Shilpa Medicare Limited

RECOMMENDATION SNAPSHOT				
*CMP	MCap (Rsbn)	Recommendation	Target	Potential Upside
Rs367	71.7	Accumulate	Rs500	36%

**as on 18th Nov, 2025*

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 7.6% to Rs3700mn as compared to Rs3438mn in Q2FY25
- The Ebitda margins for the quarter under review stood at 29.3% as compared to 25.0% in the comparative quarter last year
- The company reported profit of Rs441mn as compared to Rs179mn in the same quarter last year
- The EPS for the quarter stood at Rs2.25 as compared to Rs0.92 in the corresponding period of last year
- For H1FY26, the revenues came in at Rs6914mn as compared to Rs6363mn; growth of 8.7% while the PAT stood at Rs910mn as against Rs320mn. The EPS came in at Rs4.65 as against Rs1.65 in H1FY25

Conference Call Highlights:

Business Segments:

- **(a) APIs:** The overall API revenues in Q2FY26 came in at Rs2560mn (inclusive of captive sales) as against Rs2250mn in Q2FY25; growth of ~14% on a y-o-y basis. Within the API segment, the **oncology** revenues for the quarter under reference stood at Rs1410mn, **CDMO** at Rs70mn, **non-oncology** at Rs900mn and **others** (inclusive of peptides+polymers) at Rs180mn

Key developments across each of the API sub-verticals:

(i) Oncology: for the 2 main NCE molecules (for a big pharma client in the US markets), for the 1st NCE program Shilpa has already received an approval and the commercial supplies are expected in Q4FY26. For the 2nd NCE program, the partner is undertaking phase 3 clinical trials and the filing is expected in FY27E. For Nilotinib, the APIs for the same are supplied by the company and the Management has indicated of witnessing an increase in the quarterly volumes alongwith the market share enhancement. The company has also indicated of completion of validation for 2 new products and initiated validation for 1 new project while de-bottlenecking activities are being undertaken in various blocks. **Methotrexate** (an import substitute molecule), the PV batches have commenced in Q2FY26

(ii) **Non-oncology:** for **tranexamic acid**, the volumes are witnessing a surge on a quarterly basis and the Management expects the full capacity to be achieved in the current year. In addition to this, there are plans for an additional ~100MT for which the capex has already been started and the Management anticipates this to be commissioned in FY27E. For **UDCA** (indicated to treat cholestatic liver disease), the company has already received a CEP approval for this and the commercial supplies are anticipated in Q3FY26 in the exports market. For NorUDCA, the API has been developed already for captive formulations; commercial supplies are expected to commence from Q3FY26; with significant contribution expected in FY27E

(iii) **Peptides and Polymers:** for **Semaglutide** (peptide), all the development studies are completed and the planned PV batches too have been initiated; the validation is expected to be completed in H2FY26 with filing expected in H1FY27. The Management has indicated that they don't anticipate a market share of ~30-50% for this peptide but if the company is able to fetch atleast some portion then the same is considered as a good potential for the company. Shilpa has already partnered for this product in the Indian as well as the RoW markets. The company is investing in a new peptide facility with commissioning anticipated in FY27E. For GLP 1-**Liraglutide,** the DMF is already ready. **Polymers:** the commercial supplies continue for the large polymer project worth ~USD4mn received from a MNC for non-pharma applications (the US customer) and the company is witnessing a quarterly volume increase in the same. Additionally, the company has successfully completed proof-of-concept for an ophthalmic polymer in collaboration with a global customer and has also delivered key polymer to a leading pharma company for advanced, targeted drug delivery systems

Conference Call Highlights (contd.):

Key developments across each of the API sub-verticals (contd.):

(v) **CDMO:** at present the company has more than 25+ active CDMO programs which are in different phases of development with the clients and the company is witnessing a good traction in these programs. The Management has indicated that 1 program has received USFDA approval and expected to commercialize in FY26E. 1 program expected to commercialize in FY27E for which the NDA has been filed. During the quarter, the company added 3 new customers, including a big pharma. For the ongoing NDA program (where SML serve as a CDMO partner); the partner has obtained phase 2 clearance for new indication with fast-track status. For the project of **Unicycive Therapeutics, Inc.** {for Oxylanthanum Carbonate (OLC)}, the dedicated block for OLC is expected to be commercialized in Q3FY26 with a commercial launch anticipated in FY27E; the sales are expected to be factored in from H2FY27

- **Inspection Updates:** For unit 1, ANVISA (Brazil) inspection has been successfully completed and with regard to COFEPRIS (Mexico) regulatory audits, the GMP certificate has been received. 23 new DMFs have been filed across markets in H1FY26
- The total API DMF filings as on 30th Sept'25 stood at 269 with major regulatory authorities
- **(b) Formulations:** The overall formulations revenues in Q2FY26 came in at Rs1390mn as against Rs1200mn in Q2FY25. Within the formulations segment, **Europe** revenues for the quarter under reference stood at Rs400mn, **license fees** at Rs460mn, **RoW** at Rs240mn, **US** at Rs200mn and **domestic** markets at Rs90mn

Key developments across formulations business:

(i) **SMLNUD07 (NorUDCA), non-oncology:** indicated to treat non-alcoholic fatty liver disease (NAFLD), the company anticipates to launch the tablets in the Indian markets in Q3FY26 while at the same time is advancing for the global regulatory efforts to bring vital therapy to patients internationally. The company has already engaged in strategic partnership with 3 large companies for marketing in India

(ii) **ODF & TDS: ODFs:** for **Tadalafil** (**SMLODF010,** to treat erectile dysfunction), it is already approved in the EU markets for multiple strengths. **TDS: Rotigotine (SMLTDP08, TDS)** (indicated to treat parkinson disease): the US study has been completed and the company is preparing for the marketing application for submission. The European submission for the same was completed by the company's partner (in Q2FY25) with the launch expected in Q4FY26. The same product is expected to be filed in the US markets where the clinical studies are already completed and the submission target remains intact in Q3FY26. The company has 2 TDFs which are in advanced stages at present and are expected to be filed in FY27E. The company has received the initial authorization from European Medicine Agency (EMA), recommending the grant of the final marketing authorization for **Rivaroxaban** (blood thinner) 10/15/20mg Orodispersible Films (ODF); with commercialization expected in FY27E. The total Europe market for oral Rivaroxaban formulations is about USD2.5bn

(iii) **Topical lotion-SMLTOP09:** (indicated to androgenic alopecia), the status for this continues to remain the same wherein phase 2 studies has already been completed and submitted to the Indian regulatory body and phase 3 studies are expected to start tentatively in H1FY27. 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 Jun'25 data) and there are competitive products already in the market. As per the Management, the phase 3 studies for the Indian markets have been completed with positive results with filings expected in Q4FY26 and launch in FY27E. The global clinical development has been initiated for approval and launch 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 (and targets an early market access); the exhibit batches have been completed and BE studies are planned

(vii) **Pemetrexed injection, oncology** (indicated to treat non-small cell lung cancer): continues to gain market share in the US markets

(viii) **Nilotinib, oncology** (treat chronic myeloid leukemia): the partner continues to gain market share (growing on a quarterly basis) for Nilotinib (launched in the EU market in FY25) and the Management doesn't anticipate any generic competition even in Q3FY26

(ix) For **bortezomib** (cancer injection) RTU subcutaneous, the company is observing an increase in the market share which is also driving the US revenues

Conference Call Highlights (contd.):

- The company 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; and the Management expects atleast 1 to get commercialised
- **Recent Updates:** (i) The company's WoS Koanna International FZ LLC, UAE has entered into a definitive agreement with Pharma Pharmaceutical Industries & Biological Products (PPI) to form a new JV to build a new pharma manufacturing facility in Saudi Arabia, (ii) Shilpa Medicare has entered into share purchase agreement and shareholder's agreement with Ash Ingredients Inc. & Varcatalyst LLP to sell 31% of its stake held in Sravathi Advance Process Technologies Pvt Ltd (Sravathi), at a consideration of Rs496mn, subject to customary closing conditions
- The total regulatory filings under the formulations business as on 30th Sept'25 stood at 779 filings categorised as: (**US ANDA and NDA:** 30 ANDA, out of which 17 are approved and 13 pending for approval), **EU** (83 filings of which 77 are approved), **RoW** (656 filings of which 315 are approved) and **Canda** (10 filings of which 7 are approved). Additionally, 36 new approvals were received in H1FY26
- For **Jadcherla** unit (import alert), the Management doesn't have any latest update from the USFDA after all the submission work that was already done by the company
- **(c) Biologics:** this business contributed ~7% of the overall sales in Q2FY26 with revenues at Rs250mn. **Key developments across biosimilars business:**

(i) **Adalimumab injection** (treat rheumatoid arthritis): the Indian market is witnessing growth; the 24-month shelf life has been approved (from the earlier 18). For the filings in 15 RoW markets, the same is under progress; with approvals expected in FY26E. The RoW approvals are expected in H2FY26 while EMA SA is targeted in Q4FY26

(ii) **Aflibercept** (treat neovascular age related macular degeneration): The global market size as per IQVIA, MAT Jun'25 stood at USD5bn. The phase 3 clinical trials were already initiated and the launch timeline (for the Indian markets) continues to remain intact in FY27E; while the timeline for phase 3 in the US and the EU markets is expected later in FY27E. The company has also out-licensed to 2 partners in India and Russia, with multiple discussions in the MENA region. Aflibercept is one of the better molecule for Shilpa as compared to Adalimumab injection for the Indian markets

(iii) **Recombinant Human Albumin (rHA)** (indicated to treat liver cirrhosis): the phase 3 trials for the Indian markets are expected to take place in FY26E; the guidance remains intact. The EU phase 3 trials are expected to be initiated in FY26E, while for the US markets, the pre-IND is expected to be filed in H2FY26. 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 Jun'25 is ~USD11bn and **Pembrolizumab** (indicated to treat soft tissue and blood cancer), the global market size as per IQVIA MAT Jun'25 is ~USD33bn. For **Nivolumab,** the company is targeting human clinical studies (phase1/3) in H2FY26 whereas for **Pembrolizumab,** PCT has been completed. **Daratumumab** (cancer drug) (global market size as per IQVIA MAT Jun'25 is ~USD13bn) and **Dupilumab** (prevents wheezing, shortness of breath) (global market size as per IQVIA MAT Jun'25 is ~USD21bn), the cell line development is in progress. **Trastuzumab** (treat breast cancer), (global market size as per IQVIA MAT Jun'25 is ~USD3bn), process development as well as scale up has been completed

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

- **Other updates:** (i) Shilpa Biologicals Pvt. Ltd (SBPL, WoS of Shilpa Medicare) had entered into a binding term sheet with mAbTree Biologics AG, Switzerland for development, manufacture, marketing and sale of a New Biological Entity (NBE) for immuno-oncological applications. The key asset with **mAbTree** is underway and clinical trials are expected in FY27E, (ii) Shilpa Pharma Inc. (WoS) had agreed to make a strategic investment of USD2mn in the form of SAFE (Simple Agreement for Future Equity) notes in **Alveolus Bio.** The Management expects Alveolus and mAbTree NBE projects to enter phase 1 studies in FY27E, (iii) Shilpa's first **ADC** biosimilar is expected to enter human studies in FY27E
- **Financials:** (i) the gross margins for Q2FY26 has seen an improvement and came in at ~71.5% as against 64.5% in Q2FY25. For H1FY26, the gross margins stood at 73.2%, (ii) the interest/finance cost outgo has seen a reduction on a y-o-y basis and the Management expects the current quarterly run-rate to stabilize from here on, (iii) the net debt as of Sept'25 stood at Rs5690mn. The capex spends in H1FY26 came in at Rs1530mn, this was largely directed towards the fermentation facility at Kadechur. The Management expects additional capex to be incurred for this facility and furthermore expects to incur additional growth related capex for the API business while maintenance related capex to be factored in for the FDF/formulations business segment. All the capex requirements will be catered via internal accruals; the capex guidance for FY26E stands at ~Rs750-1000mn and once these are fructified the guidance for FY27E will be evaluated by the Management, (iv) the ROCE stands at ~17% in H1FY26 and the Management expects this to improve even further

Financials:

Performance (Q2FY26)									
Q2FY26 Result (Rs mn)	**Sept-25**	**Sept-24**	**y-o-y**	**Jun-25**	**q-o-q**	**H1FY26**	**H1FY25**	**y-o-y**	**FY26E**
Total Revenue	3700	3438	7.6%	3215	15.1%	6914	6363	8.7%	15507
EBITDA	1083	860	25.9%	916	18.2%	1999	1595	25.3%	3908
Other Income	18	50	(64.9%)	64	(72.5%)	81	145	(44.0%)	243
Interest	157	256	(38.7%)	188	(16.6%)	344	493	(30.1%)	661
Depreciation	298	283	5.4%	289	3.1%	587	554	6.1%	1166
Tax	204	188	8.2%	27	-	231	334	(31.1%)	697
Share of asso./JV	(1)	(4)	-	(7)	-	(8)	(39)	-	(8)
Net Profit	**441**	**179**	**-**	**469**	**(6.0%)**	**910**	**320**	**-**	**1618**

Outlook and Recommendations:

The company continues to report a strong performance for the quarter as well as H1FY26. The quarter under review serves a robust one where SML has delivered its highest ever quarterly revenue and Ebitda in absolute terms. Even though the topline growth appears to be moderate at ~7.6% in Q2FY26, the Ebitda margins have seen an improvement when compared both on a y-o-y and q-o-q basis and stood at ~29.3% in Q2FY26. **API**, the main business strength of the company registered a growth of ~14% on a y-o-y basis in Q2FY26; this growth is inclusive of captive sales as well. Ex-CDMO, the overall API portfolio saw a growth of ~21% on a y-o-y basis. The sub-segments of onco and non-oncology within the API division too reflected a growth of ~67% and ~14% respectively on a y-o-y basis which was led by larger contribution from the base business products. The key developments across the API portfolio for onco, non-onco, CDMO and peptides+polymers are pacing well with the launch timelines alongwith capacity expansions (under the non-onco business). The Management has indicated that the commercialisation of the expanded capacities are further expected to result in improvements in the utilisation levels. The API business is expected to continue to contribute a 2x growth on a y-o-y basis; furthermore, the company is working on multiple complex API and specialty products which will enhance the overall API business vertical over the medium to long-term. The **FDF/formulations** business, registered a growth of ~16% on a y-o-y basis with revenues earned at Rs1390mn in Q2FY26. Excluding the licensing income, the base business has registered a robust growth of ~61% when compared on a y-o-y basis. The overall formulations business is witnessing good traction in terms of incremental market share enhancement for its products both in the EU as well as the US markets. As far as the recent launch of its own brand NODUCA in the Indian markets is concerned, the patient volumes and thus the TAM offers a huge potential for Shilpa and the Management expects to fetch atleast 10-20% market share in the same spread over the next 3-5 years' timeframe. The commercial supplies will be generated from either Q3/Q4FY26 and a meaningful contribution is estimated in FY27E. The licensing income is slightly on the lower side with revenues at Rs460mn for the quarter under review and this is primarily due to the nature of business wherein the income is based on the different stages of the product development; however, the company continues to have a decent pipeline and this will continue to be an important portion in terms of the overall business. The Jadcherla unit continues to await for a revert from the USFDA; all the requisite resubmission work has already been done by the company. The company expects to file more NDAs in the upcoming quarters which will further drive the revenues for the formulation business. The **biologics** division is gradually increasing its contribution to the overall revenues. As on date, the company has 8 biosimilar programs all of which are under various developmental stages in terms of seeking approval/data submission/launch timelines. Under the CDMO biologics, the company has 6 active clients. The recent partnership agreements are expected to see the commercial benefits over the long-term. Though the Management doesn't expect any significant capex; there are plans to incur for growth related capex pertaining to the API business and the fermentation facility. In addition to this, the company will also incur some portion towards the maintenance related capex directed towards the formulations division. From a long-term perspective, the growth levers will be factored in from all the business segments (FDF, API and biologics) alongwith client additions that keeps happening in the CDMO business which is an ongoing process for the company. We thus continue to remain positive on all the key developments under each of the business segments and maintain an accumulate on the stock for an adjusted target price (adjusted for bonus corporate action) of Rs500 from a long-term perspective.

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