets	54,570	1,27,375	1,46,531	1,40,958	1,40,958	1,43,776	1,43,789
Fixed assets (Net block)	26,271	33,492	46,363	49,074	49,115	51,933	51,947
CWIP	5,197	9,812	7,150	9,563	10,186	10,186	10,186
Intangible Assest	17,745	70,890	78,147	71,176	68,215	68,215	68,215
Other non-current assets	5,357	13,181	14,871	11,146	13,442	13,442	13,442
Current assets	**78,040**	**98,874**	**1,19,542**	**1,22,009**	**1,38,536**	**1,51,378**	**1,69,116**
Cash & current investment	4,413	7,927	6,818	13,941	5,722	404	8,495
Inventories	25,036	32,737	36,423	36,625	38,368	44,466	48,437
Trade Receivables	26,475	45,488	43,073	51,922	51,498	63,560	69,236
Other Current Assets	22,116	12,723	33,227	19,521	42,948	42,948	42,948
Total (Assets)	**1,32,610**	**2,26,249**	**2,66,073**	**2,62,968**	**2,79,494**	**2,95,154**	**3,12,905**

Cash flow and Ratios

(₹mn)

Cash Flow Statement	FY15	FY16	FY17	FY18	FY19	FY20E	FY21E
Profit before tax	**34148**	**33288**	**35431**	**5468**	**15172**	**21740**	**28251**
Depreciation	4347	4871	9122	10859	10850	12182	12987
Finance Cost	98	595	1525	2044	3078	3269	3229
Others	-878	388	1500	14920	-11893	0	0
Operating Cash flows before WC	**37716**	**39142**	**47579**	**33290**	**17207**	**37191**	**44466**
Change in Working capital	-1378	-23089	3358	-8992	-2091	-14617	-7100
Total tax paid	-9436	-11701	-11490	-5584	-9017	-6739	-9040
Others	155	-1500	588	3522	0	0	0
Cash Generated from Operations	**27056**	**2852**	**40034**	**22236**	**6099**	**15835**	**28326**
Capital expenditure	-8712	-58217	-26368	-15534	-15000	-15000	-13000
Others	-1,833	-11,400	1,081	1,462	0	0	0
Cash flow from investment	**-10545**	**-69617**	**-25287**	**-14073**	**-15000**	**-15000**	**-13000**
Equity raised/(repaid)	-9	329	2	2	0	0	0
Debt raised/(repaid)	-690	62,081	9,479	-8,953	2,172	-500	-1,000
Dividend (incl. tax)	-1,573	-4,055	-4,066	-4,073	-964	-2,384	-3,007
Others	304	9	-1,083	-1,896	-3,099	-3,269	-3,229
Cash flow from fin. (c)	**-1,969**	**58,364**	**4,332**	**-14,921**	**-1,891**	**-6,153**	**-7,236**
Net chg in cash	**14542**	**-8401**	**19079**	**-6757**	**-10791**	**-5318**	**8091**

Key ratios	FY15	FY16	FY17	FY18	FY19	FY20E	FY21E
Gross Profit / Net Sales	67%	70%	71%	67%	65%	67%	67%
EBITDA /Margin	30%	27%	26%	21%	19%	20%	22%
PAT / Net Sales	19%	16%	15%	2%	4%	8%	10%
RoCE	26%	19%	15%	8%	8%	9%	10%
Total debt/Equity (x)	0.05	0.64	0.59	0.50	0.60	0.54	0.48
Net debt/Equity (x)	0.00	0.56	0.54	0.40	0.52	0.51	0.41
Du Pont Analysis							
Net margin	19%	16%	15%	2%	4%	8%	10%
Asset turnover (x)	0.98	0.80	0.72	0.60	0.63	0.65	0.67
Leverage factor (x)	1.44	1.76	1.99	1.95	1.98	1.99	1.92
Return on equity	27%	22%	21%	2%	5%	10%	12%
Valuations							
Period end (x)	FY15	FY16	FY17	FY18	FY19E	FY20E	FY21E
P/E	13.98	15.06	13.13	24.00	35.43	22.42	17.51
Price/Book	3.65	3.00	2.48	2.47	2.44	2.23	2.02
EV/EBITDA	8.28	12.03	10.00	13.45	14.29	12.74	10.24

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Name of the Security	Lupin Ltd.
Name of the analyst	Tausif Shaikh
Analysts' ownership of any stock related to the information contained Financial Interest Analyst : Analyst's Relative : Yes / No Analyst's Associate/Firm : Yes/No	NIL No No No
Conflict of Interest	No
Receipt of Compensation	No
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