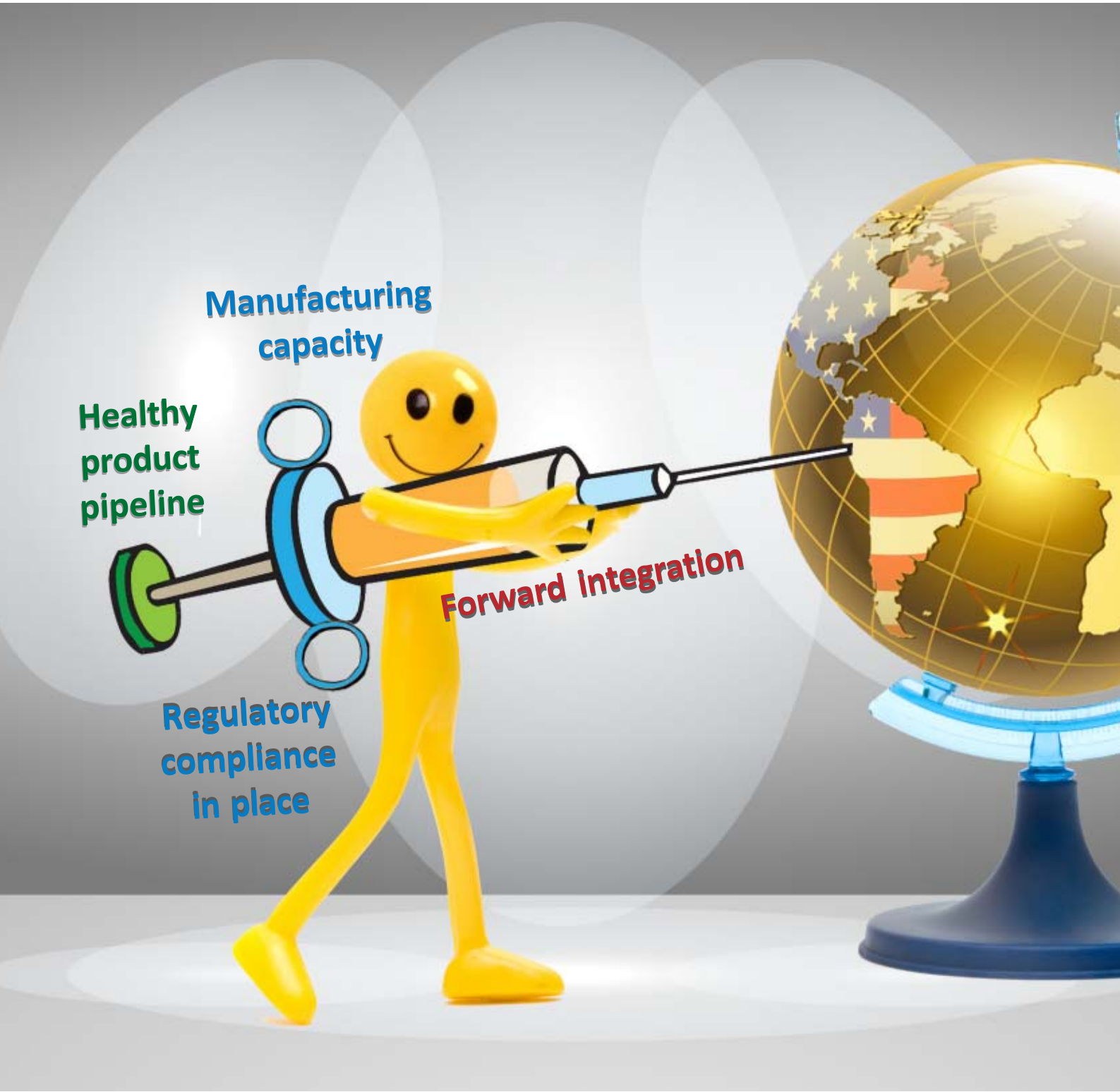
MOTILAL OSWAL

Initiating Coverage | 31 July 2017
Sector: Healthcare

Shilpa Medicare



Injecting Growth

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Contents

Shilpa Medicare

BSE Sensex	S&P CNX
31,312	9,658

CMP: INR647 **TP: INR805 (+24%)** **Buy**

Innovating for affordable healthcare

Stock Info

Bloomberg	SLPA IN
Equity Shares (m)	80
52-Week Range (INR)	787 / 442
1, 6, 12 Rel. Per (%)	-10/-29/22
M.Cap. (INR b)	53.6
M.Cap. (USD b)	0.8
Avg Val, INRm	43
Free float (%)	45.3

Financial Snapshot (INR m)

Y/E Mar	FY18E	FY19E	FY20E
Net Sales	10,682	14,028	16,810
EBITDA	2,457	3,507	4,371
NP	1,689	2,435	3,049
EPS (INR)	21.1	30.4	38.1
EPS Gr.%	50.5	44.2	25.2
BV/Share	134.3	163.1	199.1
P/E (x)	30.7	21.3	17.0
P/BV (x)	4.8	4.0	3.2
RoE (x)	17.0	20.4	21.0
RoCE (x)	12.9	16.4	18.0

Shareholding pattern (%)

As On	Jun'17	Mar'17	Dec'16
Promoter	54.7	54.7	54.7
Public	45.3	45.3	45.3
Others	-	-	-

FII Includes depository receipts

Shilpa Medicare

Injecting growth

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Please click here for Video Link

Injecting growth

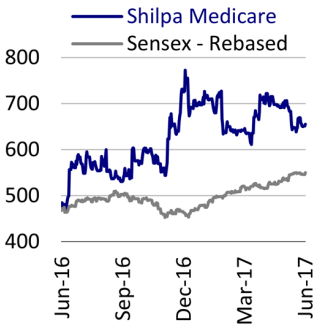
Product approvals, superior execution to drive earnings

- **Shilpa Medicare (SLPA) has been engaged in the manufacture of active pharmaceutical ingredients (APIs) since 1987. However, over a period of time, it has shifted its focus toward creating a niche in Oncology generics. In the process, it has developed a strong capability in manufacturing oncology APIs and formulations. Besides this, SLPA is investing in novel drug delivery systems (NDDS) and biotechnology.**
- **We believe that SLPA is well poised to deliver robust earnings CAGR of 41% over FY17-20, led by the commencement of sales in the US market and new product launches in the EU market. SLPA has a healthy pipeline of ~23 pending ANDAs (owned and for partners combined). We expect US sales to reach INR3.3b from INR250m in FY17. There is potential in US sales to grow 50% YoY in FY20, subject to outcome of litigation.**
- **SLPA has the necessary manufacturing capacity and US FDA clearances to succeed in APIs and formulations. It has done well on the compliance part in recent past.**
- **We expect its base business (CRAMS for ICE, Italy), which currently forms 52% of total sales, to remain stable and sustainable following 20% CAGR over FY15-17. The switchover of sourcing to SLPA led such strong growth. SLPA's customer, ICE, has been enjoying majority share in this product due to complexity associated with sourcing of raw material. With JV formation with ICE for this business, we believe, SLPA to have 13% CAGR in revenues to INR6.4bn over FY17-20.**
- **We expect SLPA's oncology API business, which currently forms 33% of total sales, to grow at 20% CAGR over FY17-20 to INR4.9bn led by increased market share in existing products and new product launches by its customers.**
- **The five-year average P/E for SLPA stands at 21x. P/E multiples for many pharma companies are lowered due to slowdown in the US business on account of regulatory hurdles/pricing pressure in the base business. However, we value SLPA at a premium valuation of 25x 12M forward earnings due to strong growth visibility from the US market, backed by a healthy product pipeline, which would also support margins improvement. In addition, SLPA has successful compliance history which has become critical factor to succeed in US market. On overall basis, we expect revenue and PAT CAGR of 29% and 41% over FY17-20E.**
- **We thus initiate coverage on SLPA with a Buy rating and a price target of INR805 on 12M forward earnings.**

Superior execution in US market to drive sales and PAT

- With capex in APIs/formulations already behind and regulatory clearances in place for both these businesses, we expect strong revenue and profit growth over next 2-3 years. SLPA had about 26 DMFs and 25 ANDAs filed till date.
- There are already two ANDA approvals in place, and the company has a healthy pipeline of ~23 ANDAs awaiting approvals. We expect SLPA to grow its revenues in the US market from nil in December 2016 (no business until then) to ~INR3.3b in FY19, subject to product approvals.

Stock Performance (1-year)



JV formation secures base business of CRAMS

- The base business (custom synthesis) has witnessed strong 31% revenue CAGR over FY13-17. It constituted ~52% of FY17 sales due to higher off-take by JV partner ICE.
- The shift of this business to the JV in December 2016 and doubling of capacity under this JV might curtail revenues due to a change in accounting. However, profit would rise with greater consolidated-level efficiency.

Capex in progress for future growth

- SLPA has guided for further INR4.5b capex over two years toward R&D, enhancing API/formulation capacities and investing in bio-similars. This would strengthen its foundation for future growth.

Valuation

- Many pharma companies have been de-rated over the past year due to slowdown in the US business on account of regulatory woes/pricing pressure on the base business. However, we value SLPA at 25x 12M forward earnings, given the strong growth visibility over FY17-19E, backed by approved products as well as a strong pipeline pending approvals. The US product pipeline has the potential to drive US revenue growth of ~50% YoY in FY20 as well. Relatively superior margin from the US business would also improve overall margin for SLPA.
- We expect sales, EBITDA and PAT CAGR of 29%, 36% and 41% to INR16.8b, INR4.3b and INR3b, respectively during FY17-20E. Assuming PAT growth and improving return ratios, we value SLPA at 25x 12M forward earnings. We thus initiate coverage on the stock with a **Buy** rating and a price target of INR805.
- At CMP of INR647, SLPA trades at 30.7x FY18E EPS of INR21.1 and 21.3x FY19E EPS of INR30.4.
- Our sensitivity analysis indicates downside of 9.9% in bear case, upside of 24.8% in base case and 65% in bull case from the current levels.

Risks

- Delay in approval for its products.
- Longer-than-expected time taken to execute in terms of manufacturing and selling.
- Higher-than-expected competition for its key products.
- Any untoward outcome of future regulatory inspections, which may have an impact on existing business and/or future product approvals.

Exhibit 1: Peer comparison (INR m)

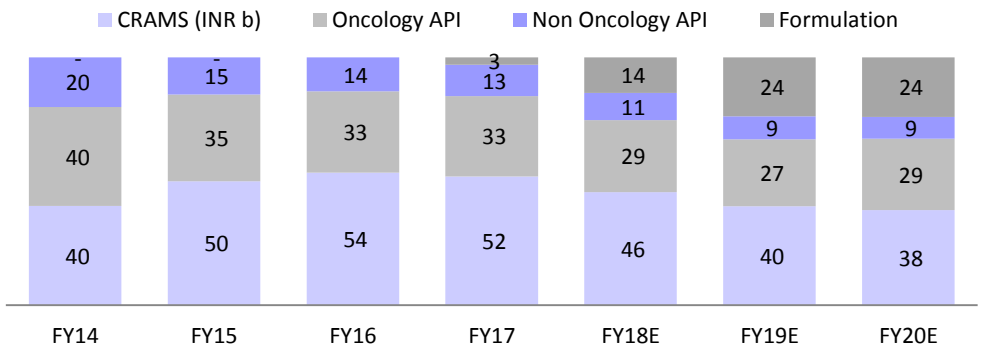
	Sales			EBITDA margin (%)			PAT			P/E (x)			EV/EBITDA (x)		
	FY17	FY18E	FY19E	FY17	FY18E	FY19E	FY17	FY18E	FY19E	FY17	FY18E	FY19E	FY17	FY18E	FY19E
Shilpa	**7,836**	**10,682**	**14,028**	**22.4**	**23.0**	**25.0**	**1,123**	**1,689**	**2,435**	**46.2**	**30.7**	**21.3**	**30.5**	**21.9**	**15.4**
Ajanta	20,020	22,554	27,428	34.9	34.7	34.2	5,168	5,848	7,037	24.1	21.3	17.7	17.8	15.7	12.8
Indoco	10,694	12,274	14,073	14.6	16.1	16.7	771	996	1,274	24.0	18.6	14.5	13.0	10.3	8.7
Natco	20,650	25,978	23,841	33.1	37.5	28.1	4,860	5,956	4,161	35.3	34.8	27.5	25.2	21.8	17.7
Unichem	15,195	18,043	20,683	11.8	13.4	14.2	1,087	1,552	1,946	22.3	15.5	12.4	14.0	10.3	8.4
Alembic	31,013	32,535	37,242	19.7	18.0	19.5	4,068	3,856	4,810	25.1	26.5	21.3	16.6	16.9	13.8
Biocon	38,760	47,806	59,271	24.1	24.0	25.5	6,118	6,219	8,629	39.1	38.5	27.7	26.2	21.5	16.1
Granules	14,353	17,051	23,390	20.8	21.6	22.4	1,654	2,075	2,926	19.0	16.8	11.9	11.7	9.0	6.6

Source: Bloomberg, MOSL

US business is key growth driver for SLPA

Until FY16, SLPA derived 100% of its revenues of INR7.2b from API and intermediates sales. We expect revenue contribution of the formulations business to increase from 0% in FY16 to 24% by end-FY19, subject to product approvals. This would be largely driven by oncology sales to the US market, in our view.

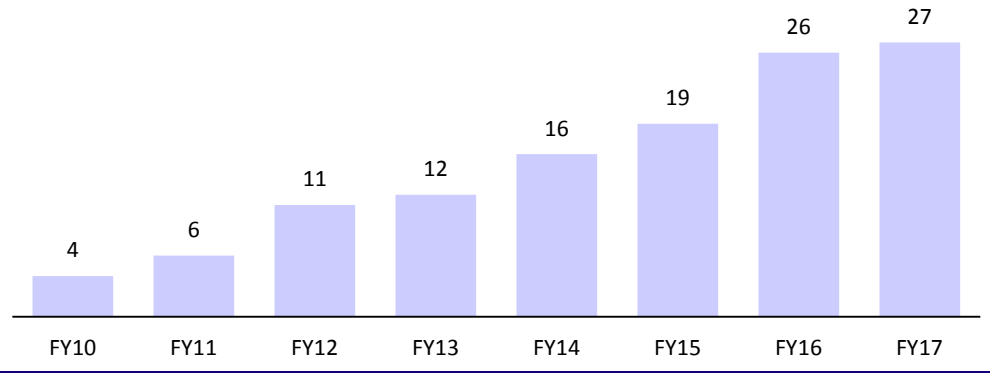
Exhibit 2: Proportion of Formulation is expected to increase to 24% by FY19



Source: Company, MOSL

The company has been developing molecules in generic oncology for regulated markets for almost a decade now. It has filed 25 DMFs till date since FY10. Most DMFs filed are in the chemotherapy category. New APIs under development are for drugs that target specific pathway in growth and development of tumor.

Exhibit 3: Cumulative number of DMFs filed



Source: Company, MOSL

SLPA had filed 25 ANDAs using these DMFs until end-4QFY17. Of these, about eight are owned and the rest are for its partners. With regulatory clearance in place, we expect a considerable increase in revenues from the US market to INR3.9b by FY19, subject to product approvals.

Oncology is an interesting therapy for the higher generics business over next five years, due to following reasons:

- Increased incidence of cancer.
- Limited scope for replacement of chemotherapy drugs or ever greening of patents due to the shift in the efforts of innovator companies toward targeted therapies. This would enhance the possibility of early generics in chemotherapy drugs.

- Oncology is low-volume/high-value segment, implying that quality is the key differentiator here.

SLPA is well positioned to grab business opportunities on the basis of following reasons:

- Manufacturing capex is already in place to support commercial production.
- Regulatory clearance for the API and formulations facility, which is a big positive given that businesses of other pharma companies are facing regulatory hurdles.
- Many molecules are already developed. Subsequently, ANDAs (owned as well as for partners) have been filed to take advantage either through para III or para IV filings.
- About 50% of oncology drugs filed in the industry are either off-patent with limited competition or going to lose patent status. This implies better business opportunity for SLPA.

Exhibit 4: Interesting product pipeline based on DMF filings

Generic Name	Brand Name	Market Size (USD M)	DMF filers	Is generic available	Sales estimate (USDm)				Remarks
						FY18E	FY19E	FY20E	
Capecitabine	Xeloda	350	28	Yes	**Launched**	11.4	15.4	12.6	❖ Interesting opportunity due to limited competition. Assuming 8% market share, 55% price discount
Azacitidine	Vidaza	240	13	Yes	**Launched**	10.7	24.0	22.5	❖ Good opportunity due to limited competition. Assuming 15% market share, 15% price discount. Market share to improve gradually
Imatinib Mesylate	Glivec	2,010	31	Yes	Launch in FY19		2.5	14.1	❖ Limited opportunity. Assumption is 90% price erosion, 5% market share. Expected to have stiff competition due to 18-20 generics in race, Expect SLPA to have better margin due to its presence from API to formulation.
Zoledronic Acid	Zometa/ Reclast	200	25	Yes	Anytime in FY18, FY19	2.1	8.5	8.5	❖ Though market size is small, it is good opportunity given low base of US business of SLPA.
Bortezomib	Velcade	600	18	No	Probable launch in FY20 subject to litigation and time for final approval. DS expiry in Nov-17			15.6	❖ Given market size and possibility of low competition, subject to federal circuit decision, we expect 5% market share, 65% price erosion. District court decision has been for generics for invalidating patent expiring 2022. Assigned 50% probability and not factored in our earnings
Fingolimod Hydrochloride	Gilenya	1,600	18	No	Probable launch in FY20 subject to litigation. DS expiry in Feb-19			14.2	❖ On market size of the product, potential could be 8% market share, 90% price erosion. PTAB quashed patent, expiring in 2026, claims stating they are obvious in patent fight with Torrent Pharma. Assigned 50% probability and not factored in our earnings.
					Total	**24.2**	**50.4**	**57.7**	❖ **Excluding revenue from g-Velcade and g-Gilenya**
								29.8	❖ **Adding revenue from g-Velcade and g-Gilenya**
					Total			**87.5**	❖ **Possible upside of 59% in US revenue in FY20 from g-Velcade and g-Gilenya**

Source: Company, MOSL

Recent approvals have kick-started US revenues from 4QFY17

Of the 25 ANDAs filed, SLPA recently received approvals for two ANDAs. The company has received final approval for the generic version of Xeloda (Capecitabine) and Vidaza (Azacitidine).

1. We expect SLPA to garner revenue of USD11m from **g-Vidaza** in FY18, based on 15% market share and 15% discount. Given that there are only two generic companies other than SLPA for this product, we expect price erosion to be 15% for this product. The market size of g-Vidaza was USD240m for the 12 months ended September 2016. We expect increased competition over next 2-3 years based on the number of DMF filings, which could result in higher price erosion, thereby factoring lower revenues in FY20 compared to that in FY19.
2. We expect SLPA to garner revenue of USD11m from **g-Xeloda** in FY18, based on 8% market share and 55% discount. The market size of g-Xeloda was USD350m for the 12 months ended September 2016. We expect 55% price erosion with 15 companies having final approval for this product, of which nine supply to the US market. We expect price erosion to continue for this product over next 2-3 years.

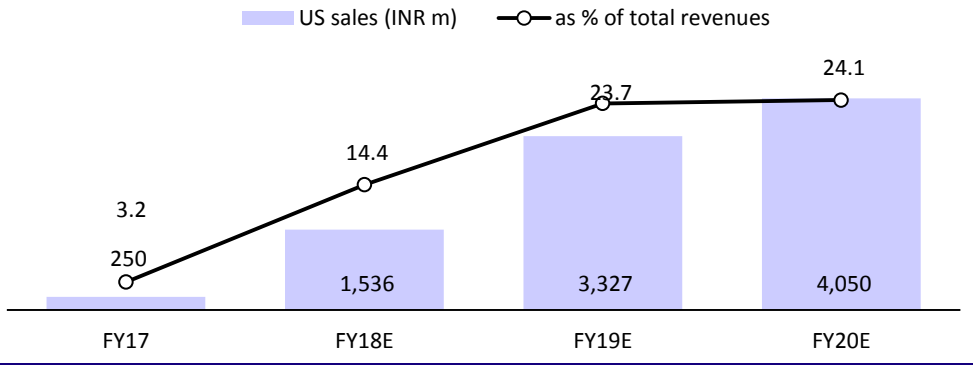
We expect INR1.4b from g-Vidaza and g-Xeloda in FY18 out of overall US sales estimate of INR1.5b. We expect sales from the US market to increase to INR3.3b in FY19 due to product launches and increased traction in existing products.

Due to manufacturing integration of API and formulation, we expect SLPA to have decent EBITDA margin of 32-35% from the US business. Accordingly, we expect EBITDA addition of INR461m and INR1b in FY18 and FY19, respectively, for SLPA.

In addition, SLPA has two ANDAs with para IV filing. Of these, one ANDA did not receive notice from the innovator. Also, SLPA has products under para IV filings with its partners, which can provide potential upside, subject to the litigation outcome.

With existing approvals and a healthy pipeline awaiting approvals, we expect SLPA to see a significant jump in US sales.

Exhibit 5: Potential for US revenue to grow at strong rate



Source: MOSL

Until now, a large part of oncology API sales has come from the EU market. Gemcitabine and Capecitabine are the major products in the company's portfolio for the EU market. SLPA continues to supply Gemcitabine in the EU and has a 30-35% market share for that product. The company has also filed for Irinotecan HCl trihydrate, Oxaliplatin and Temozolomide for EU market.

Recently, SLPA received marketing authorization from UKMHRA for Imatinib Mesylate, 100mg and 400mg. We expect better traction from this molecule for SLPA in UK market as well as other market in EU post regulatory approval.

Both API and formulations facilities cleared by FDA in recent past

SLPA would be using the API facility at Raichur and the formulations facility at Jadcherla for commercial production for the US market.

Exhibit 6: USFDA inspection history

Jadcherla formulation plant
❖ Re-inspected in July-16 and had **no 483s**
❖ Was inspected in Aug-15 and was issued form 483 with five observations

Raichur API plant
❖ Was re-inspected in Mar-15; was issued form 483 with five observations; received compliance letter in Feb-16
❖ Was inspected in May-13; was issued form 483 with six observations; received compliance letter in Jul-15

Source: Company, MOSL

Recently, in July -17, its formulation facility was inspected and was issued form 483 with one minor observation. The company was not issued form 483 post inspection of its formulations facility in July-16, which implies minimal regulatory risk over the medium term. Given that other companies are facing regulatory hurdles (which could impact their existing businesses and future approvals), we consider this to be a commendable achievement by the quality and operations team of SLPA. Notably, the company has also received two ANDA approvals post inspection.

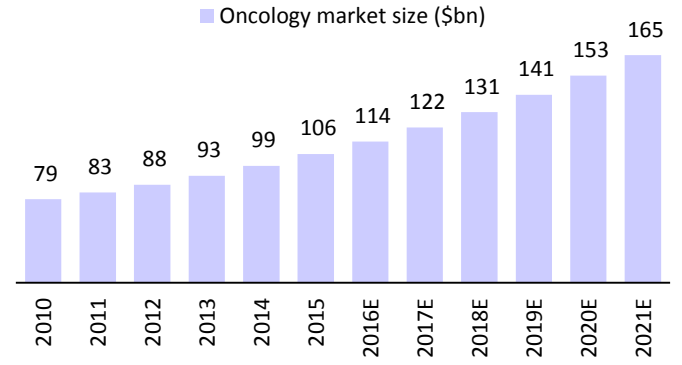
API facility was re-inspected last in March 2015. Given the general history of frequency of repeat inspections at any facility by USFDA within a year, there is possibility of re-inspection at this site at any time in near future.

Oncology industry scenario

As with any other therapy, even oncology has drugs in the off-patent and patented category. However, unlike other therapies, there is less likelihood of ever greening of patents of drugs in chemotherapy. This is mainly due to the shift in the efforts of large innovator pharmaceutical companies toward biologic targeted therapies.

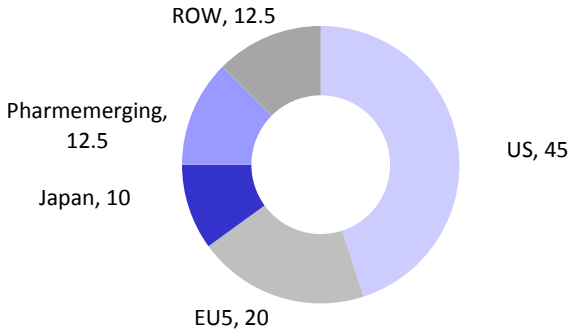
The global oncology market size is expected to grow at a steady 7-8% CAGR, from USD106b in 2015 to USD165b by 2020.

Exhibit 7: Oncology market size (USD b)



Source: Industry, MOSL

Exhibit 8: US forms majority share, followed by EU



Source: Industry, MOSL

Exhibit 9: Classification of oncology drugs

Source: Industry, MOSL

Growth in oncology industry is driven by:

- Advancement in targeted therapy (led to identification of new targets in neoplastic cells and development of novel targeted therapies).
- Increased access to medicines (price reduction in off-patented drugs has led to increased affordability of drugs).
- Technological advancement (has led to prolonging life of patients and lengthening duration of therapy).
- Increased incidences of cancer.

In terms of value, the oncology market is concentrated in the US, followed by the EU and emerging markets.

Depending on the type of cancer, a combination of therapies is used by doctors to treat patients. The global oncology chemotherapy market – currently a focus area for most generic companies – is expected record a CAGR of 8.4% over 2015-21 to reach a size of USD17b. This is largely due to the requirement of chemotherapy drugs in biologic based therapies, as well as the relatively low cost of such drugs. Also, biologics are complex in nature and take long time to develop. With less consistency in launching these drugs, not many drugs are available yet in the market. This scenario thus presents sustained business opportunities for chemotherapy drug manufacturers.

Exhibit 10: Key oncology chemotherapy drugs

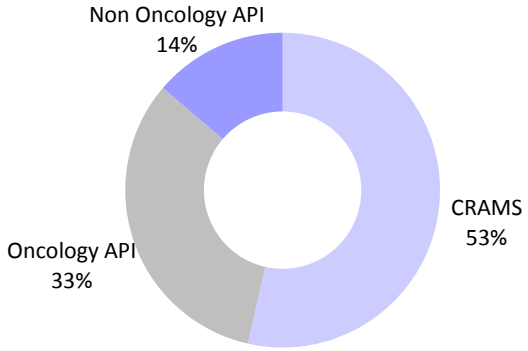
USD m	2015	2021E	CAGR over 2015-21E
Pemetrexed	2,599	1,073	(13.7)
Paclitaxel	2,086	4,329	12.9
Capecitabine	1,060	555	(10.2)
Oxaliplatin	1,060	888	(2.9)
Docetaxel	1,049	2,202	13.2
Methotrexate	958	3,071	21.4
Doxorubicin	581	1,055	10.4
Gemcitabine	536	241	(12.5)
Irinotecan	445	3,811	43.1
Carboplatin	274	278	0.2
Epirubicin	228	148	(6.9)
Venorelbine	148	148	(0.0)
Cisplatin	103	93	(1.7)
Cytarabine	91	56	(7.9)
Etoposide	80	37	(12.0)
Topotecan	57	37	(6.9)
Vinciristine	34	19	(9.7)
Daunorubicin	11	463	85.4
Total	**11,400**	**18,500**	**8.4**

Source: Industry, MOSL

CRAMS forms major share of current base business

At end-FY16, SLPA had three revenue streams: CRAMS, Onco-API and Non-Onco APIs. CRAMS (~53%) accounted for majority of the company's revenues in FY16, followed by Onco APIs (~33%) and Non-Onco APIs (14%).

Exhibit 11: Segment-wise revenue breakdown (FY16)

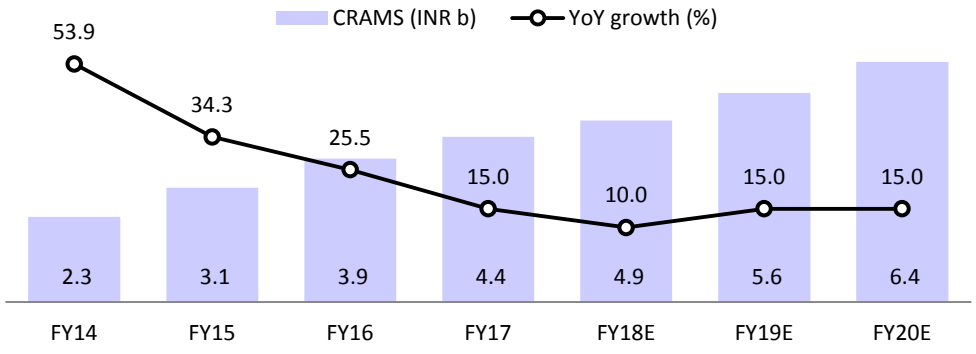


Source: Company, MOSL

JV with ICE ensures sustainability in CRAMS business

SLPA has been supplying Ursodeoxycholic acid (UDCA) to ICE. This business is mostly conducted via the CRAMs segment currently, but is expected to shift gradually to Raichem Medicare (JV with ICE).

Exhibit 12: We expect CRAMS revenue to grow at a moderate rate



Source: MOSL

About UDCA

Ursodiol suppresses synthesis and secretion of cholesterol by the liver. It inhibits intestinal absorption of cholesterol and is thus used to treat liver disorders. Since it is found in small quantities in human beings, it is chemically synthesized using animal bile.

SLPA, along with ICE, has formed a JV (Raichem Medicare) for setting up a manufacturing facility for intermediates for Ursodiol. SLPA has invested INR1b in this JV via equity, preference shares and loans & advances. The capacity of this facility is about 400t/month. The existing business of supplying intermediates for Ursodiol to ICE would be shifted to this JV. The current capacity for supplying intermediates for Ursodiol to ICE is about 200t/month. Post shifting intermediates supply for Ursodiol to the JV, the existing facility would be utilized for an alternate business. Installation

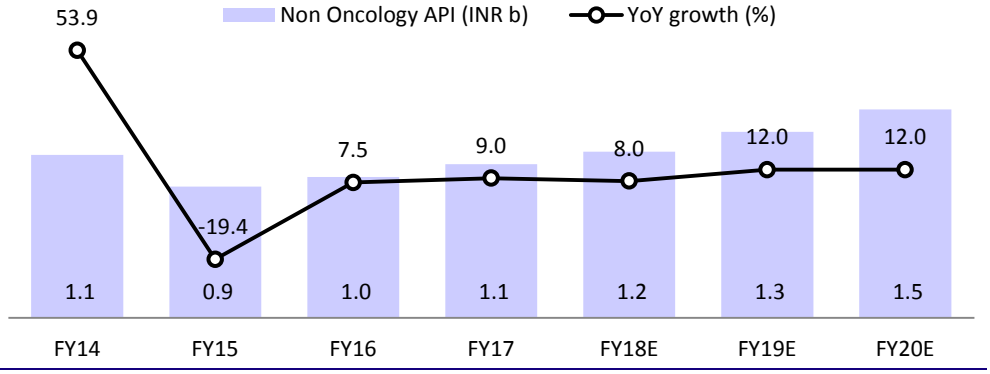
of all machineries was completed in FY16. It has also obtained drug manufacturing license, GMP certificate and consent from pollution control board for operating the plant. Initially, intermediates for UDCA would be manufactured at SLPA's site until ICE gets an import license (expected to be received soon). In addition, the validation batches for raw UDCA have been already exported, and registration of site with PMDA-Japan has been done. New validation batches with improved process and yields have been exported since November 2016.

There has been a strong CAGR of 20% over FY15-17 in sales of intermediates for Ursodiol due to the shift of manufacturing by ICE to SLPA's site. Thus, growth was largely led by volumes rather than price. We expect sales CAGR of 15% due to a high base of past year and moderate industry growth of 7-8% over next 2-3 years.

Non-Onco APIs to witness moderate growth over medium term

The primary product for SLPA in Non-Onco is Ambroxol. Non-Onco APIs formed 14% of sales in FY16. With an already strong share of ~60% in Europe, we expect growth in the company's Non-Onco segment to remain moderate. Ambroxol is a secretolytic agent used in the treatment of respiratory diseases associated with viscid or excessive mucus.

Exhibit 13: Strong market share provides limited growth in non-onco segment



Source: MOSL

Manufacturing facilities

Exhibit 14: Facilities details

API plants	
Location	**Remarks**
Raichur Unit I, India	For Onco/Non-Onco APIs and CRAMS, with capability from gram to kilo level
Raichur Unit II, India	100% EOU API unit
Austria	Capacity to produce kilo to ton quantities of APIs, intermediates, re-agents, diagnostics and controlled substances
Formulation plants	
Location	**Remarks**
Jadcherla, India	Capability to manufacture oral solid, tablets and capsules as well as injectables
Cherlapally, India	To manufacture oral fast-moving dissolving thin strip dosage form of drugs using fast disintegration technology

Source: MOSL, Company

Small investments which may reap benefit over long term

Exhibit 15: Details of investment in subsidiaries

Name of subsidiary	% stake	First year of investment	Amount invested (FY16)	Sales	PAT/ (Loss)
INM Technologies	75.0	FY15	165	-	-
Shilpa Therapeutics	67.9	FY12	75	24.5	(10.1)
Makindus	55.8	FY14	108	-	(71.2)
MAIA Pharma	34.8	FY14	93	29.6	(9.7)
Total			**441**		

Source: MOSL, Company

INM Technologies: Through this subsidiary, SLPA intends to develop products using nanotechnology. A facility for synthesis, characterization and analytical testing for nano-products, and trained manpower for process design/monitoring, have been established. INM Technologies is working on dental products with new formulation to avoid toxicity of existing filling material, dental hemostatic gels formulation with enhanced blood clotting, immediate release of drug, and temporary filling materials based on nano zinc oxide formulation for improved efficacy. The launch of these products is likely in 1QFY18, starting with India and then in other geographies as well.

INM Technologies is also working on dosage forms in ophthalmics, NDDS, SR oral thin film, parenteral and dermatology. The products are under various stages of development. Specifically, confirmative animal studies are going on for select formulations, and a few ophthalmic formulations are planned to scale up using contract manufacturing facilities.

Shilpa Therapeutics: This subsidiary is focused on the development and commercialization of novel drug delivery systems. It has commercialized prescription products on oral thin strips/films in India. The first product from this entity is Ondansetron – oral disintegrating strips. In addition, Shilpa is in the process of getting approvals from regulatory agencies of Kenya, Uganda and several other countries.

MAIA Pharmaceuticals: MAIA product pipeline consists of 15 niche generic and proprietary pharmaceutical products focused on the US, Canada and Europe. Until end-FY16, SLPA had invested INR92.8m in this entity where it has a stake of 34.8%. Recently MAIA got ANDA approval for Sodium Benzoate-Sodium Phenylacetate.

Koanaa Healthcare: Through Koanaa Healthcare (a wholly owned subsidiary), SLPA would be selling oncology products in Europe. The company would start with Austrian and German markets before exploring other European markets. SLPA will have its own commercial team in these markets. It would also have partnerships with other pharma companies in regions like northern Europe, CEE and Benelux and South Europe.

Loba Feinchemie: Loba Feinchemie was acquired in FY08. Loba provides specialty APIs, organic intermediates, biochemical diagnostics and CRAMS. The yearly run-rate of revenue has been stable at ~INR400m. There has been inflow of cash from this business from FY15. This is based on improved efficiency in manufacturing operations.

Makindus Inc.: Through Makindus, SLPA has focused on ophthalmology and rare diseases. Specifically, MI-100 is a novel ophthalmic formulation for legacy compound being developed for the Stargardt disease. This subsidiary intends to file NDA in 4Q2018 through the 505(b)(2) route. Makindus is in discussion with few companies for financial support for phase 3 clinical trials.

Navya Biologicals: In June 2016, the board of directors of SLPA approved the amalgamation Navya Biologicals. The process would be completed soon. The consideration for the acquisition is through issue of 1.4m equity shares of SLPA to the shareholders of Navya Biologicals upon implementation of the proposed scheme.
Navya Biologicals is engaged in the development of bio-pharmaceuticals, with a focus on products in Oncology, Auto-immune disease, Ophthalmology and Nephrology for itself as well as for innovators.

Exhibit 16: Navya's product pipeline

S. No	Molecule	Indication	Early Tech dvpt	Late Tech dvpt	Preclinical Studies	Human Clinical Studies	Commercialised
1	NAV-003	CKD, IBD, MDp					
2	NAV-013	Infertility					
3	NAV-012	MI					
4	NAV-001	AI Disoders					
5	NAV-002	AI Disoders					
6	NAV-004	Oncology					
7	NAV-010	AI Disorders					
8	NAV-008	Oncology, AMD					
9	NAV-009	AI Disorders, OT					
10	NAV-005	rHSA					
11	NAV-007	Oncology					

Source: MOSL, Company

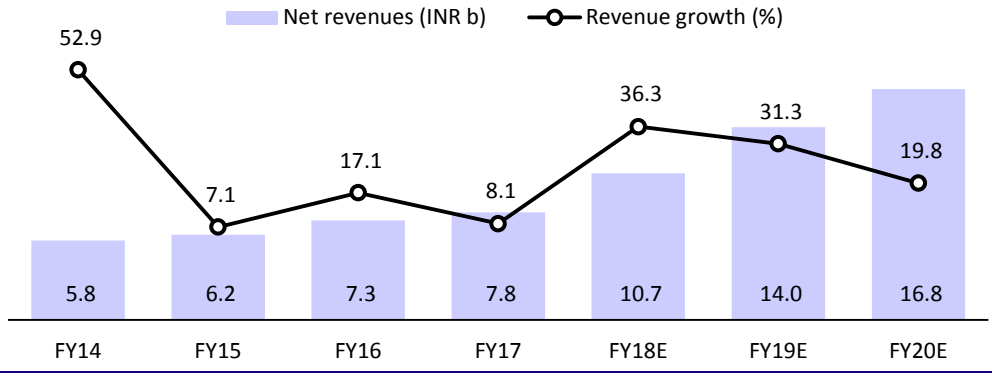
Navya recorded sales of INR39.5m and PAT of INR7.7m in FY16, largely from its product - Navalbumin. With this amalgamation, SLPA intend to make strides in the biosimilar space.

Although the potential benefit from the investment could be considerable, overall investment has been low and marginally impacting financial leverage of the company.

Return ratios set to improve

SLPA's revenues have grown at a CAGR of 19% over last five years, from INR3.2b to INR7.8b. As seen in the chart below, YoY growth in FY15 and FY16 was lower than the five-year average, mainly due to temporary disruption in supplies in Onco and Non-Onco APIs. We, however, note that CRAMS' growth rate was better than the company's five-year average growth.

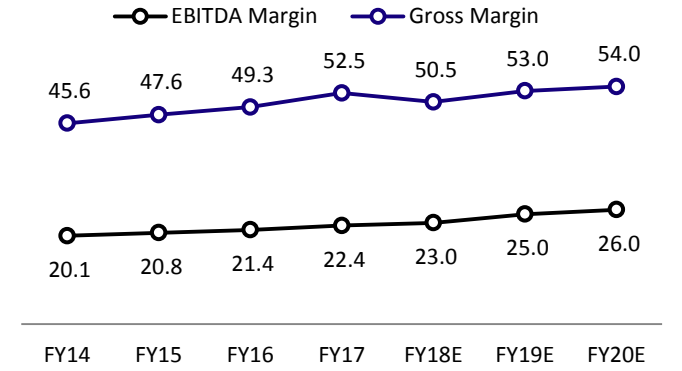
Exhibit 17: We expect trajectory of revenue growth to remain on uptrend over 2-3 years



Source: Company, MOSL

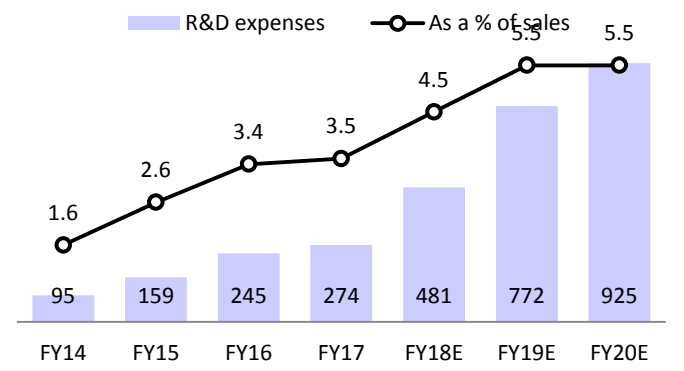
The gross margin expanded from 44% in FY11 to 49% at end-FY16. It was stable at 49% in 1HFY17. We expect the gross margin to improve from 4QFY17 as it would include sales of Capecitabine and Azacitidine (relatively high-margin products compared to the overall portfolio) to the US market. With more approvals and increased business to the US market, we expect the gross margin to improve 310bp over FY16-19.

Exhibit 18: Higher formulation sales to lead to better margins



Source: Company, MOSL

Exhibit 19: Higher R&D spent toward building US pipeline



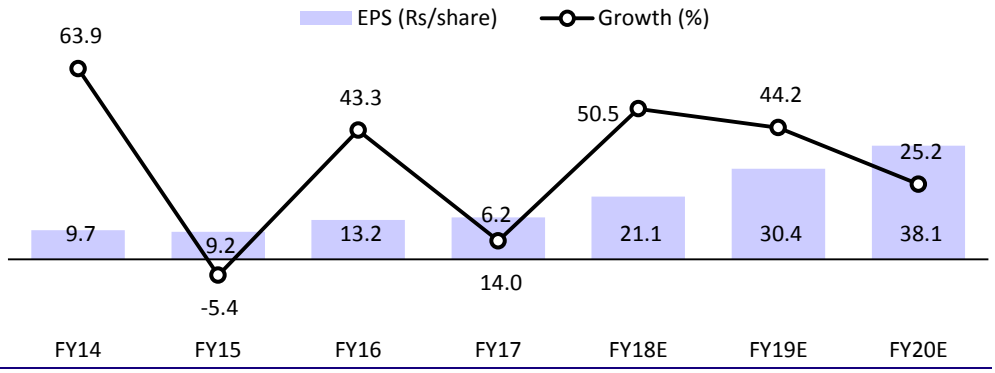
Source: Company, MOSL

Although the gross margin expanded over FY12-17 by 914bps, the EBITDA margin increased by 351bp from 19.1% to 22.4%, largely due to higher employee cost, increase in R&D expense and higher other expenses. Increase in fixed cost associated with a delay in utilization of the new facility, coupled with continued spends on product development, led to a contraction in the EBITDA margin over past five years. Commencement of commercial production for already approved products and then of newer products post approval should also offer support.

Despite improved operating efficiency, we expect the EBITDA margin to expand at a lower rate than the gross margin due to higher R&D spending for future product development.

PAT has grown at a rate lower to EBITDA due to increase in the effective tax rate from 14.8% in FY11 to 28.7% in FY16.

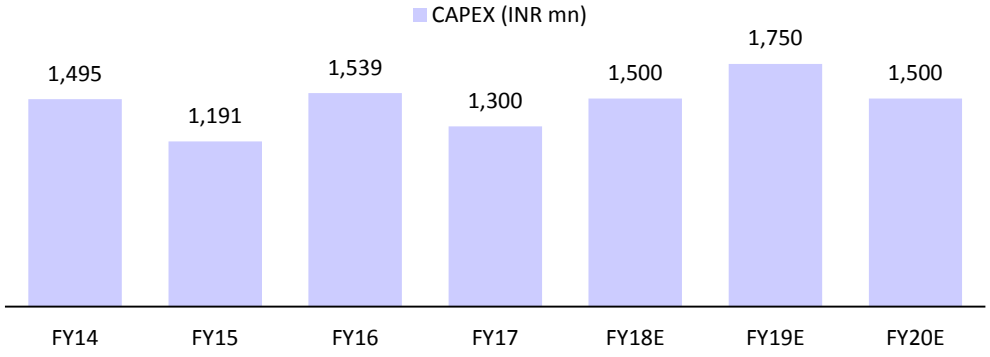
Exhibit 20: We expect strong EPS growth as quantum of US formulation business increases



Source: Company, MOSL

At end-FY16, SLPA had gross block of INR7.5b, with almost 56% of assets added over past three years. The company has envisaged capex of INR4.5b for next two years. Capex would comprise capacity expansion at Jadherla (~INR1.5b), Raichur (~INR500m), R&D, Vizag (~INR500m) and also significant investment of INR1.5b in biosimilars.

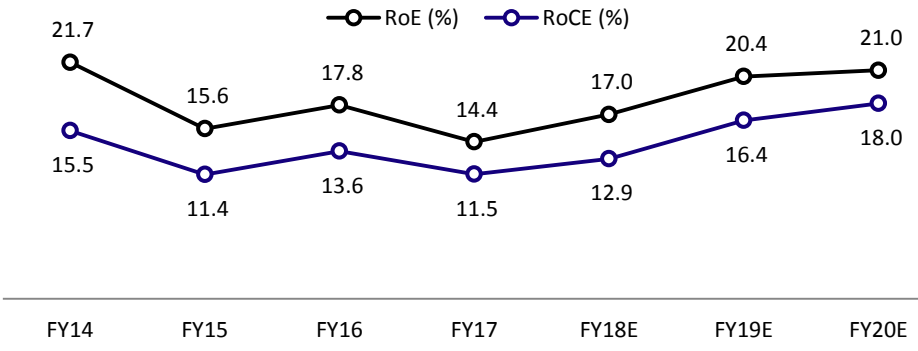
Exhibit 21: Capex (INR m)



Source: Company, MOSL

There has been deterioration in RoCE and RoE over past five years. This is mainly because of the delay in entering the US market due to regulatory hurdles, leading to lower asset turnover. RoE dropped from 30% in FY11 to 17.7% in FY16. With regulatory issues resolved and product approvals kicking in, we expect commercial production to pick up from 4QFY17, facilitating return ratio improvement. We expect RoEs to improve from 14.4% in FY17 to 21% in FY19.

Exhibit 22: Better asset utilization to drive return ratios



Source: Company, MOSL

Exhibit 23: Revenue may reduce due to shift of some CRAMS business to JV, however, it would not impact total profits (INR m)

Proforma Financials	FY17	FY18E	FY19E	FY20E
Custom Synthesis (Non Onco)	3,631	2,872	2,500	2,750
Oncology API	2,776	3,359	3,793	4,855
Non Oncology API	1,079	1,187	1,305	1,462
Onco to US market	250	1,536	3,327	4,050
Sales post transfer of CRAMS revenue to JV	7,736	8,682	10,925	13,116
EBITDA Margin (%)	21.0	23.3	24.5	25.5
EBITDA (INR m)	1,625	2,023	2,677	3,345
PAT	**1,083**	**1,346**	**1,912**	**2,427**
SLPA's share of Revenue from JV	798	2,000	3,103	3,693
EBITDA Margin (%)	16.3	21.6	26.8	27.8
EBITDA (INR m)	129.85	434	830	1,026
PAT from JV business	**40**	**314**	**510**	**624**
Total PAT including profit from JV business	**1,123**	**1,660**	**2,422**	**3,055**

With some CRAMS business getting shifted to JV (with ICE), there would be reduction in revenue as per accounting norms. However, this would not have impact on PAT as profit from JV would be added to profit from other business.

Sensitivity analysis implies limited downside from current levels

- In our base case, we factor in revenue and PAT CAGR of 29% and 41% over FY17-20 to INR16.8b and INR3b, respectively, led by improving business from the EU and US markets. With increased business from limited-competition products in the US, we expect the EBITDA margin to expand by 260bp over the same period.
- In our bear case, sales and PAT CAGR would reduce to 20%, led by lesser business from already approved products and delays in new approvals. Accordingly, FY19E EPS would be INR26.4 and the price target would be INR583, implying limited downside.
- In our bull case, sales and PAT CAGR would be 37% and 42% to INR18.3b and INR3.1b, respectively, led by increased number of approvals and subsequent launches, resulting in strong business from the US market. Accordingly, FY19E EPS would be INR39 and the price target would be Rs1,066, implying upside of 64.8% from current levels.

Exhibit 24: Sensitivity analysis

Sensitivity Analysis	Bear Case	Base Case	Bull Case
Revenue	14,387	14,028	18,387
EBITDA	3,338	3,507	4,633
EBITDA margin (%)	23.2	25	25.2
PBT	2,756	3,162	4,051
Tax rate (%)	25.0	23.0	25.0
PAT	2,036	2,435	3,008
EPS	26.4	30.4	39.0
Multiple	21.0	25.0	27.0
12m Fwd Target price	583	805	1,066
% Return	(9.9)	24.4	64.8

Source: Company, MOSL

We expect premium valuation to sustain for SLPA

- The five-year average P/E has been 21x for SLPA, higher than mid-cap pharma P/E of 16-20x one-year forward earnings.
- Over the past year, the business scenario has been muted for peers, mainly due to the delay in resolving regulatory issues and pricing pressure on the base business, mainly in the US market. This has also resulted in de-rating of many pharma companies as the US has been a focus market for superior growth in sales and profitability. However, SLPA is better positioned as it has USFDA clearance in place.
- In addition, SLPA has built a strong product pipeline, mainly in oncology space where products are relatively complex and face low competition. We expect US sales to grow from INR250m in FY17E to INR3.3b by FY19E. Accordingly, we expect PAT to increase 2.2x over FY17-19E. The pipeline for the US market has products with potential to drive YoY US revenue growth of ~51% in FY20.
- RoCE appears muted currently, largely due to lower utilization of its formulation facility. However, with a few product approvals in place and a healthy product pipeline, we expect RoCE to improve from 13.6% in FY16 to 16.4% by FY19.
- Also, for expected YoY earnings growth of 50%/44% in FY18/FY19, PEG is 0.45x/0.65x, implying that the stock is attractive at current levels.
- Accordingly, we value SLPA at 25x 12M forward earnings, implying a 29% premium to its five-year average P/E.
- We expect sales, EBITDA and PAT CAGR of 29%, 36% and 41% to INR16.8b, INR4.3b and INR3b, respectively over FY17-20E. Assuming PAT growth and improving return ratios, we value SLPA at 25x 12M forward earnings to arrive at a price target of INR805.

Key risks

- Delay in approval for products in respective markets.
- Longer-than-expected time taken to execute in terms of manufacturing and selling.
- Higher-than-expected competition in its key products.
- Untoward outcome of future regulatory inspections may have an impact on existing business and/or future product approvals as it has only one formulation facility for the US market.

Exhibit 25: Peer comparison (INR m)

	Sales			EBITDA margin (%)			PAT			P/E (x)			EV/EBITDA (x)		
	FY17	FY18E	FY19E	FY17	FY18E	FY19E	FY17	FY18E	FY19E	FY17	FY18E	FY19E	FY17	FY18E	FY19E
Shilpa	**7,836**	**10,682**	**14,028**	**22.4**	**23.0**	**25.0**	**1,123**	**1,689**	**2,435**	**46.2**	**30.7**	**21.3**	**30.5**	**21.9**	**15.4**
Ajanta	20,020	22,554	27,428	34.9	34.7	34.2	5,168	5,848	7,037	24.1	21.3	17.7	17.8	15.7	12.8
Indoco	10,694	12,274	14,073	14.6	16.1	16.7	771	996	1,274	24.0	18.6	14.5	13.0	10.3	8.7
Natco	20,650	25,978	23,841	33.1	37.5	28.1	4,860	5,956	4,161	35.3	34.8	27.5	25.2	21.8	17.7
Unichem	15,195	18,043	20,683	11.8	13.4	14.2	1,087	1,552	1,946	22.3	15.5	12.4	14.0	10.3	8.4
Alembic	31,013	32,535	37,242	19.7	18.0	19.5	4,068	3,856	4,810	25.1	26.5	21.3	16.6	16.9	13.8
Biocon	38,760	47,806	59,271	24.1	24.0	25.5	6,118	6,219	8,629	39.1	38.5	27.7	26.2	21.5	16.1
Granules	14,353	17,051	23,390	20.8	21.6	22.4	1,654	2,075	2,926	19.0	16.8	11.9	11.7	9.0	6.6

Source: Bloomberg, MOSL

About Shilpa Medicare

- SLPA has been involved in the manufacture of active pharmaceutical ingredients (APIs) since 1987. Over the period of time, it has shifted its focus toward creating a niche in pharmaceutical manufacturing. In the process, it has developed strong capability in manufacturing oncology APIs and formulations.
- Besides this, SLPA is investing in novel drug delivery systems (NDDS) and biotechnology.

Key personnel at SLPA

Vishnukant Bhutada – Managing Director

Mr Bhutada has vast and diverse business experience of API and intermediates. He leads the core business and functional teams that accelerate growth and performance by innovating affordable solutions at Shilpa Medicare Group of Companies. He is the key decision maker, and is responsible for successful API and generics formulation strategies.

Dr. Vimal Kumar Shrawat – Chief Operating Officer

Dr. Shrawat by qualification holds degrees of M.Sc (Organic Chemistry), Ph.D. (from Delhi University) and joined SLPA in 2009. He has vast experience of more than 25 years of working in large pharma industries like Ranbaxy, Fresenius Kabi Oncology, spanning across activities of R&D, Pilot and Plant Productions, QA/QC, Administration, CRAMS, Project management etc. Presently, Dr. Shrawat is spearheading the entire Operations of Shilpa Medicare. His keen interest and consistent efforts for R&D has led him to become one of key contributor in large number of Patent applications of SLPA.

Prashant Purohit – Vice President, Chemical R&D

His vast experience of nearly 35 years in R&D/production in the pharmaceuticals industry has consistently enriched the portfolio of SLPA. He is one of the key contributors in a large number of patent/applications of SLPA. Mr Purohit holds M.Sc. (Organic Chemistry) and Diploma in Business Management. He has been associated with SLPA since 1996.

R K Somani – Vice President, Formulation business development

Mr. Somani is one of the key drivers of formulation business besides handling various key contract businesses of advanced Oncology/ Non-Oncology APIs. He is known for successfully building a formulations portfolio and spearheading the generic sales operation. By qualification, he is CA and also holds diploma in central excise. He has overall experience of 21 years in the field of pharmaceuticals.

Dr. Seshachalam – Vice President, Quality and Regulatory affairs

Dr. Seshachalam has been instrumental in SLPA's efforts to achieve recognition of different authorities. His contribution in successful inspection and audit by various regulatory authorities is one of the core strengths to the organization's aims and objectives. He holds M.Sc. (Chemistry) and Ph.D (Chemistry). He joined SLPA in 2008.

Financials and Valuations

Income Statement (INR Million)

Y/E March	FY13	FY14	FY15	FY16	FY17	FY18E	FY19E	FY20E
Total income from Operations	**3,784**	**5,785**	**6,195**	**7,251**	**7,836**	**10,682**	**14,028**	**16,810**
EBITDA	**686**	**1,160**	**1,286**	**1,554**	**1,754**	**2,457**	**3,507**	**4,371**
Margin (%)	18.1	20.1	20.8	21.4	22.4	23.0	25.0	26.0
Depreciation	153	232	214	286	300	362	443	525
EBIT	**533**	**928**	**1,072**	**1,267**	**1,454**	**2,095**	**3,064**	**3,846**
Int. and Finance Charges	23	35	41	69	27	81	81	66
Other Income	61	91	48	46	180	180	180	180
PBT before EO Exp.	**571**	**984**	**1,080**	**1,245**	**1,556**	**2,194**	**3,162**	**3,960**
EO items	-1	-29	-1	-24	-45	0	0	0
PBT after EO Exp.	**570**	**955**	**1,078**	**1,221**	**1,511**	**2,194**	**3,162**	**3,960**
Current Tax	83	153	233	255	447	505	727	911
Deffered Tax	12	50	119	-21	0	0	0	0
Tax Rate (%)	16.7	20.6	32.6	18.8	28.7	23.0	23.0	23.0
LesS: Minority interest	0	-5	-11	-51	-27	0	0	0
Reported PAT	**475**	**757**	**737**	**1,038**	**1,091**	**1,689**	**2,435**	**3,049**
Adjusted PAT	**476**	**780**	**738**	**1,057**	**1,123**	**1,689**	**2,435**	**3,049**
Change (%)	16.7	63.9	(5.4)	43.3	6.2	50.5	32.8	25.2
Margin (%)	12.5	13.1	11.9	14.3	13.9	15.8	17.4	18.1

Balance Sheet (INR Million)

Y/E March	FY13	FY14	FY15	FY16	FY17	FY18E	FY19E	FY20E
Equity Share Capital	49	74	77	77	80	80	80	80
Total Reserves	3,155	3,891	5,392	6,316	9,082	10,681	12,986	15,872
Net Worth	**3,204**	**3,964**	**5,469**	**6,393**	**9,162**	**10,761**	**13,066**	**15,952**
Minority Interest	87	100	144	23	-24	-24	-24	-24
Deferred Tax Liabilities	209	259	378	510	618	618	618	618
Total Loans	1,157	989	1,631	821	2,395	2,395	2,395	1,395
Capital Employed	**4,658**	**5,313**	**7,622**	**7,747**	**12,151**	**13,749**	**16,055**	**17,941**
Net Fixed Assets	**1,756**	**2,814**	**2,984**	**3,828**	**4,327**	**5,383**	**6,690**	**7,666**
Goodwill on Consolidation	52	131	177	89	98	98	98	98
Capital WIP	1,291	1,110	2,216	916	897	897	897	897
Total Investments	**507**	**105**	**657**	**1,361**	**3,240**	**3,240**	**3,240**	**3,240**
Curr. Assets, Loans & Adv	**1,909**	**2,618**	**3,012**	**3,099**	**5,166**	**6,387**	**7,987**	**9,414**
Inventory	743	1,233	1,308	1,342	1,898	2,567	3,283	3,882
Account Receivables	418	680	814	1,254	1,709	2,330	3,060	3,667
Cash and Bank Balances	169	92	184	109	965	672	553	462
Loans and Adances	433	599	666	206	257	350	460	551
Other Current Assets	146	16	40	187	337	468	631	852
Curr. Liability and Prov.	**856**	**1,465**	**1,423**	**1,562**	**1,607**	**2,256**	**2,857**	**3,374**
Account Payables	513	930	755	1,007	1,112	1,581	1,972	2,312
Other Current Liabilities	234	382	493	365	286	389	511	613
Provisions	110	153	175	190	209	285	374	449
Net Current Assets	**1,053**	**1,153**	**1,588**	**1,537**	**3,559**	**4,131**	**5,130**	**6,040**
Deferred tax Assets	0	0	0	14	0	0	0	0
Appl.of Funds	**4,658**	**5,313**	**7,622**	**7,747**	**12,151**	**13,749**	**16,055**	**17,941**

Financials and Valuations

Ratios

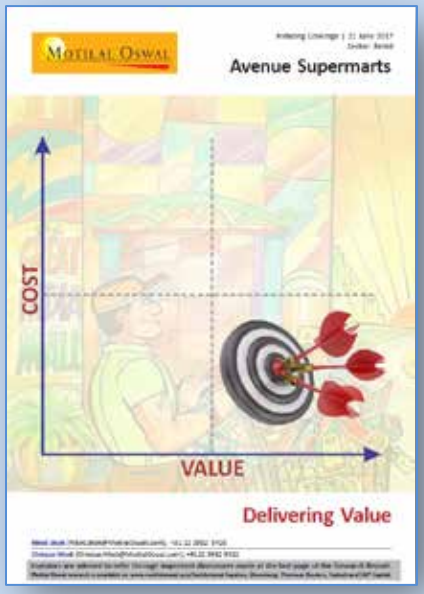
Y/E March	FY13	FY14	FY15	FY16	FY17E	FY18E	FY19E	FY20E
(INR)								
EPS	5.9	9.7	9.2	13.2	14.0	21.1	30.4	38.1
Cash EPS	12.8	13.8	12.3	17.4	17.8	25.6	35.9	44.6
BV/ Share	65.3	53.9	70.9	82.9	114.4	134.3	163.1	199.1
DPS	0.6	0.5	0.5	0.6	0.6	0.9	1.4	1.7
Payout (%)	11.0	5.4	6.0	4.5	4.3	4.5	4.5	4.5
Valuation (x)								
P/E				49.4	46.2	30.7	21.3	17.0
Cash P/E				37.4	36.4	25.3	18.1	14.5
P/BV				7.9	5.7	4.8	4.0	3.2
EV/Sales				7.1	6.8	5.0	3.8	3.2
EV/ EBITDA				33.0	30.5	21.9	15.4	12.1
Dividend Yield (%)				0.1	0.1	0.1	0.2	0.3
FCF per Share				(3.0)	(10.1)	(2.5)	3.0	13.4
Return Ratios (%)								
ROE	15.9	21.7	15.6	17.8	14.4	17.0	20.4	21.0
ROCE	11.9	15.5	11.4	13.6	11.5	12.9	16.4	18.0
Working Capital Ratios								
Inventory (Days)	83.5	78.0	94.5	84.9	97.2	99.1	101.5	105.1
Debtor (Days)	39.7	34.6	44.0	52.0	69.0	69.0	70.1	73.0
Creditor (Days)	63.6	56.9	62.6	56.4	63.6	59.8	61.6	62.8
Leverage Ratios (x)								
Current Ratio	2.7	1.7	2.5	2.5	5.1	4.2	4.0	3.8
Interest Coverage Ratio	23.5	26.3	26.5	18.5	54.1	25.8	37.8	58.1
Debt/Equity	0.4	0.3	0.3	0.2	0.3	0.3	0.2	0.1

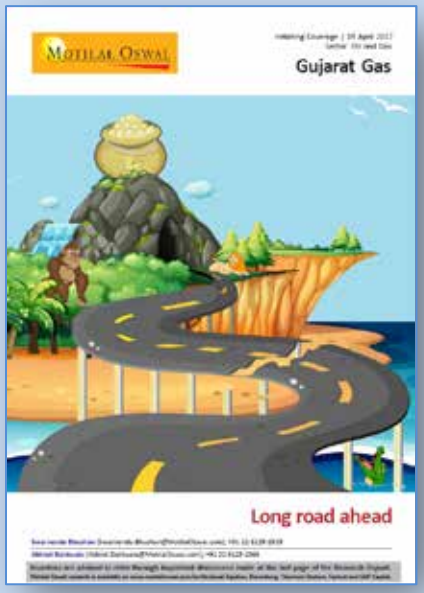
Cash Flow Statement **(INR Million)**

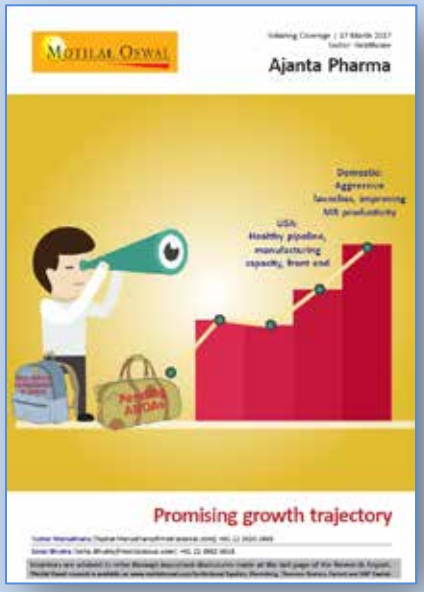
Y/E March	FY13	FY14	FY15	FY16	FY17	FY18E	FY19E	FY20E
OP/(Loss) before Tax	570	955	1,078	1,221	1,511	2,194	3,162	3,960
Depreciation	153	232	214	286	300	362	443	525
(Interest received)	(4)	(14)	(17)	(5)				
Direct Tax Paid	(110)	(216)	(254)	(316)	(447)	(505)	(727)	(911)
(Inc)/ Dec in WC	(139)	(234)	(401)	74	(1,357)	(865)	(1,118)	(1,001)
CF from Operations	**471**	**723**	**621**	**1,261**	**7**	**1,186**	**1,761**	**2,572**
Others	(34)	(22)	67	68				
CF from Operating incl EO	**437**	**701**	**688**	**1,329**	**7**	**1,186**	**1,761**	**2,572**
(Inc)/ Dec in FA	(1,025)	(1,086)	(1,428)	(1,568)	(816)	(1,389)	(1,750)	(1,500)
Free Cash Flow	**(588)**	**(386)**	**(740)**	**(239)**	**(809)**	**(203)**	**11**	**1,072**
(Pur)/ Sale of Investments	177	429	(550)	149	(1,581)	-	-	-
Others	(104)	168	26	5	-	-	-	-
CF from Investments	**(952)**	**(489)**	**(1,951)**	**(1,414)**	**(2,397)**	**(1,389)**	**(1,750)**	**(1,500)**
Issue of Shares	4	-	814	-	1,720	-	-	7
Inc / (Dec) in debt	666	(213)	586	197	1,537	-	-	(1,000)
Dividend Paid	(25)	(37)	(45)	(106)	(58)	(90)	(130)	(163)
Interest paid	(22)		(37)	(54)				
Others	41	(33)	44	4	47			(7)
CF from financial activity	**663**	**(283)**	**1,362**	**41**	**3,246**	**(90)**	**(130)**	**(1,163)**
Inc / (Dec) in Cash	148	(72)	99	(44)	856	(293)	(120)	(91)
Opening Balance	23	169	92	184	109	965	672	553
Closing Balance	**169**	**92**	**184**	**159**	**965**	**672**	**553**	**462**

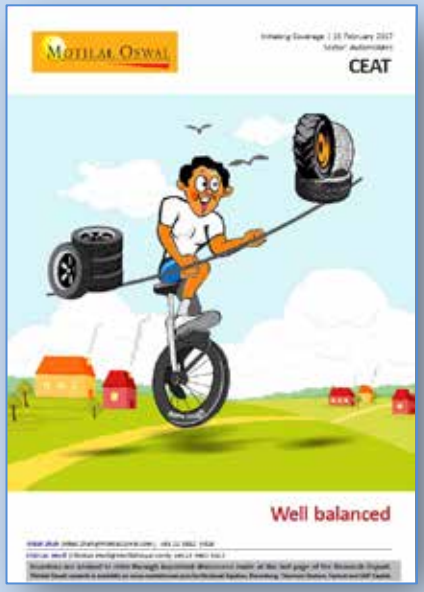
REPORT GALLERY

RECENT INITIATING COVERAGE REPORTS









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