Equity Research

July 25, 2016

BSE Sensex: 27803

Pharmaceuticals

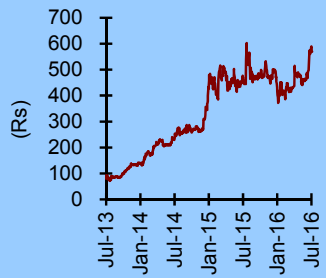
Target price Rs614

Shareholding pattern

	Dec' 15	Mar '16	Jun '16
Promoters	53.1	53	56.9
Institutional investors	15.0	14.8	13.8
MFs and UTI	0.1	0.1	0.1
Insurance co		0	0
FIIs	14.9	14.7	13.7
Others	38.1	32.2	29.3

Source: BSE

Price chart



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INDIA

Shilpa Medicare

ADD

Niche oncology play

Rs548

Reason for report: Initiating coverage

Shilpa Medicare (Shilpa) is a niche oncology player with robust portfolio of APIs and formulations, supplying to a clutch of leading global players in regulated markets such as Europe, Japan and South Korea among others. Going ahead, the US too would be a key market for the company as it has already received USFDA approval for its two API facilities and awaits approval for its formulation facility. Further, steady growth is most likely to continue in the company's non-oncology API and custom synthesis business. With an estimated earnings CAGR of 32.7% over FY16-FY19 and substantial improvement expected in return ratios despite the continued investment phase, we initiate coverage on Shilpa with an ADD rating and target price of Rs614/share (22x Sep'18E EPS).

- **Oncology – niche segment with high growth potential:** Shilpa has successfully established its presence in the complex oncology API space as evident from its ~20 oncology DMF filings, USFDA approval for two API plants (in Raichur, Karnataka) and ~36% revenue contribution (~US$40mn) from oncology business. Shilpa is looking to move up the value chain to emerge as a formidable player in oncology formulations. The company has already filed 19 ANDAs and is awaiting USFDA approval for its formulation plant. We believe this would be the key growth and margin driver going ahead. We expect revenues from the oncology API and formulations business to grow at 42.8% CAGR over FY16-19 largely driven by supplies to the US market.
- **Non-oncology business to grow at steady pace:** Having built a good base in oncology, Shilpa has also developed and commercialized APIs in other categories such as multiple sclerosis. The company has also formed strategic partnerships in non-oncology areas to venture into niche products like ursodeoxycholic acid with Italy-based Industria Chimica Emiliana (ICE) and tranexamic acid with a Japanese player. These partnerships work under the custom synthesis business model. We expect these businesses to grow at steady pace of 10.7% CAGR over FY16-FY19.
- **Sound financials:** Considering the high growth potential of generic oncology business, we expect Shilpa to report revenue and earnings CAGRs of 24.6% and 32.7% respectively over FY16-FY19. Further, RoE and RoCE would also improve substantially to 23.9% and 20.3% respectively in FY19E despite the continued investment phase. We expect Shilpa to start generating meaningful free cashflow from FY19 and debt/equity to come down to 0.1x in FY19.
- **Valuation and risks:** We value the stock at Rs614/share (22.0x Sep'18E EPS). We initiate coverage on Shilpa with a **ADD** rating. The key risks to our call are: delay in clearance of Form 483 observations at the Jadcherla plant and forex volatility.

Market Cap	Rs422 mn / US$6.3bn
Reuters/Bloomberg	SHME.BO/SLPA IN
Shares Outstanding (mn)	77.0
52-week Range (Rs)	603/373
Free Float (%)	43.1
FII (%)	13.7
Daily Volume (US$'000)	3,407
Absolute Return 3m (%)	12.5
Absolute Return 12m (%)	21.5
Sensex Return 3m (%)	8.4
Sensex Return 12m (%)	(1.0)

Year to March	FY16P	FY17E	FY18E	FY19E
Net Revenue (Rs mn)	7,194	8,547	11,321	13,926
Net Profit (Rs mn)	1,038	1,271	1,909	2,471
Dil. EPS (Rs)	13.5	16.2	24.3	31.5
% Chg YoY	43.3	20.2	50.3	29.4
P/E (x)	40.7	33.9	22.5	17.4
CEPS (Rs)	41.1	21.4	43.7	26.2
EV/EBITDA (x)	27.9	22.7	15.5	11.8
Dividend Yield (%)	0.3	0.3	0.5	0.6
RoCE (%)	13.6	13.8	17.6	20.3
RoE (%)	17.7	18.1	22.7	23.9

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Oncology: Niche segment with high growth potential

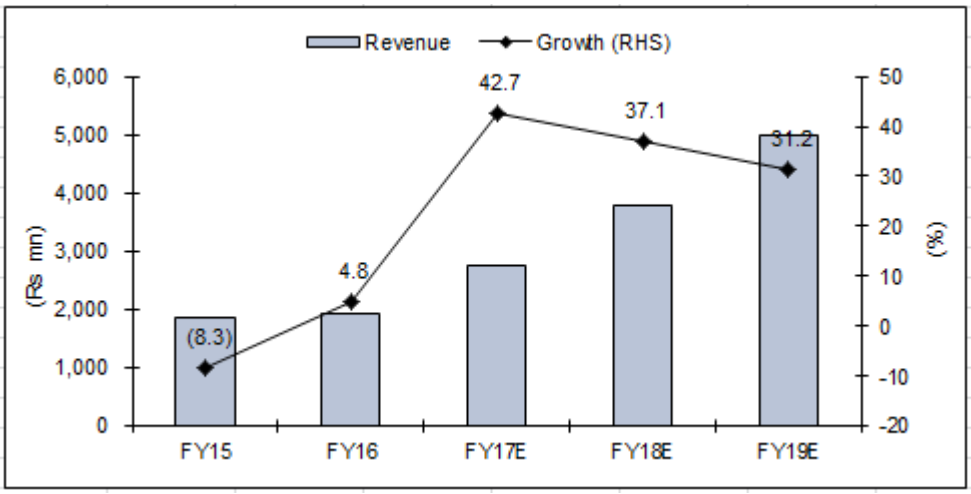
We believe the oncology segment in pharmaceutical industry worldwide provides strong growth potential with high profit margins due to following reasons:

- Oncology is the largest disease category in developed nations and is the biggest specialty category in emerging countries.
- The global oncology market size is expected to cross US$100bn by CY18 implying absolute growth of US$20bn-50bn over CY13-CY18 on base of US$65bn in CY13.
- Competition is limited due to complexity of synthesis, regulatory hurdles and high capital outlay.

Among India's leading oncology API players

Leveraging its prior experience with Dabur Pharma, which is presently known as Fresenius Kabi Oncology Ltd, Shilpa Medicare (Shilpa) decided to concentrate on building its expertise in the oncology space. While the company set up its first oncology API block way back in 2006, sales of oncology APIs did not contribute meaningfully to the company's overall revenues till FY09. However, the patent expiry of Gemcitabine in key European markets in 2009 provided Shilpa with an important opportunity to grow its oncology API business. Since then, there has been no looking back for the company, which has now emerged as one of the leading Oncology API and intermediate manufacturers in India. Oncology API business contributes ~27% to Shilpa's overall revenues. We expect revenues from this segment to grow at 36.9% CAGR over FY16-FY19 led by commencement of commercial supplies to the US and steady growth of 10-15% in supplies to countries other than the US.

Chart 1: Revenue growth in oncology API business



Source: Company data, I-Sec research

Shilpa has one of the largest oncology API manufacturing capacities in India with six fully-equipped cytotoxic blocks, supplying to some of the leading global pharmaceutical companies in important markets such as Europe, Brazil, Japan, Russia and Australia in addition to other emerging markets. The company has also received USFDA and PMDA (Japan) approvals for its two API facilities (in Raichur, Karnataka) recently, which would accelerate the growth momentum FY17 onwards. It currently has a basket of >25 products including important products such as

capecitabine, gemcitabine hydrochloride, oxaliplatin, erlotinib hydrochloride, azacitidine and irinotecan hydrochloride. Further, the company's R&D team is working on almost all the oncology products that are slated for patent expiry till 2029.

One of the main growth drivers for the company has been its timely capacity expansion and product filings. Over the years, based on its customer interactions and its assessment of demand-supply situation, the company has invested in additional capacities well ahead of time. This has helped it emerge as a leading supplier of gemcitabine and capacitabine in Europe with meaningful market share. In both these molecules, the company has increased its capacity by more than 4x over the past four years.

Table 1: Country-wise key oncology API filings by Shilpa

Molecule	Brand name	USA US	Europe EU	Canada TPD	Japan PMDA	Australia TGA	Europe EDQM	Korea KFDA	Gulf GCC	New Zealand Medsafe
Azacitidine	*Vidaza*	√								
Bendamustine	*Treanda*	√	√							
Bicalutamide	*Casodex*	√		√	√					
Bortezomib	*Velcade*	√		√				√		
Busulphan	*Myleran*	√				√	√			
Capecitabine	*Xeloda*	√	√	√		√		√		√
Carboplatin	*Paraplatin*						√			
Decitabine	*Dacogen*	√								
Erlotinib HCL	*Tarceva*	√								
Gemcitabine	*Gemzar*	√	√	√	√	√	√	√	√	
Irinotecanl	*Camptosar*	√	√	√		√			√	√
Letrozole	*Femara*	√								
Oxaliplatin	*Eloxatin*	√	√	√		√	√	√		√
Pemetrexed Disodium	*Alimta*	√		√						
Temozolomide	*Temodar*	√	√	√		√		√		√
Zoledronic acid	*Reclast*	√								

Source: Company data, I-Sec research

Growth rate to accelerate with US supplies

Shilpa Medicare (Shilpa) has recently received USFDA approval for two its oncology API manufacturing facilities, namely Unit I and Unit II located in Raichur, Karnataka. Both these plants have also been recently approved by Japan's PDMA. We believe this would be the key growth driver over FY16-FY19 as DMF filings are already in place and the company has also tied up with different generic players for supplying the APIs. We expect Shilpa to garner revenue of US$8mn, US$20mn and US$30mn from oncology API supplies in FY17, FY18 and FY19 respectively.

Given that the US is one of the key markets for oncology products, Shilpa has invested in dedicated oncology API facilities at Raichur (Unit I and Unit II). The USFDA approved both these facilities in Feb'16. The company also has a US product pipeline of about >20 DMF filings with cumulative branded sales of more than US$ 8bn. These DMF filings include some interesting opportunities such as azacitadine, decitabine, capecitabine, and temozolomide, which are already off-patent and have less than four generic players in the market. The company's DMF list also features some important products whose patents are set to expire over the next few years. These include, APIs for generic *Gleevec*, *Velcade*, *Alimta*, *Treanda*, and *Gilenya*.

Given that oncology API development and manufacturing facilities involve highly specialised technical capabilities and high capital investments, there is relatively lower competitive intensity in the space, which ensures better profitability for the manufacturer. Hence, the USFDA approval for Shilpa's Raichur facilities would help

the company to monetise its robust DMF pipeline. Further, for its formulation facility at Jadcherla, Telangana, which is awaiting USFDA approval, the company would be sourcing a significant part of the API from its own facilities, which would provide good visibility for its oncology API business.

Table 2: Oncology drugs under development by Shilpa

Generic drug	Brand name	Innovator	Patent expiry in US	Therapy
Bosutinib	*Bosulif*	Wyeth	Sep 2017 - Nov 2026	Blood cancer
Lapatinib Ditosylate	*Tykerb*	Novartis	Sep 2017 - Sep 2029	Breast cancer
Vemurafenib	*Zelboraf*	Hoffmann La Roche	Aug 2016 - Jul 2030	Skin cancer
Carfilzomib	*Kyprolis*	Onyx Pharms	Jul 2017 - Dec 2027	Blood cancer
Nintedanib	*Ofev*	Boehringer Ingelheim	Oct 2019 - April 2024	Lung cancer
Crizotinib	*Xalkori*	PF Prism	Aug 2016 - Nov 2029	Lung cancer
Nilotinib	*Tasigna*	Novartis	Oct 2014 - Aug 2028	Blood cancer
Afatinib	*Gilotrif*	Boehringer Ingelheim	Jul 2018 - Dec 2029	Lung cancer
Ibrutinib	*Imbruvica*	Pharmacyclics	Feb 2017 - June 2031	Blood cancer
Vismodegib	*Erivedge*	Genentech	Jan 2017 - Nov 2028	Skin cancer
Pomalidomide	*Pomalyst*	Celgene	Jul 2016 - Jun 2031	Blood cancer

Source: Company data, I-Sec research

Table 3: DMF filings by the company

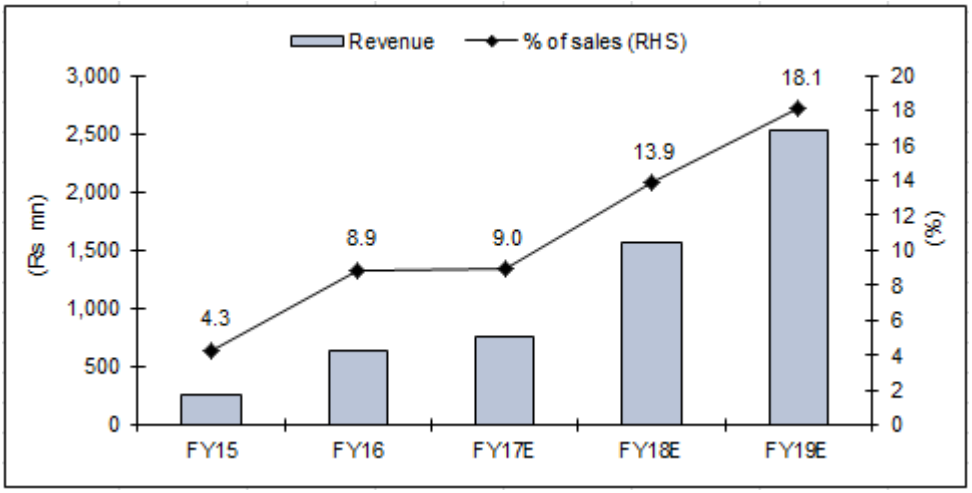
Submit date	Molecule	Brand name	Innovator	Therapy	Patent expiry	Market size (US$ mn)
23-09-2009	Anastrozole	*Arimidex*	Astrazeneca	Oncology	Off-patent	
22-01-2010	Temozolomide	*Temodar*	Merck Sharp Dohme	Oncology	Off-patent	400
23-02-2010	Irinotecan Hydrochloride Trihydrate	*Camptosar*	Pfizer Inc	Oncology	Off-patent	200
23-02-2010	Oxaliplatin	*Eloxatin*	Sanofi Aventis Us	Oncology	Off-patent	100
04-03-2011	Gemcitabine Hydrochloride	*Gemzar*	Lilly	Oncology	Off-patent	634
24-03-2011	Capecitabine	*Xeloda*	Hoffmann La Roche	Oncology	Off-patent	754
11-05-2011	Bicalutamide	*Casodex*	Astrazeneca	Oncology	Off-patent	100
23-08-2011	Bortezomib	*Velcade*	Millennium Pharms	Oncology	Post FY18	740
21-09-2011	Pemetrexed Disodium (Hemipenta Hydrate)	*Alimta*	Lilly	Oncology	Jan-17	1200
09-11-2011	Bendamustine Hcl	*Treanda*	Cephalon	Oncology	Apr-16	780
08-12-2011	Busulfan	*Myleran*	Aspen Global	Oncology	Off-patent	NA
18-07-2012	Zoledronic Acid	*Reclast / Zometa*	Noartis	Oncology	Off-patent	355
9/23/2013	Azacitidine	*Vidaza*	Celgene	Oncology	Off-patent	379
9/26/2013	Decitabine	*Dacogen*	Eisai Inc	Oncology	Off-patent	260
9/26/2013	Letrozole	*Femara*	Novartis Pharms	Oncology	Off-patent	100
3/28/2014	Imatinib Mesylate	*Gleevec*	Novartis	Oncology	Sun launched in Feb 2016. Patent expiry till Jun 2022	2000
5/30/2014	Fingolimod Hydrochloride	*Gilenya*	Novartis	Multiple sclerosis	Feb-19	1200
1/3/2015	Melphalan Hydrochloride	*Alkeran*	Gsk	Oncology	Off-patent	
4/13/2015	Erlotinib Hydrochloride	*Tarceva*	Osi Pharms	Oncology	Post FY18	640
9/19/2015	Dimethyl Fumarate	*Tecfidera*	Biogen	Multiple sclerosis	2018	2908
9/25/2015	Clofarabine	*Clolar*	Genzyme	Oncology	2018	NA

Source: Company data, USFDA website, I-Sec research

Moving up the value chain to oncology formulations

With experience and expertise of more than 15 years in development and manufacturing of oncology APIs, Shilpa is looking to move up the value chain and become a formidable player in oncology formulations. The company had filed its first ANDA in 2013 (in own name) and currently has about 19 ANDA filings, most of which are in the name of its partners and 6-7 are in its own name. There are a few FTFs as well in this ANDA pipeline, which could provide substantial upside on successful launch. The key point to note is that all these ANDA filings are in the oncology space where competition and pricing erosion is generally less than in other disease categories. We expect the company to generate revenues of US$11mn, US$23mn and US$38mn in FY17, FY18 and FY19 respectively from oncology formulations. We have assumed US supplies to start from FY18 onwards. Further, the company is also filing dossiers in Europe for the products getting filed as ANDA, which could provide upside over the longer term.

Chart 2: Revenue trend in Shilpa's oncology formulations business



Source: Company data, I-Sec research

In 2010, Shilpa invested in a state-of-the-art manufacturing facility for oncology formulations at Jadcherla (Hyderabad, India). The company has already invested Rs3bn in this facility and will be spending around Rs1.5bn more in the near term. This facility currently houses two lines for Oral Solid Drugs (OSD) dosages, two lines for injectable dosages, and one line for liquid-lyophilization. The company is also looking to add one more line for OSD and injectable dosages over the next two years, which would entail an additional investment of about Rs1.5bn. While this facility will mainly cater to the regulated markets of US and Europe, it has also been successfully inspected by regulators from Brazil, Mexico and other emerging markets.

In terms of USFDA approval, the Jadcherla facility was inspected in Aug'15 by the drug regulator, which issued Form 483 with a few observations. The company has already responded to these observations, and expects USFDA approval for the facility in the near term. Shilpa has also filed dossiers in markets other than the US, which could receive approval in the near term. In FY16, the Jadcherla facility posted revenues of around Rs640mn on account of product development and supply of some validation batches to customers. However, going forward, the company expects a

good ramp-up in revenues from this facility, as it gets approvals from various regulators.

Table 4: Key ANDA filings (based on DMF filings)

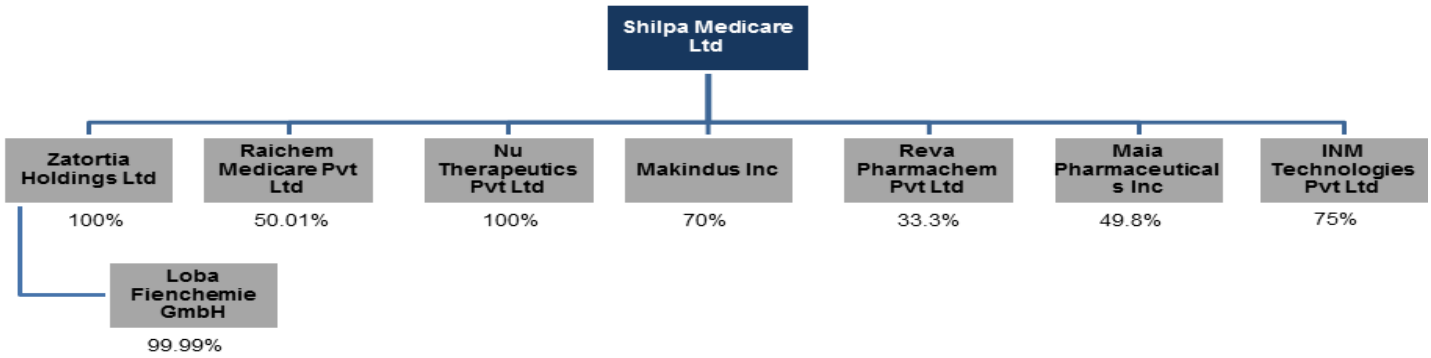
API name	Brand name	Innovator	Therapy	Patent status	Market size (US$ mn)	Other generic players (ANDA)
Imatinib Mesylate	*Gleevec*	Novartis	Oncology	Sun launched in Feb-16 as FTF	2000	Final approval for Sun and tentative approval for Apotex
Gemcitabine Hydrochloride	*Gemzar*	Lilly	Oncology	Off-patent	634	More than 10 players including – Cipla, Teva, Hospira, Actavis, Sun, Dr. Reddy's, Accord and Emcure
Capecitabine	*Xeloda*	Hoffmann La Roche	Oncology	Off-patent	754	Mylan, Teva, Accord Healthcare
Bendamustine Hcl	*Treanda*	Cephalon	Oncology	Apr-16	780	Eagle Pharms has tentative approval
Azacitidine	*Vidaza*	Celgene	Oncology	Off-patent	379	Dr. Reddy's

Source: Company data, USFDA, I-Sec research

Steady growth in non-oncology business with potential upside triggers

Having built a good base in the area of oncology, Shilpa Medicare (Shilpa) has also developed and commercialised APIs in other categories including multiple sclerosis. It has also forged strategic partnerships in non-oncology areas to venture into niche products like ursodeoxycholic acid with Italy-based Industria Chimica Emiliana (ICE) and tranexamic acid with a Japanese player. These partnerships work under the custom synthesis business model. Besides these partnerships, Shilpa has also made strategic investments in some promising areas such as disintegrating strips and ophthalmic drug with orphan status.

Chart 3: Corporate structure



Source: Company data, I-Sec Research

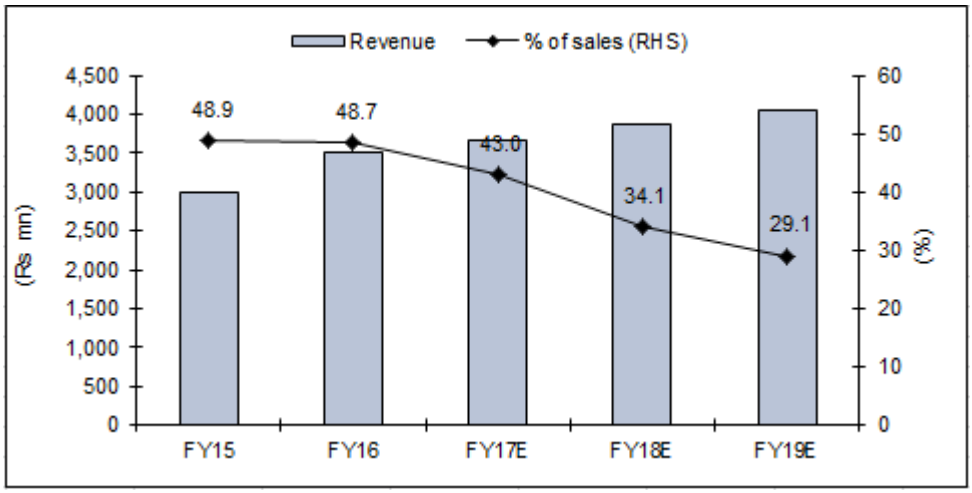
Strengthening custom synthesis business

Ursodeoxycholic acid*:* Shilpa started the custom synthesis business for ursodeoxycholic acid in 2008, which currently contributes around 49% to the company's overall revenues. Under this business, Shilpa supplies ursodeoxycholic acid to Italy-based Industria Chimica Emiliana (ICE), the global leader in bile acid derivative APIs. ICE provides raw material (from animal source), process and technical knowhow for the product to Shilpa. Shilpa's facility is ICE's only facility outside Italy to source this product, which underlines the confidence and trust ICE has in Shilpa. We expect revenues from this product/JV to move up to Rs4.0bn in FY19 from Rs3.5bn in FY16. We don't have clarity on the accounting policy to be followed for the JV; hence our estimates reflect modest level of sales. In case the company decides to show only profit from the JV in income statement, there would be no impact on our earnings estimates though reported revenues would be lower.

Italy-based Industria Chimica Emiliana (ICE) and its subsidiary Prodotti Chimi Alimentari (PCA) together constitute the world's largest manufacturer of bile acid derivatives such as cholic acid and ursodeoxycholic acid. ICE and PCA control more than 40% of the world's demand for these two products. Ursodeoxycholic acid is a naturally occurring bile acid found in small quantities in normal human bile and in larger quantities in the bile of certain species of animals (ox, bears, etc). Ursodeoxycholic acid helps regulate cholesterol by reducing the rate at which the intestine absorbs cholesterol molecules. Because of this property, ursodeoxycholic acid is used to treat (cholesterol) gallstones non-surgically and to treat primary biliary cirrhosis – an autoimmune disease of the liver.

Given Shilpa's good execution track record and the robust demand-supply scenario for ursodeoxycholic acid, ICE has entered into a JV with Shilpa, which has invested in a state-of-the-art facility at Raichur for manufacturing the product. The new facility is almost complete and the company expects production to gradually shift to this new manufacturing facility under the JV over the next 12-18 months. The new facility has a capacity of around 45-50te per month, which is almost double the capacity at Shilpa's current ursodeoxycholic acid manufacturing facility. The company has started working on exhibit batches and stability data from the new facility. Given ICE's interest in the JV, the facility should ensure good orderbook visibility over the longer term. The new facility will not only lead to higher volumes but also improve the profit margin from this business, as it may also supply higher-level ursodeoxycholic acid. Further, the terms of contract with ICE will allow Shilpa to sell some quantities of ursodeoxycholic acid not only in India but also a in few emerging markets, which may provide further upside to our estimates.

Chart 4: Revenue trend in ursodeoxycholic acid



Source: Company data, I-Sec research

Tranexamic acid: Tranexamic acid is a synthetic compound derived from cyclohexane, which inhibits the breakdown of fibrin in blood clots and is used to treat or prevent excessive blood loss from trauma, surgery and in various medical conditions including haemophilia and heavy menstrual bleeding. It is on the World Health Organisation's List of Essential Medicines, which is the list of the most important medications needed in a basic health system.

With the help of a Japanese pharmaceutical company, Shilpa has invested about Rs400mn in setting up a dedicated block at Raichur to manufacture tranexamic acid for India, Europe, and other emerging markets. While the technical knowhow will be provided by the Japanese company, which has significant experience in the development and manufacturing of tranexamic acid, Shilpa will develop its own manufacturing process and procure raw material directly to enhance profitability in this product. We expect commercial revenues from tranexamic acid to start from FY18 and revenue of US$8mn in the same year and grow at a steady rate of ~10% per year thereafter.

Base non-oncology API business to grow at steady pace

Shilpa Medicare (Shilpa) generates ~10% of its total revenues from base non-oncology API business. We expect this business to grow at 14.9% CAGR over FY16-FY19. The growth would be driven by launch of new products and the extra capacity that would be available post shifting of ursodeoxycholic acid manufacturing to the new JV plant in Raichur. The company has developed APIs like acebrophylline, ambroxol, fingolimod, nifedipine, sildenafil citrate, etc.

Table 5: Key non-oncology API filings

Molecule	Therapeutic area	Tech Pack	US USFDA	Canada TPD
Acebrophylline	Asthma / COPD		√	
Ambroxol HCl	Respiratory		√	√
Fingolimod HCl	Multiple sclerosis		√	
Nifedipine	Hypertension / Angina		√	
Sildenafil Citrate	Erectile dysfunction	√	√	
Echothiophate	Opthalmology	√		
Perfenidone	Idiopathic pulmonary fibrosis	√		
Prucalopride Succinate	Constipation	√		
Phenylephrine HCL	Nasal discomfort	√		
Dimethyl Fumarate	Multiple sclerosis	√		

Source: Company data, I-Sec research

Strategic investments for future value creation

Shilpa has made several strategic investments over the past few years into niche segments such as disintegrating strips, NDDS and ophthalmic drug with orphan status. This would enable company to launch new and differentiated products in the coming years and would also provide diversification from oncology concentration. We have not built any upside from these investments in our estimates or valuation; hence the same may provide an upside. Following is a rundown of the investments:

- **NU Therapeutics Pvt Ltd (NTPL)** is a, Hyderabad based, novel drug delivery company dedicated to the development and commercialisation of fast disintegrating oral strip technology. The orally disintegrating formulation resembles a postage stamp in size and shape and is a taste-masked, fast dissolving, convenient and potentially effective dosage form. The oral strip when placed on the patient's tongue instantly wets by saliva and rapidly hydrates and stays on the tongue. It then disintegrates and dissolves within seconds to release the medication in the mouth and promotes gastrointestinal absorption without the need of water. This dosage form is generally preferred by patients who do not want to be pricked with injections or cannot swallow tablets or capsules. The company has already launched a few such products in India for its partners, who have received good response from patients and prescribers. NTPL has also got some of its products registered in international markets such as Kenya, Uganda, and Congo. Recently, Shilpa acquired remaining stake in NTPL, thus making it a wholly-owned subsidiary. Shilpa's total fund exposure in this subsidiary stood at Rs143mn (including investment in equity, preference shares and unsecured loans) as at FY15-end.

Table 6: Orally disintegrating strips

Key features of orally disintegrating strips	
Thin strips - 40 to 140 microns	
Easy to administer just 'on the go'	
Dissolves in less than 10 seconds	
Instantly releases the active drug in to the system	
Eliminates the choking hazards	
Pleasant flavor & Taste	
Better patient compliance	

Source: NU Therapeutics Private Limited Website

Table 7: Products commercialised

Molecule	Category
Ondansetron Hydrochloride 2 mg , 4 mg & 8 mg Orally Disintegrating Strips	For the prevention of Chemotherapy Induced Nausea and Vomiting (CINV)
Simethicone 62.5 mg Orally Disintegrating Strips	Anti-flatulent
Sildenafil Citrate 25 mg & 50 mg Orally Disintegrating Strips	For treatment of erectile dysfunction
Tadalafil 10 mg & 20 mg Orally Disintegrating Strips	For treatment of erectile dysfunction

Source: NU Therapeutics Private Limited Website

- **Makindus Inc –** Makindus is a clinical stage biotechnology company focused on the development of late-stage products specifically for ophthalmic indications. The company's efforts are mainly directed towards rare eye diseases where treatment is either not available or unsatisfactory. The company is currently in advanced stages of development of its lead candidate, MI-100, which is targeting the Stargardt disease, a genetic eye disorder that causes progressive vision loss. Stargardt disease affects a small area near the centre of retina called the macula, which is responsible for sharp central vision needed for tasks such as reading, driving, and recognising faces. The signs and symptoms of Stargardt's disease typically appear in late childhood to early adulthood, and worsen over time. Estimated prevalence of this disease in the US is 1 in 8,000-10,000 individuals. There is currently no cure for the disease, and little can be done to slow its progression.

  Makindus has received an Orphan Drug Designation for MI-100 from the USFDA, and it plans to pursue the 505-(b)-(2) route of submission. Currently, the product is in phase-3 clinical program. While MI-100 presents a great value proposition for Makindus, the future will largely depend upon the success it meets in the ongoing clinical trials and the USFDA approval thereafter. Shilpa has 45% holding in this company.

- **Maia Pharmaceuticals Inc (MAIA):** Founded in 2013 and headquartered in Princeton, New Jersey, MAIA is a speciality pharmaceutical company that develops, manufactures and markets innovative and niche generic products. The company is currently working on seven products {ANDAs or 505-(b)-(2)}, which it expects to file by Dec'16. In case ANDA approval is obtained, Shilpa could also be a potential supplier of the API to MAIA. Shilpa currently has 34.8% holding in this company.

- **INM Technologies Pvt Ltd (INM)** was formed in Jan'15 and is based out of Bangalore. The company is mainly into new technology development (especially nano technology). Shilpa holds 75% equity in the company and has a total fund exposure of about Rs11mn in it.
- **Loba Feinchemie GmbH (Loba):** Germany-based Loba is a 100% stepdown subsidiary of Shilpa. Investment in Loba was made through a special purpose vehicle, Zatortia Holding Ltd. Loba manufactures APIs, intermediates, reagents, and diagnostics and control substances. The product range manufactured by Loba covers 500 organic compounds available from kilo to tonne quantities. Loba also has its own dedicated facilities for R&D, pilot, and commercial operations. The company provides custom manufacturing too.

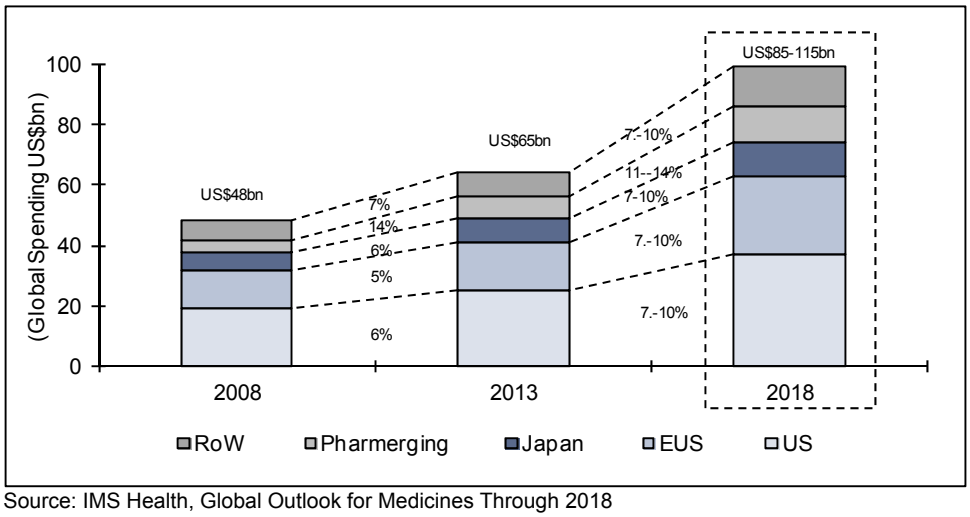
  In FY15, Loba posted a net loss of Rs10.4mn vis-à-vis net loss of Rs16.8mn in FY14. The main focus for Shilpa going forward is to bring down the losses in this business and make it self-sufficient. Shilpa is also looking to manufacture formulations at Loba, which should help improve later's profitability. Shilpa's total fund exposure in this company stood at Rs226mn as at FY15-end.

Global oncology market to cross US$100bn by CY18

As per IMS Health (*Global Outlook For Medicines Through 2018*), oncology spending is expected to cross US$100bn globally by 2018, an absolute growth of US$20bn-50bn through 2013-2018 compared to absolute growth of US$17bn through 2008-2013. The expected growth would be driven by greater numbers of drug approvals and increase in cancer incidence. Oncology continues to be the largest medicinal category in the developed countries and the largest speciality area in emerging countries.

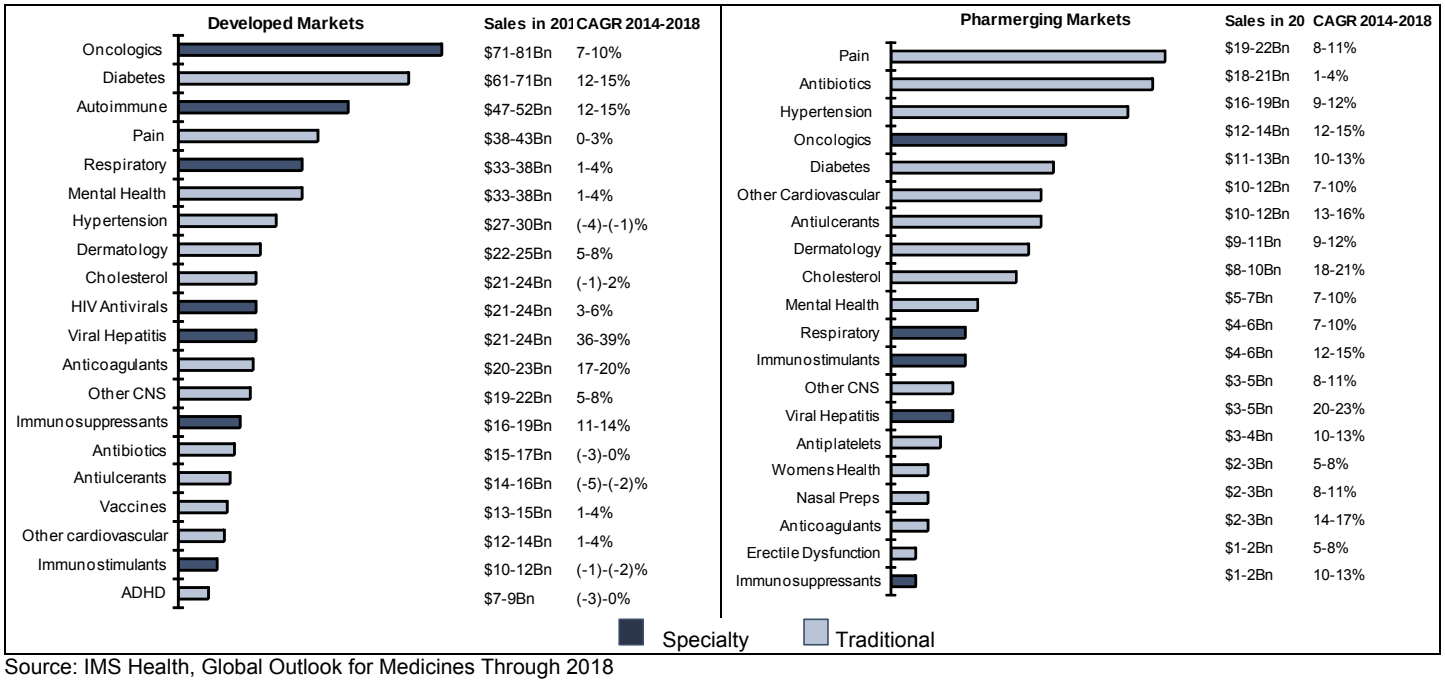
Global oncology market is expected to grow at 7-10% CAGR through 2014-18

Chart 5: Global oncology market presents >US$100bn opportunity



Source: IMS Health, Global Outlook for Medicines Through 2018

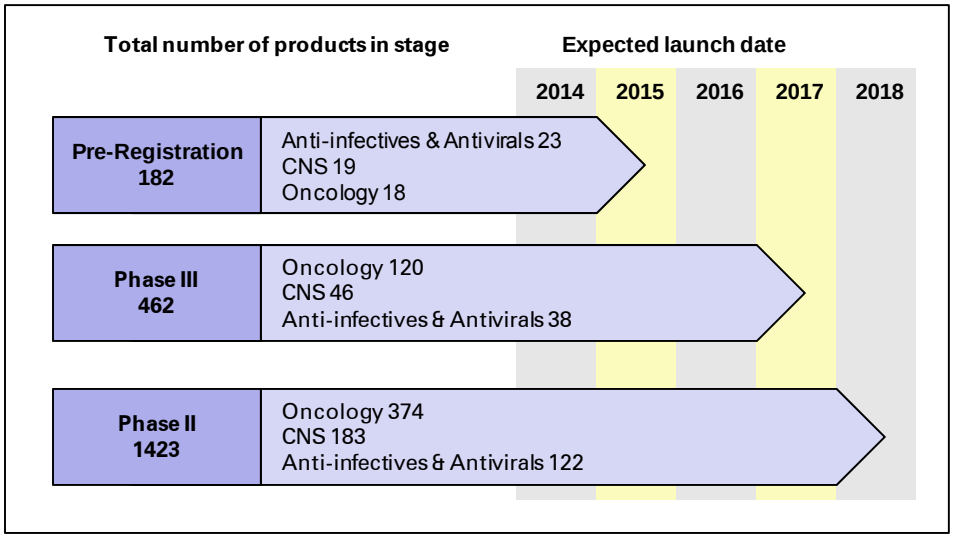
Chart 6: Oncology is one of the fasted growing therapies in both developed and emerging markets



Source: IMS Health, Global Outlook for Medicines Through 2018

Globally, oncology makes up 31% of the total pharmaceutical pipeline, 25% of the late-stage pipeline (phase-2 through pre-registration) and is double the size of the next highest class. High numbers of global drug approvals and a strong pipeline will drive growth in the developed markets, going forward.

Chart 7: Surge in cancer drug innovation



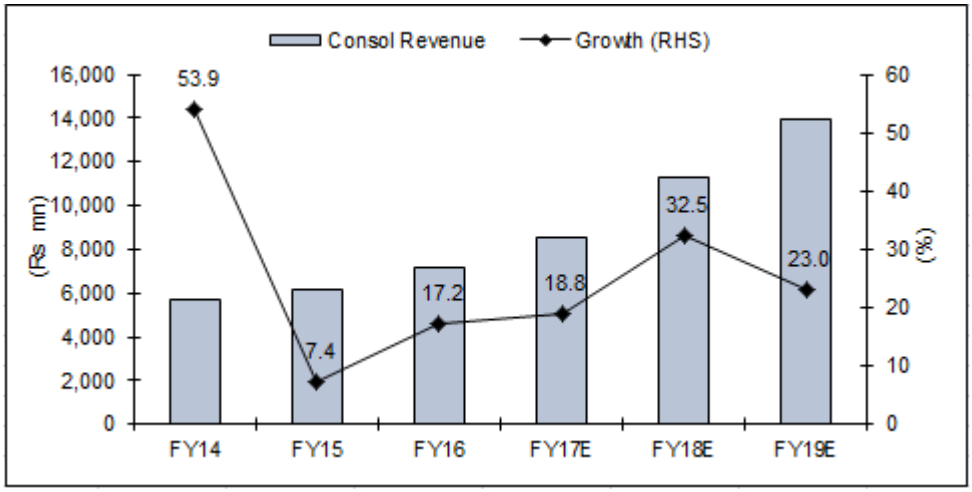
Source: IMS Health, Global Outlook For Medicines Through 2018

Financial performance

Expect revenue CAGR of 24.6% over FY16-FY19

Shilpa Medicare (Shilpa) reported healthy revenue CAGR of 24.7% over FY13-FY16 on the back of launch of new products, capacity expansion and strong traction in its custom synthesis business (ursodeoxycholic acid). We expect this growth rate to be maintained going ahead with 24.6% revenue CAGR over FY16-FY19 led by commencement of API and formulation supplies to the US market, ramp-up in the custom synthesis business and steady growth in non-oncology API business.

Chart 8: Healthy revenue growth ahead

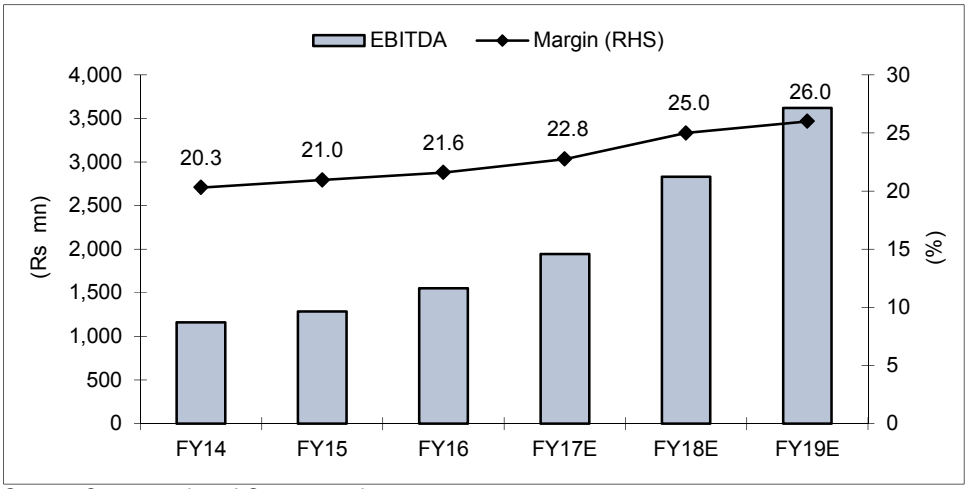


Source: Company data, I-Sec research

EBITDA margin to expand 440bps through FY16-FY19

We expect Shilpa to register a strong 440bps EBITDA margin expansion to 26.0% over FY16-FY19. This would be led by higher growth in the high-margin oncology API business, commencement of oncology formulations supplies to the US market and increased capacity utilisation, which would result in benefit from operating leverage. The company is currently incurring operating expenses of ~Rs400mn on its Jadcherla unit without any compensating revenue.

Chart 9: 440bps expansion in EBITDA margin over FY16-FY19

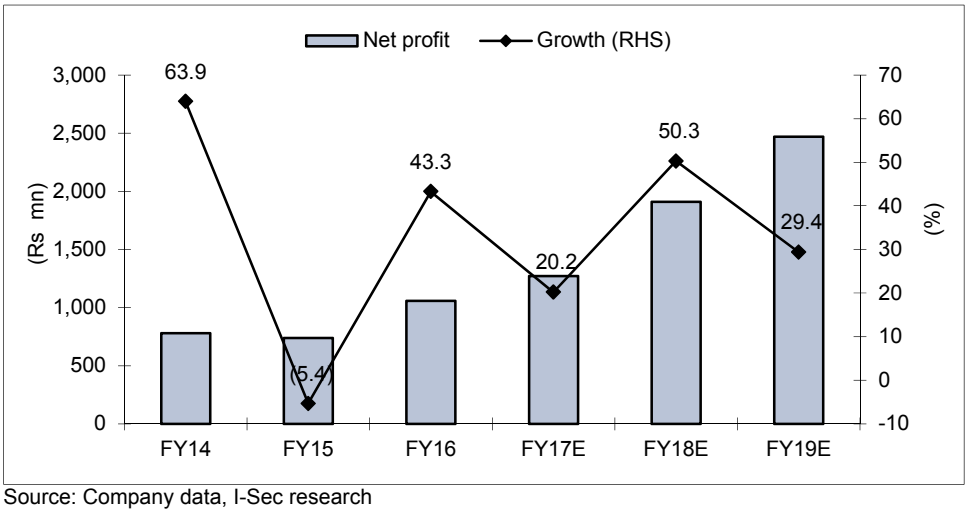


Source: Company data, I-Sec research

Expect adjusted net profit to grow at 32.7% CAGR

Considering the strong revenue growth trajectory and substantial improvement in EBITDA margin over FY16-FY19, we believe Shilpa would be able to report healthy bottomline growth. We expect the company to register 32.7% adjusted net profit CAGR over FY16-FY19 to Rs2.47bn. Net profit margin would also by improve 330bps over FY16-FY19 to 17.7% aided by EBITDA margin expansion.

Chart 10: Adjusted net profit growth to strengthen

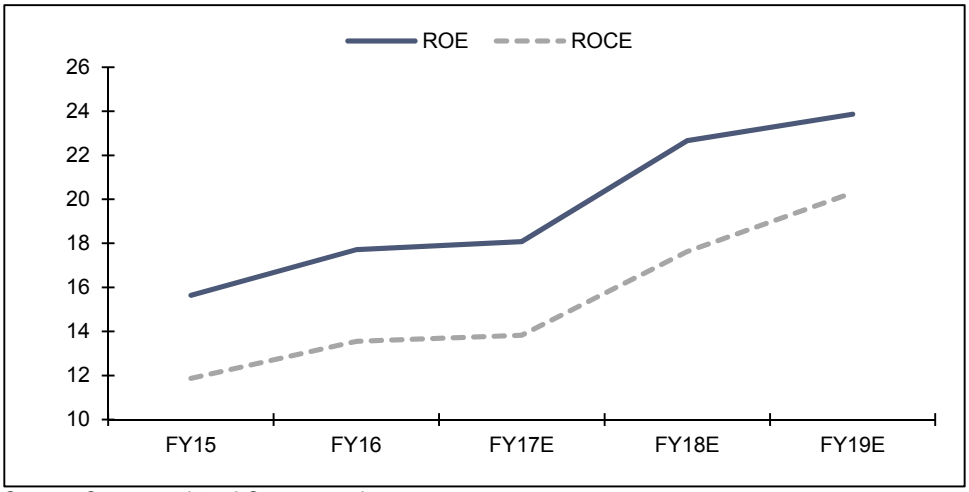


Source: Company data, I-Sec research

Expect strong improvement in return ratios

Though RoE and RoCE dropped in FY15 due to equity dilution of ~5% and high capex over FY14-FY15, we expect the ratios to improve substantially going ahead with strong growth and increased capacity utilisation (resulting in better operating leverage). We expect RoE and RoCE to improve to 23.9% and 20.3% by FY19 from 17.7% and 13.6% in FY16 respectively. This is despite the fact that capex phase is still continuing and that US formulations business would commence only in FY18.

Chart 11: Improving return ratios

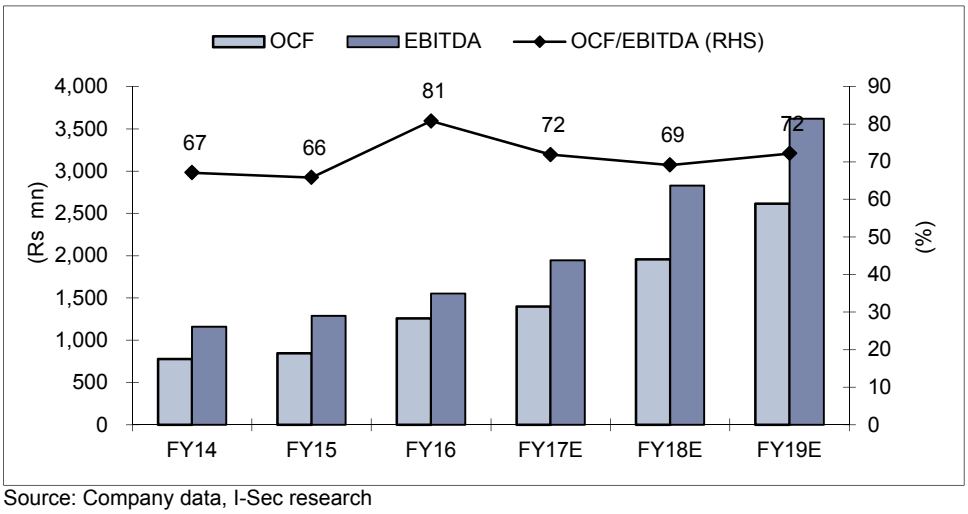


Source: Company data, I-Sec research

Strong cashflow from operations

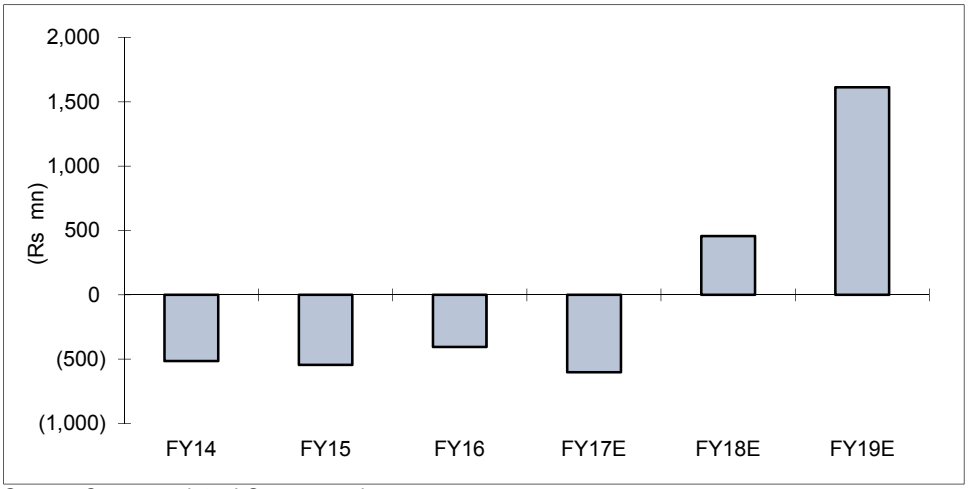
Considering Shilpa's strong revenue growth trajectory, improving EBITDA margin and stable working capital cycle, we believe the company would see strong growth in operating cashflow (OCF) going ahead. We expect operating OCF to grow at 27.7% CAGR to Rs2.6bn in FY19 and the OCF-to-EBITDA ratio to settle around 72%. However, the company would be spending about Rs4.5bn as capex over the next three years for capacity expansion, which would result in negative free cashflow (FCF) in FY17E and then becoming positive in FY18E and grow further in FY19E.

Chart 12: OCF/EBITDA ratio to settle at 70%



Source: Company data, I-Sec research

Chart 13: Company to turn FCF-positive from FY18E

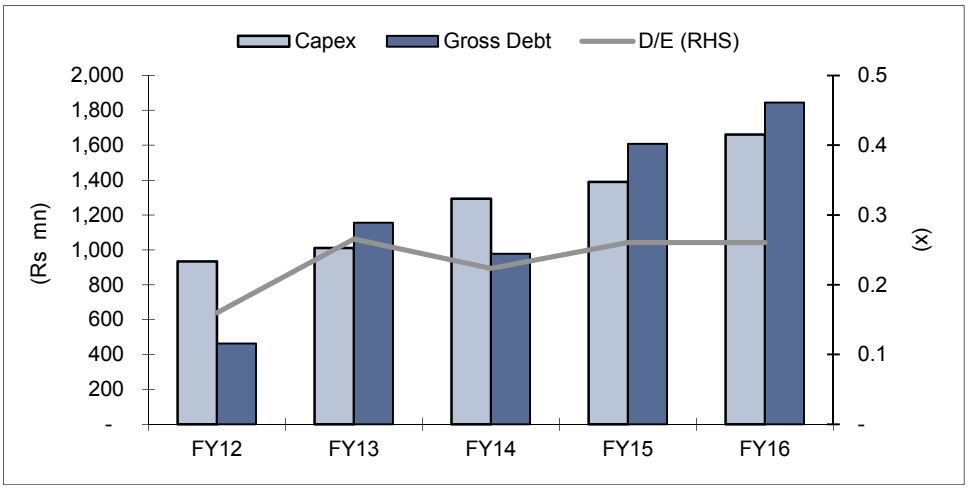


Source: Company data, I-Sec research

Completing capex phase largely from internal accruals

Shilpa has incurred capex of more than Rs6bn over the past five years to create capacities, infrastructure and strategic investments. However, gross debt has increased by just Rs1.38bn over the same period. This clearly shows that the company has been generating large part of capex requirement from internal accruals. Further, we believe the capex phase would by and large be over by FY19-end and the net debt to equity would also come down to 0.1x by FY19. Shilpa has been able to manage its net debt to equity well below 0.5x.

Chart 14: Capex funding largely from internal accruals



Source: Company data, I-Sec research

Key assumptions

With receipt of USFDA approval for two API facilities, we expect Shilpa to register revenues of US$8mn and US$20mn from API supplies in US. Assuming supplies to US for APIs and formulations commence from FY17 and FY18 respectively, we expect the company to report revenue CAGR of 24.6% over FY16-FY19. Though, we expect the gross margin to expand by 310bps over FY16-FY19, higher capacity utilisation would help the EBITDA margin expand by 440bps over the same period. We also expect tax rate to be around 22% due to the API plants being in EOU and R&D spend. The company's operating cashflow is expected to remain strong at ~72% of EBITDA over FY16-FY19.

Table 8: Key assumptions

(Rs mn)

	FY16P	FY17E	FY18E	FY19E	Comments
Oncology API	1,938	2,765	3,792	4,975	Expect US supplies to start from H2FY17
Non-onco API	680	816	1,474	1,622	Expect tranexamic acid supplies from FY18
Oncology formulations	640	768	1,568	2,525	Assuming US supplies from FY18
Custom synthesis	3,500	3,675	3,859	4,052	Steady growth of 5% p.a. expected
Subsidiaries	436	523	627	753	Expect 20% CAGR
Net revenues	**7,194**	**8,547**	**11,321**	**13,926**	
EBITDA	1,554	1,944	2,830	3,621	
EBITDA margin (%)	21.6	22.8	25.0	26.0	US supplies to expand margins
PBT	1,245	1,554	2,368	3,147	
PBT Margin (%)	17.3	18.2	20.9	22.6	
Tax rate (%)	19.2	21.5	21.5	21.5	
PAT	1,057	1,271	1,909	2,471	
PAT Margin (%)	14.7	14.9	16.9	17.7	
Capex	1,661	2,000	1,500	1,000	Capex phase to continue till FY18

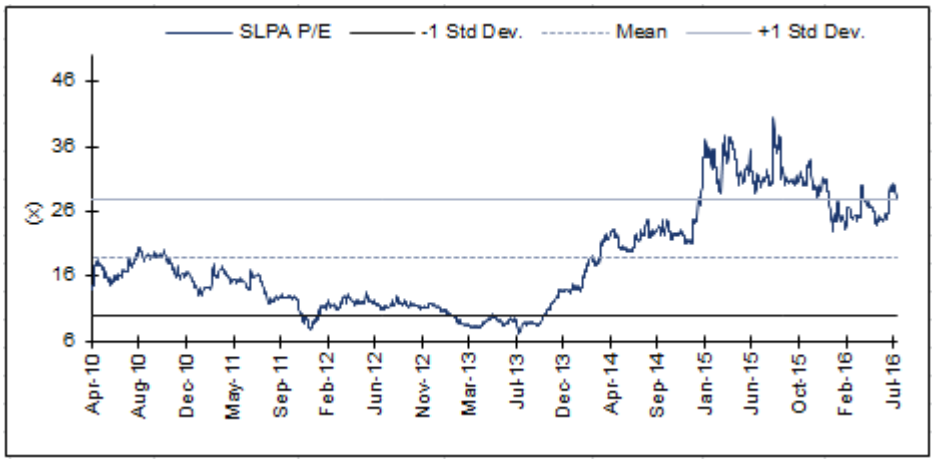
Source: Company data, I-Sec research

Valuations and risks

We expect Shilpa Medicare's (Shilpa) earnings to grow at a CAGR of 32.7% over FY16-FY19 supported by revenue CAGR of 24.6% and EBITDA margin expansion from 21.6% in FY16 to 26.0% in FY19E. Robust profit growth and increase in capacity utilization would result substantial improvement in ROE and ROCE to 23.9% and 20.3% by FY19.

We initiate coverage on Shilpa with an **ADD** rating. We value the stock at Rs614 based on 22x Sep'18E earnings. Though the stock has rerated since Apr'14, we believe it has potential for further rerating given that the US opportunity is still to be unfolded. Given the niche business model and strong presence in one of the most complex oncology area, we believe that the company would enjoy premium valuations. The company has traded at an average PE of 23.5x one year forward earnings over the past three years. We have valued the stock at P/E of 22x on Sep'18E EPS considering 32.7% PAT CAGR and potential for strong growth to continue beyond FY19.

Chart 15: 1-year forward P/E



Source: Bloomberg, I-Sec research

Risks

Delay in approval of formulation plant

Any delay in approval of Shilpa's formulation plant at Jadcherla or conversion of Form 483 into warning letter or import alert would impact our estimates significantly as we have assumed US supplies of formulations from FY18.

Delay in API supplies to US

Any delay in API supplies to US beyond H2FY17 would impact our estimates negatively since that is when we expect supplies to commence considering that USFDA approval for the API plants came in Feb'16.

Forex volatility

Considering that majority of Shilpa's revenues are generated from exports, any adverse fluctuations in forex rates would impact the company's financial performance.

High concentration of revenue on single product/customer

About 49% of revenues for Shilpa come from a single customer for a single product, viz. ursodeoxycholic acid – notwithstanding the fact that the customer has entered into a JV with Shilpa for manufacturing of this product.

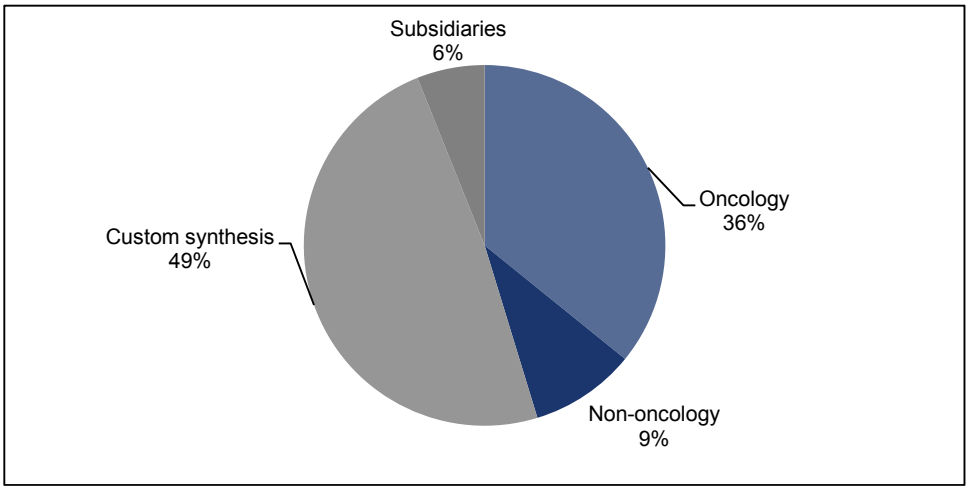
Company background and key management personnel

Company profile

Shilpa Medicare has established itself as one of few companies with integrated development, manufacturing and commercial expertise in complex categories of generic pharmaceuticals globally. The company develops, produces and markets a portfolio of approximately 50 + high-quality and cost-effective generic medicines globally. Currently the company is handling about ~ 50 niche products from 8 manufacturing sites and 2 R&D centres.

Shilpa is one of the leaders in the Oncology market and it offers a complete range of products in this segment spanning across APIs, formulations both in terms of R&D and manufacturing capabilities. The company is also putting in extreme effort in the field of Novel Drug Delivery System (NDDS) and peptides/biotechnology apart from focusing on expansion into different therapy areas.

Chart 16: Revenue mix



Source: Company data, I-Sec research

Table 9: Key management personnel

Name	Designation	Background
Mr. Vishnukant C. Bhutada	Managing Director	He has vast and diverse Business experience of API and Intermediates and is the key decision maker with the teams for Shilpa Group for successful API and Generics formulation strategies. He has received several awards for his entrepreneurial skills
Dr. Vimal Kumar Shrawat	Chief Operating Officer	He has vast experience of more than 25 years in large pharma industries like Ranbaxy spanning across activities of R&D, Pilot and Plant Productions, QA/QC, Administration, CRAMS, Project management etc. He holds degrees of M.Sc (Organic Chemistry), Ph.D. (from Delhi University) and is spearheading the entire Operations/ Control of the company.
Mr. Prashant Purohit	Vice President - CRD	He holds degrees of, M.Sc.(Organic Chemistry) and Diploma in Business Management. He is presently heading Chemical R&D wings of the company and has vast 35 years of experience in R&D, CRAMS and Generics APIs. He is one of key contributor in large number of Patent/applications of Shilpa Medicare..

Source: Company

Financials

Table 10: Profit and Loss statement

(Rs mn, year ending Mar 31)

	FY16P	FY17E	FY18E	FY19E
Net Sales	7,194	8,547	11,321	13,926
Other operating income	-	-	-	-
Net Sales	**7,194**	**8,547**	**11,321**	**13,926**
Less:				
Cost of goods sold	3,674	4,273	5,547	6,684
Employee cost	914	1,068	1,358	1,671
R&D expenses	800	919	1,132	1,393
Others	252	342	453	557
Total Operating Expenses	**5,640**	**6,602**	**8,490**	**10,305**
EBITDA	**1,554**	**1,944**	**2,830**	**3,621**
Depreciation	286	360	434	487
Other income	46	56	67	80
EBIT	**1,314**	**1,640**	**2,463**	**3,214**
Less: Financial expenses	69	86	95	66
Recurring Pre-tax Income	**1,245**	**1,554**	**2,368**	**3,147**
Less: Taxation	234	334	509	677
Less: Minority Interest / Subsidiary loss	(51)	(51)	(51)	-
Net Income (Adjusted)	**1,062**	**1,271**	**1,909**	**2,471**
Extraordinary Items	(24)	-	-	-
Reported Net Income	**1,038**	**1,271**	**1,909**	**2,471**

Source: Company data, I-Sec research

Table 11: Balance sheet

(Rs mn, year ending Mar 31)

	FY16P	FY17E	FY18E	FY19E
ASSETS				
Current Assets, Loan & Advances				
Current Investments	527	527	527	527
Inventories	1,625	1,902	2,446	2,969
Sundry debtors	846	1,005	1,331	1,638
Cash and bank balances	159	54	82	151
Loans and advances	673	718	810	897
Other current assets	36	42	56	69
Total Current Assets	**3,866**	**4,249**	**5,253**	**6,250**
Current Liabilities & Provisions				
Current Liabilities	1,621	1,900	2,486	3,020
Provisions and other liabilities	143	170	225	276
Total Current Liabilities & Provisions	**1,764**	**2,070**	**2,711**	**3,296**
Net Current Assets	**2,102**	**2,179**	**2,543**	**2,954**
Investments	**2**	**2**	**2**	**2**
Fixed Assets				
Tangible Assets	5,523	7,164	8,229	8,742
Intangible assets	49	49	49	49
Goodwill	231	231	231	231
Total fixed assets	**5,804**	**7,444**	**8,510**	**9,023**
CWIP	**947**	**947**	**947**	**947**
Miscellaneous Expenses not written off	-	-	-	-
Total Assets	**8,856**	**10,573**	**12,002**	**12,926**
LIABILITIES AND SHAREHOLDERS' EQUITY				
Shareholders Fund				
Equity share capital	77	77	77	77
Reserves and surplus	6,392	7,510	9,190	11,364
Total Shareholders Fund	**6,469**	**7,587**	**9,267**	**11,441**
Borrowings				
Long term	975	975	775	525
Short term	870	1,520	1,520	520
Total Borrowings	**1,845**	**2,495**	**2,295**	**1,045**
Deferred Tax Liability	**359**	**359**	**359**	**359**
Minority interest	**148**	**97**	**46**	**46**
Other long term liabilities	**35**	**35**	**35**	**35**
Total Liabilities & Shareholders' Equity	**8,856**	**10,573**	**12,002**	**12,926**

Source: Company data, I-Sec research

Table 12: Cashflow statement

(Rs mn, year ending Mar 31)

	FY16P	FY17E	FY18E	FY19E
Cashflow from Operating Activities				
PBT	1,221	1,554	2,368	3,147
Add: Depreciation	286	360	434	487
Less: Taxes	(234)	(334)	(509)	(677)
Operating Cashflow Before Working Capital change (a)	**1,273**	**1,580**	**2,293**	**2,958**
Changes in Working Capital				
(Increase) / Decrease Trade & Other receivables	(32)	(159)	(326)	(306)
(Increase) / Decrease Inventories	(317)	(277)	(544)	(523)
Increase / (Decrease) Trade Payables	259	165	352	314
Others	92	89	183	172
Working Capital Inflow / (Outflow) (b)	**2**	**(182)**	**(335)**	**(343)**
Net Cashflow from Operating Activities (a) + (b)	**1,275**	**1,398**	**1,957**	**2,615**
Cashflow from Capital commitments (c)	**(1,661)**	**(2,000)**	**(1,500)**	**(1,000)**
Free Cashflow after capital commitments (a) + (b) + (c)	**(386)**	**(602)**	**457**	**1,615**
Cashflow from Investing Activities				
Purchase of Investments	126	-	-	-
Other non-operating income				
Net Cashflow from Investing Activities (d)	**126**	**-**	**-**	**-**
Cashflow from Financing Activities				
Increase in reserves	-	-	-	-
Proceeds from fresh borrowings	237	650	(200)	(1,250)
Dividend paid including tax and others	(157)	(152)	(229)	(296)
Net Cashflow from Financing Activities (e)	**80**	**498**	**(429)**	**(1,546)**
Misc items (f)	(19)	-	-	-
Total Increase / (Decrease) in Cash (a) + (b) + (c) +(d) + (e) + (f)	(199)	(104)	28	68
Opening Cash and Bank balance	184	159	54	82
Closing Cash and Bank balance	(15)	54	82	150
Increase / (Decrease) in Cash and Bank balance	**(199)**	**(104)**	**28**	**68**

Source: Company data, I-Sec research

Table 13: Key ratios

(Rs mn, year ending Mar 31)

	FY16P	FY17E	FY18E	FY19E
Per Share Data (Rs)				
EPS	13.5	16.2	24.3	31.5
Cash EPS	17.4	21.1	30.4	38.4
Dividend per share (DPS)	1.7	1.6	2.5	3.2
Book Value per share (BV)	83.9	98.4	120.2	148.4
Growth (%)				
Net Sales	17.2	18.8	32.5	23.0
EBITDA	20.8	25.1	45.6	27.9
PAT	43.3	20.2	50.3	29.4
Cash EPS	41.1	21.4	43.7	26.2
Valuation Ratios (x)				
P/E	40.7	33.9	22.5	17.4
P/CEPS	35.2	29.0	20.2	16.0
P/BV	6.5	5.6	4.6	3.7
EV / EBITDA	27.9	22.7	15.5	11.8
EV / Sales	6.0	5.2	3.9	3.1
Operating Ratios				
Raw Material / Sales (%)	51.1	50.0	49.0	48.0
Employee cost / Sales (%)	12.7	12.5	12.0	12.0
R&D / Sales (%)	3.5	4.0	4.0	4.0
SG&A / Sales (%)	11.1	10.8	10.0	10.0
Effective Tax Rate (%)	19.2	21.5	21.5	21.5
Working Capital (days)	79.8	76.4	72.9	75.0
Inventory Turnover (days)	94.9	97.5	93.5	95.9
Receivables (days)	42.1	39.5	37.7	38.9
Payables (days)	57.3	60.7	58.3	59.8
Net D/E Ratio (x)	0.3	0.3	0.2	0.1
Return/Profitability Ratios (%)				
Net Income Margins (Adjusted)	14.7	14.9	16.9	17.7
RoACE	13.6	13.8	17.6	20.3
RoAE	17.7	18.1	22.7	23.9
Dividend Payout	12.6	10.0	10.0	10.0
Dividend Yield	0.3	0.3	0.5	0.6
EBITDA Margins	21.6	22.8	25.0	26.0

Source: Company data, I-Sc research

Index of tables and charts

Tables

Charts

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