Shilpa Medicare Limited

RECOMMENDATION SNAPSHOT				
*CMP	MCap (Rsbn)	Recommendation	Target	Potential Upside
Rs335	65.4	Accumulate	Rs500	49%

**as on 09th Feb, 2026*

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. Mr. Vishnukant Bhutada is the Managing Director of the company.

Results: Quick Glance:

- The net sales for the quarter reported growth of 28.3% to Rs4,097mn as compared to Rs3,193mn in Q3FY25
- The Ebitda margins for the quarter under review stood at 27.9% as compared to 25.2% in the comparative quarter last year
- The company reported profit of Rs446mn as compared to Rs318mn in the same quarter last year
- The EPS for the quarter stood at Rs2.36 as compared to Rs1.63 in the corresponding period of last year
- For 9MFY26, the revenues came in at Rs11,012mn as compared to Rs9,556mn; growth of 15.2% while the PAT stood at Rs1,355mn as against Rs638mn. The EPS came in at Rs10.56 as against Rs3.28 in 9MFY25

Conference Call Highlights:

- **(a) APIs:** The overall API revenues in Q3FY26 came in at Rs2,430mn (inclusive of captive sales) as against Rs2,180mn in Q3FY25; growth of ~11.4% on a y-o-y basis. Within the API segment, the **oncology** revenues for the quarter under reference stood at Rs1,110mn, **CDMO** at Rs310mn, **non-oncology** at Rs970mn and **others** at Rs40mn

Key developments across each of the API sub-verticals:

(i) Oncology: the company has added 10 new products for the quarter under review. In addition to this, there are other new products which are under validation stages and the Management expects this business to continue to do well going forward as well. For **Nilotinib**, the company doesn't foresee any competition as on date; SML has partnered with one generic company based out of Europe and has a decent market share as well. SML has validated 2 new commercial products and 1 complex, multi-step intermediate during Q3FY26. It has also scaled up and validated 3 new products, advancing multiple candidates from lab to pre-commercial stage; the validation batches are expected to start in Q4FY26; while de-bottlenecking activities are being undertaken in various blocks

(ii) **Non-oncology:** SML commissioned the expanded capacities of high-demand products such as UDCA, tranexamic acid, and other key onco molecules. For NorUDCA, (the 1st NCE molecule) the launch has exceeded the internal expectations and the company has received good responses from the physicians as well; for the same the company already has a good order book in hand for Q4FY26 with a significant potential for next FY as well

(iii) **Peptides and Polymers:** for **Semaglutide** (peptide), the company is working on developing both the injectable and oral form for formulations where the validation batches are ongoing and the registration batches are anticipated in H1FY27 to be filed at global level as well. SML is even working on API development (synthetic as well as semi-synthetic API). The plant scale-up and validation batches have been initiated and is expected to be completed in Q4FY26/Q1FY27. For **Liraglutide,** the company has already completed the API manufacturing and has filed for US DMF; the validation batches are ongoing. It also has a new peptide candidate that has advanced to plant scale up with initiation of PV batches, and formally added to development pipeline. For the new peptide project; the company has supplied the initial quantities to an MNC. **Polymers:** the company has successfully completed proof-of-concept for an **ophthalmic** polymer in collaboration with a global customer. A key polymer has also been delivered to a leading pharma company for advanced, targeted drug delivery systems

(v) **CDMO:** SML has added 3 new programs during the quarter under review. As on date, it has 25+ ongoing programs that are under different phases of development for the clients under the CDMO business segments. Amongst the existing NCE programs, for the 1st (US customer) the same is comercialised by the partner while for the 2nd NCE, the phase 3 trials are ongoing at present for the US partner. For 1 program it has received USFDA approval and commercialization is expected in Q4FY26. 1 program is expected to commercialize in FY27E; the resubmission of NDA has been done and accepted by the USFDA

Conference Call Highlights (contd.):

(v) **CDMO (contd.):** The partner has achieved phase-2 clearance for new indication with fast-track status and also received Orphan Drug Designation (ODD) by the USFDA. For the project of **Unicycive Therapeutics Inc;** {for Oxylanthanum Carbonate (OLC)}, the dedicated block is expected to be commercialised in FY27E. The PDUFA date is scheduled for 29th Jun'26

- The total API DMF filings as on 31st Dec'25 stood at 273 with major regulatory authorities; 9 new DMFs filed across the markets in 9MFY26
- **(b) Formulations:** The overall formulations revenues in Q3FY26 came in at Rs1,770mn as against Rs1,180mn in Q3FY25. Within the formulations segment, **Europe** revenues for the quarter under reference stood at Rs730mn, **license fees** at Rs300mn, **RoW** at Rs240mn, **US** at Rs280mn and **domestic** markets at Rs210mn

Key developments across formulations business:

(i) **SMLNUD07 (NorUDCA), non-oncology:** indicated to treat non-alcoholic fatty liver disease (NAFLD), the company has successfully launched the same in India under the proprietary brand, **NODUCA** (own label and 3 via partnership tie-ups)**,** secured rapid market access through partnerships with 3 leading domestic pharma companies (the company has a strong order book for Q4FY26 from all these 3 partners which is inclusive of captive sales as well). The efforts to advance the vital therapy to patients at the international level is under progress. Phase-4 studies for the Indian market have been initiated. The Management intends to scale the brand to both the EU as well as the US markets; the human studies for the EU market are expected to commence in FY27E. Additionally, the company is also working on developing the same product for different indications as well

(ii) **ODF & TDS: ODFs:** for **Tadalafil** (**SMLODF010,** to treat erectile dysfunction), it is already approved in the EU markets for multiple strengths. The USFDA has also approved the suitability petition for Tadalafil ODF, authorizing the submission of an ANDA for this innovative oral strip dosage form. **TDS: Rotigotine (SMLTDP08, TDS)** (indicated to treat parkinson disease): here the company has received final marketing authorization from EMA and is gearing up for H1FY27 launch. The US bioequivalence studies are concluded and the company is preparing for the marketing application submission scheduled in Q4FY26

(iii) **Topical lotion-SMLTOP09:** (indicated to androgenic alopecia); received phase 3 approval from India's drug regulator (DCGI) and successfully initiated the pivotal clinical trial in January 2026, with study completion targeted by FY27E. The EU regulators have validated the clinical development approach through scientific advice

(iv) **SMLINJ011, Ondansetron ER:** this is an injection to prevent nausea associated with initial and repeat courses of emetogenic cancer chemotherapy, radiotherapy and other associated medication. The global market size stands at ~USD375mn (as per IQVIA MAT Dec'25 data). As per the Management, positive response for phase-3 results have been received for the Indian markets with the launch planned in early 2026. Additionally, the company has received approval to initiate phase-3 study for new indication; Radiation-Induced Nausea and Vomiting (RINV). The global clinical development has been initiated for approval and launch the same in the US, EU and RoW markets

(v) **SMLTDP012:** an innovative delivery platform offering enhanced compliance and steady plasma levels for Alzheimer's patient. This is once a weekly transdermal patch delivery system. The preliminary clinical trials have been initiated with full development expected to be completed by end of FY26E

(vi) **SMLOSD014:** a unique patient friendly formulation enabling early market access in underserved anticoagulation segments. The company is targeting a ~USD10bn+ US branded market; the exhibit batches have been completed and BE studies are planned. The registration batches are already completed and the clinical trials are expected to start in Q1FY27 and the filing in the US markets are expected to happen in H2FY27

(vii) **Nilotinib, oncology** (treat chronic myeloid leukemia): the partner continues to gain market share (growing on a quarterly basis; the innovator still controls 40% of the market in the EU) for Nilotinib (launched in the EU market in FY25) and the Management doesn't anticipate any generic competition even for the next couple of quarters. For the profit share component, SML gets updates from its partner on a quarterly basis. The traction in terms of volumes as well as sales has been good so far on a q-o-q basis

- It has already commercialised 3 complex/505(b)(2) projects and there are 5 more complex/505(b)(2) projects which are under various stages of development
- **Recent Updates:** (i) Shilpa Biologicals Pvt. Ltd, a part of the Shilpa Medicare Group together with mAbTree Biologics AG has been granted the Orphan Drug Designation (ODD) by the USFDA for its biologic product being developed for the treatment of Essential Thrombocythemia (ET) and Polycythemia Vera (PV) indicated for treatment of rare blood cancer, (ii) Koanna Healthcare Canada Inc., (WoS of Shilpa Medicare) has allotted 28,421,020 equity shares for a total consideration of CAD2000 pursuant to share sale-purchase agreement. Consequent to the investment already done, Koanna Healthcare Canada Inc. ceases to be a WoS of Shilpa Medicare

Conference Call Highlights (contd.):

- **Recent Updates (contd.):** (iii) Shilpa Pharma Lifesciences Ltd (a material subsidiary) and FTF Pharma Pvt. Ltd (WoS) has received an ex parte ad-interim injunction order from the High Court of Delhi restraining the company from manufacturing, stockpiling, exporting, offering for sale and/or supplying, directly or indirectly, the pharmaceutical drug product containing the compound Ruxolitinib and/or Ruxolitinib salts API along with any other form or compound or formulation which would amount to patent infringement and (iv) The company's Unit IV Jadcherla, Telangana was inspected by the USFDA and towards the end of the inspection issued Form 483 with 8 inspectional observations
- The total regulatory filings under the formulations business as on 31st Dec'25 stood at 813 filings categorised as: (**US ANDA and NDA:** 30 ANDA, out of which 17 are approved and 13 pending for approval), **EU** (67 filings of which 61 are approved), **RoW** (705 filings of which 333 are approved) and **Canada** (11 filings of which 7 are approved). Additionally, 30 new approvals were received in 9MFY26
- For Jadcherla unit (import alert), SML has already submitted its CAPA (corrective and preventive action) response to the USFDA and is waiting for a revert from their end
- **(c) Biologics:** this business contributed ~12% of the overall sales in Q3FY26 with revenues at Rs480mn

Key developments across biosimilars business:

(i) **Adalimumab injection** (treat rheumatoid arthritis): delivered ~25% growth in India and advancing global rollout, with filings in ~20 RoW markets. The EMA scientific advice is targeted in Q4FY26. The global market size as per IQVIA, MAT Dec'25 stood at USD27bn

(ii) **Aflibercept** (treat neovascular age related macular degeneration): The global market size as per IQVIA, MAT Dec'25 stood at USD6bn. The target to launch in the Indian market is set at FY27E (the phase 3 trials are as planned and submission is expected in H1FY27); the company has out-licensed to two partners in India and Russia, with active discussions in MENA region

(iii) **Recombinant Human Albumin (rHA)** (indicated to treat liver cirrhosis): the phase 3 trials for the Indian markets are expected to take place in Q4FY26 (the India market studies are expected to be completed by end of FY27E/Q1FY28). The EU phase 3 trials are expected to be initiated in Q4FY26, while for the US markets, the pre-IND is expected to be filed in Q4FY26. For the excipient grade (non-therapeutic), the samples are already shared with few clients in the US markets

(iv) **Additional products: Nivolumab** (indicated to treat lung/renal cancer), the global market size as per IQVIA MAT Dec'25 is ~USD12bn and **Pembrolizumab** (indicated to treat soft tissue and blood cancer), the global market size as per IQVIA MAT Dec'25 is ~USD35bn. **Daratumumab** (cancer drug) (global market size as per IQVIA MAT Dec'25 is ~USD15bn) and **Dupilumab** (prevents wheezing, shortness of breath) (global market size as per IQVIA MAT Dec'25 is ~USD25bn)

(v) **CDMO:** the company has 5 active Novel Biologic Entity (NBE) programs advancing for multiple partners and the company is witnessing an increase in the number of RFQs from various global biotech players

- **Other updates:** The key asset with **mAbTree** is underway and clinical trials are expected in late FY27E; the product (for rare blood cancer) has received Orphan Drug Designation (ODD) status from the USFDA. With regard to **Alveolus Bio** for the novel Live Biotherapeutic Product (LBP) development & manufacturing contract; the company has initiated the development activities for the same. Alveolus and mAbTree NBE projects are expected to enter phase 1 studies in FY27E. Shilpa's first ADC biosimilar is expected to enter human studies in FY27E. The process development for the second ADC has been initiated as well while the GMP facility for ADC is targeted in Q4FY26. The company has also received test license for initiation of manufacturing & testing from Indian agencies, placing the company amongst few companies in India with end-to-end, GMP-grade ADC manufacturing and testing capabilities
- **Financials:** (i) the gross margins for Q3FY26 has seen an improvement and came in at ~67.4% as against 71.5% in Q3FY25. For 9MFY26, the gross margins stood at 71.8%, (ii) the interest/finance cost outgo has seen a reduction on a y-o-y basis (as well as on a q-o-q basis); the outgo has achieved its stability and the Management expects the current quarterly run-rate to be the new base from here on, (iii) the net debt as of Dec'25 stood at Rs6250mn. The capex spends in Q3FY26 came in at Rs870mn, (iv) the ROCE stands at ~17.1% in 9MFY26 and the Management expects this to improve even further

Financials:

Performance (Q3FY26)									
Q3FY26 Result (Rs mn)	**Dec-25**	**Dec-24**	**y-o-y**	**Sept-25**	**q-o-q**	**9MFY26**	**9MFY25**	**y-o-y**	**FY26E**
Total Revenue	4097	3193	28.3%	3700	10.7%	11012	9556	15.2%	15474
EBITDA	1143	806	41.7%	1083	5.6%	3142	2402	30.8%	4255
Other Income	8	12	(31.0%)	18	(53.6%)	89	157	(43.0%)	175
Interest	107	117	(9.1%)	157	(31.8%)	451	610	(26.1%)	562
Depreciation	304	288	5.4%	298	1.8%	891	842	5.8%	1180
Exceptional Items	129	0	-	0	-	129	0	-	129
Tax	163	98	65.6%	204	(20.1%)	393	433	(9.1%)	731
Share of asso./JV	(4)	3	-	(1)	-	(12)	(36)	-	(12)
Net Profit	**446**	**318**	**40.3%**	**441**	**1.2%**	**1355**	**638**	**-**	**1816**

Outlook and Recommendations:

Maintaining its growth consistency over quarters, the company has reported the highest ever quarterly revenues reporting growth of ~28.3% y-o-y. For 9MFY26 as well the overall sales reported a growth of ~15.2% on a y-oy basis. Ebitda also reached quarterly high of Rs1143mn, up by 40% y-o-y. The Ebitda margins expanded to 27.9% for the quarter translating into PAT growth of 40.3% y-o-y; clearly depicting substantial acceleration in growth. Excluding the exceptional item amounting to Rs128mn pertaining to labour code changes; the adjusted PAT reported a growth of ~80.7% on a y-o-y basis. Growth is largely attributed to formulations business (grew by ~50%) particularly in the EU markets (reported growth of more than 100%) and ~1.62x growth from the biologics business on a y-o-y basis. The **API** sales (inclusive of captive sales) reported a growth of 11.4% in Q3FY26; the captive business grew consistently supported by robust demand environment. Ex-captive, the API revenues stood at Rs1,860mn for the quarter under review. Under the sub-verticals of the API business, both the onco as well as non-onco portfolio contributed to a growth of ~7.7% and ~31.0% respectively on a y-o-y basis. The Management has indicated that the non-onco portfolio continues to have additional headroom on the capacities and anticipates an increase in the non-onco sales in the upcoming quarter as well as for the next FY. On the oncology front, the company has added 10 new products for the quarter under review. In addition to this, there are other new products as well which are under validation stages and the Management expects this business to continue to do well going forward as well. The Management anticipates a strong pipeline from the oncology vertical for the next 1 year with anticipation of filings also be undertaken. The CDMO division continues to report steady performance with revenues earned at Rs310mn in Q3FY26. During the quarter under review, the company has added 3 new programs for this division and as on date has 25+ ongoing programs that are under different phases of development for the clients. From a long-term perspective, the company has been continuously developing multiple complex APIs and specialty products. Within the **formulations** business, sales from the EU region stood at Rs730mn in Q3FY26; reflecting a growth of ~109% on a y-o-y basis and ~83% on a q-o-q basis. Ex-licensing income, the overall formulations business reported a growth of ~1.03x when compared on a y-o-y basis.

The **EU business** is purely tender driven and the overall surge in this geography is attributed to product revenues with no major one-offs reported during the quarter. This growth was on account of sustained demand and market share gains for Nilotinib alongside volume growth in base business. The company continues to witness q-o-q improvement/traction both on the volumes as well as sales front for Nilotinib and the Management doesn't anticipate any generic competition for this drug for the next couple of quarters. Furthermore, atleast 2 new launches in the EU market for the next FY are anticipated. The **RoW** market revenues remained flat on a sequential basis at Rs240mn which was on account of certain tenders which were undertaken in the previous quarters; thus, this market is bound to see variations when compared sequentially; however there has been an improvement of ~41% on a y-o-y basis. The **domestic formulations** sales stood at Rs210mn in Q3FY26; the overall momentum was backed by the successful launch of NorUDCA in the domestic market (under its own label: NODUCA); the novel NALFD therapy. The company already has a strong order book for Q4FY26 from all the 3 partners (leading domestic pharma companies). Additionally, the Management intends to scale the brand to both the EU as well as the US markets; the human studies for the EU market are expected to commence in FY27E and the company is also working on developing the same product for different indications as well. Going forward, the Management expects atleast Rs1,600mn as the new base for the formulations business over the next couple of quarters.

Outlook and Recommendations (contd.):

On the **biologics** business, the overall revenue contribution stands increased to ~12% in Q3FY26 with revenues at Rs480mn. The company continues to witnesses strong traction with steady progress in key pipeline assets. 2 biosimilar products are expected to enter the human studies in FY27E. The Management envisions major contribution to come from the formulations and the biologics business for the next FY whereas the API is expected to report steady state growth. There are no major capex plans but for the growth capex over the medium to long-term. The Management expresses confidence in a significantly better FY27E with multiple product launches and pipeline advancements expected to fuel further growth and margin improvement. Some of the key triggers to be watched for achieving the ambitious targets include commercialization success of Noduca in India, performance of new launches in the EU, CDMO business and progress in the biologics pipeline, particularly rHA. We continue to remain positive on all the key developments under each of the business segments and maintain an accumulate on the stock for a target price of Rs500 from a long-term perspective.

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