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08 October, 2024 | **PICK OF THE MONTH** | **VOL-10, NO-11**

Industry: Pharmaceuticals | **Shilpa Medicare Limited** | **BUY**

CMP: Rs.757 | **TARGET PRICE: Rs.1000** | **TIME : 12 months**

Shilpa Medicare Limited (SML) is one of the leading API and formulations manufacturers with strong capabilities in the therapeutic areas of oncology as well as non-oncology APIs. SML has established its presence in APIs and formulations for both domestic as well as the international markets. The products offered by the company are exported to the US, Europe, and other international markets.

The API business **contributes maximum** to the overall revenues (~67% in FY24), followed by Formulations (~30% in FY24) and the balance from Biosimilars. Under the niche **API business**, the main focus of SML has always been towards **oncology** therapeutic area with simultaneous product developments and expansions undertaken to strengthen the other sub-verticals of API division viz; non-oncology (that work as import substitute), CDMO and others (includes peptides and polymers). For Formulations and Biosimilars business, the pipeline is extremely strong and well on track with the internal targets set by the company.

We initiate coverage on Shilpa Medicare with a **BUY** rating and a TP of Rs1000, implying an upside of ~32%. The existing business segments alongwith the upcoming opportunities from the new projects in the CDMO, peptides, polymers and value-added offerings in the form of TDS and ODFs will drive the overall growth for SML in the medium to long term.

Oncology Expertise: SML is a **prominent** player in the **oncology** space. As per WHO reports, the new number of cancer cases are anticipated to rise by ~77% to 35 million cases by 2050. Patent expiries permit the new oncology related molecules to be introduced in the market giving the generic drug makers an opportunity to provide cost effective treatments. SML has a strong pipeline of molecules and is well-equipped to leverage on the opportunity in the off-patent oncology drugs.

Growth Strategy: The company will continue to strengthen the formulation and complex API business, enhance the international market presence, develop novel products, pursue opportunities in the non-oncology APIs and peptides along with prospects in biological, biosimilars and provide one-stop solution for CDMO requirements to the global pharma players. These are some of the key pillars that will drive the overall business of SML in the near term.

Shift to Biosimilars: There has been a shift in the IPM from generics to biosimilars. The off-patent biologics can lead to a rise in demand for biosimilars, offer cost-effective alternatives to expensive biologic therapies and expand access to crucial medications. SML's biosimilars programs are well on track and so far have made significant progress which will be beneficial for the company in the long run.

SNAPSHOT	
52 week H/L	**Mcap (INR mn)**
960/296	74,008
Face value: 1	
BSE Code	**NSE CODE**
530549	SHILPAMED

Shareholding Pattern as on 30th June, 2024		
Parameters	**No of Shares**	**%**
Promoters	43,409,715	44.3
Institutions	16,320,253	16.7
Public	38,060,938	38.9
TOTAL	**97,790,906**	**100.0**

Annual Performance				
(Rs mn)	**FY22**	**FY23**	**FY24**	**FY25E**
Total Revenue	11,455	10,501	11,516	14,392
EBITDA	2,039	1,023	2,445	3,411
EBITDA (%)	17.8	9.7	21.2	23.7
Other Income	142	174	82	104
Interest	412	587	918	628
Depreciation	798	955	1,079	1,000
PBT	971	(345)	530	1,887
PAT	606	(310)	*320	1,122
Equity (Rs mn)	87	87	87	98
EPS (INR)	7.3	(3.7)	3.7	11.5

Quarterly Performance				
Parameters (Rs mn)	**Sept-23**	**Dec-23**	**Mar-24**	**Jun-24**
Sales (Net)	3,130	2,865	2,917	2,925
EBITDA	603	659	701	736
EBITDA (%)	19.3	23.0	24.0	25.2
Other Income	18	22	25	94
Interest	232	262	242	237
Depreciation	278	267	266	271
PAT	16	46	221	141
Equity (Rs mn)	87	87	87	87

Ratio Analysis				
Parameters (Rs mn)	**FY22**	**FY23**	**FY24**	**FY25E**
EV/EBITDA (x)	39.5	79.9	34.0	23.5
EV/Net Sales (x)	7.0	7.8	7.2	5.6
M Cap/Sales (x)	6.5	7.0	6.4	5.1
M Cap/EBITDA (x)	36.3	72.4	30.3	21.7
Debt/Equity (x)	0.4	0.5	0.6	0.4
ROCE (%)	6.4	1.1	6.4	10.8
Price/Book Value (x)	3.6	3.7	3.6	3.9
P/E (x)	46.8	67.2	-	63.3

Source: Annual Report, Progressive Research

*Note: Data calculated as on 07th October, 2024, *FY24 includes an exceptional item of Rs61mn*

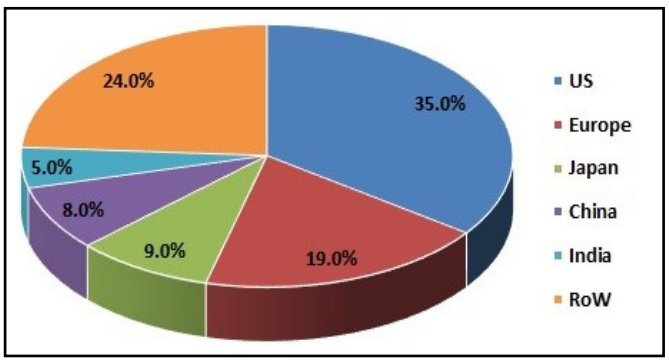
08 October, 2024	PICK OF THE MONTH	VOL-10, NO-11
Industry: Pharmaceuticals	Shilpa Medicare Limited	BUY
CMP: Rs.757	TARGET PRICE: Rs.1000	TIME : 12 months

Pharmaceutical Industry Overview: The global pharmaceutical market size stood at USD1559bn in 2023 and is expected to grow at a CAGR of ~6.1% to USD2832bn by 2033 (as per Vision Research). The US markets have secured a dominant position in the global pharma industry accounting for ~40% of the overall pie, followed by Europe at ~26% and Asia-Pacific at ~21%. On the domestic front, the Indian pharmaceutical industry is ranked world's third largest by volume (valued at Rs3.6-3.8trn as of FY23). India exports pharmaceutical products/drugs to more than 200 countries and territories, including the highly regulated markets of US, UK, the European Union (EU) and Canada. India has a complete ecosystem for the development and manufacturing of pharmaceutical drugs, with companies having state-of-the-art facilities and skilled/technical manpower. According to the Ministry of Commerce, Indian exports of drugs and pharmaceuticals reported a growth of ~9.6% in FY24 (USD28bn) as against ~3.2% in FY23 (USD25bn). The top export markets include US (contributing ~31% of the overall exports), followed by the UK, Netherlands, South Africa and Brazil.

Global Active Pharmaceutical Ingredient (API) Market: APIs serve as the key raw material required for manufacturing finished dosage forms/formulations. The global API market consists of regional hubs where manufacturers specialize in producing different types of ingredients for different sections of the global pharma market. In Asia particularly in China, the API industry is known for its low-cost, high-volume API manufacturing and is one of the key global sources. The global API market is valued at ~USD164bn in 2024 and expected to reach USD238bn by 2029, CAGR of ~7.8% during the forecast period (as per Markets and Markets.com). The rising demand for novel APIs (developed using advanced technologies) on account of more specialised drugs to treat complex illness, rising importance and demand for generic drugs (due to cost savings benefits), outsourcing operations in order to reduce costs and thus focus on core business and R&D, rising prevalence of chronic ailments are some of the factors that would boost the overall demand in the global API market. In terms of therapeutic share, **oncology** (~12% of the overall global API market) **and cardiology** (~16% of the overall global API market) are the major therapeutic areas catered in the global API market; and region wise US and EU are one of the largest markets as of 2023 contributing ~35% and ~19% respectively to the overall industry.

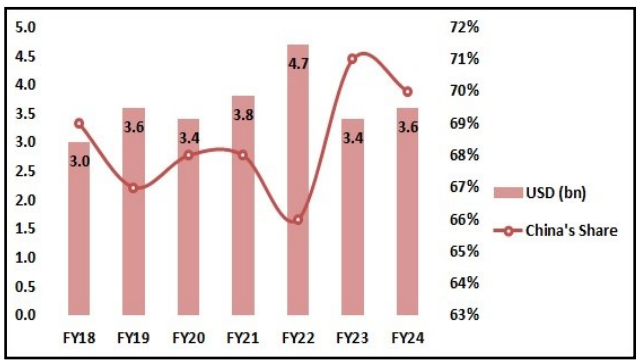
Indian API Market: India is the **third largest producer of API** after US and China (in volume terms), accounting for ~8.0% of the global API industry. India operates over 250 USFDA and UKMHRA approved facilities, providing generic drugs at affordable prices. The Indian API market stood at USD14bn in 2024 and is expected to reach USD20bn by 2029; CAGR of ~8.3% during the forecast period (as per Mordor Intelligence). Increasing prevalence of infectious, genetic, cardiovascular, and other chronic disorders, the growing geriatric population, adoption of biologics and biosimilars, and the rising production of generic drugs in the country are some of the notable factors boosting the overall growth momentum. High dependency on Chinese imports has always been a cause of concern for the domestic pharma industry. As per statistics from Pharmexcil, India imported USD3.6bn worth of APIs from China (accounting for ~70% of the overall API imports) in 2024, up by ~2.6%. The over dependence on the Chinese imports for essential drugs was more visible during the global pandemic breakdown. In order to overcome these challenges and become self-reliant, the govt. introduced initiatives such as the PLI scheme (introduced in 2021 for an outlay of Rs150bn for a duration of 2021-2029) and development of bulk drug parks (to manufacture 41 bulk drug parks with an outlay of Rs69bn for a duration of 2021-2030) to promote the Indian bulk drug industry. As per the Department of Pharmaceuticals (DoP), within three years of launch, the sector attracted Rs292.68bn to expand production capacities and diversify the pharmaceutical base. In May 2024, the PLI investments came in at Rs9.4bn, thereby leading to a total investment worth Rs292.68bn; an increase of ~3.3% as compared to investments worth Rs283.28bn in April 2024. The adoption of such an integrated approach towards reducing the dependence on China (the benefits of which would take atleast 5-7 years to reduce the overall dependence) will ensure adequate domestic supply of bulk drugs and APIs.

Exhibit 01: Global API Market Share (CY23)



Source: Market Reports, Progressive Research

Exhibit 02: India's Dependency on China

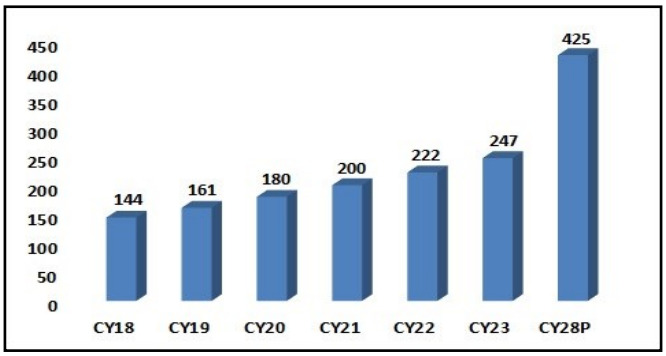


Source: Market Reports, Progressive Research

Pharmaceutical Industry Overview (contd.):

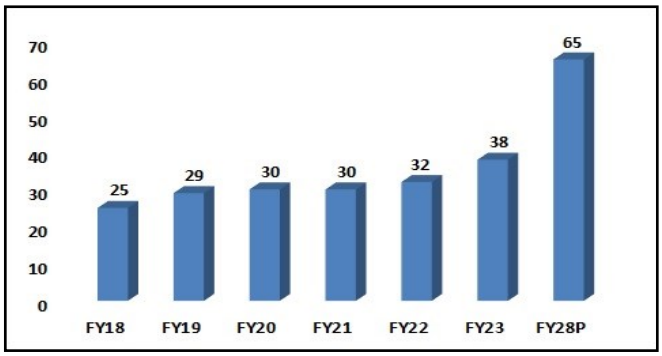
Oncology Therapeutic Segment & Oncology API: Oncology is one of the key therapeutic areas in the overall pharma industry. In line with the global trends, oncology API market has also seen a healthy growth in the overall API market. Oncology API manufacturing is aided by the development of complex APIs in oncology, peptides and complex injectables. The oncology segment in the global formulation market was valued at USD247bn in 2023 and is expected to increase to USD425bn by 2028, registering a CAGR of ~10.5-11.5% during the forecast period while the same was valued in the Indian markets at USD38bn in 2023 and anticipated to reach USD65bn by 2028; CAGR of ~10.5%. Oncology segment share in the overall global formulation market is expected to increase to ~22% by 2028 from the current ~12%. The demand for oncology APIs is primarily driven by the increasing incidence of cancer, growing R&D activities related to anti-cancer drugs, as well as growing demand for biologics and biosimilars for oncology therapeutic segments. Considering the huge market potential and unmet clinical needs, growth in the oncology API molecules is expected to continue in the near future.

Exhibit 03: Global Oncology Market Size (USD bn)



Source: Market Reports, Progressive Research

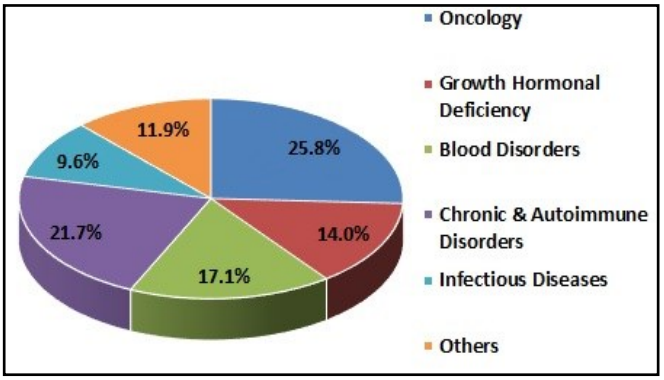
Exhibit 04: Indian Oncology Market Size (USD bn)



Source: Market Reports, Progressive Research

Biologics and Biosimilars Market: **Biologics** are complex drugs made by reproducing living cells through techniques such as genomics (mapping of genes), study of structure of proteins, mutation analysis (change in the DNA sequence of a cell) and systems biology (study of complex interactions in a biological system) intended for human/animal treatment. **Biosimilars** are biologic drugs that are highly similar to an already approved biologics termed as the reference product. These drugs generally enter the market after the reference drugs patent and data protection has expired. The global biosimilar market stood at USD25.1bn in 2022 and is expected to reach USD1.3trn by 2032; CAGR of ~17.6%. In 2022, oncology related applications accounted for the largest market share at ~24.2% as compared to other diseases and is further anticipated to maintain a leading position in the coming years. The Indian biosimilars market stood at USD349mn in 2022 and is expected to grow at a CAGR of ~25.2% to reach USD2bn by 2030. Between 2024-2030, biologic products worth USD170bn are expected to lose their patent protection leading to opportunities for the Indian biopharma players to explore more on the biosimilar products in the medium term.

Exhibit 05: Global Biosimilars Market Share (2032)



Source: centerforbiosimilars/view/global-biosimilar-market, Progressive Research

Growth Ahead: The Indian pharma industry addressed as the **Pharmacy of the world** is strongly on an upward growth trajectory. The industry was valued at USD40bn in 2021 and is expected to reach USD130bn by 2030 with further projections valued at USD450bn by 2047 (as per market reports). India has the maximum number of USFDA approved facilities outside the US; also **US continues** to be the **largest exporting** partner of India. As per industry experts, consistent growth in exports is attributed to the increased market opportunities and robust demand from countries like the US. Drug shortages in the US markets on account of demand-supply mismatch arising from production constraints, supply chain issues and increased regulatory challenges; such concerns open doors for the Indian generic players to expand their market share. Though this opportunity comes at a cost for the Indian generic players who have to bear the brunt of price erosion; in order to offset the same, the companies try and launch new products. Domestic players are shifting their focus towards complex products and biosimilars; and this changing trend portrays an attempt for strong and well-balanced growth of Indian generic companies carrying a blended portfolio of traditional as well as complex products over the medium to long term. PLI schemes, capturing on near term opportunities and having a well balanced portfolio of drugs are some of the key triggers for the sector.

08 October, 2024	PICK OF THE MONTH	VOL-10, NO-11
Industry: Pharmaceuticals	Shilpa Medicare Limited	BUY
CMP: Rs.757	TARGET PRICE: Rs.1000	TIME : 12 months

About the Company: Shilpa Medicare Limited (SML) started its operations as an API manufacturer in 1987 at Raichur, Karnataka. SML is one of the leading API and formulations manufacturer with strong capabilities in the therapeutic areas of oncology as well as non-oncology APIs; with established presence in domestic as well as the international markets. The products offered by the company are exported to US, Europe, and other international markets. SML has best in class manufacturing facilities that supply high quality and affordable drugs within the defined cost and delivery schedules. The regulatory filings demonstrate the company's capability and commitment to comply with the global standards thus ensuring safety as well as quality for the products offered. As of Q1FY25, the total DMF filings stood at 244. The Intellectual Property Management (IPM) team of the company is responsible for building a global generic product pipeline, creating, managing and protecting high value patents. As of FY24, the company has filed 9 new patents, taking the cumulative patent count to 564 (APIs: 213, Films and Topical: 37, Biologicals: 14 and Formulations: 300) in India and other countries. Mr. Vishnukant Bhutada is the Managing Director of the company.

Exhibit 06: Manufacturing Facilities

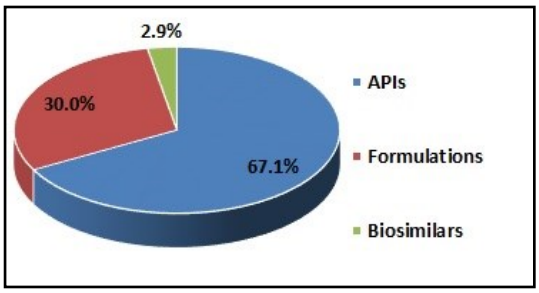
Facilities/Units	Capability	Approvals
Unit I & II, Raichur	Oncology, non-oncology APIs, peptide, polymers and intermediates	USFDA, EUGMP, PMDA, Cofepris, KFDA, WHO-GMP
Dharwad	Biosimilars, CDMO/CMO manufacturing plant & R&D facility	WHO-GMP & DSIR approved
Jadcherla	Formulations (onco & adjuvant therapy of onco-injectables and oral)	USFDA, EUGMP, Anvisa, Cofepris, DIGIMED-Peru, WHO-GMP, etc.
Hyderabad	Formulations (oral dissolving films), Bio-analytical/Pharmacovigilance/QC lab	WHO-GMP, Kenya, Yemen, Malaysia
Bangalore	TDS & ODF manufacturing facility & formulation R&D center	UKMHRA, UAE, WHO-GMP & DSIR approved
Ahmedabad	CRO & CDMO, R&D formulation	-
Kadechur	Recombinant Albumin & fermentation facility (currently under construction)	-

Source: SML March 2024 PPT, Progressive Research

Investment Rationale:

(A) Business Mix: The company's business is classified into **APIs, Formulations and Biosimilars**. The **API** business is further categorised into oncology, non-oncology, CDMO, peptides and polymers. SML is a niche player in high-potent oncology and select non-oncology products. Under the **formulations** business, the company has a differentiated portfolio focusing on improved patient compliance for both onco and non-onco products while at the same time the company is also venturing into Novel Drug Delivery Systems (NDDS) platforms with development of oral dispersible films (ODFs) and transdermal patches/systems (TDS) product pipeline. For the **biosimilars** business, SML focuses on high value low competition molecules.

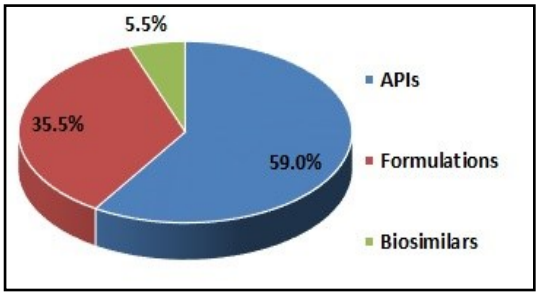
Exhibit 07: Revenue Breakup (FY24)



Source: SML March 2024 PPT, Progressive Research

(a) API: the major revenue contributor, accounts for **~67% of the overall revenues in FY24** (~59% in Q1FY25). The business is carried out by the company's wholly owned subsidiary (WoS) **Shilpa Pharma Lifesciences** with focus on API manufacturing indicated for oncology, non-oncology, CDMO, peptides and polymers. The company has 2 dedicated state-of-the-art manufacturing units at Raichur, India (aggregate installed capacity of 1,015KL as of FY24) backed by a strong R&D and IPM team for all the regulatory functions and quality control. Both the API units are cGMP compliant and approved by national as well as international regulatory authorities like the USFDA, EU, COFEPRIS -Mexico, PMDA-Japan, Korean FDA, TPD Canada and TGA-Australia and have ISO 9001:2015, ISO 14001:2015, OSHAS 18001:2007 and DSIR certifications. The APIs and intermediate manufacturing blocks are diversified into **oncology and non-oncology manufacturing facilities** (9 dedicated blocks for oncology and 8 blocks for non-oncology) having the capability to handle small, medium and high volume scale batches ranging from 500gm to 350kg in oncology and 4kgs to 2,000kgs in the non-oncology space. Over the years, SML has broadened its presence in terms of DMF filings across various geographies (which stood at 202 in FY22, 227 in FY23 and 244 as of FY24 as well as Q1FY25) as well as tried to leverage its expertise in diverse areas of API business.

Exhibit 08: Revenue Breakup (Q1FY25)



Source: SML June 2024 PPT, Progressive Research

Investment Rationale (contd.):

(a) API (contd.):

API Manufacturing Units:

Shilpa Pharma Lifesciences, Unit I: this facility caters to oncology/non-oncology APIs and has the competence for gram to kilo scale synthesis. The annual production capacity for FY24 stood at ~422MT while the actual production came in at ~359MT with capacity utilisation at ~85%. The facility has approvals from regulators such as USFDA, EU-GMP, TGA, PMDA, KFDA. The unit has 6 manufacturing blocks (3 each for oncology and non-oncology).

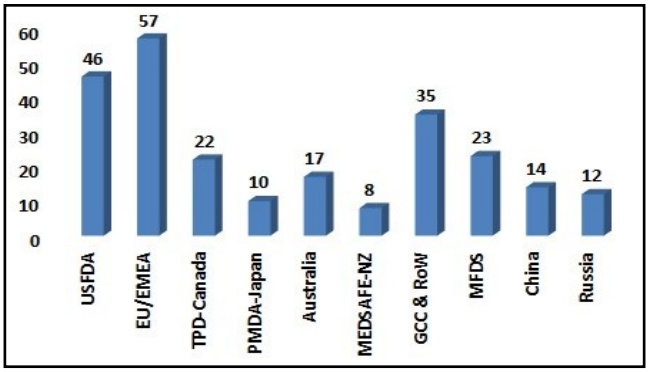
Shilpa Pharma Lifesciences, Unit II: this a 100% export oriented API unit and is located adjacent to Unit I. The unit is certified by ISO 14001:2004 and approved by USFDA, WHO-GMP, EU-GMP, TGA, PMDA, KFDA and TPD. The unit has 10 manufacturing blocks (5 each for oncology and non-oncology). The annual production capacity for FY24 stood at ~485MT while the actual production came in at ~361MT leading to capacity utilisation of ~75%. In Q1FY25, the unit successfully completed the ANVISA Brazil GMP audit for all 29 products; this paves the way for good opportunity in the Brazilian markets.

Exhibit 09: API Units Regulatory Filings

Particulars	Filed in FY24	Cumulative Filed	Status	FY25
US DMF	-	44	25 approved, 3 under review and 16 CA listed	15 molecules are planned for validation (incl. of 3 products)
CEP-EDQM	4 CEPs	27	19 approved and 8 under review	3 molecules are planned for file for CEP
EDMF	4 ASMF	30	24 approved and 6 under review	15 molecules are planned for validation (incl. of 3 products)

Source: SML Annual Report 2024, Progressive Research

Exhibit 10: API DMF Filings



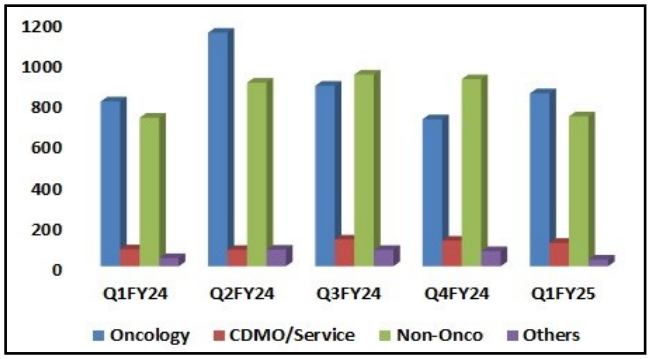
Source: SML June 2024 PPT, Progressive Research

The API sub-verticals:

(i) Oncology: In the overall API segment; oncology is the largest contributor and accounted for ~46% (revenues at Rs3,556mn) in FY24 and ~49% (revenues at Rs846mn) in Q1FY25 of the overall API revenues. As of FY24, SML has manufactured 29 oncology APIs which includes key products such as Capecitabine, Gemcitabine Hydrochloride, Pemetrexed, Axitinib, Erlotinib Hydrochloride and Irinotecan Hydrochloride for international markets including US, Europe, Japan, South Korea, Russia, Mexico, Brazil, and other emerging markets.

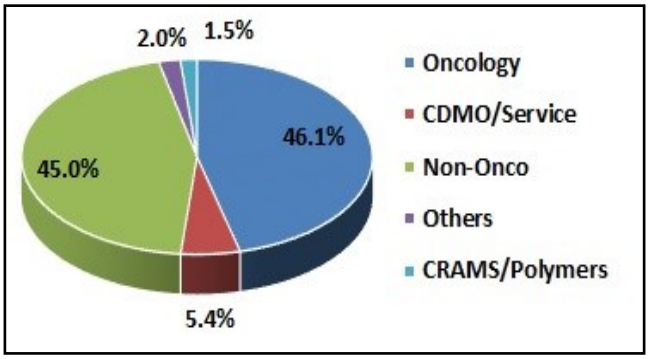
Oncology API Developments: Under the **oncology** segment, SML has completed validations for 3 molecules in Q1FY25. For **Methotrexate** and **Abiraterone Acetate**; the Management expects to file the same with the US and the European authorities in Q3FY25. Additionally, there are 2 NDA molecules which SML is developing for its clients. NDA molecule 1 (for the US client) is expected to be filed by the client in Q4FY25. The company has already secured a pre-launch order in Q1FY25 and will be supplied in Q2FY25 and subsequent quarters. For NDA molecule 2, the project is currently under phase III; SML has already received an order and the deliveries have been completed in Q1FY25. In addition to this, there are several other onco molecules which are in the development/validation stage; **Olaparib and Palbociclib (onco molecules)**, the validations are planned to be undertaken in Q2FY25.

Exhibit 11: Q1FY25 API Revenue Breakup (Rs in mn)



Source: SML June 2024 PPT, Progressive Research

Exhibit 12: API Revenue Breakup (FY24)



Source: SML Annual Report 2024, Progressive Research

Investment Rationale (contd.):

The API sub-verticals (contd.):

(ii) Non-oncology: this accounted for ~45% (revenues at Rs3,475mn) in FY24 and ~42% (revenues at Rs733mn) in Q1FY25 of the overall API revenues. Over the years, SML has developed a robust portfolio across various therapeutic areas such as respiratory, CNS, urology, nutraceuticals and anti-infectives. As of FY24, the company has manufactured 20 non-oncology APIs and derives its revenues from select key molecules like **Ambroxol Hcl** (mucolytic agent, used to clear congestion) in Europe, **Tranexamic acid** (helps in blood clotting) and **Ursodeoxycholic acid (UDCA),** a complex and niche API (indicated for treatment of cholestatic liver disease) in India. The focus in the non-oncology space is more towards products with high growth potential with the intend to offer solutions that can substitute imports. ***Tranexamic acid:*** *With the help of a Japanese pharmaceutical company, SML in the past had invested ~Rs400mn in order to set up a dedicated block at Raichur to manufacture Tranexamic acid for India, EU and other emerging markets. In 2022, SML received a Central Drugs Standard Control Organisation (CDSCO) approval for Tranexamic acid spray (hemostatic spray) and has been granted patents till 2037 for the Indian markets and 2038 for the US, Australian, Russian and South African markets.*

Non-oncology API Developments: Under the **non-oncology segment**, over the past 2 years, SML has expanded capacity of **Tranexamic acid** from 5.5MT to 14MT per month and as of Q1FY25 the company is scaling towards 25MT per month (the project for which has already been initiated with an estimated capex chalked at ~Rs250mn for FY25; the Management expects the same to be completed by December 2024), for **Ambroxol Hcl**, SML has expanded the capacity from 135MT to 175MT p.a. in FY24 by optimally utilising the Ambroxol manufacturing facility and by making the manufacturing equipment into two bays; the capacity enhancement to 230MT is underway via de-bottlenecking some of the equipments within the same facility. The company has 3 more non-oncology products in pipeline. In the case of **UDCA**, the volume has enhanced from 48MT in FY23 to 100MT in FY24; the Management further expects to expand the volumes to 150MT in FY25. In Q1FY25, the company received European Certificate of Suitability (CEP) approval for UDCA and the Management expects good traction in the exports market (on an overall volume terms) over the next couple of quarters. In addition to this, in Q1FY25 the company has completed the lab validation for **2 new non-oncology** molecules and for the same product plant scale-up has been initiated; SML is working on completion of plant validation and subsequent DMF filings and anticipates sustainable revenue contribution in the long term.

(iii) CDMO: this accounted for ~5% (revenues at Rs420mn) in FY24 and ~7% (revenues at Rs115mn) in Q1FY25 of the overall API revenues. The company provides a comprehensive service portfolio to assist researchers in applications requiring CDMO activities. SML offers high-quality intermediate as well as final API products with cost-effective solutions for cutting-edge research. As of FY24, the company has 4 CDMO customers in phase III and 7 customers in phase I & II.

CDMO Developments: As of Q1FY25, the preclinical supplies for the US client is successfully completed and the program has advanced to phase I/phase II clinical studies for which the company has already received an order and the supplies are expected to be completed in Q2/Q3FY25. On the other hand, order for the Taiwan client has moved to phase III study, the plant validations are expected to be completed in FY25. Apart from the existing ones, the company has signed for 2-3 additional CDMO projects; the initial large scale development for these have already commenced. The CDMO business continues to receive positive feedback from the customers with consistent growth led by new client additions. During Q1FY25, SML **partnered with Unicycive Therapeutics Inc.** for a period of 4 years (with renewal option for another 4 years) to provide end-to-end CDMO services right from development & supply of APIs to finished dosage form. Based on the outcome of the pivotal clinical studies, Unicycive has entered into long term manufacturing and supply agreement with SML and agreed to place a binding purchase order for 5 million tablets of Oxylanthanum Carbonate Tablets (OLC) {indicated to treat hyperphosphatemia in patients with chronic kidney disease (CKD) on dialysis} by 30th June 2025. Unicycive has also agreed to place orders for additional tablets (~15 million) to be delivered between 31st December 2025 and 30th June 2026. Apart from the supply arrangement, the Management anticipates to receive ~USD10mn as milestone income (cumulative in nature) spanning over filing, approval and product launch after which the revenue generation is expected to kick in once SML starts commercial supplies for the tablets. In anticipation of increased product demand, Unicycive will also fund the establishment of new manufacturing block at Shilpa's site; at a capex amount of ~USD6.5mn; the new dedicated block is expected to start commercializing in the next 1 year. The API will be supplied by SML's current API unit (at Raichur) to the formulation unit and from this unit the final product will be supplied to Unicycive. **This will eventually be recorded under the US formulations business**. On 4th September, 2024 Unicycive Therapeutics announced NDA submission for OLC to the USFDA. The NDA submission package is based on data from three clinical studies (a phase-I study in healthy volunteers, a bioequivalence study in healthy volunteers and a tolerability study of OLC in CKD patients on dialysis), multiple preclinical studies and the specifications and practices related to chemistry, manufacturing and controls (CMC). This submission serves as the first regulatory application from the CDMO partnered initiative and further strengthens its credentials as a one-stop reliable partner for all the CDMO requirements of global pharma companies. Initially the target markets for OLC will be particularly in the US (with revenue generation expected to be more than a billion dollar) and then enhance the footprint further in Japan and Chinese markets.

Investment Rationale (contd.):

The API sub-verticals (contd.):

(iv) Others: The company is also involved in developing its capabilities in the manufacture of peptides and polymers. Client addition under this business is a quarterly process. The revenues stood at Rs33mn in Q1FY25. As of FY24, the company has 2 approved peptides (with CEP filings in place for the regulated markets) products with additional 5 in the pipeline.

Others Developments: The major focus of SML has been towards a mix of Glucagon-like peptide (GLP-1) portfolio and some complex products. In one such update, for **Liraglutide** (1st GLP-1 product) the 3rd peptide molecule; the plant validation has been successfully completed in FY24 with a DMF filing expected in the US markets in Q3FY25 and thereafter the product will also be filed for the RoW markets. **In the upcoming quarters, the Management expects initial sales contribution from Liraglutide.** Apart from this, there are several other peptides under development stage viz; **Teriparatide** is the 4th peptide molecule, the development phase has been completed in FY24. As per SML's Annual Report 2024, the osteoporosis market was valued at ~Rs4,660mn, CAGR of ~43.0%. SML has already captured a market share of ~1.3% in the 1st year of launch for Teriparatide. **Semaglutide** is the 5th peptide molecule which is under lab validation with DMF anticipated to be filed in FY25 and commercial sales are expected to start in FY25. As far as polymers are concerned, in Q1FY25, the company developed a specialty polymer for which the clinical supplies for the US markets have already commenced and is expected to be completed in Q2/Q3FY25. In addition to this, there is another new polymer project that has been initiated and is expected to be completed by Q2FY25.

Exhibit 13: Key API Developments

API Segment	Drug/Product	Indications	Status
Oncology	Methotrexate	Treat inflammatory arthritis and slow down growth of cancer cells as well	Validation phase has been completed. Expected to be filed in the US and the EU markets in Q3FY25
	Olaparib	Treat ovarian/breast/pancreatic/prostate cancer	Validations are expected to be undertaken in Q2FY25
	Palbociclib	Treat breast cancer	Validations are expected to be undertaken in Q2FY25
	Abiraterone Acetate	Treat prostate cancer	Expected to be filed in the US and the EU markets in Q3FY25
	NDA molecule 1	-	Developing for the US client and is expected to be filed in Q4FY25. The pre-launch order has been received in Q1FY25, supplies to be done in Q2 and subsequent quarters
	NDA molecule 2	-	The client project is under phase III trials, delivery has been completed in Q1FY25
Non-oncology	Tranexamic acid	Controls blood clot	Scaling towards 25MT per month capacity; the project is expected to be completed in December, 2024
	Ambroxol Hcl	Mucolytic agent	Capacity enhancement towards 230MT is underway via de-bottlenecking (capacity for FY24 stood at 175MT p.a.)
	UDCA	Treat cholestatic liver disease	Expand the volumes to 150MT in FY25 (FY24: 100MT). In Q1FY25 SML received a European CEP approval
Peptides	Liraglutide	Treat type 2 diabetes	Plant validation has been successfully completed in FY24 with a DMF filing expected in the US markets in Q3FY25; later expected to be filed even in the RoW markets
	Teriparatide	Treat osteoporosis in postmenopausal phase	Development phase has been completed in FY24
	Semaglutide	Treat type 2 diabetes	Under lab validation with DMF anticipated to be filed in FY25
	Desmopressin	Helps to reduce frequent urination and excessive thirst	Recently received a CEP approval from EDQM
Polymers	Specialty Polymer	-	Clinical supplies for the US markets has commenced and expected to be completed in Q2/Q3FY25
	New Polymer Project	-	Expected to be completed by Q2FY25
CDMO	US Client	-	Program advanced to phase I/II; supplies are expected to be completed in Q2/Q3FY25
	Taiwan Client	-	Order has moved to phase III trials. Plant validations are expected to be completed in FY25
	Unicycive Therapeutics Inc.	-	Agreement for 4 years with renewal option for another 4 years

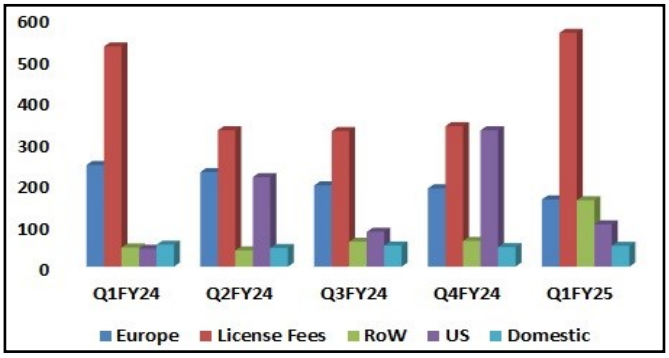
Source: SML Annual Report 2024 and Quarterly Reports, Progressive Research

Overall, the company has plans of commercialization of 3-4 new APIs every year, expand its capacity, and also expects strong growth momentum in the portfolio of oncology, non-oncology, peptides, polymers and CDMO. The primary focus is oncology and the company is working to build a differentiated long-term complex pipeline, which would lead to sustainable growth going forward.

Investment Rationale (contd.):

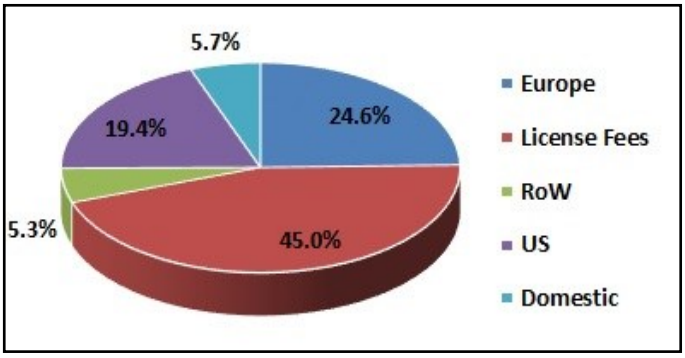
(b) Formulations: This segment contributed **~30% to the overall revenues in FY24** (~36% in Q1FY25). The business is carried out by SML and Shilpa Therapeutics Ltd (100% subsidiary of SML). The company has made notable progress in developing products such as **Azacitidine, Docetaxel, Tarceva,** etc. Under formulations, (i) the company manufactures range of products including oral solids (tablets and hard gelatin capsules), liquid injections (aseptically and terminally sterilised) and lyophilised injectables for pharmaceutical organizations across various countries; and (ii) the domestic business comprises of manufacture of specialized oncology formulations. For Q1FY25, of the total formulations revenue, ~54% accounted for license fees, ~16% from Europe, ~15% from RoW, ~10% from the US markets and the balance from the domestic market.

Exhibit 14: Q1FY25 Formulations Revenue Breakup (Rs in mn)



Source: SML June 2024 PPT, Progressive Research

Exhibit 15: Formulations Revenue Breakup (FY24)



Source: SML Annual Report 2024, Progressive Research

Manufacturing Units: The formulation facilities are located at Jadcherla (Telangana) and Hyderabad; these facilities are well designed and equipped in order to provide high quality products of different batch sizes and various dosage forms.

Unit IV Jadcherla, Telangana: the finished dosage manufacturing facility manufactures potent products (inclusive of oncology products) which caters to different regulatory markets. In addition to this, the facility is well-equipped with oral solid block having 2 commercial scale tablet manufacturing line, 1 commercial scale capsule manufacturing line, 2 blister packing lines and 1 bottle filling line. The products include lyophilisation, tablets and capsules, large and small volume parenteral injectables. The facility is approved by agencies such as EU-GMP AGES-Austria, ANVISA, Health Canada, Peru, Argentina, South Africa, COFEPRIS Mexico, TGA -Australia, Ministry of Health-UAE & UKMHRA. The annual production capacity in FY24 stood at ~3.05 million vials while the actual production came in at ~1.21 million vials; capacity utilisation of ~39.7%. The annual production capacity in FY24 for tablets & capsules stood at ~29.39 million tablets/capsules while the actual production came in at ~18.04 million tablets/capsules; capacity utilisation of ~61.3%.

Exhibit 16: USFDA Inspection History

Inspection	Observation
August 2015	Issued form 483: 5 observations
July 2016	Issued form 483: Zero observations
November 2017	Issued form 483: 10 observations
March 2018	Received an EIR status
February 2020	Issued form 483: 15 observations
February 2021	Received import alert 66-40
November 2023	Issued form 483: 10 observations, OAI status

Source: Market Reports, Progressive Research

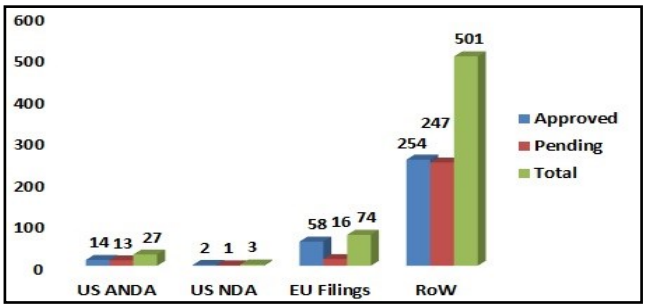
Import Alert: The company's Unit IV was inspected in the past with Form 483 issued followed by observations and warning letters. However, on 17th Feb'21, the USFDA issued an import alert 66-40 *(which essentially means the existing approved products from this facility can no longer be marketed in the US markets until a clearance is provided by the USFDA)* for this facility after being inspected in Feb, 2020 for failure to comply with cGMPs. Following the import alert decision, various products manufactured at this facility were banned except 3 major products viz; **Azacitidine for injection** (for bone marrow treatments), **Cyclophosphamide capsules** (treat ovarian/blood/breast cancer) and **Erlotinib tablets** (treat lung and pancreatic cancer). In order to address this issue, the company had undertaken a systematic remediation plan with the assistance of a third-party consultant to address the concerns of the regulatory authorities *(the incremental costs incurred on annual basis stood at Rs86mn in FY21, Rs297mn in FY22 and Rs70mn in FY23; as per the Management most of the remediation costs have been completed).* In Nov'23, the USFDA inspected the facility and concluded with 10 observations (none of which were regarded as repeat observations) for which the company has duly submitted the response and was granted an OAI status. As per the latest update, the facility was inspected by AGES-Austria from 22nd-26th Jan'24 and towards the end of the inspection, the unit was issued a GMP certification from the regulatory authority. Additionally, in Apr'24, the unit received a EU-GMP approval. Both these certificates indicate continuous supply of medicines for commercial distribution to various EU countries. During Q1FY25, the USFDA recommended to assign some subject experts/consultants for which the appointment is completed by SML and the review process has already commenced. The review is expected to be completed in Q3FY25; thereafter SML will re-apply with the regulatory authorities for further course of action.

Investment Rationale (contd.):

(b) Formulations (contd.):

Unit V, Hyderabad: the facility is managed by Shilpa Therapeutics that manufactures oral fast dissolving thin strip dosage form of drugs that makes use of a fast disintegration technology *(the strips are designed in such a way that they disintegrate and can be swallowed without the need of water as compared to conventional dosage form).* The unit is equipped with a layering machine and an 8 track packing machine with an output of 800,000 units/day. Ondansetron oral disintegrating strips *(indicated to prevent nausea)* was the first launched product from this unit. The facility is approved by WHO-GMP, Kenya, Yemen and Malaysia.

Exhibit 17: Q1FY25 Regulatory Filings



Source: SML June 2024 PPT, Progressive Research

Filing Status: As of March 2024, the company has a healthy product pipeline in the formulations segment with 605 filings in the US (27 ANDA, out of which 14 are approved and 13 pending, 3 NDA products of which 2 are approved), European Union (74 fillings of which 58 are approved) and RoW (501 fillings of which 254 are approved). The Management intends to file ~12 products and ~30 products for the US and the European markets in FY25 (as per SML Annual Report 2024).

Formulations Developments:

Topical Lotion SMLTOP09: Androgenic Alopecia is a common form of hair loss. In 2022, the global Alopecia market was valued at USD8.2bn and is expected to grow at a CAGR of ~9.0% from 2023-2030. SML has successfully completed phase II clinical trials and expects **phase III** trials to start in Q3FY25.

Pemetrexed Injection (oncology): this is a ready to use (RTU) injection used in the treatment of non-small cell lung cancer in combination with other chemotherapy agents. This injection eliminates the need for refrigeration which improves the efficiency. SML along with its marketing partner Amneal Pharmaceuticals (under a profit sharing agreement) has recently launched PEMRYDI RTU (Pemetrexed Injection 10mg/mL) formulation in the US market. At present the product is available in 2 vial sizes of 100mg/10mL and 500mg/50mL and the Management expects to introduce 1000mg/100mL in the near term. The product has already been granted permanent J-code (J9324) by US Centers for Medicare & Medicaid Services (CMS). *J-codes are granted for niche products and indicates premium pricing.* As per Q1FY25 update, the partner has applied for K code *(which will help them in insurance reimbursement)*; the approval for the same is anticipated in Q2FY25. As per IQVIA, the annual sales for Pemetrexed Injection for 12 months ending February 2024 stood at USD287mn. Post the launch, Amneal was in a position to sell more than 1,000 vials in the US markets (the product contributed ~Rs200mn of the overall US formulation revenues in Q4FY24). In the subsequent quarters, Pemetrexed is expected to garner a good market share in the US markets.

Bortezomib Injection (oncology): this an oral oncology liquid (which is an RTU) indicated for the treatment of adult patients with multiple myeloma. This is the 2nd NDA approval for SML in the US markets from the novel injectable portfolio. It is available as a single dose vial of 3.5mg/1.4mL (2.5mg/mL). This will be marketed by Amneal Pharmaceuticals LLC. As per MAT Q4FY23, the market size for the injection stood at USD95mn.

Nilotinib (oncology): this is indicated to treat chronic myeloid leukemia; type of cancer of the white blood cells. During Q1FY25, the regulatory review for the product is completed and the launch is anticipated in Q3FY25 (SML has partnered with the #1 company in the generic space in oncology selling in Europe; this is expected to generate overall good revenues in the European markets). The drug had an estimated market size of USD453mn (as per IQVIA MAT Dec'23).

SMLNUD07-NorUDCA (non-oncology): this product is developed by SML for the treatment of non-alcoholic fatty liver disease (NAFLD). SML had initiated **phase III** studies for NorUDCA alongwith patient recruitments conducted on 165 candidates across India. On 26th August, 2024, the company successfully completed the trials with no serious adverse events reported and the treatment was well tolerated for 1500mg per day dose for duration of 24 weeks. The Management intends to submit the results to CDSCO, India for seeking a marketing authorization (the filing for the Indian markets is expected to be undertaken in Q3FY25). The company also foresees significant opportunities in the EU and RoW markets for the product.

Investment Rationale (contd.):

Formulations Developments (contd.):

Dr. Clot Spray (non-oncology): innovative formulation of tranexamic acid, designed to address the critical issue of uncontrolled bleeding during trauma, accidents, battle field, surgery, suturing and ambulance transportation of patients from the site of accidents to the hospital. Dr. Clot is a globally patented formulation by SML and is already launched in the Indian market. The product has already received a CDSCO approval and the Management is working with various government agencies to get this product under the essential drug list *(at present the product is available on a Rx basis, the company is working to get the same approved under OTC; thereafter the Management anticipates a decent commercial market share for the product).*

ODFs and TDS: For **ODFs,** the company has received approval for Betahistine Dihydrochloride ODF (indicated for anti-vertigo medication), 24mg in the UK market; the filing is expected in Sept'25. Apart from this, Tadalafil ODF and Sildenafil ODF (indicated to treat erectile dysfunction) are gearing up for filings. Clinical studies for Bilastine ODF (anti-histamine) have been completed and the filing is expected soon. In Q1FY25 the company has developed a new product namely **SMLODF010** which provides a unique opportunity in the US markets. The human clinical studies have been completed and the product is expected to be launched in the US markets tentatively in Q3/Q4FY25 while for the European markets the pivotal stage has been completed and the submission is expected to be filed in Q3FY25. For the **transdermal patch**, the company has partnered in Europe and emerging countries for SMLTDP08 Rotigotine (indicated to treat Parkinson disease) which is expected to be filed in Q3FY25 in the European markets; with a market potential of ~USD227mn (as per IQVIA MAT Dec'23). Apart from this there are 2 more new products under development. With a total of 3 transdermal products now licensed for the EU markets, SML is well-positioned to capitalise on emerging opportunities to serve patient needs from different parts of the globe.

Exhibit 18: Key Formulations Development

Drug	Indications	Status
Topical Lotion SMLTOP09	Treat androgenic alopecia (a common form of hair loss)	Phase II clinical trials are completed; phase III trials are expected to start in Q3FY25
Pemetrexed Injection	Treat non-small cell lung cancer	Marketing partner Amneal Pharmaceuticals has applied for K code in Q1FY25; the approval is expected in Q2FY25
SMLNUD07 (NorUDCA)	Treat non-alcoholic fatty liver disease (NAFLD)	Phase III trials in India were completed on 26th August; Indian markets filings expected in Q3FY25
Dr. Clot Spray	Controls blood clot	SML working to get the same under the OTC category
Nilotinib	Treat chronic myeloid leukemia	Launch is expected in Q3FY25. Market size of the drug stood at USD453mn (as per IQVIA MAT Dec'23)
Bortezomib Injection	Treatment of adult patients with mantle cell lymphoma	2nd NDA approval in the US markets. This will be marketed by Amneal Pharmaceuticals LLC. The market size as per MAT Q4FY23 stood at USD95mn
Betahistine Dihydrochloride ODF	Treat vertigo	Filing is expected in Sept, 2025
Tadalafil ODF	Treat erectile dysfunction	Filings are expected soon
Sildenafil ODF	Treat erectile dysfunction	Filings are expected soon
Bilastine ODF	Treat skin rash, allergies	Clinical studies are completed and the filing is expected soon
SMLODF010	-	New product developed in Q1FY25; the launch in US markets is anticipated in either Q3/Q4FY25 while for the European markets the submission is expected in Q3FY25
Rotigotine (TDS)	Treat parkinson disease	Expected to be filed in Q3FY25 in EU. The market potential stood at USD227mn (MAT Dec'23)

Source: SML Annual Report 2024 and Quarterly Reports, Progressive Research

Overall, the company has been expanding its geographical reach entering into several emerging markets through marketing partners, providing it access to private markets and enabling to participate in local tenders. This diversification will help to drive sustainable growth in its formulation business in the long term.

(c) Biosimilars: Considering the attractive opportunities in the Indian biosimilars market (expected to reach USD2bn by 2030), SML incorporated a separate entity Shilpa Biologicals Pvt. Ltd (SBPL) (at Dharwad) which lays its focus on core segments of orthopedics, rheumatology (biosimilar programs for Adalimumab and Abatacept); while the production of excipient and therapeutic grade recombinant human albumin (rHA) is carried out by Shilpa Biocare (at Kadechur, Karnataka). The business involves innovative healthcare offerings such as transdermal patches, oral films, biologicals and biosimilar drugs. This strategic expansion underscores the company's commitment to advanced therapeutic solutions, thereby providing its offerings to diverse medical needs.

Investment Rationale (contd.):

(c) Biosimilars (contd.):

Unit VI, NDDS, Bangalore: is managed by SML and Shilpa Therapeutics. It produces advanced drug delivery products such as TDS and ODFs. An *ODF is a modern expansion in the drug delivery system and is well designed for comfort of the patients. These are water-based soluble polymers and work like conventional oral dispersible tablets. TDS are composed of either a single or multi-layer polymeric adhesive matrix, with one layer containing the drug substance. These function well for older patients having difficulty in swallowing pills and these patches can be self-administered.* The facility is well-equipped for large-scale production with multiple ISO certifications at its credit, ensuring high standards of quality and compliance. The unit is supported by global registrations, with recognition from UKMHRA, the Ministry of Health in the UAE and a COPP/WHO license, among others.

Biosimilars Developments:

Adalimumab Injection: this is indicated for the treatment of rheumatoid arthritis. In 2022, SBPL successfully completed the phase III human clinical trials of Adalimumab (1st biosimilar). This is the **highest selling** product in the US markets; while the Indian market opportunity stands at ~Rs1,220mn (as per SML Annual Report 2024). In FY24, the company launched the high concentration 40mg/0.4ml injection {of a higher concentration formulation (100mg/mL) in India} in prefilled syringe under its **own brand name** ORIADALI (biosimilar to Humira) via a partnership with **Sun Pharma** (in the launch of just 6 months, SML has achieved ~1% market share); in Q3FY24 SML already executed 2 commercial supplies for the product with a quarterly binding agreement with Sun Pharma going forward. The company is also trying to venture into RoW as well as the EU markets. In Q1FY25, the product received an approval for the Morocco market. The Management has indicated of engaging in partnerships with other clients as well.

Recombinant Human Albumin (rHA): *Human serum albumin (HSA) is the serum albumin found in human blood produced in liver; the most available protein in human blood plasma. This is mainly used in the treatment of liver cirrhosis, hemorrhage shock, severe burn, plastic surgery, etc. However, in recent years on account of shortage of blood plasma, the HSA short supply particularly in China and Asian countries raised concerns. India continues to remain a large importer of both plasma and HSA. In order to address this concern, regulatory authorities such as the FDA and EMEA are explicitly encouraging the application of the recombinant HSA with animal free component.* SML's NavAlbumin is a synthetically developed product as against the current process of drawing the same from blood plasma. It also supersedes in terms of predictable supply chain (produced via a scalable fermentation process) and possess a high degree of purity, free from any potential contamination from HIV/HBV/HCV. SML has successfully completed the **phase I** trials (in the European markets on 62 candidates) for the product while **phase III** trial initiations are likely to kick start by Q4FY25 and is expected to be completed over next 9-12 months' post commencement. The Management expects the filing for product approval across various geographies to commence in FY26E. The company is undertaking parallel clinical studies for the Indian and Emerging markets as well as the European markets. SML foresees immense opportunity (global albumin market is roughly USD9bn) from rHA both as an **excipient** (the DMF has been filed in FY24 for the US markets; the excipient can be sold without clinical trials) and as a drug with more scope in the Indian markets (which currently has only 2 unlisted players: Reliance Lifesciences and Intas). Due to the significant short supply in various geographies, the company proposes to set up and commission a large scale manufacturing greenfield facility at Kadechur in Karnataka; where the project is on track and expected to be completed in Q3FY25 (at a capex of ~Rs500mn in FY25).

Aflibercept (biosimilar to Eylea): this is a complex product in the ophthalmic range and is indicated to treat neovascular age related macular degeneration, diabetic macular edema. In 2022, the company received a no-objection-certificate from the Review Committee to conduct clinical studies. As on date, the company has received approval from CDSCO to conduct **phase III trials** for the Indian markets which would be initiated from Q3FY25. In addition to this, the Management is also working on developing the product for the RoW and EU markets as well and is already in discussion to seek permission from the EMA agency to conduct phase III studies.

CDMO (Korean client): the complex project was well executed by SML and various orders for the preclinical and phase I supplies have already started. The client could also successfully sail through the GMP audit which serves SML as a primary supplier currently for the client for both phase I and phase II supplies. In addition to this, the Management expects 2 new CDMO projects to be signed in Q2FY25.

Apart from the above mentioned biosimilars, the company has **3 more products** which are currently under development i.e. **Abatacept: biosimilar** to **Orencia-BMS** (indicated to treat moderate to severe rheumatoid arthritis), **Etanercept:** biosimilar to Enbrel-Amgen (indicated to treat autoimmune diseases) and **Pembrolizumab:** biosimilar to Keytruda-Merck Sharp & Dohme's (indicated to treat types of skin cancer). In the quarters going forward, biosimilars will be a robust portfolio for the company. SBPL's biosimilar programs for Adalimumab, Aflibercept and Abatacept are progressing well towards approvals from different regulatory authorities. In line with the 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.

Investment Rationale (contd.):

(c) Biosimilars (contd.):

Exhibit 19: Key Biosimilars Development

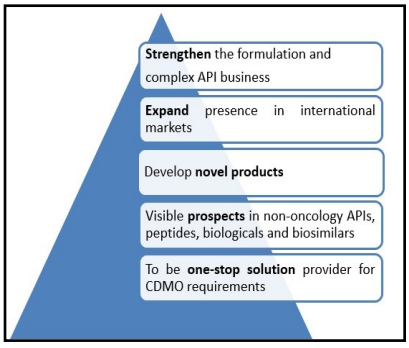
Drug	Indications	Status
Adalimumab Injection	Treat rheumatoid arthritis	In Q1FY25, the product received an approval for the Morocco market
rHA	Treat liver cirrhosis	Completed phase I studies in EU and phase III trials are expected to start in Q4FY25. For the excipient, the company has filed a DMF in FY24
Aflibercept	Treat neovascular age related macular degeneration	Phase III trials in India are expected to start in Q3FY25; seeking permission from the EMA agency to conduct phase III studies
Abatacept	Treat moderate to severe rheumatoid arthritis	Under development
Etanercept	Treat autoimmune diseases	Under development
Pembrolizumab	Treat types of skin cancer	Under development
CDMO (Korean client)	-	Orders for preclinical and phase I supplies have already commenced

Source: SML Annual Report 2024 and Quarterly Reports, Progressive Research

(B) R&D Reach: SML has best-in-class manufacturing facilities that supply high quality affordable drugs. The company has to its credit a team (~310 experts as of FY24) of qualified, experienced and well-trained staff that look after the design of clinical studies and quality control. Over the years, R&D has played an important role in strengthening the overall competitive advantage for SML in the global pharma space. SML has emerged as an important player in providing onco API, generic equivalents (both for onco and non-onco) and formulations (injectables as well as oral dosage forms). The IPM team at SML is responsible for building a global generic product pipeline, create, manage and protect high value patents. The team is also looking at patenting new products, processes, methods of use, drug delivery systems and medical devices in India, US, EU and other countries. As of FY24, the cumulative patents count stood at 564 in India and other countries. SML serves as a key supply chain partner to many leading pharma companies. The company's focus continues to be on generic commitment (by ensuring early access to generic products), complex API process development (involves complex processes for both onco as well as non-onco molecules), flow chemistry advancements (handle complex processes with precision), self-dependency on KSM and intermediates (ensures reduction on external supplies which portrays a robust supply chain) and continuous process technology improvements all of which contributes significantly for research and innovation developments. The company's R&D operations are primarily undertaken by its WoS FTF Pharma which has its R&D centre at Ahmedabad for handling high potent drugs with well-equipped modern instruments. Overall, the company has best-in-class R&D centres in Raichur, Bangalore, Ahmedabad, Dharwad and Hyderabad. The respective units are capable of designing and developing generic APIs, develop oncology and non-oncology injectable/oral formulations, transdermal patch and topical preparations, ophthalmic formulations and oral disintegrating film formulations.

(C) The Overall Growth Ahead: SML's capabilities across its business segments marks significant opportunities over the medium term. Under the API business, SML continues to enhance the capacities for its non-oncology products and commercialise additional APIs. For the **formulations** business, there are various products/drugs which are either already launched, some have completed their phase I/II/III trials or are waiting for initiation of phase III trials/filings of the same. As far as the updates on the **ODFs and TDS** are concerned; they too are progressing well in terms of filings and target launch date. The **biosimilars** pipeline is well on track with immense opportunities (the Management anticipates SBPL to attain a market share of ~7% over the next 3 years) to unfold for the company in the near term. Each business segment depicts strong capabilities going forward. The near-term focus for the company would be a blend of offerings across small molecules (CDMO projects), large molecules (biologics), therapeutic peptides and polymers.

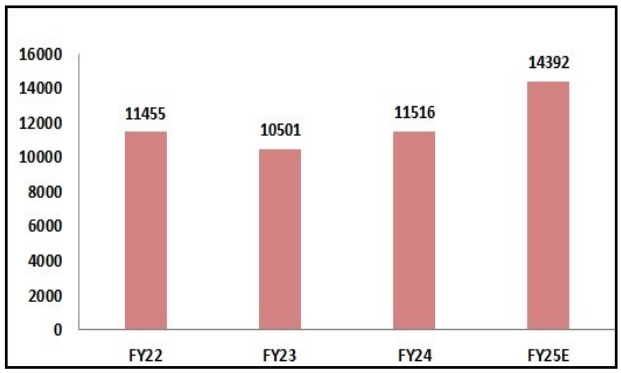
Exhibit 20: Strategic Plan



Source: SML AR2024, Progressive Research

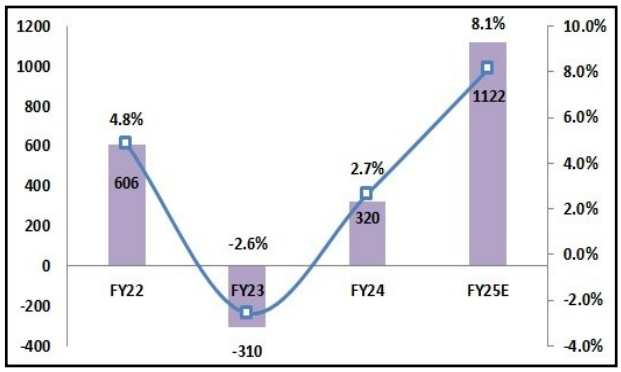
Financials: The **API business** continues to be the cash cow for SML; contributing maximum to the overall revenue pie. Within the API segment, **oncology** is the core focus. Additionally, the company is also focusing on development of complex APIs which have an early launch possibility or where there is a possibility to gain a decent market share. Strong product pipeline (peptides and polymers), q-o-q client additions for the CDMO business and new DMF filings would lead to an overall steady growth momentum in the near term. As far as **formulations business** is concerned, recently the Jadcherla facility (Unit IV) received a GMP clearance from the EU and AGES-Austria authorities enabling the supplies to these regions. In Q1FY25, SML has submitted the necessary replies, the subject experts/consultants appointment is completed and the review process has already commenced which is expected to be completed in Q3FY25. Thereafter the company will re-apply with the regulatory authorities for further course of action, approval of which would add to revenue visibility from this segment. Furthermore, various products under the formulations segment are either under different stages of clinical trials or waiting for a launch date. The **biosimilars business** is making significant progress with a pipeline of high value molecules in its late phase clinical trials. The sales have reported a CAGR of ~8.5% from FY21-24. Over the past financial years, the Ebitda margins have been in the range of ~18 -20%; however, huge remediation and increased raw material costs coupled with pricing pressures led to an overall impact on the Ebitda margins in FY23 which stood at ~9.7%. Better product mix, decent growth in the formulations business (regarded as a better margin business as compared to API) led to an overall improvement in the Ebitda margins that stood at ~21.2% in FY24 (in Q1FY25 the margins came in at ~25.1%). The Management anticipates the Ebitda margins to continue to be in more or less the same range going forward as well.

Exhibit 21: Revenue Trend (Rs in mn)



Source: Annual Reports, Progressive Research

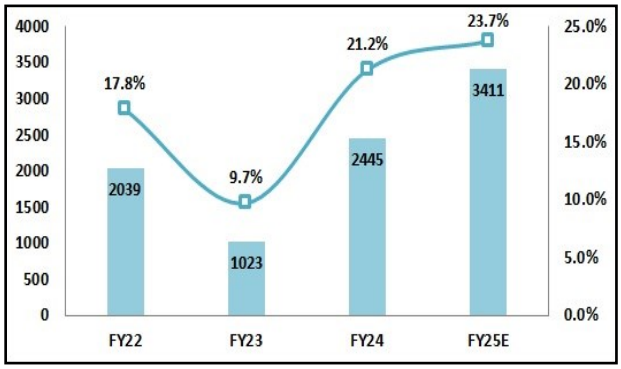
Exhibit 22: PAT (Rs in mn) v/s PAT Margins



Source: Annual Reports, Progressive Research

During FY24, the company incurred net capex of Rs1,720mn (accounting for ~15% of the overall sales). The capex for Q1FY25 stood at Rs580mn. The Management has chalked a capex plan of ~Rs1.25bn for FY25 bifurcated as ~Rs500mn for the Albumin greenfield facility (Kadechur),~Rs500mn as maintenance capex and ~Rs250mn towards Tranexamic acid expansion. The company will continue to rely on monetizing the existing assets going forward as well. The net debt as on 30th June, 2024 stood at ~Rs5.1bn (Rs9.1bn in FY24); the Management has indicated of undertaking a systematic debt reduction plan and intends to de-leverage its balance sheet over the next 2-3 years. In one such move, in April 2024, the Board approved allotment of 1.09 crore equity shares (FV of Rs1 each) to eligible institutional buyers in order to raise ~Rs5,000mn via the QIP route at an issue price of Rs455 per equity share (offering a discount of ~4.68% to the floor price of Rs477.33 per equity share). The company had earmarked ~Rs3bn of the QIP which the Management intends to utilise for repayment of NCDs (the long term debt). As of 12th August 2024, SML redeemed NCDs worth Rs1bn of SBPL and Rs500mn of Shilpa Pharma Lifesciences (Series I of 5,000 senior, secured, rated, unlisted NCDs) and Rs1.5bn of Series II 15,000 senior, secured, rated, unlisted NCDs. As a result of this, the company reduced the debt on a consolidated level by ~Rs3bn. The further planned repayments will reduce the finance cost and boost the overall profitability over the coming years. On the ratios, the ROCE has improved, owing to the sharp margin improvement, while the ROE ratio remained healthy due to profitability turnaround.

Exhibit 23: Ebitda (Rs in mn) v/s Ebitda Margins



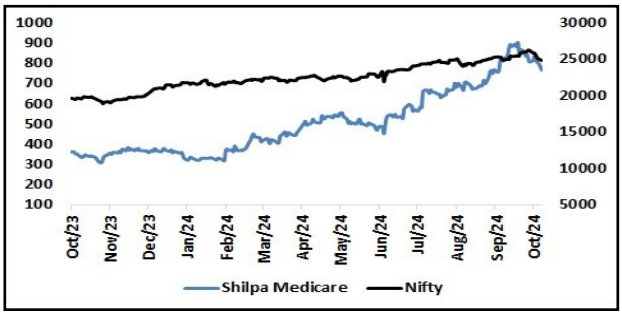
Source: Annual Reports, Progressive Research

08 October, 2024	PICK OF THE MONTH	VOL-10, NO-11
Industry: Pharmaceuticals	Shilpa Medicare Limited	BUY
CMP: Rs.757	TARGET PRICE: Rs.1000	TIME : 12 months

Risks and Concerns: SML operates in a **highly regulated industry** which is under constant scrutiny of periodic inspections from various local, state, federal and national regulatory authorities. Any form of non-compliance can hamper the development, testing as well as approvals of both existing and new drugs from such facilities; thereby affecting the business operations and overall profitability. **API business** contributes the maximum share to the overall revenues; exposing the operations to **segmental business** risk. Increased competition, pricing pressure, fluctuations in the demand-supply of products can affect the company's growth. In order to **mitigate** the same, the company is focusing on other two businesses (formulations and biosimilars business) where various products are progressing well in terms of internal targets set for each of them. The market in which SML operates is quite diverse and fragmented. ~50% of the revenues are accounted from the **international** markets (USA, Europe, RoW), this poses a threat/raises concerns related to **currency fluctuations**, as well as abiding by the legal and regulatory environments in each country where SML provides its services. Failure to introduce **new products/services** in these markets can disrupt the operations. The company operates in a **capital-intensive** business that requires R&D investments and upgradation of manufacturing facilities which would need constant monitoring on borrowed funds, ability to meet the working capital requirements or the need to raise additional funds. Industry analysis and periodic scanning of the pharma sector trends will enable the company to mitigate the above mentioned risks.

Outlook and Recommendations: SML is one of the largest specialty generic pharmaceutical company and has established its presence in APIs and formulations serving both the domestic and the international markets. The company provides high quality and affordable medicines backed by the trusts built by healthcare professionals and patients across countries. The company's manufacturing capabilities encompasses various dosage forms that range from oral solids & injectables, ODFs and TDS. The facilities are well accredited by various regulatory authorities such as Russian MOH, KFDA, ANVISA, PMDA, etc. Apart from this, the company has to its credit the ISO and DSIR certifications as well. SML has recorded strong revenue growth over the past quarters despite the headwinds that the API industry faced. In terms of business operations, **API continues** to be the main **revenue contributor**. Within the API business, SML focuses on **oncology** while at the same time the company is also developing proficiencies to build a portfolio in the **non-oncology** therapeutic segment. Oncology continues to remain the major therapeutic and high growth business segment for SML given the rising cancer cases and patent expirations. Manufacturing of oncology products requires high level of containment and SML retains its focus on **reduce, recycle & reuse** of the wastes generated. SML is also a signatory to SBTI (Science based Targets Initiative) and intends to become **Net Zero** by 2040. Over the years, the company has broadened its market presence and DMF filings across various geographies. In addition to the niche API business, SML is leveraging its expertise in diverse areas of polymers, peptides, CDMO (where addition of clients in each of these areas is a quarterly process). The Management expects the mix of CDMO + peptides + polymers to contribute in a decent manner to the overall topline as well as bottom-line over the next 2-3 years (with ~Rs1bn collective revenue potential). Under the **formulations** division, for the Jadcherla facility (Unit IV), the completion of the review process (expected in Q3FY25) and re-submission to the regulatory authorities for further course of action will pave the way for the US formulations business growth in the long run. The company is also re-designing its sales mix apart from the US markets and **enhancing** its presence in the EU and RoW markets. More **value-added** offerings in the form of TDS, ODFs and biosimilars are considered as **growing business** for SML. Transdermal patches are gaining wide acceptance amongst physicians and patients and SML has products under development for the same. The **biosimilar programs** related to Adalimumab, Aflibercept, rHA are on track with three more under development stage. The latest binding purchase agreement for OLC with Unicycive is also expected to start contributing in a positive manner to the overall US formulations business. On the financials, the Management has indicated of de-leveraging its balance sheet over the next 2-3 years. The capex plans are in place for FY25 to be deployed for the Albumin greenfield facility as well as towards Tranexamic acid expansion. SML is expected to improve its margins through cost optimization, better efficiencies and rationalizing the R&D investments. The company continues to focus on managing cash flows, maximizing revenues and the overall bottom-line. Backed by the progress and projects under each of the business segment, we believe the company is decently placed. We thus initiate a Buy on the stock for a target price of Rs1000 over a 12 months' horizon.

Exhibit 24: Price v/s Nifty



Source: Ace Equity, Progressive Research

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