

Shilpa Medicare

S H I N I N G S T A R S E R I E S

Investment Thesis

- ⇒ Strong footing of API business enhances business growth visibility
- ⇒ Healthy product pipeline and new product development in the formulation business to drive sustainable growth
- ⇒ Foray into Biologics to open new growth avenues and provide value unlocking potential
- ⇒ Strong operational performance, significant capex plan and debt reduction to drive financial performance

Company Background

Shilpa Medicare Ltd. is an established player in the Formulation and Active Pharmaceutical Ingredients (API) segment in the domestic and international markets. Shilpa is one of the leading API and formulation manufacturers with strong capabilities in the oncology therapeutic area. Shilpa supplies more than 30 oncology APIs, including key products such as Anastrozole, Bicalutamide, Capecitabine, Lenalidomide etc. for various international markets, including the USA, Europe, Japan, South Korea, Russia, Mexico, Brazil, and other emerging markets. Shilpa derives revenues from select key molecules, including Ambroxol, Tranexamic Acid and Ursodeoxycholic Acid on the non-oncology API front. While Shilpa's underlying expertise is in the field of APIs, it is also strengthening its position in the formulations business with revenue generation from products such as Azacitidine, Pemetrexed, Capecitabine, Imatinib, Erlotinib etc., in domestic as well as various international markets. It also pursues niche growth businesses like Biologics, Transdermal, and Oral Dissolving Films. Shilpa's manufacturing capabilities encompass various dosage forms ranging from oral solids & injectables to orally dispersible films & transdermal patches. It is now an integrated pharmaceutical company with seven facilities (six in India and one in Austria) and three R&D centres.

Company and Subsidiaries

Shilpa Medicare Ltd.

Company Name	Product line	Plant location	Approvals
Shilpa Medicare (Parent listed entity)	a) Formulation - Onco & Adjuvant Oral & Inj b) Formulation - ODF & Transdermal + R&D center	a) Jadhchelra b) Bangalore	a) USFDA (under IA), EUGMP, ANVISA, TGA, Health Canada, COFEPRIS, DIGIMED-Peru, WHO GMP b) UK MHRA, UAE, WHO - GMP & DSIR approved
Shilpa Pharma Lifesciences (100%)	API – Onco & Non-onco, Peptides, Polymers, Intermediates	2 plants in Raichur	USFDA, EUGMP, PMDA, Cofepris, KFDA, WHO - GMP
Shilpa Biologics (100%)	Biosimilars (MABs, Microbial & Vaccine manufacturing), CDMO/CMO	Dharwad	WHO - GMP & DSIR approved
Shilpa Biocare (100%)	Recombinant Albumin & fermentation facility	Kadechur	
Shilpa Therapeutics (100%)	Formulation - ODF	Hyderabad	WHO - GMP, Kenya, Yemen, Malaysia
FTF Pharma (100%)	Formulation CRO	Ahmedabad	

Source: Company Reports, BP Equities Research

Stock Rating

BUY	HOLD	SELL
> 15%	-5% to 15%	< -5%

Sector Outlook

Positive

Stock

CMP (Rs.)	760
Target Price (Rs.)	891
BSE code	530549
NSE Symbol	SHILPAMED
Bloomberg	SLPA IN
Reuters	SHME.BO

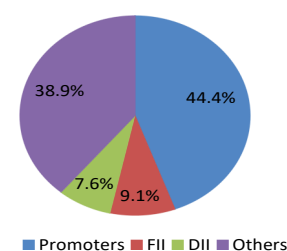
Key Data

Nifty	25,273
52 Week H/L (Rs.)	798/297
O/s Shares (Mn)	97.8
Market Cap (Bn)	72
Face Value (Rs.)	1

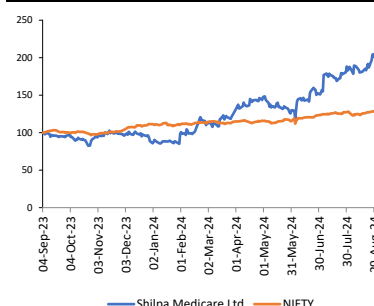
Average volume

3 months	490,590
6 months	501,270
1 year	532,910

Share Holding Pattern (%)



Relative Price Chart



Research Analyst

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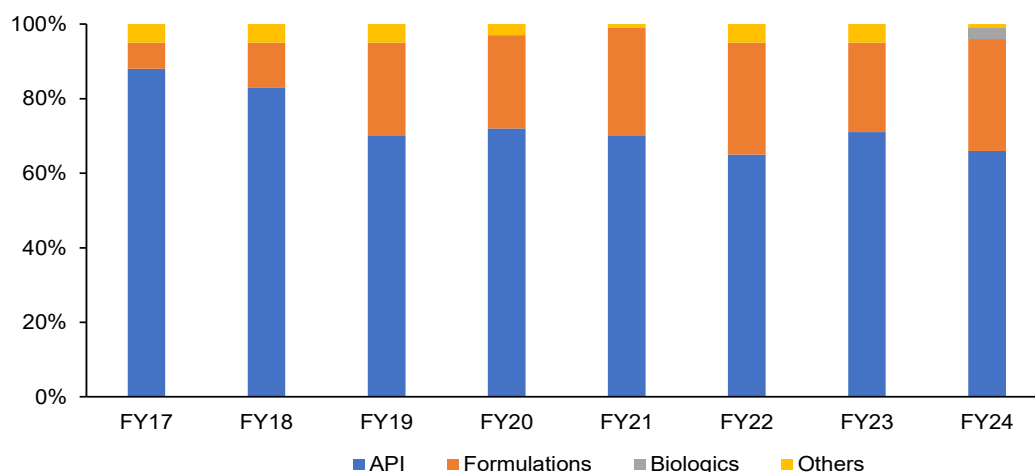
Shilpa Medicare Ltd.

Manufacturing units as on FY24

Plants	Annual Capacity (MT)	Capacity Utilization (%)	Manufactures (Formulations, Biologics & API)
Dharwad			Biologics Manufacturing plant & R&D Facility
Jadcherla Unit	3.05 - (Mn Vials) 29.39 - (Mn Tablets)	Vials - 39.7% Tablets - 61.4%	Formulations (Onco & Adjuvant Therapy of Onco - Injectable & Oral)
Bengaluru Unit			TDS & ODF Manufacturing Facility & Formulation R&D
Hyderabad			Formulations (ODF) Bio Analytical Lab, Pharmacovigilance Lab & Quality control lab
Raichur Unit I & II	Unit 1 - 422 MT Unit 2 - 485 MT	Unit 1 - 85% Unit 2 - 75%	API (Oncology - Non-Oncology) API (Oncology - Non-Oncology) and R&D API, CRAMS, Peptide and Polymer
Ahmedabad			CRO & CDMO R&D Formulation

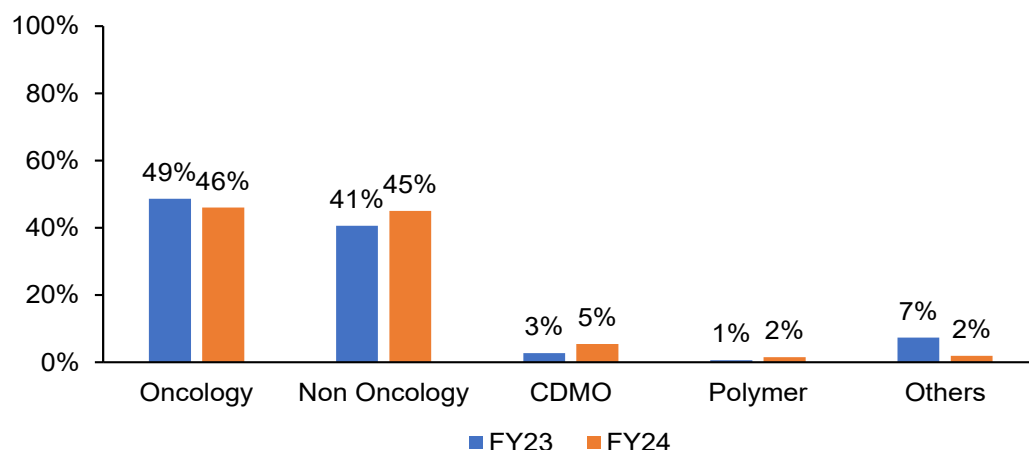
Source: Company Reports, BP Equities Research

Revenue Breakup



Source: Company Reports, BP Equities Research

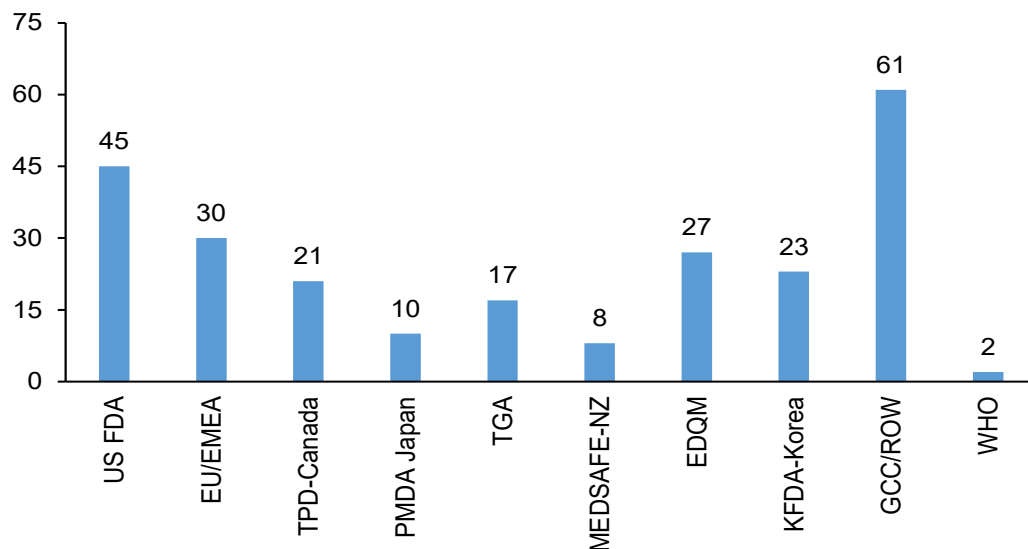
API Business Highlights



Source: Company Reports, BP Equities Research

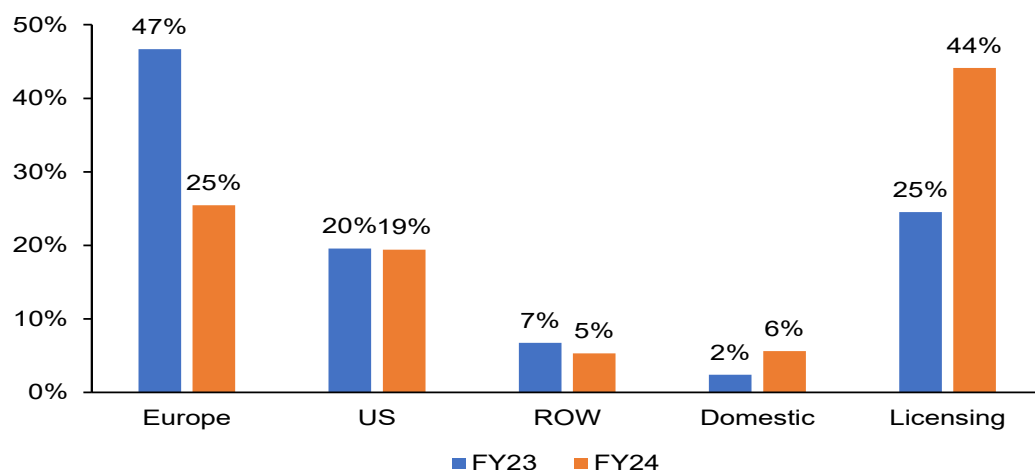
Shilpa Medicare Ltd.

API - DMF Filings as on 31st March, 2024



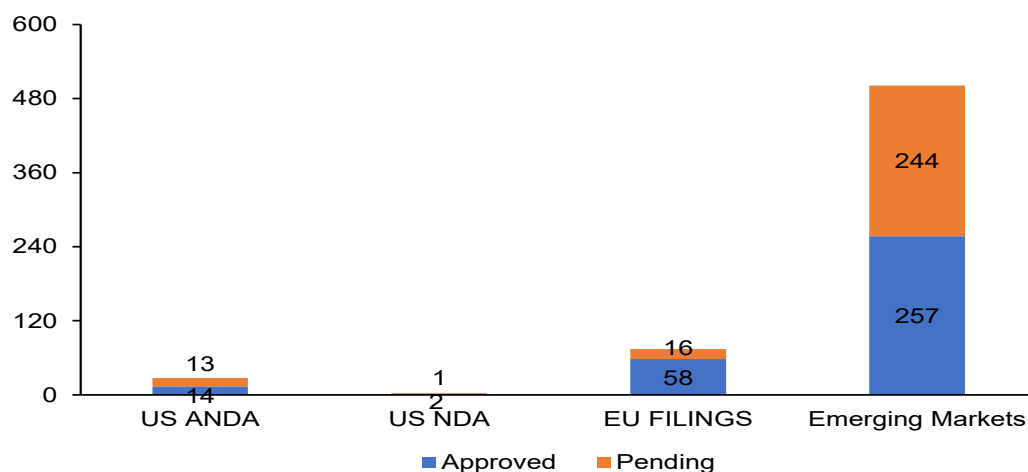
Source: Company Reports, BP Equities Research

Formulations Business Highlights



Source: Company Reports, BP Equities Research

Robust regulatory filings to strengthen the base for growth in the formulation segment



Source: Company Reports, BP Equities Research

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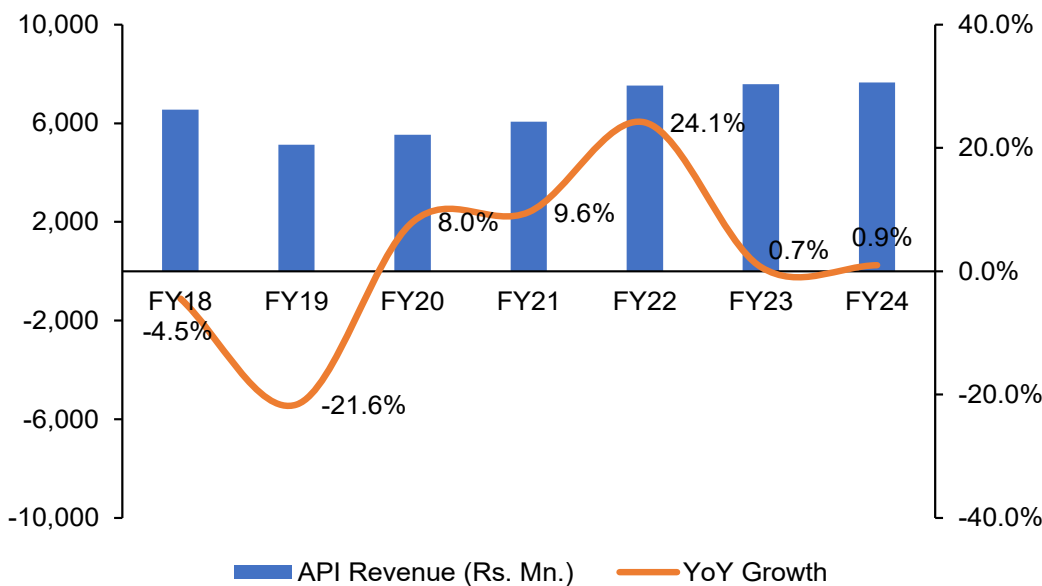
Investment Rationale

Strong footing of API business enhances business growth visibility

Shilpa Medicare is one of the leading API and formulations manufacturers with strong capabilities in the therapeutic area of oncology. It supplies more than 30 oncology APIs for various regulated markets, including the USA, Europe, Japan, South Korea, Russia, Mexico, Brazil, and other emerging markets. Oncology contributed over 39% to its API sales during FY24, while the balance was from the non-oncology and contract research and manufacturing service. On oncology APIs, Shilpa Medicare is developing almost eight APIs, which will come at the plant level before FY26 for API and CDMO services. These are growing with great potential, providing a significant growth opportunity in the upcoming years. In addition to oncology APIs, the company is exploring high-growth potential products in non-oncology API segments, which can also serve as import substitutes. During Q1FY25, the company in the oncology segment, the major updates were two NDA molecules developing for a client for many years in which NDA Molecule No.1, Pre-launch orders received from a US MNC and NDA Molecule 2 supplied to a US MNC for Phase III clinical studies. The company has added three molecules to its portfolio: Methotrexate, Liraglutide, and Teriparatide, which completed validation in Q1FY25. Shilpa Medicare is also enhancing the capacity of two oncology molecules, Palbociclib & Olaparib, for validation, which is planned for Q2FY25. Non-oncology business received European CEP for Ursodeoxycholic Acid, a complex and niche API. The approval of CEP opens a significant opportunity for Shilpa Medicare in export markets. Two new non-oncology molecules have completed lab validation, initiated plant scale-up, and are planned to finish plant validation and DMF filing. While specialty polymer was developed and clinical supplies were made for the US market, a new polymer project was initiated and planned to be completed by Q2FY25. Clinical supplies and commercialization for a CDMO project are in progress. The European client's initial development phase is completed, and is moving to the next phase. The company plans commercialization of three to four new APIs every year, expand its capacity, and expects strong growth momentum in the portfolios of oncology, non-oncology peptides, polymers, contract development, and manufacturing organizations. With the existing portfolio, the primary focus in oncology is to build a differentiated long-term complex pipeline, which can give sustainable growth in years to come. Thus, we expect the company to grow strongly in its core API business.

“The company expects to deepen its presence in the API market and continue to launch new drug applications.”

API business grew at a healthy pace



Source: Company Reports, BP Equities Research

Shilpa Medicare Ltd.

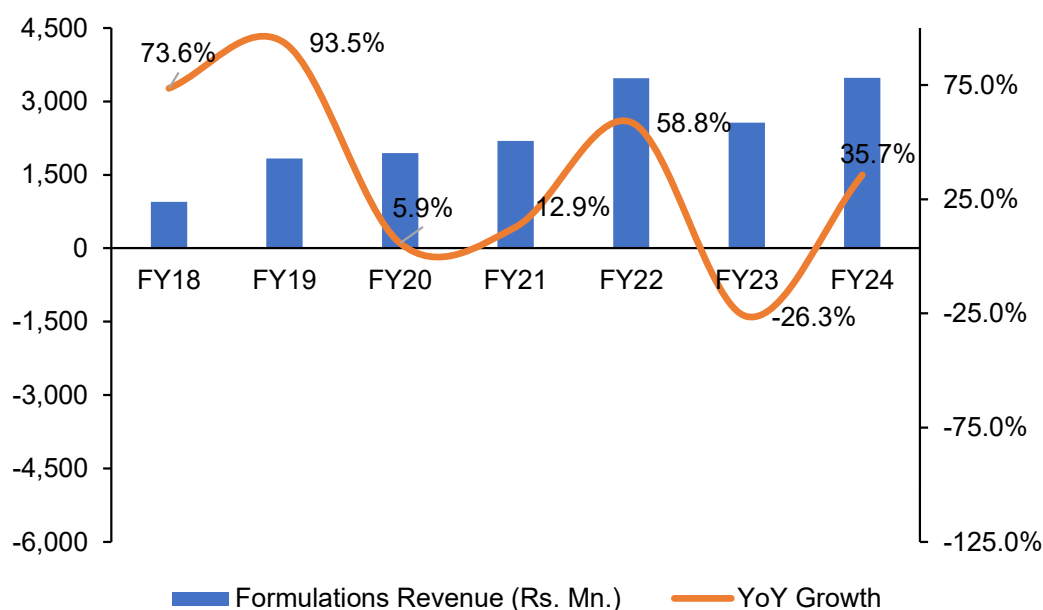
Healthy product pipeline and new product development in the formulation business to drive sustainable growth

Shilpa Medicare is an emerging player in the formulation space with a strong product pipeline and focuses on developing new products to drive continuous growth. The company further leverages its API capabilities to integrate into the formulation business. It has commenced supplies to the US generic formulations market through the launch of Capecitabine and Azacitidine in FY17. Since then, the segment has staged a strong performance. As of March 2024, the company has a healthy product pipeline in the formulations segment of 600 filings in the US (27 ANDA, out of which 14 are approved and 13 pending, 3 NDA products of which two are approved), European Union (70 fillings of which 48 are approved) and ROW (500 fillings of which 242 are approved). They have also made notable progress in developing products such as Azacitidine, Capecitabine, Docetaxel, Tarceva, Gemcitabine hydrochloride, and Irinotecan. The formulation business has reached new heights by launching the first New Drug Application (NDA) product, Pemetrexed RTU, under the J Code for premium pricing in the lucrative US market by its partner Amneal Pharmaceuticals LLC, and has applied for the same product for K-code which will help them in insurance reimbursement. Shilpa Medicare is confident about Pemetrexed's potential in the US market and expects to gain good market share in the upcoming quarters. Additionally, the company has another NDA molecule, an oncology oral liquid, for which the partner has already filed in the US. This is a first-of-its-kind US NDA, and approval is expected in Q4FY25. Shilpa is optimistic about its strong pipeline for the US market, expecting growth in the coming years. In the European market, the upcoming big launch is for Nilotinib, with regulatory review already completed and the product launch anticipated in Q3FY25. The company has partnered with a leading generic oncology company in Europe for this product, predicting strong sales. Additionally, the company is developing a product called NU D07 and has completed Phase 3 trials for a topical lotion solution, SML TOP09, aimed at treating Androgenic Alopecia. Shilpa Medicare has also signed two new Transdermal Patch product deals with partners, the development of which has already started. These achievements highlight the company's commitment to innovation and the ability to deliver cutting-edge products to global markets. Overall, the company has strategically expanded its geographical reach by entering into several emerging markets through marketing partners, providing access to private markets and enabling them to participate in local tenders. This diversification will strengthen the company's position and help to drive sustainable growth in its formulation business in the long term.

“Shilpa Medicare has been moving up the value chain through the formulations business, specialising in complex therapies on a global scale.”

“Shilpa Medicare has strategically expanded its geographical reach by entering several emerging markets, This diversification will strengthen the company's position.”

Formulations business to drive sustain revenue growth



Source: Company Reports, BP Equities Research

Shilpa Medicare Ltd.

Foray into Biologics to open new growth avenues and provide value unlocking potential

Shilpa Medicare has forayed into the new area of biosimilars with world-class manufacturing facilities at Dharwad, Karnataka, as it sees a massive potential from this segment going ahead. To unlock value in the biologics business, Shilpa Medicare has formed a 100% subsidiary company - Shilpa Biologicals, which currently houses all biologics assets. The subsidiary company has six biosimilars and one new biological entity in its pipeline, with a significant cost advantage. The Dharwad facility commissioning with in-house R&D would enable the company to vertically integrate into the biopharmaceutical space, a key plus point from a growth perspective. Shilpa Medicare's biosimilar portfolio focuses on limited competition differentiated products. The company's Adalimumab product has already launched in the Indian market, in partnership with Sun Pharma. This is a crucial step into the realm of biological offerings aimed at enhancing patient comfort in treating Rheumatoid Arthritis. The company also made substantial progress in the product development pipeline by getting permission for the Phase-3 trial for recombinant Albumin, a life-saving product in short supply. This has opened up potential licensing opportunities and positioned the company at the forefront of innovation in this category. In addition, the company is focusing on developing Aflibercept, a complex ophthalmic product, with plans to launch it globally and seek regulatory approval in various regions. The client scale-up batches for Aflibercept are underway, and Phase 3 human studies are expected to commence in Q3FY25. The company has also strategically partnered with leading Indian multinational corporations to commercialize Aflibercept after approval. Moreover, the company has CDMO space in biologics for Korean clients. This complex project was well executed, and various preclinical and Phase 1 supply orders have already started. Apart from this, two new CDMO projects are likely to be signed in Q2FY25. Overall, we expect good traction in the biologics business, where the development space has a lot of opportunity. In the upcoming quarters, biologics will be a robust portfolio for Shilpa Group. Shilpa Biologicals' biosimilar programs for Adalimumab, Aflibercept, and Abatacept are progressing well toward approval from different regulatory authorities. In line with this strategy, marketing teams are working towards expanding into different ROW markets. This will allow the company to expand its market reach beyond India and cater to patients in various regions.

“Shilpa Medicare has forayed into the new areas of biosimilars, as it sees a massive potential growth going ahead from this segment.”

Shilpa Medicare to strengthen its position in biosimilars

Program	Indication	Dev	Pre-clinical	Phase 1	Phase 2	Phase 3	Launch
Etanercept Biosimilar SBDM-01	Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Plaque Psoriasis	✓	✓	✓			
Adalimumab Biosimilar SBDM-02	Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis, Psoriatic Arthritis, Ankylosing Spondylitis, Plaque Psoriasis, Crohn's Disease	✓	✓	✓	✓	✓	✓
Aflibercept Biosimilar SBDM-03	Neovascular (Wet)	✓	✓	✓	✓	✓	
Abatacept Biosimilar SBDM-04	Adult Rheumatoid Arthritis, Polyarticular Juvenile Idiopathic Arthritis	✓	✓				
SBDM-05	Myocardial Infarction	✓					
SBDM-06	Anemia associated with Chemotherapy	✓					
SBDM-07	Ovarian hyperstimulation	✓					
SBDM-08	Colon Cancer, Lung Cancer	✓					
SBDM-09	Lung cancer, Head & Neck cancer	✓					
SBDM-10	Multiple Myeloma	✓					
SBDM-11	Chronic Lymphocytic Leukemia	✓					

Source: Company Reports, BP Equities Research

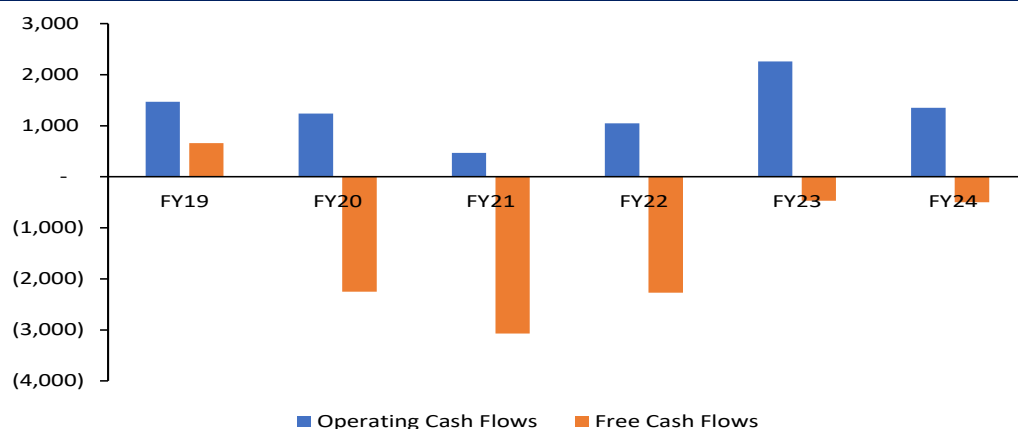
Shilpa Medicare Ltd.

Strong operational performance, significant capex plan and debt reduction to drive financial performance

Shilpa Medicare registered a revenue CAGR of 8.6% between FY2021-24, driven by a robust pipeline in APIs and expansion in the formulation business while maintaining a strong financial position and focus on operational efficiency. The company has also made significant R&D investments to augment new capabilities such as biosimilars and transdermal and oral films. The company's operating margin profile has also moved upwards, attributable to lower input costs, enhanced operational efficiency and rationalized R&D investment. The company expects this momentum to continue in FY25 as well, led by stabilizing pricing scenario in formulations and API businesses, aided by lower raw material cost and other expenses. Apart from expanding its API and formulation facilities, the company has made significant investments in R&D and capex to enhance the capacity of its new segments such as biosimilars, oral thin films, and synthetic Albumin. It has also lined up many products in newer therapy areas such as films, topicals and transdermal. Moreover, the company has completed most of its capex cycle of Rs. 17 bn during the last five years for capacity enhancements and future initiatives. The company might incur a capex of around Rs.1 bn for FY25 for the remaining capex of Albumin facility, modernization of machines, and maintenance capex. On the ratio side, Shilpa Medicare's RoCE improved, owing to sharp margin improvement, while the RoE ratio remained healthy due to profitability turnaround. The cash flow from operations decreased to Rs. 1.4 bn in FY24 from Rs. 2.3 bn in FY23 due to unfavourable changes in working capital. The free cash flow remained negative at Rs. 1.8 billion during FY24 due to the capex cycle undertaken by the company over the last three years. The company expects positive FCF generation, led by minimal capex and net debt reduction. The company's net debt as of 30 June 2024 stood at Rs. 5.1 bn compared to Rs. 9.1 bn at the end of FY24. Thus, we believe that Shilpa Medicare should strengthen its financial position and take initiatives to reduce debt, laying a solid foundation for potential acquisitions.

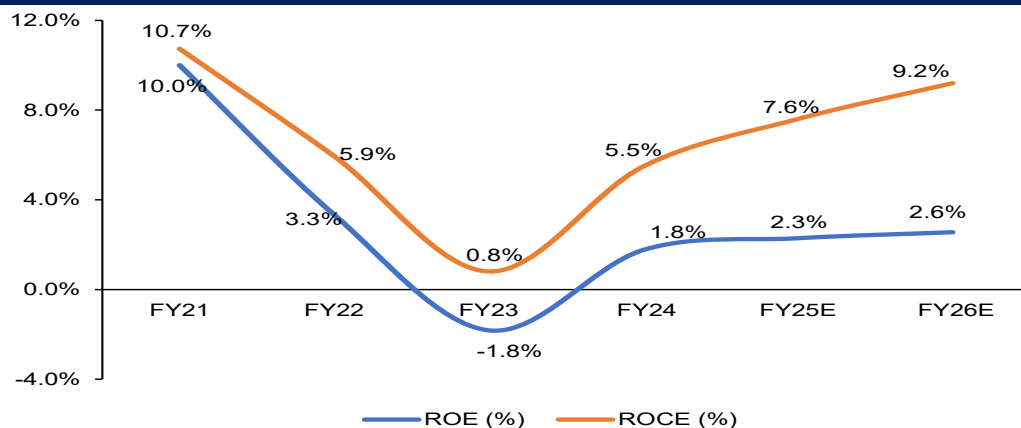
“Shilpa Medicare made significant R&D investments to augment new capabilities and focus on debt reduction”

Strong OCF ; Heavy Capex weighing on FCF (Rs. Mn.)



Source: Company Reports, BP Equities Research

Return ratios to improve going ahead



Source: Company Reports, BP Equities Research

Shilpa Medicare Ltd.

Q1FY25 Concall Highlights

(1) Shipla Medicare's formulations, particularly in emerging markets, and licensing income were vital growth drivers this quarter. The company's R&D engine continues to fuel innovation and asset monetization. The company has taken significant steps in API, CDMO, and formulations. (2) The improvement in EBITDA margin was attributed to the business mix, including a higher proportion of licensing income and growth in the formulation business which has better margins than API. (3) Albumin has completed its Phase 1 human study, with Phase 1 data to be submitted to the European regulatory authorities for Phase 3 permission. Phase 3 human study is expected to start in Q4 FY25 and will have a one-year study duration. (4) During the quarter, the company announced a significant CDMO agreement with Unicycive Therapeutics for Oxylanthanum Carbonate. (5) Shilpa Medicare has completed Phase-3 clinical studies of its novel product SMLNUD07 - Nor Ursodeoxycholic Acid (NorUDCA) tablets that are expected to revolutionize the treatment of patients suffering from Nonalcoholic Fatty Liver Disease (NAFLD). This trial was a multicentric, placebo-controlled, double-blinded study conducted on 165 NAFLD patients across India. (6) The company's partner has applied for a K-code for Pemetrexed which will aid in insurance reimbursement, with expected approval in the current quarter. The company expects to gain good market share for Pemetrexed in the US in the coming quarters. (7) The company has planned Rs. 125 crores of capex requirements for the entire year, out of which about Rs. 50 crores for Albumin project, Rs. 50 crores for maintenance capex and Rs. 25-odd crores for Tranexamic Acid expansion.

Companies	Revenue (Rs. Mn.)		EBITDA Margin		PAT Margin	
	FY25E	FY26E	FY25E	FY26E	FY25E	FY26E
Shilpa Medicare Ltd.	12,676	13,718	22.3%	25.9%	3.4%	3.7%
Peers						
Piramal Pharma Ltd.	92,955	106,020	16.0%	18.1%	3.1%	5.9%
Gland Pharma Ltd.	62,373	70,305	17.9%	20.5%	14.9%	16.7%
Suven Pharma Ltd.	11,528	14,602	38.7%	43.3%	29.5%	32.3%
Caplin Point Laboratories Ltd.	19,237	21,911	32.7%	33.2%	26.7%	27.3%
Orchid Pharma Ltd.	10,342	15,024	16.2%	16.5%	14.7%	14.4%

Source: BP Equities Research, Bloomberg estimate

Companies	Market Cap (Rs. Mn.)	P/E (x)		EV/EBITDA (x)		ROE	
		FY25E	FY26E	FY25E	FY26E	FY25E	FY26E
Shilpa Medicare Ltd.	71,876	167.0	136.1	27.9	21.9	2.3	2.6
Peers							
Piramal Pharma Ltd.	250,300	85.5	40.5	19.6	15.2	3.7	7.2
Gland Pharma Ltd.	307,089	31.3	25.4	19.6	15.9	9.6	11.4
Suven Pharma Ltd.	287,660	81.9	59.1	59.5	42.9	15.8	18.7
Caplin Point Laboratories Ltd.	138,049	27.0	23.4	21.6	18.6	19.6	18.1
Orchid Pharma Ltd.	75,490	51.1	36.3	44.3	29.8	11.5	14.8

Source: BP Equities Research, Bloomberg estimate

Shilpa Medicare Ltd.

Valuation & Outlook

Shilpa Medicare recorded strong revenue growth in the past quarters, which is a good sign considering the headwinds faced across API manufacturers in the pharma business. We expect growth to be supported by its formulation space which has a strong product pipeline and focuses on new product development. Additionally, Shilpa Medicare has forayed into the new areas of biosimilars with world-class manufacturing facilities, as it sees massive potential growth from this segment going ahead. The launch of its recently approved adalimumab biosimilar will open a new page in Shilpa's journey towards becoming a biosimilar firm. Further, the company is currently poised for a turnaround, with plans to bolster its presence in the CDMO market, driven by the scale-up of operations through new product launches. As we advance, Shilpa Medicare is expected to improve margins through cost optimization, operational efficiencies and rationalizing R&D investment. Shilpa Medicare is better placed to capitalize on opportunities due to its robust APIs, formulations, and biologics pipeline. Given these factors, we expect Shilpa Medicare's revenue and operating performance to improve led by (1) Leading API manufacturer with strong capabilities in the therapeutic area of oncology, providing significant growth opportunities in coming years; (2) Emerging player in the formulations space with strong product pipeline; (3) Focus on operational efficiency; (4) Foray into new areas of biosimilars due to massive growth potential; (5) Focus on debt reduction and strategic capex plan. **Thus, we expect Shilpa Medicare to generate stable revenues over the long term and is trading at an EV/EBITDA of 27.9x/21.9x on FY25e/26e estimates. We ascribe a BUY rating for a TP of Rs. 891, which implies an upside of 17.2%.**

Shilpa Medicare Ltd.

Key Financials

YE March (Rs. mn)	FY21	FY22	FY23	FY24	FY25E	FY26E
Net Sales	8,990	11,414	10,462	11,516	12,676	13,718
Growth %	-1.0%	27.0%	-8.3%	10.1%	10.1%	8.2%
EBIDTA	1,805	2,018	987	2,397	2,822	3,550
Growth%	-17.7%	11.8%	-51.1%	142.8%	17.7%	25.8%
Net Profit	1,478	607	-325	319	431	504
Growth %	-5.4%	-59.0%	-153.5%	198.1%	35.1%	17.2%
Diluted EPS	18.1	7.0	-3.7	3.7	4.4	5.4

Key Ratios

EBIDTA (%)	20.1%	17.7%	9.4%	20.8%	22.3%	25.9%
NPM (%)	16.4%	5.3%	-3.1%	2.8%	3.4%	3.7%
ROE (%)	10.0%	3.3%	-1.8%	1.8%	2.3%	2.6%
ROCE (%)	10.7%	5.9%	0.8%	5.5%	7.6%	9.2%
P/E (x)	41.9	108.7	-203.2	207.1	172.7	140.7
EV/EBITDA (x)	43.4	38.5	80.0	33.5	27.9	21.9
Net Debt/ EBITDA (x)	1.7	1.5	1.6	1.0	0.6	0.2

Source: Company Reports, BP Equities Research

Disclaimer Appendix

Analyst (s) holding in the Stock : Nil**Analyst (s) Certification:**

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