



July 13, 2021

Industry: Pharmaceuticals

PICK OF THE MONTH Sun Pharmaceutical Industries Limited

VOL-7, NO-9 BUY

CMP: Rs.669

TARGET PRICE: Rs.770

TIME : 12 months

Industry Overview: The Global Pharmaceutical market valued at USD5.32bn in 2019 is expected to exhibit a CAGR of 7% to reach USD2151.1bn by 2027. The pandemic has given impetus to pharmaceutical companies for developing Covid related drugs and vaccines. The healthcare industry has been spending a fortune on R&D for vaccines and new drug development. The rising focus on healthcare amid the pandemic situation is anticipated to boost market growth in the near future. US continues to be the largest market, accounting for ~41% of global pharmaceutical spending. It recorded ~4% CAGR for 2014-19 and is expected to grow at CAGR of 3-6% to USD605-635bn by 2024. The growth is likely to be driven majorly by the development and launch of innovative specialty drugs. This could however be hampered by patent expiries going forward.





Source: Annual Report, Progressive Research

Indian Pharma Market: is one of the fastest growing, globally and the largest exporter of generic drugs by volume. The domestic formulations market in India has recorded ~9.5% CAGR in 2014-19 to reach USD22bn and is expected to grow at 8-11% CAGR to USD31-35bn by 2024. The impact of Covid-19 on the Indian Pharma companies was relatively limited in FY21 due to the inelastic demand for Pharma products and resumption of imports of key input materials from China (March 2020 onwards). There was some impact seen on the volume growth owing to lockdowns which led to lesser OPDs and elective surgeries. Due to the low base and higher sales of Covid related medication; the market grew 51.5% and 47.8% for the month of April and May respectively. India is playing a key role in supplying essential medicines to the world while making distribution more efficient and responsive. The Indian Pharma industry also called the 'pharmacy to the world' has successfully met the domestic needs while supplying 40% of the generics demand of the US and a quarter of Europe's. The government has taken active steps through the PLI (Production-Linked Incentive) 1.0 and 2.0 schemes (The recent introduction of the PLI schemes and promotion of bulk drugs park augur well for the IPM in the form of reducing dependence on imports of critical input materials as well as promoting production and exports of value-added products such as biosimilars, complex generics, etc., thereby supporting future growth) to take forward the AtmaNirbhar agenda for the Pharma industry. These initiatives will be important to build on the strength of the Indian Pharma industry and be a reliable supplier of high-quality affordable medicine around the globe for the benefit of patients. Outlook: Fitch expects sales of drugs used to treat acute medical conditions and elective procedures to continue to recover in FY22E. The costs would rise to normal levels as companies step up marketing and R&D activities but higher sales will cushion the impact on margins. Capex is expected to rise in FY22E, but this should not affect the strong financial flexibility of most companies. As the trend in drug sales normalises to the pre-pandemic levels over the next few months, the Indian Pharma market is likely to revert to an annual growth of around 10% that includes 4-5% price growth. Going forward, the industry thrives to be quick to respond to dynamic situations by utilizing underused capacities and making the supply chains efficient and agile to ensure easy accessibility of the drugs.

TIME : 12 months				
SNAPSHOT				
52 week H / L	Mcap (Rs mn)			
722/453		1,604,795		
	Face va	lue: 1		
BSE Code]	NSE CODI	E
524715	524715 SUNPHARMA		1A	
А	Annual Per	formance		
(Rs mn)	FY19	FY20	FY21	FY22E
Sales (Net)	290,659	328,375	334,981	374,998
EBITDA	63,076	69,898	84,914	91,875
EBITDA (%)	21.7	21.2	25.3	24.5
Other Income	10,255	6,360	8,355	8,355
Interest	5,553	3,027	1,414	995
Depreciation	17,533	20,528	20,800	21,309
РВТ	50,246	52,702	71,055	77,925
РАТ	26,654	37,649	29,038	63,751
Equity	2,399	2,399	2,399	2,399
EPS (INR)	11	16	12	27
· /		erformanc		
Parameters (Rs mn)	Jun-20	Sept-20	Dec-20	Mar-21
Sales (Net)	75,853	85,531	88,368	85,230
EBITDA	18,435	21,933	24,061	20,484
EBITDA (%)	24.3	25.6	24,001	20,404
Other Income	1,538	2,558	3,150	1,110
Interest	520	333	261	301
Depreciation	4,959	4,986	5,319	
PAT				5,535
	(16,556)	18,128	18,525	8,942 2,399
Equity (Rs mn)	2,399	2,399	2,399	2,399
Provensi (Dr. 1997)	Ratio A	1	EV21	EVAAE
Parameters (Rs mn)	FY19	FY20	FY21	FY22E
EV/EBITDA (x)	25.9	23.2	18.6	17.0
EV/Net Sales (x)	5.6	4.9	4.7	4.2
M Cap/Sales (x)	5.5	4.9	4.8	4.3
M Cap/EBITDA (x)	25.4	23.0	18.9	17.5
Debt/Equity (x)	0.27	0.20	0.16	0.08
ROCE (%)	12	11	14	15
Price/Book Value (x)	3.9	3.5	3.5	3.1
P/E (x) TTM	56.1	29.3	24.3	25.1
Shareholdin	-		Tarch 2021	
Parameters		f Shares		%
Promoters		,134,535	_	4.48
Institutions		777,389	_	3.29
Public		423,046		2.23
TOTAL	2,399	,334,970		100

Source: Annual Report

Note: All the data is calculated as per Market Price on 12 July,2021

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Industry Overview (contd.)



Exhibit 03: Growth Trend of Key Therapies

Growth (%)	FY17	FY18	FY19	FY20	FY21
Cardiac	11	6	13	12	11
Anti-infective	4	1	6	10	(5)
Gastro intestinal	10	6	9	8	5
Anti-diabetic	19	12	15	11	6
Vitamins	10	4	9	9	8
Respiratory	9	8	8	13	(9)
Analgesics	10	4	8	10	(3)
CNS	10	6	10	9	5
Derma	12	10	11	7	3
Gynecological	11	4	9	6	(1)
IPM	10	6	10	10	2

Source: AIOCD, Ind-Ra, Progressive Research

Source: AIOCD, Ind-Ra, Progressive Research

Global Specialty Pharmaceutical Market:

Global Specialty Pharmaceutical market is expected to be USD568bn by 2026. The specialty market in the US is anticipated to play a significant role on the global front. It is expected to be around USD387bn by 2026. It is likely to account for ~40% of global pharmaceutical spending by 2024, with the fastest growth expected to be in the developed markets, where contribution of specialty products is likely to cross 50% by 2024. Oncology, Autoimmune diseases and Immunology are the main segments in this space and will likely remain the key growth drivers in the 2019-2024 period. The specialty pharmaceutical market is estimated to witness good growth due to the plateauing of generic dispensing rate. Moreover, fast-track development of new pharmaceutical segments, major M&As among pharmacies and improvement in Pharmacy Benefit management (PBM) and healthcare plans are anticipated to bring about consolidation in the specialty pharmaceutical market. Given the erosion of generic drug prices in the US; Indian generic drug manufacturers are exiting certain drug portfolios and are focusing on developing differentiated specialty generics, including biosimilars.



Source: Annual Report, Progressive Research

Active Pharmaceutical Ingredients (API):

The global API market valued at USD190bn in 2020, is projected to reach approximately USD232bn by 2024, growing at a CAGR of about 6%. The demand drivers include:

- spike in infectious diseases and chronic disorders
- consumption for manufacturing formulations in the anti-infective, diabetes, cardiovascular, analgesics and pain management segments
- rising use of APIs in novel formulations to pursue niche therapies like immunology, oncology, biologics and orphan drugs
- expiration of patented biologics/investments in biosimilars
- rising incidence of chronic and lifestyle-associated diseases, e.g., cancer, diabetes and cardiovascular diseases
- government initiatives promoting generic drugs
- increasing healthcare expenditure
- surging awareness about diseases



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Industry Overview (contd.) Active Pharmaceutical Ingredients (API) (contd.)

The captive manufacturing category i.e. API held the largest market share between 2015-2020 and will continue to be dominant between 2021-2030 as well. The adoption of biological therapies for disease management, increasing number of approvals for biologics and increasing number of branded drugs going off-patent, as well as high investments in the biotechnology research and biopharmaceutical sectors will all drive a higher CAGR for biotech APIs. Based on the therapeutic application, oncology is expected to achieve the highest CAGR, driven by the high prevalence of cancer and increasing demand for Highly Potent APIs (HPAPIs) for its treatment. The Indian API industry meets 20% of the global demand in generics in terms of volume. India has the largest percentage of DMFs filed in the United States (15%). Also, ranked third in the world, the Indian bulk drug industry has grown at a CAGR of around 9% over 2016-2020 and is expected to grow at a CAGR of around 9.6% during 2021-2026.

Consumer HC-OTC (Over The Counter) drugs: OTC drugs are effective and safe drugs which do not need a doctor's prescription. The global OTC consumer health products market size was approximately at USD175.47bn for 2020. It is projected to grow at 8.55% CAGR to reach ~USD264.46bn by 2025. The Indian OTC market is poised to grow at a CAGR of 9.2% over the forecast period (2021-26). The global OTC drugs market is set to gain momentum from the increasing inclination of manufacturers towards over-the-counter medications from prescription drugs. Rising disposable income of consumers and spending on healthcare and wellness products are the major factors, likely to foster global market growth of OTC consumer health products. The other growth propelling factors of this market are product innovations, high penetration in the emerging market, favourable regulatory framework and inclination of pharmaceutical companies toward OTC drugs from Rx drugs.

About the Company: Sun Pharmaceutical Industries Limited (SUNP), is the largest Indian pharmaceutical company both in terms of market capitalisation as well as turnover (FY21) through a blend of an impressive track record of organic and inorganic growth. SUNP has forayed into the regulated markets by acquiring a majority stake in Caraco Pharma and has strengthened its presence by acquiring Taro and Ranbaxy. It is amongst the first few Indian Pharma players to have shifted focus to specialty from generics. Within specialty; dermatology and ophthalmology are the key focus areas. The company has entered into the commercialisation phase for most of its specialty products, but continues to invest in development of specialty products. SUNP manufactures and markets a large basket of pharmaceutical formulations in India, US and several other markets across the world. US and Indian formulations are by far the core strength and growth

Exhibit 05: Geographical Breakup FY21



Source: Company, Progressive Research

drivers of the company with global presence via 43 manufacturing facilities and R&D centers in six different continents. The company has Mr. Dilip Shanghvi as the Managing Director.

INVESTMENT RATIONALE:

A) Business Segments:

a) India Business: SUNP commands numero uno position with 8.2% share of the Indian Pharma market, with continued leadership in the high-growth chronic segments and specialisation in technically complex products. It has a strong sales force of 10,900+ which reaches 4,00,000+ doctors across the country. It has a leadership position in chronic segment and strong positioning in acute segment. As of FY21, Acute/Chronic/Sub chronic sales mix stood at 39%, 46% and 15% respectively. SUNP specializes in technically complex products and offers a complete therapy basket. The top 10 brands contribute ~19% of India revenues, indicating a de-risked growth profile and low product concentration. SUNP has more than 5% market share in all of the top 8 therapeutic segments (CVS, CNS being the leading therapies since inception) except for Respiratory and Vitamins, thereby the portfolio ideally representing the IPM. In the CVS segment, SUNP is the number one player, but has been witnessing loss of market share due to the double digit growth across other established and emerging players. On the other hand, in CNS the



Source: AICOD, Progressive Research

leadership is retained through brands like Levipil and Oxetol. Gradually this segment is also expected to start facing competition putting chronic performance under pressure. In the acute space, the company has strong presence across Gastro, Anti-infective, Pain management (some of the key brands being Pantocid, Sompraz, Mox and Volini.) The top therapeutic segments which contribute significantly to the company's revenue and market share are Neuro-Psychiatry (18%), Gastroenterology (12%), Anti-Infective (9%), Diabetology (10%) and Pain/Analgesics (7%) among others. SUNP enjoys leadership in key therapeutic areas across 9 doctor categories.

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INVESTMENT RATIONALE (contd.)

xhibit 07: Growth across key brands			
Brands	Therapy	FY21(Rsbn)	
Rosuvas	Cardiac	3.2	
Volini	Pain	3.2	
Levipil	Neuro/ CNS	3.1	
Istamet	Anti-diabetic	2.4	
Gemer	Anti-diabetic	2.4	
Susten	Gynaecology	1.9	
Revital H	Vit/ Min/Nut	1.9	

Source: Market Reports, Progressive Research

The top 10 brands contributed around Rs23bn to sales of FY21 (19% contribution)

Exhibit 09: Legacy brands from Ranbaxy + OTC

Therapy	Brands
Pain Management	Volini
Vitamins	Revital H
	Montek LC
Respiratory	Teczine
	Ab Phylline
	Chericof
Derma	Lulifin
	Silverex Ionic
Urology	Silodal D
	Silodal

Source: Market Reports, Progressive Research

Field Force With Highest Productivity:

SUNP has one of the most expansive reaches in India's medical fraternity, with a $\pm 10,000$ strong sales force. The driver for higher MR productivity has been a large number of blockbuster legacy brands in the portfolio. SUNP had undertaken expansion of sales force for the India business in order to expand its geographical footprint in India and to ensure that all brands get the focus they deserve. The company added ≈ 1000 MRs in FY21. The productivity was flat/ marginal decline in FY21. This field force is well settled, so in FY22E there should be benefit of the expansion and reach to the doctors, with improvement in PMPM and productivity.





Source: Company reporting, Progressive Research

Please Turn Over	

Exhibit 08: Top 10 brands across key segments				
Cardiac	Diabetes	CNS	Gastro	Anti infective
Rosuvas	Istamet	Levipil	Pantocid	Mox
Rozavel	Gemer	Oxetol	Pantocid DSR	Moxdav
Storvas	Oxra	Encorate Chrono	Sompraz D	Sporidex
Aztor	Trivolib	Nexito	Ursocol	Cepodem
Prolomet XI	Istavel	Strocit	Rifagut	Mox CV
Metosartan	Glucored	Qutipin	Mesacol	Faronem
Cardivas	Volibo	Nexito plus	Sompraz	Zanocin
Axcer	Volix	Strocit plus	Pantocid L	Cifran
Prazopress XI	Gemer P	Lonazep	Lactifiber	Cepodem XP
Rosuvas F	Oxramet	Dicorate	Sompraz L	Ivermectol
Source: Market	Reports Progr	essive Research		

Source: Market Reports, Progressive Research

Exhibit 10: Key successful launches in past 2-3 years

Brands	Therapy	
Oxramet	Anti diabetic	
Ostoshine	Pain management	
Alcros	Anti infective	
Cwin	Derma	
Volitra Aps	Pain management	
Volini Maxx	Pain management	
Pruease	Gastro	
Dicalis	Vitamins	
Prohance Mom	Vitamins	
Freedase	Gynaecology	

Source: Market Reports, Progressive Research

Exhibit 11: Sales per MR (Rsmn)



Source: Company ppt, Progressive Research

For FY21, India formulation sales were at Rs103.4bn, growth of 6.5% y-o-y accounting for about 31% of overall revenues. The chronic and sub-chronic therapies are progressing well, with sub-chronic showing marked recovery in 4QFY21. SUNP derives ~60% of its domestic revenues from chronic/semi chronic while the balance comes from acute. The leading presence in the chronic segments coupled with strong brand equity with doctors is helping SUNP increase its market share in an intensely competitive market.



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Exhibit 13: Growth across years (Major impact of Covid led disruptions seen in FY21)

Parameters (%)	FY17	FY18	FY19	FY20	FY21
Volume	6	6	3	2	(4)
Value	2	(2)	2	6	6
New Product	3	2	2	2	1

Source: Company reportings, Progressive Research

SUNP has increased its Covid product offerings by launching Favipiravir and Remdesivir as well as increasing production for Amphotericin B. This, along with increased demand for other Covid drugs (such as Ivermectin), is expected to drive sales over the short term. Based on its established presence in the Chronic category, increased demand for Covid products and an expanded field force to reach optimum productivity, the company is well-placed to outperform the industry over the next 2-3 years. Although we believe SUNP will lose market share in chronic therapies due to aggressive competition, acute will provide support with large brands and increased medical literacy. We project a 9-10% revenue CAGR for India business which is in line with expected IPM growth for the next two years, backed by a lower base, new launches and price hikes.





b) US Business:

SUNP is the 11th largest specialty generic company in the US with presence across generics, specialty, branded and OTC segments. It has been over more than two decades that SUNP has been supplying generics to the US, with growth driven by a mix of organic and inorganic initiatives. Its primary focus areas include CNS, derma, cardio, oncology and ophthalmic, among others. It is ranked 2nd by prescriptions in the US dermatology market. It offers a comprehensive portfolio across therapies tailored for the US market, which accounts for 31% of the company's revenues. Among the Indian pharmaceutical companies operating in the US, SUNP enjoys a unique positioning, with capabilities for on-shore and off-shore integrated manufacturing for the US. The company's manufacture various dosage forms, including liquids, creams, ointments, gels, sprays, injectables, tablets, capsules and drug-device combinations.

i) US Specialty:

SUNP's Specialty business accounted for ~34% revenues in FY21. The global specialty portfolio registered USD473mn revenues during FY21. The speciality business is the focus segment of the company, evident through the number of assets being added to the US portfolio. There have been more than six product launches/acquisitions over the last three years. Due to a challenging environment on the generics front, the management plans to diversify into specialty products such as Ilumya and Levulan (dermatology), BromSite, Cequa, Xelpros (ophthalmic), Odomzo, Yonsa (oncology), etc.

Key Speciality Molecules:

Ilumya: (tildrakizumab-asmn)

Ilumya is a humanized lgG1/k monoclonal antibody designed to selectively bind to the p19 subunit of interleukin (IL)-23 and inhibit its interaction with the IL-23 receptor, leading to inhibition of the release of pro-inflammatory cytokines and chemokines. Ilumya is used for the treatment of moderate-to-severe plaque psoriasis. Psoriasis affects close to 125 million people globally of which ~8 million are in the US (US accounted for ~40%) Psoriasis drug market share in 2019). About 80-90% of the people living with Psoriasis do experience Plaque Psoriasis. SUNP acquired worldwide rights of the drug from Merck in 2014 through an upfront payment of ~USD80mn while the product was still in Phase-3 of its development. Ilumya received its USFDA approval in May-18 and was subsequently launched in the US by Oct-18. The US market opportunity in Plaque Psoriasis is estimated to be around USD5.6bn, which is growing at 10%. There has been increased adoption of IL's from traditional TNF inhibitors seen which should help their overall market share improve from current levels of ~60% to ~85% by 2026E.





Source: Market Report, Progressive Research



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Exhibit 16: Other key products in pipeline for Plaque Psoriasis in adults

Company	Molecule	Estimated Ph III completion	Estimated launch
Biocad	BCD-085	Jan-22	FY24
BMS	BMS-986165	Jan-22	FY24
CanFite Pharma	CF101	Apr-22	FY24
Amgen	ABP654	Aug-22	FY25
UCB BioPharma	Bimekizumab	Jan-23	FY25
AbbVie	Risankimuzab	Mar-23	FY25
Eli Lilly	Mirikizumab	May-24	FY26

Source: Market Reports, Progressive Research

AbbVie is the leading player in the Psoriasis segment with its brand Humira being the most prescribed biologic. In the IL-23 type, Abbvie launched Skyrizi which was backed by its high efficacy score, manageable side effects and presence in other indications like Pustular Psoriasis, Psoriatic arthritis has seen its US revenues reach to over USD1bn (CY20) within two years of launch. It is further expected to be the prime candidate for market leadership cannibalizing Humira's market. The 5 years sustained efficacy and safety results were also encouraging {65.9% of patients achieved PASI-90, and 32.8% achieved clear skin (PASI-100)}. Also on calculating the annual cost of 6 doses to be taken annually, it is one of the most cost-effective IL therapies available in the US. Thereby, Ilumya has recorded good efficacy along with manageable side effects and is a proven cost effective treatment measure. Apart from the US, Ilumya is present in Europe and Australia under the brand name Ilumetri since Dec-18. In Jun-19 it was out-licensed to CMS for the China market. In Sep-20, SUNP launched Ilumya for the Middle East and North Africa (MENA) region. Competition from Humira & Enbrel's biosimilars and the expected entry of additional players from 2024E could cause its market share to flatten. Ilumya is currently undergoing phase 3 trials for Psoriatic Arthritis, which could be completed by Aug-23. Ilumya clocked global sales of USD143mn growth of 51% y-o-y in FY21. It should achieve a market share of ~6.5% by FY25E (from the currently ~4.5%). One can expect the peak sales reach USD300mn by FY25E.

Cequa:

It is a calcineurin inhibitor immunosuppressant that increases tear production in patients with kerato-conjunctivitis (dry eye). North America holds the majority of the market with market size of USD2.4bn as it affects close to 38 million people of which only 50% of the patient pool is diagnosed and only 25% are on Rx therapy. Thus, with more awareness and improving product quality on the chronic treatment side, the dry eye drug market is expected to grow at ~15% CAGR over 2020-25E.

In the chronic treatment category, there are three approved products in the US namely 1) Restasis, 2) Xiidra, and 3) Cequa. There is a fourth product, Eysuvis, which was launched in Jan-21. Apart from Rx-driven chronic treatment, there are OTC options (fake tears) and lubricants like Lacrisert. SUNP got Cequa by acquiring Ocular



Exhibit 17: Dry Eye Market Growth (USDbn)



Therapeutics in 2016. SUNP paid an upfront payment of USD40mn, in addition to milestone payments and royalties. It received approval from the USFDA in Aug-18 followed by the launch in the US in Oct-19. Post this, the FDA has made several treatment options available and it is a competitive market.

Absorica:

This product was launched by Ranbaxy in 2012 and is one of the most significant products in SUNP's portfolio. The FY21 sales for Absorica stood at USD125mn. The drug is indicated for the treatment of severe recalcitrant nodular acne. Absorica has seen generic competition with launch by Teva Pharmaceuticals in April, 2021. In response, the company launched its own authorized generic, Absorica LD capsules in the US market. *(Isotretinoin oral capsules have annual sales of more than USD158mn in the U.S., according to IQVIA data as of February 2021)*.

Levulan:

Levulan is a specialty product that SUNP had acquired in Nov-12 through the DUSA acquisition. It is drug-device combination therapy used to treat liaisons on the skin. The company had achieved more than USD100mn sales from this product in FY20 before seeing a dip in FY21 due to Covid. The last patents expired on March 9th, 2021. However, we do not expect immediate competition as it is a drug-device combination, which is difficult to copy.



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Odomzo:

It is another product added to SUNP's specialty portfolio in the US through an acquisition from Novartis in Dec-16. It is indicated for treating adult patients with locally advanced basal cell carcinoma (BCC) who are not amenable to curative surgery or radiation. Post-acquisition, the sales ramp-up of Odomzo has been negligible. SUNP has generated USD25mn from this product in FY21. We expect this product to remain below USD50-60mn in size till FY23E unless SUNP re- strategizes to market this product in a different and aggressive way.

Ophthalmic Product Portfolio: Small Size Specialty Products

Along with Cequa, SUNP also has two more ophthalmic specialty products in the US market namely Bromsite and Xelpros. **BromSite:** BromSite is the first NSAID approved by the USFDA for prevention of ocular pain & treatment of inflammation following cataract surgery. The drug has been developed by InSite Vision which the company had acquired in November 2015. Xelpros and Cequa are the other key products in the Ophthalmology offerings of SUNP.

Despite generic entry in Absorica, SUNP expects to grow the business, led by ramp-up in Ilumya, Cequa and Yonsa. There has been 8-10% growth seen on m-o-m basis for Ilumya. Feedback for Cequa from the doctors and patients also has been positive. Levulan is yet to see normalized sales due to slower pick-up in surgeries in hospitals. Excluding Absorica and Levulan, the rest of the specialty portfolio for SUNP is expected to cross USD500mn revenues in FY23E led by ramp-up expected in Ilumya and Cequa.

Product	Molecule	Therapy	Launch Date	US market size (USDmn)
Ilumya	Tildrakizumab	Derma	Oct-18	8000
Cequa	Cyclosporine	Opthalmology	Oct-19	2000
Absorica/Absorica LD	Isotretinoin	Derma	Feb-20	1200
Levulan	Aminolevulinic	Derma	Nov-12	100
Odomzo	Sonidegib	Derma	Dec-16	1500
Yonsa	Abiraterone	Oncology	May-18	450
BromSite	Bromfenac	Derma	Nov-16	400
Xelpros	Latanoprost	Ophthalmology	Jan-19	2000
Infugem/InfuS MART	Gemcitabine	Oncology	Apr-19	35

Exhibit 18: Key Specialty Products

Source: Company Reporting, Progressive Research

Targeting New Markets: SUNP has been working to target two important markets for its specialty products namely Japan and Greater China. In June 2019, it entered into licensing agreements with a subsidiary of China Medical System Holdings Ltd. (CMS) for the development and commercialisation of two of the specialty products namely Tildrakizumab (for Psoriasis and Psoriatic Arthritis) and Cyclosporine A 0.09% (CsA) eye drops (for dry eye disease) for Greater China market. These licensing agreements will facilitate SUNP's entry into the Greater China market, which is the second largest pharmaceutical market globally.

ii) US Generics:

The focus of business in US has been shifted to specialty for SUNP and hence generics has taken the back seat. Where SUNP used to have more than 150-200 ANDAs in pipeline, the





Source: Company filings, Progressive Research

pending now stand below 100. There have been regulatory hurdles like that of the Halol plant with an insufficient drug pipeline which has led to muted growth of generics.

ANDA Profile: The US product basket comprises 501 approved ANDAs, 94 pending final approvals (including 23 tentative approvals). It also has 55 approved NDAs and nine pending NDAs.

For the Halol plant which has been under the USFDA radar for the last few years under the warning letter and close to USD1bn revenue base, the company has been waiting for the regulator to inspect the facility. It continues to be a drag on the US base business.



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INVESTMENT RATIONALE (contd.)

Products like Doxil, Paliperidone, Metformin and Gleevec from the base business could see erosion in coming years due to increasing competition. But on the other hand, the support will be provided by new product launches from the pending ANDAs with the USFDA, and some of the notable launches could be Alimta, Exparel, Invanz, and the Mesalamine franchise.

The Non-Injectable generic sales of US comprise of primarily Oral Solids:

In the base portfolio, molecules like Imatinib Mesylate (ranks No.1 with 17% market share), Tramadol HCl (ranks No.1 with 54% market share), Paliperidone ER (ranks No.2 with 26% market share), Carbidopa; Levodopa (ranks No.2 with 20% market share), Sumatriptan; Naproxen (ranks No.2 with 21% market share), Metoprolol Tart (ranks No.2 with 34% market share) and Metformin HCl ER (ranks No.3 with 17% market share).

With regard to the expected near term launches in oral solids, some of the key molecules are:

- Sutent (Sunitinib Malate) with market size of USD1,000mn
- AsacolHd (Mesalamine) with market size of USD800mn
- Korlym (Mifepristone) with market size of USD300mn
- Evista (Raloxifene) with market size of USD200mn
- Prevacid Solu (Lansoprazole) with market size of USD160mn

Exhibit 22: Para IV Filings

Exhibit 20: Key Injectables Performance in the base business

Molecule	Rank	Market Share
Vecuronium Bromide	1	26
Azelastine HCL	2	29
Doxorubicin HCL	3	24
Chlorothiazide Sodium	3	14
Desmopressin Acetate	3	12
Leuprolide Acetate	4	1
Testosterone Cypionate	5	6
Ketorolac Tromethamine	6	1
Pantoprazole Sodium	6	3
Decitabine	6	5
Medroxy Prgesterone Acetate	18	1

Source: Market Reports, Progressive Research

Exhibit 21: Expected near term launches in injectables

Product	Molecule	Market Size (USDmn)
Alimta	Pemetrexed Disodium	1200
Exparel	Bipuvacaine	400
Invanz	Ertapenem	250
Chlorpromazine HCL	Chlorpromazine	200
Miacalcin	Calcitonin Salmon	180
Flolan	Epoprostenol	150

Source: Market Reports, Progressive Research

	0		
Brands	Molecules	Market Size (USDmn)	Expected launch
Effient	Prasugrel Hydrochloride	600	
Savella	Milnacipran Hydrochloride 150 Paricalcitol 100		American Franceste d
Zemplar			Anytime Expected
Angiomax	Bivalirudin	100	
Velcade	Bortezomib	600	FY22-23
Abraxane	Paclitaxel	700	FY23
Rapamune	Sirolimus	120	FY23
Vimpat	Lacosamide	100	FY23
Xeljanz	Tofacitinib Citrate	1700	FY24
Ibrance	Palbociclib	2000	FY24

Source: Company Filings, Progressive Research



July 13, 2021	PICK OF THE MONTH	VOL-7, NO-9
Industry: Pharmaceuticals	Sun Pharmaceutical Industries Limited	BUY
CMP: Rs.669	TARGET PRICE: Rs.770	TIME : 12 months

Recent Development: Revlimid Settlement

SUNP announced generic Revlimid (lenalidomide) patent litigation settlement with innovator-Celgene, a wholly-owned subsidiary of Bristol Myers Squibb for the US market. SUNP is the 5th player to settle the Revlimid patent with the innovator, *while Natco (2015), Alvogen (2019), DrReddy's (2020) and Cipla (2020) have already settled for a limited volume launch after March 2022.* On the other hand, Cadila has settled to launch post patent expiry in FY26E. The settlement allows SUNP to start selling certain volume-limited amounts of gRevlimid after March 2022 and unlimited quantity beginning 31st January 2026, subject to regulatory approvals by USFDA. This settlement is broadly on similar lines of previous settlements by innovator with generic players such as Natco, Alvogen, Dr. Reddy's and Cipla. We feel, this settlement by SUNP will not bring any incremental competition in the gRevlimid opportunity in the visible future (till the patent expiry), as all players have settled to launch limited of gRevlimid (indicating no great price competition/erosion over FY22-FY26E).

Taro: Drag on Generic Growth of SUNP: Taro Pharma was acquired by SUNP in 2010 and currently it owns 77.8%. Taro develops, manufactures and markets prescription and OTC pharmaceutical products primarily in the US, Canada and Israel, with major revenues from the US. Taro's primary focus areas include paediatric creams and ointments, liquids, capsules and tablets, mainly for the dermatological, topical, cardiovascular, neuropsychiatric and anti-inflammatory therapeutic categories.

Taro Product Offerings: At one point of time, the US market contribution to Taro revenues stood at ~90%, which then fell to 13% CAGR growth in FY16-20 majorly due to the increased competition in the derma space.



Exhibit 24: Steady decline in US sales contribution



Source: Taro Filings, Progressive Research

Source: Taro Filings, Progressive Research

For the full year FY21, sales were USD549mn, down by 14.9% over same period last year. Adjusted net profit for FY21 was USD141mn compared to USD244mn in FY20. Taro's reported net loss for FY21 was USD387mn. Taro continued to see pricing pressure in its strong dermatology portfolio. However, it is likely bottoming out of Taro's performance (with the market opening up, stable derma pricing after years of intense competition and its Rx outperformance seen in US derma market during Covid period i.e. -1% for Taro vs. -29% for industry).

Exhibit 25: Taro ANDA filings

ANDA Pipeline	FY16	FY17	FY18	FY19	FY20	FY21
Taro filings	207	216	224	230	235	236
Taro Approved	172	181	193	203	211	219
Taro Pending	35	35	31	27	24	17

Source: Taro Filings

c) Emerging Markets:

The key markets for this segment include Brazil, Mexico, Russia, Romania and South Africa. It has manufacturing facilities in 7 countries and a sales force of ~2300. SUNP is amongst the largest Indian companies in the Emerging markets and offers a wide spectrum of market-specific branded products. The focus of SUNP for these markets is towards selling large-size brands in various therapies while leveraging its capability in India. The local manufacturing facilities provide more flexibility in servicing the local markets. The key focus areas are to gain critical foothold in key markets through organic and inorganic initiatives and enhance the product basket to offer a broad and profitable portfolio coupled with the launch of complex products.





Source: Company reports, Progressive Research



July 13, 2021PICK OF THE MONTHVOL-7, NO-9Industry: PharmaceuticalsSun Pharmaceutical Industries LimitedBUYCMP: Rs.669TARGET PRICE: Rs.770TIME : 12 months

INVESTMENT RATIONALE (contd.)

Exhibit 27: RoW Sales (Rs mn)

d) RoW:

This majorly includes Western Europe, Canada, Japan, Australia, NZ & Other markets. The company has a basket of products including injectables and hospital products as well as products for the retail market. Development and commercialization of complex generics and differentiated products would drive sustainable and profitable growth following the distribution led model. In Mar-16, SUNP had acquired 14 prescription brands from Novartis and in FY19, it acquired Pola Pharma in Japan to strengthen its presence in the Japanese dermatology segment. An acquisition like Pola Pharma improved the performance from Taro's Canadian business and the launch of specialty products have driven the growth in this segment. Future growth is mainly dependent on Ilumya's performance in Japan and Australia and ramp-up in acquired businesses.



Source: Company Reports, Progressive Research

e) Global Consumer Healthcare Business:

In India, SUNP is amongst the top 10 consumer healthcare companies. The focus markets for this business are Romania, Russia, South Africa, Nigeria, Myanmar, Ukraine, Poland, Thailand, Belarus, Kazakhstan, Morocco, UAE and Oman. The business is promoted through a dedicated sales force in each market. In India, SUNP's key consumer healthcare brands namely Volini and Revital-H are ranked 26th and 83rd, respectively in the Indian pharmaceutical market. The distribution network spans 1,000+ cities and towns, supported by approximately 400,000 retail outlets.



Source: Company

Future focus in this segment is to maintain market leadership through brand building, brand extensions and product innovation. SUNP is working towards expanding its presence in high-growth markets and increase the retail and online presence.

f) Active Pharmaceutical Ingredients (API):

This business has strategic importance of backward integration that provides cost competitiveness and supply reliability. Besides using APIs for captive consumption, the company supplies APIs to external customers as well. It caters to large generic and innovator companies with a portfolio of \sim 300 APIs. With regard to the pipeline development; SUNP has \sim 20 APIs scaled up annually. The company's API business provides cost competitiveness and supply reliability, reducing dependence on third-party suppliers. The focus is to commercialise strategic APIs for captive consumption, seek new customers to grow the API business, ensure consistent supplies and service standards.

B) Research & Development:

R&D is imperative for any pharmaceutical company's future. The focus of the company is to continue investing in R&D to develop differentiated generics and innovative specialty products. The global generic business requires a constant flow of new products and hence R&D capabilities to develop such products and meet the individual requirements of each market are very important. R&D is absolutely vital for strengthening the global specialty pipeline. Investments for developing the long-term specialty pipeline are expected to continue. The company had invested Rs21,499mn in the R&D in FY21 (6.5% of the total revenues). Of this the specialty segment R&D stood at ~32% of the total R&D expense. Going forward, the management expects



Source: Company Filings

R&D expenses to be in the range of 8-9% of the revenues in FY22E with the spiking spend for innovative products.



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Financials:

Net Sales: While the company's US generics business is going through product rationalisation, the specialty segment looks promising due to robust product pipeline, steady progress. This shift from generics to specialty, however, is likely to weigh on US growth in the near term. That said, higher contribution from specialty and strong domestic franchise is likely to change the product mix towards more remunerative businesses by FY23E.

Ebitda Margins: There could be a dip witnessed in the operating margins with the increase in the other expenses that includes the sales and marketing expenses as well as increase in the R&D going forward. (these were lower in FY21 due to the pandemic restrictions). There would be positive implications on margins as we expect faster absorption of frontloaded costs on the specialty front.

Net Debt: SUNP has repaid debt of about USD580mn in FY21. Ex-Taro, net debt stood at USD179mn. The company continues to evaluate opportunities for deployment of Taro's cash, which could be a combination of buyback and possibly in-licensing and M&A deals. SUNP has guided for USD200mn capex in FY22E.

Financials in Charts:









Source: Annual Report, Progressive Research



Exhibit 33: D:E Ratio



Source: Annual Report, Progressive Research





Source: Annual Report, Progressive Research



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Risks and Concerns:

- o Delay in USFDA resolution of Halol 483s and higher than estimated price erosion in the US generic portfolio.
- o Delay in ANDA approvals could postpone the realization of revenues from those products.
- Drug price fixing lawsuits in the US.
- o Underperformance or slower ramp up of specialty business.
- Though the entry of generic Absorica remains a threat in near term, the scale-up of Ilumya (although two more competitors are expected in CY22E) and Cequa could offset this impact.
- Forex fluctuation could hinder revenues and margin especially as ~60% of revenues of SUNP comes from exports/global markets.

Outlook and Valuations:

Among the Indian pharmaceutical companies operating in the US, SUNP enjoys unique positioning with capabilities through integrated manufacturing for US. The company has displayed enough appetite to maintain leadership in existing markets through focus on innovative solutions and thus enhance presence in high growth markets. The US revenues are expected to increase backed by the marketing efforts (like for Ilumya which would drive incremental prescription driving overall profitability) in the specialty space, stabilization of Taro sales (FY21 was down by 15% y-o-y but Q4FY21 sales grew by 5% q-o-q), and new launches expected going forward. However, the generic launch of Absorica in the specialty portfolio may put some pressure on the overall growth prospects of SUNP over the near term, but overall specialty and branded generics would trigger the required growth for the company. The second contributing segment would be the domestic formulations which has shown chronic and sub-chronic progressing well. SUNP has also increased production of its Covid portfolio (Favipiravir, Remdesivir, Amphotericin B, Ivermectin, in-licensed Molnupiravir from Merck and Baricitinib from Eli Lilly to enhance the Covid portfolio) which should drive sales in the short term. The key triggers for the DF segment are the steady growth across the Chronic segment, expanded field force to capitalize and increased demand in Covid products. We initiate Buy on the stock with a target price of Rs770 over a 12 months horizon.

Exhibit 35: Price vs. Sensex



Source: Ace Equity, Progressive Research

Exhibit 36: One Year Forward P/E



Source: Ace Equity, Progressive Research





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