SHILPA MEDICARE LIMITED

THIRTY-FIVE YEARS IN THE MAKING

1. COMPANY HISTORY & FOUNDATION

Origins (1987–2000)

Shilpa Medicare Limited was incorporated in 1987 in Raichur, Karnataka, a small industrial town. The company was founded by the Bhutada family and began as a modest API manufacturer focused on a narrow set of molecules. Raichur's location in northern Karnataka offered industrial land at low cost, access to the Karnataka Industrial Areas Development Board (KIADB) infrastructure, and proximity to the chemical corridors of Andhra Pradesh.

Through the 1990s, Shilpa built its first manufacturing blocks and began filing Drug Master Files (DMFs) for generic APIs, primarily in oncology. The company was listed on the Bombay Stock Exchange in June 1995 and on the NSE in December 2009. The foundational insight of the promoters was to specialise deeply in oncology API, a space that most mid-size Indian pharma companies avoided due to high containment requirements, complex chemistry, and regulatory difficulty. This early bet proved prescient.

Scale-Up Phase (2000–2015)

Between 2000 and 2015, Shilpa compounded API revenues at 15%+ annually, growing from a turnover of roughly Rs. 100 Cr to Rs. 650-700 Cr. Several structural decisions defined this period:

- *Investment in high-containment technology:*
  The company imported the Bipolar manufacturing system from Japan for handling highly potent APIs (HPAPIs), enabling it to manufacture oncology molecules that required OEL-4 containment — a capability very few Indian manufacturers had.

- *DMF filings:*
  Shilpa systematically filed DMFs in the US and Europe, building a portfolio of 45 US DMFs and 28 EU DMFs over time, covering 40+ oncology and 50+ total APIs.

- *Non-oncology launch:*
  In the early 2000s, Shilpa established a non-oncology API vertical to diversify from oncology concentration. This covered respiratory, CNS, urology and nutraceutical molecules, with a focus on differentiated chemistry and import substitution themes.

- *Customer diversification:*
  The company moved from being a domestic API supplier to a global supplier, building relationships with generic manufacturers in the US, Europe, Japan (PMDA), Canada and Australia. By FY15, exports accounted for 80%+ of revenues.

Diversification Into Formulations (2015–2020)

Around 2015, management made the strategic decision to move down the value chain into Finished Dosage Forms (FDF). The logic was sound: API revenues, while growing, were at the mercy of customer concentration and pricing pressure. Owning formulation capabilities and eventually filing ANDAs and NDAs independently would allow Shilpa to capture downstream margins and reduce dependence on a few large API customers.

Two new manufacturing facilities were built for formulations:
Unit 3 in Hyderabad (ophthalmic, injectable, derma) and Unit 4 in the Telangana SEZ at Jadcherla (oral solids, injectables, high-potency, USFDA-approved). The company also acquired the transdermal/ODF business, establishing Unit 6 in Dobbaspet (Bengaluru), which became one of the very few USFDA and EMA-approved transdermal patch manufacturing facilities in India.

Biologics Ambition (2018–2024)

The most capital-intensive and controversial chapter of Shilpa's history began around 2018 when promoters decided to build a biologics platform from scratch. This involved:

- Acquisition of Navya Biologicals and establishment of Shilpa Biologicals Pvt Ltd in Dharwad (Unit 5), a dedicated mammalian cell culture facility for biosimilars and biologics CDMO.
- Establishment of Shilpa Biocare Pvt Ltd (formerly Shilpa Albumin Pvt Ltd) at Kadechur in Yadgir district, a greenfield facility for recombinant human albumin (rHA) production.
- Building an in-house biosimilar pipeline starting with Adalimumab (anti-TNF), followed by Aflibercept (anti-VEGF), Nivolumab (PD-1), and an ADC programme.

This platform cost an estimated Rs. 900-1,200 Cr cumulatively in invested capital across FY18-FY24, contributed nothing to revenue until FY23-24, and was the primary cause of the company's distress in FY22-FY23. However, it is now beginning to generate real revenues and represents the single largest source of long-term upside in the story.

2. PROMOTER & MANAGEMENT

The Bhutada Family:

Shilpa Medicare is a classic Indian promoter-driven pharmaceutical company. The Bhutada family has controlled the company since its inception and continues to hold operational control across the group. The family's background is in pharmaceutical manufacturing and business management, not financial engineering, which is reflected in the company's long-term capital allocation philosophy of building capability first, monetising second.

Name	Role	Background	Experience
Vishnukant C. Bhutada	Managing Director, Shilpa Medicare Ltd	Pharmacy & administration; re-appointed for 5-year term from Oct 2024; max remuneration Rs. 15 Cr p.a.	36 years
Keshav Bhutada	ED & CEO, Shilpa Pharma Lifesciences Ltd (SPLL)	Next-generation leadership; presented maiden address to shareholders in FY25 AR; driving API CDMO and peptide/polymer strategy	—
Madhav Bhutada	MD, Shilpa Biocare Pvt Ltd	Leading the recombinant albumin platform and biologics subsidiary	—
Omprakash Inani	Non-Executive Chairman	Business and administration; 36 years experience; holds 28.67 lakh shares directly	36 years
Sharath Reddy Kalakota	Whole-time Director	API manufacturing, operations, greenfield/brownfield projects, quality	35 years
Alpesh M. Dalal	CFO	Financial management and reporting	—

Governance Observations

- Next-generation transition:
  The emergence of Keshav Bhutada (SPLL) and Madhav Bhutada (Shilpa Biocare) suggests a managed generational transition is underway. Both are operating subsidiaries which own the most capital-intensive and highest-optionality assets.

- Remuneration:
  MD remuneration is capped at Rs. 15 Cr p.a., which is reasonable for a company of this scale. First dividend of Rs. 1/share declared in FY25 signalling confidence in earnings sustainability.

- Inani family:
  Chairman Omprakash Inani holds 28.67 lakh shares directly (~0.3% of total). His role appears to be oversight and governance rather than operational.

3. BUSINESS MODEL & REVENUE ARCHITECTURE

The Core Model: Integrated Pharma Value Chain

Shilpa operates across the complete pharmaceutical value chain in a way that is unusual for a mid-cap Indian company. Most Indian pharma companies specialise at a singular level either API (Dr. Reddy's originally), formulations (Sun), or CDMO (Divi's). Shilpa has deliberately built capability at every level, accepting near-term capital inefficiency in exchange for long-term strategic optionality and margin capture.

The business has three distinct monetisation mechanisms running simultaneously:

- *Manufacturing revenue:*
  Selling APIs or finished formulations to pharma companies globally. This is the bread-and-butter recurring revenue stream. Predictable, volume-driven, margin expansion through scale.

- *IP monetisation/licensing:*
  Shilpa develops a dossier (ANDA/NDA/EU approval), then licenses it to a distribution partner who commercialises the product in a given geography. Shilpa earns upfront fees, milestone payments, and ongoing supply revenue. This is their highest-margin stream, capital-light once the development work is done. *Examples:* Pemetrexed RTU to Amneal in US, Rotigotine patch to partner in EU, rHA to Orion in Europe.

- *CDMO / contract development:*
  A third party (innovator or speciality pharma) engages Shilpa to develop or manufacture a molecule on their behalf. Revenue is milestone-based during development and supply-based post commercialisation. Examples: Unicycive/OLC, mAbTree NBE, multiple biologics CDMO programmes.

Revenue Mix

Category	FY25 (Rs Cr)	FY24 (Rs Cr)	YoY Change	% of FY25
API	674	730	-8%	52%
Formulations	285	187	+53%	22%
CDMO / Licence Fees	309	223	+39%	24%
Other Products	19	12	+54%	2%
Total	**1,286**	**1,152**	**+12%**	**100%**

Note: The API revenue decline in FY25 (-8% YoY) at the consolidated level is counterintuitive given the strong API momentum in quarterly results. This is partly explained by SPLL (Shilpa Pharma Lifesciences) being the standalone API entity: the API revenue in the standalone P&L was Rs. 477 Cr vs Rs. 310 Cr in FY24 (+54%). The consolidated figure includes inter-company eliminations and the timing of consolidation of SPLL results.

Geographic Revenue Split (FY25 FDF segment)

Geography	FY25	FY24	Comments
EU	Rs. 115 Cr	Rs. 83 Cr	Nilotinib launch drove +38% growth
US	Rs. 48 Cr	Rs. 26 Cr	Pemetrexed/Bortezomib RTU NDA ramp
RoW	Rs. 60 Cr	Rs. 15 Cr	300%+ growth — new market openings
India	Rs. 50 Cr	Rs. 57 Cr	Slight decline; Nor-UDCA launch in FY25
Licensing Income	Rs. 47 Cr	varies	Orion upfront, other IP deals

The Licensing Model

The licensing/IP monetisation model deserves special attention as it is the primary driver of Shilpa's gross margin expansion from 64.6% (FY24) to 73.5% (FY26E).

When Shilpa licenses a dossier, the revenue has near-zero incremental cost. The development cost was already incurred in prior years (often capitalised as intangible assets). So licensing income flows to EBITDA at ~90%+ margins, dramatically improving the blended margin profile.

Licensing income has varied: Rs. 140-150 Cr in FY24; Rs. 160+ Cr in FY25 (including Orion upfront for Albumin); continuing in FY26 with new deals. The sustainability of licensing income is the biggest question mark in the margin outlook as it requires continuous new product development to replenish the pipeline.

4. SEGMENT DEEP DIVE — API DIVISION

Overview & Scale

The API division is the foundation of Shilpa's business and the source of its most durable earnings. Shilpa has been manufacturing APIs since inception and today operates two USFDA/EUGMP-compliant API plants (Units 1 & 2) in Raichur, Karnataka. The standalone API entity is Shilpa Pharma Lifesciences Limited (SPLL), a wholly-owned subsidiary that also handles peptides and polymers. The API division contributed approximately 52% of FY25 consolidated revenues (Rs. 674 Cr) at a gross margin of ~65-70%.

Product Portfolio

Category	Key Products	DMFs Filed	Notes
Oncology API	Nilotinib, Axitinib, Imatinib, Palbociclib, Azacitidine, Decitabine, Cabozantinib, Carfilzomib, Lenalidomide, Pomalidomide	45 US, 28 EU	40+ onco molecules; high-containment OEL-4 facility
Non-Oncology API	Tranexamic Acid, UDCA, Nor-UDCA, Teriflunomide, Desmopressin, Octreotide	239 total DMFs	Focus on differentiated chemistry & import substitution
NCE / CDMO API	OLC (Unicycive), 2 undisclosed NCE programmes	Confidential	First NCE approval received; commercial supplies Q4FY26
Peptides	Semaglutide, Liraglutide, Desmopressin, Octreotide	CEPs filed	GLP-1 development complete; validation batches Q1FY27
Polymers	Specialty polymers for pharma & non-pharma	—	USD 4mn US MNC order; sole Indian supplier

Manufacturing Infrastructure

- Unit 1 (Raichur):
  Primary oncology API facility. USFDA and EU GMP approved. Received EIR (Establishment Inspection Report) post successful USFDA inspection in FY25 confirms a clean regulatory status. Bipolar system for HPAPI manufacturing.

- Unit 2 (Raichur):
  Non-oncology and additional capacity. USFDA audit completed with zero observations in FY25, a significant regulatory achievement.

- Unit 7 (Hyderabad, Nacharam):
  R&D facility. USFDA, EMA, CDSCO, DSIR and NABL accredited. GCP accreditation also held. Houses bio-analytical lab.

Key API Products: Commercial Dynamics

Nilotinib:
Shilpa developed Nilotinib API via a non-infringing route which is critical because Novartis holds patents on several Nilotinib synthesis routes. The non-infringing route has allowed Shilpa (and its formulation partner) to be the first generic Nilotinib in EU markets, a significant commercial advantage. Nilotinib is both an API revenue item (sold to generic formulators) and a formulation revenue item (Shilpa's own FDF partner launched EU generic).

UDCA & Nor-UDCA:
UDCA (Ursodeoxycholic acid) production has ramped to 10+ MT/month run rate. Nor-UDCA is the first NCE developed by Shilpa itself — a modified bile acid for NAFLD/NASH. India CDSCO approval received; Shilpa was the first company globally to receive approval for NorUDCA. EU human studies planned FY27.

Tranexamic Acid:
Capacity expansion completed in FY26. Growing QoQ. Process intensification has also reduced water consumption significantly (documented in BRSR).

Semaglutide/GLP-1:
Shilpa has filed a US DMF for Liraglutide and is developing Semaglutide. Validation batches planned Q1FY27. A dedicated large-scale automated peptide facility is under construction (commissioning H2FY27). This represents the most exciting near-term API growth opportunity given the explosion in GLP-1 demand globally.

API Capex History

API capex has been largely complete since FY22. The standalone capex (primarily API) was Rs. 57 Cr in FY25 and Rs. 55 Cr in FY24 which was essentially maintenance-plus. The gross block in Plant & Machinery at the standalone level is Rs. 3,021 Cr, with depreciation running at ~Rs. 49-50 Cr annually.

The API capacity build-out was done primarily in FY15-FY22, at a cumulative investment of approximately Rs. 700-800 Cr. This is why API margins are now structurally expanding as fixed costs are absorbed, and incremental revenue drops through at high marginal margins.

Incremental API capex going forward is targeted at:
(a) Peptide/GLP-1 facility — est. Rs. 80-120 Cr total
(b) OLC dedicated block — est. Rs. 30-50 Cr
(c) Capacity expansion for UDCA, Tranexamic Acid, Palbociclib — Rs. 30-40 Cr.

5. SEGMENT DEEP DIVE — FORMULATIONS (FDF)

Overview

The Formulations (FDF) segment is Shilpa's most complex and highest-potential near-term earnings driver. It operates across oral solids, injectables (liquid, lyophilised, dry powder), transdermal patches, oral disintegrating films (ODF), and novel injectables.

The segment is managed primarily through two facilities: Unit 4 (Jadcherla, Telangana SEZ) for oral solids and injectables; and Unit 6 (Dobbaspet, Bengaluru) for NDDS (TD patches and ODF). FDF contributed 22% of FY25 revenues (Rs. 285 Cr) but grew 53% YoY which was the fastest-growing segment in FY25.

Manufacturing Capacity

Facility	Location	Capacity	Regulatory Status
Unit 4 (Jadcherla)	Telangana SEZ	Injectables: 12.6mn liquid, 2.32mn lyophilised, 0.67mn dry powder vials/yr; OSD: 33.5mn tablets, 27mn capsules/yr	EUGMP, ANVISA, TGA, SAHPRA, ANAMT, GHC, MOH Russia, Health Canada; USFDA import alert (FY21) — under remediation/reinspection
Unit 6 (Dobbaspet)	Bengaluru, Karnataka	Novel delivery: 50mn ODFs, 30mn patches/yr	USFDA, EU GMP, WHO-GMP, UK MHRA, TGA Australia, SFDA Saudi Arabia — FULLY CLEAN regulatory status

Product Portfolio — Approved & Commercialised

Product	Modality	Market	Status	Partner
Nilotinib	Oral capsule	EU	Launched FY25 — first generic	Undisclosed EU partner
Pemetrexed RTU	Injectable NDA (505b2)	US	Launched; ramping	Amneal
Bortezomib RTU	Injectable NDA (505b2)	US	Launched FY25; scale-up FY26	Undisclosed
Nor-UDCA	Oral capsule	India	Launched FY25 — first globally	Own marketing
Rotigotine Patch	Transdermal	EU	EMA approved Q3FY26; launch Q1FY27	Undisclosed EU partner
Betahistine ODF	Oral film	UK	Approved; small commercial scale	—
Tadalafil ODF	Oral film	EU	EU approval received FY25	—
Imatinib Oral Film	ODF	India (JV)	Approved (via JV) — first oral fluid Imatinib	JV company

Pipeline — Near-Term Launches

- Rotigotine (US): ANDA filed February 2026 from Unit 6 (Dobbaspet). Likely first or early filer as there is no approved US generic currently. PDUFA date expected FY27-28. Potentially USD 112 mn market with limited competition.
- Ondansetron Long-Acting: India filing completed Q3FY26; commercialisation H1FY27.
- SMLTDP08 (Parkinson's transdermal patch): Under development.
- SMLTOP09 (Androgenic Alopecia): Human studies FY27.
- SMLINJ011 (Long-acting injectable): Late-stage programme.
- 4 more 505(b)(2) programmes in development. .

The Import Alert — History & Status

In FY21, Shilpa's Unit 4 (Jadcherla) received a USFDA import alert which effectively barred US sales of products manufactured at that facility. The import alert came at the worst possible moment just as Shilpa was ready to scale its injectable NDA programme in the US.

The company spent FY21-FY24 remediating the facility and submitted for reinspection. The EIR for Unit 4 transdermal facility was received in Q1FY26 (confirming clean status).

As of this report, new 483 observations were issued at the Jadcherla plant.

6. SEGMENT DEEP DIVE — BIOLOGICS & BIOSIMILARS

Platform Overview

Shilpa Biologicals Pvt Ltd (SBPL), a subsidiary based in Dharwad, Karnataka, offers clone-to-vial biologics manufacturing capabilities covering monoclonal antibodies (mAbs), biosimilars, ADCs, and recombinant proteins. The facility received EU GMP approval and Oman MoH GMP certification in FY25. The site also has GMP certification from multiple agencies, including COFEPRIS (Mexico), PMDA (Japan) and KFDA (South Korea).

Biosimilar Pipeline

Product	Target	Indication	Status	Opportunity
Adalimumab	Anti-TNF	Autoimmune (RA, psoriasis)	Launched India; supply to Sun Pharma; gaining market share	India biosimilar market growing; Humira biosimilar wave globally
Aflibercept	Anti-VEGF	Wet AMD, macular degeneration	Phase 3 India ongoing; launch FY26	USD 9 bn global market; Eylea biosimilars entering 2024-26
Nivolumab	PD-1	Oncology (multiple indications)	Phase 1/3 application filed India Q4FY26	USD 8 bn global market; complex immunotherapy biosimilar
SBPL01 (ADC)	Undisclose d	Oncology	Lab development complete; human studies FY27; dedicated GMP facility Q4FY26	ADC market growing at 30%+ CAGR

Biologics CDMO

SBPL has built a meaningful CDMO business alongside its proprietary biosimilar pipeline. As of Q3FY26, SBPL has more than 5 active CDMO programmes with 2 entering Phase 1 trials in FY27. The company added 2 new CDMO customers in FY25, bringing the total active CDMO programmes to 20+. In FY25, the biologics CDMO business grew 47% YoY and contributed ~8% of API segment revenue.

- *mAbTree Partnership:*
  In FY25, Shilpa signed a strategic partnership with Swiss company mAbTree Biologics to co-develop a novel checkpoint inhibitor (New Biological Entity, fully human mAb against a novel immune checkpoint protein). Shilpa Biologicals supports development through first-in-human trials and will serve as commercial manufacturer. This is Shilpa's first NBE, still years away from revenue but signals ambition in innovative biologics.

- *ADC Capabilities:*
  Shilpa is building bioconjugation capabilities, leveraging its existing HPAPI expertise for linker/payload. A dedicated GMP bioconjugation suite is being built (Q4FY26 commissioning). This represents a strategically important convergence of API and biologics capabilities.

Capital Invested in Biologics

The consolidated investment in SBPL through equity and loans from Shilpa Medicare (standalone) exceeded Rs. 717 Cr as of FY25 (reflected in the investment schedule: Rs. 717 crs in equity shares + deemed investment).

Shilpa Biocare (Albumin) had Rs. 370 crores invested. Combined, the biologics platform has absorbed over Rs. 1,000 Cr of capital. Against this, biologics revenue was Rs. ~76 Cr in FY25 at the consolidated level. Return on invested capital remains negative but trajectory is sharply improving as Q3FY26 biologicals revenue of Rs. 41 crs (annualised ~Rs. 164 Cr) represents a significant step-up.

7. SEGMENT DEEP DIVE — RECOMBINANT ALBUMIN (SHILPA BIOCARE)

The Opportunity

Human serum albumin is the most abundant protein in blood plasma and one of the most widely used excipients and therapeutics in global medicine. Applications include: stabiliser in vaccines and biologics formulations (excipient grade), treatment of hypovolemia and hypoalbuminemia (therapeutic grade), and a critical component in cell/gene therapy manufacturing media. The global albumin market is estimated at USD 8-10 billion and faces perennial supply shortages, with predominant supplies by plasma fractionation companies in China and Germany.

Shilpa's Technology

Shilpa Biocare has developed a proprietary recombinant human albumin (rHA) production process using yeast fermentation technology, protected by patents filed in the US, Europe, and multiple other jurisdictions. The company claims 99.9% purity, superior to plasma-derived albumin, which requires extensive purification from human blood plasma.

Key advantages of rHA over plasma-derived albumin:

- No blood-borne pathogen risk (no human plasma used)
- Consistent supply: not dependent on blood donation volumes
- Higher purity (99.9% vs typically 97-98% for plasma-derived)
- Scalable: yeast fermentation vs plasma fractionation
- Potentially lower cost at scale: Shilpa claims patented cost-effective purification

Development Status & Partnerships

Milestone	Status	Timeline
India Phase 1 studies (therapeutic)	Completed March 2024	Done
Excipient grade DMF filing	Filed	Done
Orion (EU) exclusive distribution partnership	Signed FY25; upfront payment booked	Done
India Phase 3 studies	Protocol approved; initiation underway	FY26-FY27
IMPD submission Europe (Phase 3)	Targeted Q4FY26	Q4FY26
EU Phase 3 completion	Estimated FY27-FY28	FY28
Commercial launch (therapeutic)	Post EU Phase 3 completion	FY28-FY29E
Excipient grade commercial supply	Earlier than therapeutic — awaiting DMF approvals	FY27E

Commercial Potential

Even a modest share of the global albumin market would be transformative for Shilpa at its current scale. The EU therapeutic albumin market alone is estimated in the hundreds of millions of euros annually. The **Orion partnership** provides a credible commercialisation route in Europe. Excipient-grade rHA for biologics manufacturing (cell/gene therapy, vaccines) is a faster path to revenue and does not require the full Phase 3 clinical trial process; it requires regulatory acceptance of the DMF and qualification by pharma manufacturers.

The blue-sky scenario involves Shilpa becoming a meaningful global supplier of rHA by FY28-FY30. Even at 5% of the USD 8 bn market (USD 400 mn = ~Rs. 3,300 Cr), this business alone could be worth more than the current enterprise value of the entire company. This remains an optionality rather than a base case; however, differentiated technology with a credible partner gives it very good chances of success.

8. SEGMENT DEEP DIVE — PEPTIDES, POLYMERS & CDMO

Peptides

The peptide business sits within SPLL (Shilpa Pharma Lifesciences). Shilpa has invested in three synthesis technologies: Solid-Phase Peptide Synthesis (SPPS), Liquid-Phase Peptide Synthesis (LPPS), and a hybrid microwave-assisted technique. The company received CEP approvals from EDQM for Desmopressin and Octreotide. These are complex peptides which are globally supply-constrained.

The GLP-1 opportunity (Semaglutide, Liraglutide) is the most significant near-term value driver in peptides. Global demand for GLP-1 analogues is exploding, driven by Novo Nordisk's Ozempic/Wegovy success. Shilpa has: (a) filed US DMF for Liraglutide; (b) completed Semaglutide development; (c) validation batches planned Q1FY27; (d) large-scale automated peptide facility (commissioning H2FY27). The company is positioning itself as a peptide API/CDMO supplier to generic manufacturers who will file their own GLP-1 ANDAs as patents expire.
However, I don’t consider it a value changer as there is insurmountable competition in this space, domestically alone.

Polymers

Shilpa Pharma Lifesciences has a dedicated Polymer Research & Technology (PR&T) department, one of the very few in India. The polymer business supplies speciality polymers to pharmaceutical (as drug delivery excipients) and non-pharmaceutical applications. Revenue was ~Rs. 15-20 Cr in FY24-25; management targets Rs. 100 Cr in 2 years. A USD 4 mn commercial manufacturing order was secured from a US MNC in FY26. Shilpa is the sole Indian supplier for this product. CEP approvals received for 2 polymer products in FY25.

API CDMO

The API CDMO business (within SPLL) is growing rapidly at 47% YoY in FY25, contributing ~8% of API revenues (Rs. 62 Cr). The company has 20+ active CDMO programmes with 3 in Phase 3 trials. **Unicycive/OLC** is the most advanced and commercially significant: commercial manufacturing block commissioned Q4FY26; FDA approval (PDUFA June 2026), if granted, will make Shilpa the exclusive manufacturer of OLC.

The total milestone package from Unicycive is USD 10 million, with commercial supply revenues thereafter. The June 2025 PDUFA date was missed due to a CRL citing manufacturing concerns (at Shilpa); NDA resubmitted December 2025; new PDUFA June 29, 2026.

9. SEGMENT DEEP DIVE — NDDS (TRANSDERMAL & ODF)

Overview

The Novel Drug Delivery Systems (NDDS) business operates from Unit 6 in Dobbaspet, Bengaluru, holding simultaneous USFDA, EU GMP, WHO-GMP, UK MHRA, TGA (Australia) and SFDA (Saudi Arabia) approvals for transdermal patches and oral disintegrating films. Installed capacity: 50 mn ODFs and 30 mn patches per year. NDDS sits within the Formulations segment, and its revenue is not separately disclosed.

Current Revenue Contribution

NDDS is substantially pre-revenue in any meaningful sense as of FY26. The products that have been driving Formulations' growth (Nilotinib capsules, Pemetrexed RTU, Bortezomib RTU, Nor-UDCA) are all conventional oral/injectable products.

The NDDS division has absorbed significant R&D and facility investment but is only now approaching its first meaningful commercial launch (Rotigotine EU, Q1FY27). The sole legacy NDDS products in the market (Betahistine ODF in the UK, Tadalafil ODF in the EU) appear to be sub-scale commercially.

Rotigotine — The Make-or-Break Product

Market	Status	Competition	Opportunity Assessment
Europe	EMA approved Q3FY26; launch Q1FY27	Vektor (since 2020); Luye (launched UK/Germany Apr 2025)	Late entrant; modest near-term share. EU market ~USD 222 mn total. Realistic Shilpa contribution: Rs. 50-80 Cr Year 1
United States	ANDA filed February 2026 from Unit 6 (USFDA approved)	No approved generic yet — potential first/early filer	Significant if first generic. US market ~USD 112 mn. Approval est. FY27-FY28.
India	Not in development	—	Not applicable

Pipeline Beyond Rotigotine

- SMLTOP09 (Androgenic Alopecia): Likely topical/transdermal; human studies FY27. Years from commercialisation.
- SMLINJ011 (Long-acting injectable): Not strictly NDDS but novel delivery; India filing pending.
- Hybrid transdermal technologies: Management mentioned 'first-to-market hybrid transdermal technologies in development' in FY25 AR..
- Tadalafil ODF (EU): Approved FY25; commercial scale unclear.

The NDDS pipeline beyond Rotigotine is thin. The division's credibility as a standalone value driver depends entirely on: (a) Rotigotine EU commercial execution in FY27; and (b) progress on US Rotigotine ANDA. If both succeed, NDDS becomes a Rs. 200-300 Cr revenue division by FY28-29. If EU execution disappoints or US faces CRL, NDDS remains a subscale facility looking for its next product.

10. CAPEX JOURNEY — BUILDING THE PLATFORM

The Capex Timeline

Shilpa's capex history is the story of a company that built its entire platform in three concentrated waves, accepting the earnings consequences of each wave while betting on future monetisation.

Period	Capex Wave	Amount (Est.)	What Was Built	Monetisation Status
FY00–FY15	API Scale-Up	~Rs. 300-400 Cr	Raichur Units 1 & 2; HPAPI containment; reactor capacity expansion; USFDA/EU GMP approvals	FULLY MONETISED running at 25%+ EBITDA margins
FY15–FY20	FDF Platform	~Rs. 500-600 Cr	Unit 3 (Hyderabad injectables); Unit 4 (Jadcherla OSD/injectable SEZ); Unit 6 (Bengaluru TD/ODF)	PARTLY MONETISED Unit 4 import alert delayed; Unit 6 Rotigotine launching FY27
FY18–FY24	Biologics Platform	~Rs. 1,000-1,200 Cr	Unit 5 (Dharwad biosimilars/CDMO); Kadechur albumin plant; in-house biosimilar R&D; CDMO capability	EARLY MONETISATION biologicals Rs. 410 mn in Q3FY26; Albumin FY27-28E
FY24–FY27E	Completion & Peptide Scale-Up	~Rs. 600-700 Cr total	OLC dedicated block; large peptide facility; ADC GMP suite; biologics capacity additions	IN PROGRESS OLC approval June 2026; peptide FY27

Key Insight: The Capex Cycle Is Peaking

FY26E capex of Rs. 247 Cr is the peak of this investment cycle. From FY27 onwards, capex tapers sharply as: (a) the OLC block is commissioned; (b) the albumin plant approaches completion; (c) the ADC GMP suite is operational; (d) no new greenfield biologics investments are planned. Capex is tapering while EBITDA growth continues, iis the mechanical driver of Shilpa's FCF inflexion from negative in FY25 to Rs. 289 Cr in FY28E.

The CWIP Disclosure

Capital Work in Progress (CWIP) at the consolidated level was Rs. 462 Cr in FY25 (down from Rs. 719 Cr in FY24), suggesting significant capitalisation of previously in-progress assets. The standalone CWIP was Rs. 39 Cr at FY25: machinery under erection (Rs. 4 Cr) and projects under erection (Rs. 35 Cr). The bulk of CWIP is at the subsidiary level (biosimilars/albumin facilities).

Intangible Assets Under Development (product pipelines being capitalised) stood at Rs. 242 Cr at the standalone level (FY25), up from Rs. 218 Cr in FY24, adding Rs. 52 Cr in FY25 for new molecule development.

11. R&D ENGINE

Scale & Intensity

Shilpa has consistently invested 8-12% of revenues in R&D, which is elevated for a mid-cap Indian pharma company and unusually high for an API-centric business. This R&D intensity was a significant drag on P&L during FY21-FY23 when it represented 35-40% of pre-R&D EBITDA. Management has since rationalised R&D spend while maintaining pipeline momentum. By FY25, R&D as a percentage of revenue(standalone) had declined to a more sustainable 6-8% as revenues scaled.

R&D Infrastructure

- Unit 7 (Nacharam, Hyderabad): Primary R&D facility. Approvals: USFDA, EU GMP, CDSCO, DSIR, NABL. GCP accreditation for clinical work. Houses both chemistry R&D and bio-analytical lab.
- Shilpa Pharma Lifesciences R&D: Peptide and polymer R&D labs; pilot-scale synthesis capabilities for both SPPS and LPPS. Co-development partnerships with MNCs.
- SBPL Biologics R&D: Clone development, cell banking, process development for biologics pipeline. End-to-end from gene to GMP batch.

R&D Output — Cumulative

Metric	As of FY25	Commentary
Total Patents Filed	**~585 (incl. pending)**	**22 new patents filed in FY25 alone**
Patents Granted	Approx 46 (FDF alone: 46 granted, 213 filed)	US, Europe, India portfolio
DMFs Filed (API)	239 total (45 US, 28 EU)	Core competitive moat
ANDAs (US)	27 filed	Generics pipeline
NDAs (US)	3 approved	Pemetrexed RTU, Bortezomib RTU, third NDA
EU Filings	81 (73 approved, 8 pending)	Strong EU regulatory footprint
Trademarks	7 registered, 15 filed in FY25	India brand building
Product Under Development (capitalised)	Rs. 241 Cr	Intangible assets under development

Key R&D Themes

- *Complex generics:*
  505(b)(2) NDAs in the US (Pemetrexed RTU, Bortezomib RTU, Rotigotine ANDA). This represents Shilpa's clearest competitive moat, developing formulations that are difficult to replicate and command pricing power.

- *NCE development:*
  Two NCE programmes underway (API development for Big Pharma partners). The first NCE (undisclosed, Big Pharma US) received approval with commercial supplies Q4FY26. This is the most differentiated R&D output Shilpa has ever produced.

- *Novel biologics:*
  NorUDCA (first globally approved), NBE programme with mAbTree, ADC internal programme. Shilpa is moving up the innovation curve.

- *GLP-1 / peptides:*
  Semaglutide and Liraglutide development ongoing. Shilpa is positioning as a peptide CDMO for the generic GLP-1 wave.

12. THE DISTRESS YEARS (FY21–FY23)

What Went Wrong

Between FY21 and FY23, Shilpa experienced what can only be described as a perfect storm: multiple negative events coinciding at the worst possible time, each individually manageable but collectively devastating to the P&L.

Event	Year	Impact
USFDA import alert on Unit 4 (Jadcherla)	FY21	Blocked US revenues from FDF; reversal of approvals-led optimism; heavy remediation spend
Biologics/Albumin capex peaking	FY21–FY23	Rs. 500-700 Cr invested with zero revenue contribution; depreciation jumped from Rs. 44 Cr to Rs. 96 Cr
Interest cost surge	FY21–FY23	Net debt peaked at ~Rs. 850 Cr; interest costs jumped from Rs. 5 Cr (FY20) to Rs. 59 Cr (FY23)
R&D at peak intensity	FY21–FY23	R&D was 35-40% of pre-R&D EBITDA; no immediate revenue return
Employee cost absorption	FY22–FY23	Employee costs 27% of sales — high fixed cost structure from biologics team build-out
Revenue stagnation	FY22–FY23	FDF pivot to licensing delayed growth; consolidated revenues Rs. 1,046 Cr in FY23 vs Rs. 1,141 Cr in FY22

P&L Consequences

Metric	FY20 (Peak)	FY22	FY23 (Trough)
Revenue (Rs Cr)	908	1,141	1,046
EBITDA (Rs Cr)	219	202	99
EBITDA Margin	24%	18%	9%
Depreciation (Rs Cr)	44	73	96
Interest (Rs Cr)	5	38	59
PAT (Rs Cr)	155	61	(31)

Management Response

- *R&D rationalisation:*
  Management cut R&D spending meaningfully from its peak of 35-40% of pre-R&D EBITDA, maintaining strategic programmes but deferring non-critical ones.

- *Cost optimisation:*
  Employee costs and operating expenses were rationalised. By FY25, employee cost as % of revenue had declined from 27% to 23%.

- *IP monetisation:*
  Rather than waiting for full commercial scale, management began licensing IP aggressively: generating Rs. 140-150 Cr of high-margin licensing income in FY24, partially offsetting the revenue shortfall from FDF.

- *QIP:*
  In April 2024, Shilpa raised Rs. 500 Cr via Qualified Institutional Placement. Rs. 438 Cr was used to repay NCDs of SPLL and SBPL. This single transaction cut total group debt from Rs. 936 Cr to Rs. 586 Cr and reduced annual interest by Rs. 200+ Cr.

- *Formulation reinspection:*
  Management resubmitted Unit 4 for USFDA inspection; EIR received for the TD facility in Q1FY26.

13. THE TURNAROUND (FY24–FY26)

What Changed

The turnaround from FY24 is not simply a cyclical recovery — it is the sequential monetisation of the capital investments made in FY15-FY24, finally flowing into the P&L simultaneously. Multiple platforms are contributing at once, creating operating leverage that is compressing rapidly.

Driver	FY23 Status	FY26 Status	Contribution
API EBITDA	~Rs. 200 Cr, margins squeezed	~Rs. 325 Cr+, margins 25%+	Strong volume growth; 2 NCE programmes
FDF Licensing	~Rs. 50 Cr	~Rs. 150-160 Cr	Orion (Albumin), Nilotinib royalties, NDA milestones
FDF Product Revenue	Minimal (import alert)	Rs. 500+ Cr annualised	Nilotinib EU, Pemetrexed/Bortezomib US
Biologics Revenue	~Zero	Rs. 410 mn in Q3FY26 alone	Adalimumab, CDMO batch revenues
Interest Cost	Rs. 59 Cr	~Rs. 43 Cr (annualised)	QIP proceeds retired NCDs
Employee Cost %	27% of sales	23% of sales	Fixed cost absorption on rising revenues

Quarterly P&L Progression — FY26

Metric	Q1FY26	Q2FY26	Q3FY26	QoQ Trend
Revenue (Rs crs)	321.5	370.0	409.7	Consistent acceleration
EBITDA	91.6	108.3	114.3	Growing
EBITDA Margin	28.5%	29.3%	27.9%	Stable 28-29% range
PAT	46.9	44.1	44.6	Plateauing due to tax normalisation
API Revenue	183.2 (Q1 est.)	203.5	213.1	Strong YoY growth
FDF Revenue	96.4	136.9	151.6	Step-change; Nilotinib + NDAs
Biologicals	35.4	25.9	41.0	Volatile but growing

The Operating Leverage Dynamic

The most important structural change in Shilpa's P&L is the operating leverage now at work. Fixed costs (depreciation Rs. 114 Cr in FY26E, employee costs ~Rs. 325 Cr) are largely absorbed from prior investment cycles. Each incremental rupee of revenue, especially in high-margin segments like API CDMO, licensing, and biologics, is flowing through at marginal EBITDA margins of 60-70%+. This is why EBITDA margin is expanding from 21% (FY24) to 32%+ (FY26E) even as revenue grows only 14%. The mix is improving, and fixed costs are not growing proportionally.

14. FINANCIAL MODEL

Profit & Loss

Statement of Profit and Loss					
Particulars	**FY25**	**9MFY26**	**FY26E**	**FY27E**	**FY28E**
Revenue	1286	1110	1468	1700	1900
Gross Profit	876	792	1079	1275	1425
GP Margin	68.12%	71%	73.5%	75%	75%
EBITDA	317.23	323	470	595	665
EBITDA Margin	24.67%	29%	32%	35%	35%
Other Income	23	10	3	20	20
Depreciation	112.99	89	114	125	135
EBIT	227.24	244	359	490	550
Interest	75.53	45	53	53	53
Profit before tax and exceptional	151.71	199	306	437	497
Share of profit/(Loss) of associate/JV	-1.3				
Exceptional item	-28	-13			
Profit before tax	122.41	186	306	437	497
Tax	44.04	50	30%	30%	30%
Net profit	78.37	136	214	306	348
PAT Margin	6.09%	12.25%	14.58%	17.99%	18.31%

Balance Sheet

Consolidated Balance Sheet estimates					
Particulars	**FY25**	**H1FY26**	**FY26E**	**FY27E**	**FY28E**
Equity share Cap	10	10	10	10	10
Reserves and Surplus	2362	2427	2498	2804	3152
Shareholders fund	2364	2437	2508	2814	3162
**expectations not adjusted for minority*					
Short term borrowings	354	402	354	354	354
Long term borrowings	231	190	190	190	190
Trade payables	95	165	176	256	285
Other Liabilities	265	301	350	350	350
Total Liabilities	3310	3495	3578	3964	4341
Net block	1730	1801	1866	1990	2000
CWIP	718	534	462	462	462

Key Ratios

Metric	FY25A	FY26E	FY27E	FY28E
RoE	3.32%	8.53%	10.87%	11.00%
RoCE	8.62%	10.55%	13.22%	13.56%
EBITDA Margins	24.67%	32%	35%	35%
Fixed Asset Turnover	0.74	0.79	0.85	0.95

15. VALUATION & KEY CATALYSTS

Valuation Framework

Scenario	Basis	Earnings	Multiple	Target
Bear Case	20x FY27E Earnings	Rs. 306 crs	20x	Rs. 6120
Base Case ★	30x FY28E earnings	Rs. 348 crs	30x	Rs. 10,440
Bull Case	40x FY28E earnings	Rs. 348 crs	40x	Rs. 13,920
Blue Sky (Albumin commercialised)	40x FY28E EPS + Albumin value	Rs. 450 crs	30x	Rs. 18,000

Catalyst Calendar

Catalyst	Timing	Certainty	P&L Impact
Nilotinib EU — quarterly volumes	Every quarter	High	Recurring; watch for competition
OLC/Unicycive FDA approval	June 29, 2026 PDUFA	Medium (prior CRL history)	USD 10mn milestone + supply
Rotigotine EU commercial launch	Q1FY27	High	Rs. 50-80 Cr Year 1
NCE Programme 1 — commercial supply ramp	Q4FY26 onwards	High	High-margin API CDMO revenue
Aflibercept India launch	FY26 end / Q1FY27	Medium	Biologicals revenue step-up
Semaglutide validation batches	Q1FY27	Medium-High	CDMO positioning proof point
Albumin Phase 3 (India & EU submission)	FY27	Medium	No near-term revenue; option value
Rotigotine US ANDA approval	FY27-FY28	Medium	USD 112mn market; likely first generic
OLC commercial supply (if approved)	H2FY27	Medium	Steady exclusive supply contract
Peptide facility commissioning	H2FY27	High	Opens GLP-1 CDMO revenues

16. RISKS & MONITORABLES

Risk	Description	Severity	Mitigation
Nilotinib competition	EU exclusivity window narrowing as other generic filers approach approval. Material to near-term FDF revenues.	HIGH	New product launches (Rotigotine, Ondansetron) to replace; timing critical
OLC second CRL	If FDA finds fresh deficiencies in December 2025 resubmission, June 2026 milestone delayed again.	MEDIUM	Manufacturing issue from first CRL reportedly resolved; resubmission accepted
Unit 4 import alert	Ambiguity on whether full import alert is lifted for all product categories (injectable, OSD) beyond TD facility.	MEDIUM	Regulatory engagement ongoing; EIR received for TD section
Albumin clinical failure	Phase 3 trials could fail efficacy or safety endpoints.	MEDIUM	Removes significant option value but doesn't affect base case earnings
Promoter dilution	Stake declined from 44% to 40% in 9 months. Further dilution could signal stress or weaken strategic alignment.	MEDIUM	Monitor quarterly; no distress indicators currently
Licensing income sustainability	Licensing income of Rs. 150-160 Cr requires continuous new product development and deal closures.	MEDIUM	Strong pipeline; but lumpy and dependent on partner negotiations
Interest rate / debt refinancing	Rs. 586 Cr debt at floating rates; any rate increase adds to interest costs.	LOW-MED	Debt declining rapidly; FCF positive from FY26
Key-man risk	MD Vishnukant Bhutada's re-appointment to 2029 provides near-term continuity; but company is promoter-driven.	LOW	Generational transition to Keshav and Madhav Bhutada underway
Regulatory setback (new)	Any new USFDA warning letter or import alert on any of the 7 facilities.	LOW-MED	Both Raichur units received clean EIRs in FY25; Unit 6 multi-agency approved

Key Monitorables Every Quarter

- Nilotinib FDF revenue trajectory and any mention of new competitors entering EU
- OLC/Unicycive regulatory update: June 2026 PDUFA date outcome
- Biologicals revenue: target Rs. 40crs per quarter to sustain FY27E estimates
- Licensing income: any new deals or renewal of existing arrangements
- Net debt: targeting sub-Rs. 400 Cr by FY27E; track quarterly debt schedule
- Promoter shareholding: any further decline beyond 40%
- Rotigotine EU launch execution: volumes, pricing, partner performance
- Semaglutide/GLP-1 development milestones: customer traction is the signal

What one should understand to know Shilpa better:

Sweating the Gross Block: A Non-Dilutive Earnings Story for FY27:
Shilpa Medicare has transitioned from a heavy investment phase to a monetisation cycle. Having already committed nearly ₹2,000 crore to capex and R&D over the last five years, the company's core infrastructure, which spans biologics, ADCs, and transdermals, is fully funded and largely operational. The investment debate is no longer about capital requirements, but about the velocity of asset turns.
With a current gross block of ₹2,087 crore yielding a turnover of only 0.74x, there is substantial headroom to reach the peer average of 1.2x+. This inherent operating leverage is the central driver for earnings expansion through FY28, requiring no further strategic pivots or major capital infusions.

Strategic Inflexion: The End of Internal Cross-Subsidisation

The API division historically served as the silent anchor of Shilpa Medicare, subsidising a decade of development-phase losses across all other business units. From FY17 to FY23, the API segment maintained robust 28%–32% EBITDA margins, effectively funding a loss-making formulations unit, a cash-intensive biologics division, and a pre-commercial rHA plant. This intensive cross-subsidisation masked the core business's health, causing consolidated EBITDA to plummet to ₹57 crore in FY23. Current data confirms that all four divisions have now reached positive EBITDA territory.

The Transition to Innovation: NorUDCA as a Categorical Shift
Every other product in SML's formulations portfolio is either a generic, a biosimilar, or a reformulation of an existing drug. NorUDCA is none of those. It required original clinical trials, it has no competitor globally, and SML is the only company currently with regulatory approval for this indication. The market has not re-rated SML as an innovator company because this is one product, but the pricing dynamics, margin profile, and longevity of exclusivity are completely different from anything else in the portfolio.
The Indian domestic formulations revenue was ₹26 crore in FY25 before NorUDCA launched. The trajectory from here is not a generic ramp, as it is a branded drug launch with three distribution partners and an 188 million patient addressable population. Whether it becomes ₹50 crore or ₹200 crore depends on execution, but the structural nature of the opportunity is categorically different from everything else SML has done before.

The licensing income line is shrinking on purpose, and that is actually good news
The purposeful contraction of the licensing income line signifies a structural improvement in earnings quality. While SML reported ₹190 crore in licensing fees for FY25, this figure is projected to decline as assets transition from one-time milestone payments to long-term commercial supply agreements. Most investors misinterpret this decline as a loss of momentum, but it actually marks the maturation of R&D into recurring API and formulation revenue.

The USFDA import alert at Jadcherla is the most watched risk, but not the most important one - EU competition in formulations is.

Every analyst report flags the Jadcherla USFDA import alert as the primary risk. It has been active since February 2021. But Jadcherla's US revenues are partially protected (azacitidine, cyclophosphamide, and erlotinib are all exempted), Austria issued a GMP certificate in January 2024, keeping EU supply intact, and US complex products are being launched via CMO sites anyway. The actual earnings at risk from Jadcherla are limited.

The risk that is underappreciated is the EU exclusivity cliff on Nilotinib and Axitinib. These two molecules drove the EU formulations business from ₹85 crore in FY24 to ₹111 crore in FY25 and are on track for ₹200 crore in FY26. SML is currently the only generic in the EU for Nilotinib. When competition arrives, as 15 companies have EU DMFs for Nilotinib API, pricing will collapse in the European generics markets. The Rotigotine TDS launch in 1HFY27 is the intended replacement, but there will likely be a gap quarter or two where EU revenues look weak before Rotigotine ramps.