

Date: 13<sup>th</sup> August, 2025

#### Shilpa Medicare Limited

#### **Corporate & Admin Office:**

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Email: info@vbshilpa.com, Web: www.vbshilpa.com

CIN: L85110KA1987PLC008739

To,

Corporate Relationship Department, BSE Limited Phiroze Jeejeebhoy Towers, Dalal Street, Fort, Mumbai-400 001 National Stock Exchange of India Limited Exchange Plaza, 5th Floor, Plot No.C/1, G Block Bandra Kurla Complex, Bandra (E) Mumbai-400 051

Scrip Code: BSE-530549, Stock Symbol: NSE – SHILPAMED

Dear Madam/Sir,

**Sub:** Investor presentation of the Company for the quarter ended 30 June 2025

**Ref:** Disclosure under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements)

Regulations, 2015

With reference to the captioned subject, the Investor Presentation for the quarter ended 30 June 2025, on Company Overview, Business highlights, financial performance and other updates is enclosed herewith for your consideration.

A copy of this intimation is also being made available at:

https://vbshilpa.com/investor-presentation.php

We requesting you to take the above information on record.

Thanking you.

Yours faithfully, For Shilpa Medicare Limited

Ritu Tiwary Company Secretary & Compliance officer



Shilpa Medicare Ltd

**1QFY26 Earnings Presentation** 

Date: 13th August 2025



### Safe Harbour





Certain statements in this document may be forward - looking statements. Such forward looking statements are subject to certain risks and uncertainties like regulatory changes, local political or economic developments, and many other factors that could cause our actual results to differ materially from those contemplated by the relevant forward-looking statements. Shilpa Medicare Limited (SML) will not be in any way responsible for any action taken based on such statements and undertakes no obligation to publicly update these forward-looking statements to reflect subsequent events or circumstances.

# Shilpa Medicare at a glance



Established in 1987, we have 35+ years track record





Existing Business Segments: API, Formulation, CDMO, Biologics



Emerging Businesses: NDDS, ADC and Recombinant Human Albumin



**10+** Regulatory approved manufacturing + R&D facilities (incl Analytical Lab)



400+ R&D Personnel



**500+** Regulatory Filings across the world



Worldwide presence in **50+** countries



**1Q FY26** Financials

Revenue INR 328 crores (+9% YoY)
EBITDA INR 98 crores (+18% YoY)

## Key operating verticals

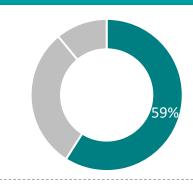


1QFY26 Revenue contribution

# **Legal Entities**

Areas of Operation

API



Shilpa Pharma Lifesciences

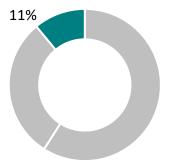
- Oncology
- Non-Oncology
- Payloads and Linkers
- Peptides
- Polymers
- CDMO

**Formulations** 



- Shilpa Medicare
- Shilpa Therapeutics
- FTF Pharma
- Tablets/Capsules
- Injectables
- Oral Dissolving Films
- Transdermal patches
- CDMO

**Biologics** 



- Shilpa Biologicals
- Shilpa Biocare
- NBE
- Microbials Products
- Mammalian Products
- GLP-1
- CDMO
- ADCs

# **Management Commentary**





Our API division(including captive) has reported growth ~25% YoY basis. New product launches, CDMO expansion, expanded capacities, and an improved product mix favoring regulated markets is expected to drive further growth for FY26.

In Biologics, our strategic investment in Alveolus Bio accelerates innovation and solidifies Shilpa's position as a global biotech enabler—bridging cutting-edge science with scalable solutions. Our Novel Biological Entities (NBEs), developed in collaboration with mAbTree and Alveolus, remain on track for Phase I human trials in FY27. On the biosimilar front, Aflibercept has advanced to Phase III clinical trials in India, while Nivolumab has completed PCT, with Phase I trials expected to commence by the end of FY26. We have also received the initial milestone payment for Recombinant Human Albumin from Orion Corporation, and the program is progressing as planned.

On the regulatory front, we continue to achieve key accreditations for our facilities. During the quarter, Unit VI at Dabaspet, Karnataka—equipped with ODF & TDP manufacturing capabilities—received an EIR from the US FDA. This milestone will support the monetization of our differentiated product portfolio in the US market. Our focus remains on optimizing asset utilization across key verticals, and we are confident in delivering improved profitability in FY26.







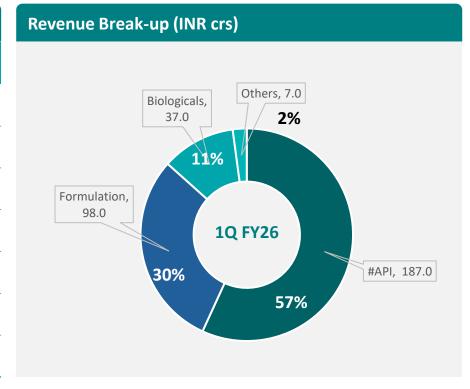
1QFY26 Performance

# 1Q FY26 – Financial Highlights

### Shilpa Innovating for affordable healthcare

### Highest Quarterly EBITDA

1Q FY26 (Consolidated)							
Particulars (INR cr)	1QFY26	1QFY25	YoY	4QFY25	QoQ		
<b>Total Revenue</b>	328	302	9%	338	(3%)		
Gross Profit	248	209	19%	234	6%		
GP Margin	76%	69%	700 bps	69%	700 bps		
EBITDA	98	83	18%	84	17%		
EBITDA Margin	30%	27%	300bps	25%	500 bps		
PAT	47	14	236%	33*	42%		
PAT Margin	14%	5%	900 bps	10%	400bps		



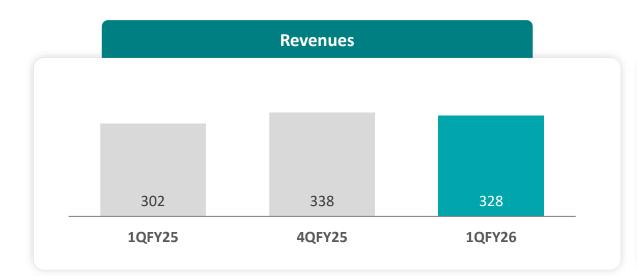
### **Result commentary**

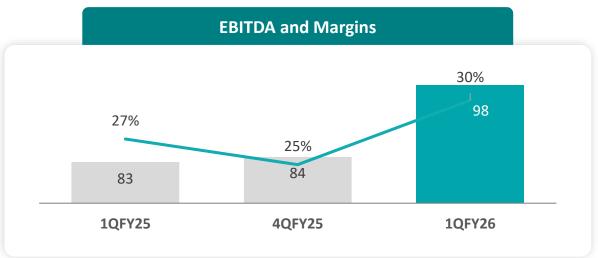
- Revenue grew by 9% on YoY basis, driven by growth in our API and Biologics verticals
- Highest quarterly EBITDA at INR 98crs growing 18% YoY; EBITDA Margins at 30%

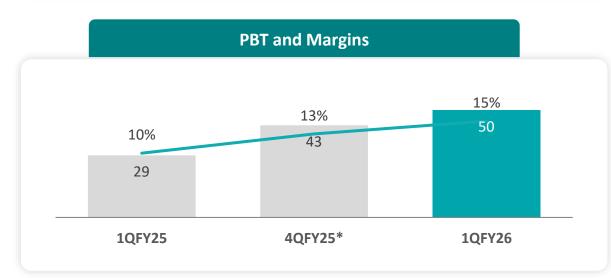
### **Consolidated Performance**

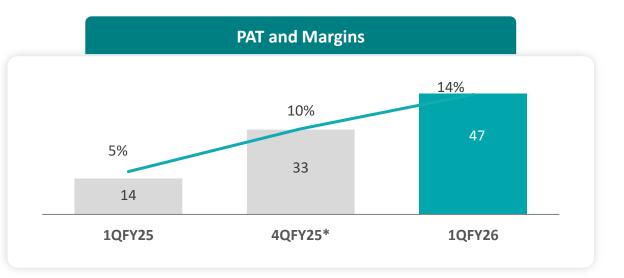


(INR in Cr.)



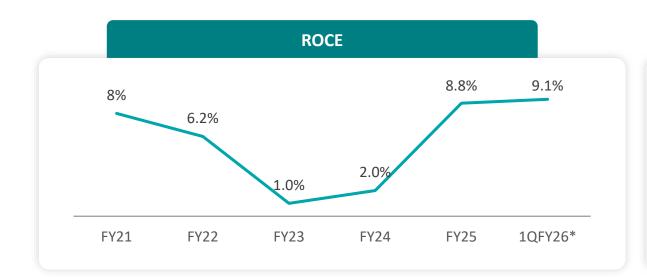


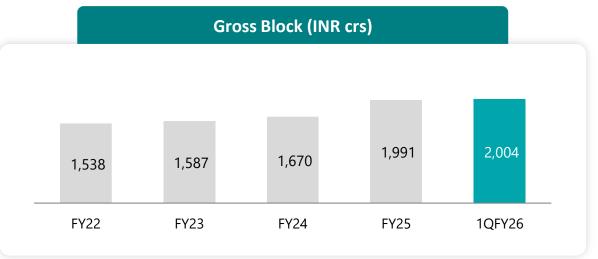


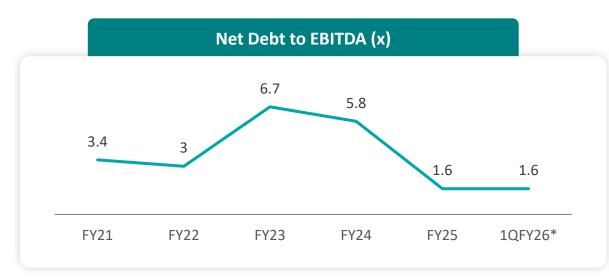


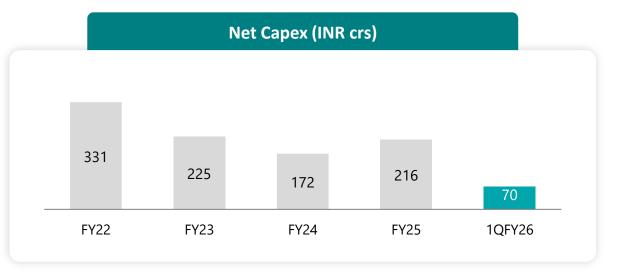
### Financial Summary











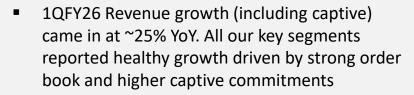




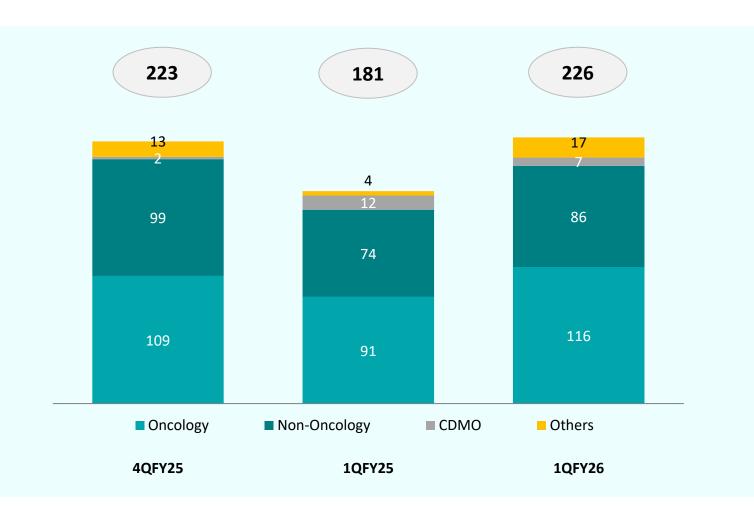
### Multiple growth drivers with strong order book



(INR in Cr.)



- Newly increased capacities for key products viz.
   UDCA, Tranexamic Acid, Azacitidine, Palbociclib and Nilotinib to contribute materially in FY26
- The large Polymer contract commenced commercial revenue this quarter, marking a key milestone
- Expanding product portfolio with launches in multiple complex APIs and Specialty portfolio
- Added new clients in various geographies



### API - Ongoing Developments



#### **API Molecules**

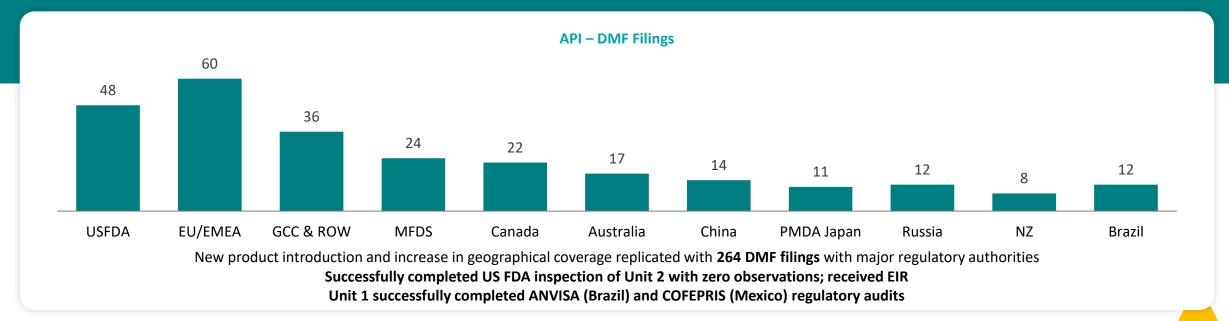
- Commercial-Scale Manufacturing Capacities commenced operations for High-Demand Products – UDCA, Tranexamic Acid, and key Onco molecules
- New product introductions, optimized production scale, and strong captive demand is expected to deliver consistent growth momentum
- Completed validation for 2 new products
- Initiated de-bottlenecking in various blocks

#### **CDMO**

- 2 programs expected to commercialize in FY27, NDA filed
- Secured a new contract for the supply of a high-value specialty chemical to a global healthcare leader
- As a CDMO in NDA program, partner obtained Phase II clearance for new indication with fast-track status
- New dedicated block for OLC expected to be commercialized in FY26
- 25+ programs are ongoing in different phases of development for our clients

### **Polymer and Peptide**

- Commercial supplies started of large polymer project worth ~USD 4mn received from a US MNC for non pharma applications. Sole supplier from India, with order value expected to increase going forward.
- Initiated development of specialty polymers for eye care in collaboration with U.S.-based partner
- GLP 1 Liraglutide DMF readied and Semaglutide Process Qualification expected to be completed in 1HFY26
- Initiated scale-up to commercial batches for peptide APIs with CEP approval

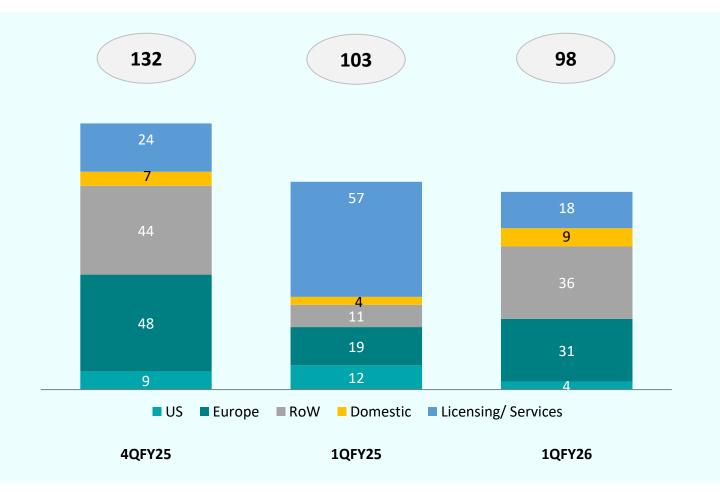






Formulations Business

### Pipeline monetization to drive growth







- All 3 approved and launched NDAs have limited competition. More NDAs will be filed in coming quarters
- Launched our 2nd NDA viz. Bortezomib RTU
   Subcutaneous in US, scale up expected in FY26
- Pemetrexed gaining market share in US, with profit share upside expected to materialize in coming quarters
- Our partner continues to gain market share for Nilotinib; order book for Nilotinib remains strong
- Launched Axitinib in EU region via partner
- Received approval NorUDCA, India's first-in-class therapy for NAFLD, revenue to start from 3QFY26
- Strong order book as the underlying demand for the products remains healthy

### FDF – Update on key assets



#### SMLNUD07 NorUDCA

- Received historic approval for NorUDCA, India's first-in-class therapy for NAFLD—making Shilpa the first company globally to obtain approval for NAFLD.
- To Launch NorUDCA tablets in India, while advancing global regulatory efforts to bring vital therapy to patients internationally

### SMLTDP08 Rotigotine

- Transdermal Patch for treatment of Parkinson's disease
- US Study dosing has been completed with results expected in 2QFY26
- US Submission planned Q3 FY26
- Europe submission completed by our partner and expecting a limited competition launch in FY26

#### **SMLTOP09**

- Topical lotion for treatment of Androgenic Alopecia
- Phase II concluded with data submitted to Indian regulators -Phase III to commence upon receiving authorization
- EU regulators
   validated our clinical
   development
   approach through
   Scientific Advice,
   significantly de-risking
   our regulatory
   pathway

#### SMLODF010 Tadalafil Film

- First company to secure EU approval for multiple strengths of tadalafil films under hybrid application
- Expected to launch in European market in FY26

#### SMLINJ011

- Long Acting Injection for prevention of Acute and Delayed nausea and vomiting associated with initial and repeat courses of highly emetogenic cancer chemotherapy, radiotherapy and other associated medication. Market Size is ~USD 375 mn (Global)\*
- Dosing in Phase III clinical trials in India has been completed
- Received positive Scientific Advice responses from both EU and US (pre-IND) regulators, planning clinical study designs

#### SMLTDP012

- An innovative delivery platform offering enhanced compliance and steady plasma levels for Alzheimer's patients
- A once-weekly transdermal patch delivery system enhancing patient adherence, compliance and convenience
- Preliminary clinical trials initiated; full development to be completed by end of FY26

#### SMLOSD014

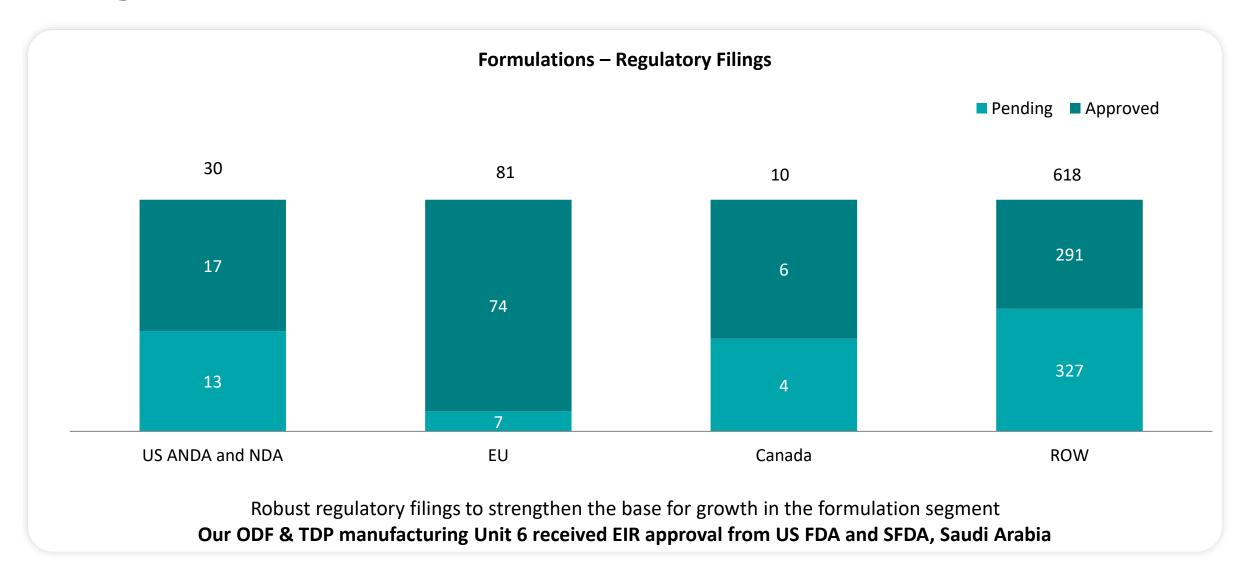
- A unique patientfriendly formulation enabling early market access in underserved anticoagulation segments
- Targeting earlier market access in the US market compared to the conventional formulation
- Targeting a ~USD 10+ bn U.S. branded market with our enhanced delivery platform
- Exhibit batches completed and BE Studies planned

\*Source: IQVIA - MAT-March 25

Note: Our project numbering does not include #13

### Filings – Formulations









**CDMO** Business

# CDMO – Strong capabilities in various technologies



			Very strong capability	Strong capability Developing capability Negligible cap			Negligible capability
	•		— Indian CDMOs —	• •		- Global CDMOs	
	Shilpa Medicare	Peer 1	Peer 2	Peer 3	Global Peer 1	Global Peer 2	Global Peer 3
Specialized technologies							
Small molecule							
Peptide							
Monoclonal Antibodies and Recombinant technology							
Antibody – Drug conjugates							
Fermentation							
Offerings							
Development							•
Manufacturing							

- Early phase to late phase from AI/ML led discovery (target to hit, hit to lead and lead to NCE) to custom synthesis, scale up and clinical materials (for advanced intermediates, RSMs
- "Clone-to-vial" capabilities makes us a preferred one-stop outsourcing partner, securing strong market position
- Leveraging expertise to offer interconnected tech platform for various fast growing opportunities in the areas of fermentation, Antibody-Drug Conjugates (ADCs), and GLP-1
- Leveraging exquisite strengths in complex chemistry across pharma and specialty chemicals. Integrated CMC approach for delivering drug substance and drug product to pharma customers

## Robust business model encompassing various stages









Value chain stages

**Development & Clinical supplies** 

**Late stage development & Commercial** Manufacturing

**Phases** 

**Pre-Clinical Development** 

**Clinical development** & Supplies

Registration

Commercial Manufacturing

Key steps

- Drug metabolism, pharmacokinetics (DMPK)
- Toxicology studies (Safety studies)
- Manufacturing clinical supplies
- Phase 1 and 2 clinical trails

- Phase 3 clinical trials
- Drug filing with regulatory authorities
- Drug substance manufacturing (RSM, intermediates, APIs) and formulation

Number of projects

25+

3

### Comprehensive CDMO Development



Unicycive Therapeutics Inc's
Oxylanthanum Carbonate (OLC) is a
Potential best-in-class product being
developed under FDA's 505(b)(2)
regulatory pathway for the treatment of
hyperphosphatemia



NDA accepted by the US FDA

Long term manufacturing and supply agreement with SML.



SML is receiving significant milestone income spanning over various stages viz. filing, approval and launch of the product



Building back-end to develop & manufacture both API & Formulation

#### Product Profile<sup>1</sup>

- Potential best-in-class product for the treatment of Hyperphosphatemia
- Advantages: (1) Potency: Shares high phosphate binding capacity of lanthanum; (2) Pill Burden: Smaller and fewer pills; (3) Palatability: swallowed whole with water and not chewed

- A comprehensive CDMO contract for both API and formulation development – a One-stop-Solution
- Unicycive received a Complete Response Letter (CRL) from the FDA, citing deficiencies related to a third-party drug product manufacturer (unaffiliated with Shilpa Group).
- In response, the Company has proactively qualified an alternative supplier that has already successfully produced OLC drug product batches. This vendor will support resolving the CMC issues outlined in the CRL
- Expect commercialization in FY27

1. Source: Unicycive Presentation





### Biologics – Growth envisioned on 4 pillars



### **Biologics**

- Adalimumab: India market sees growth, 24-month shelf life approved (from 18). Filing in progress in 15 RoW markets, with approvals expected in FY26. RoW approvals expected in this quarter
- Aflibercept: Ophthalmic biologic with a global market size of ~USD 5 bn¹.
   Enters Phase III, targeting FY27 launch; Out-licensed to two partners in India and Russia, with active discussions in MENA region
- Nivolumab (USD 11 bn) <sup>1</sup>, Small-scale development completed; PCT completed, targeting clinical initiation in 4QFY26.
- Pembrolizumab (USD 33 bn) <sup>1</sup> small scale development completed and PCT in progress
- Daratumumab (USD 13 bn)<sup>1</sup> and Dupilumab (USD 21 bn)<sup>1</sup> cell line development initiated; PCT targeted in FY26
- Trastuzumab (USD 3 bn) <sup>1</sup> process development completed

### **Novel Biologics**

- Novel MAB (oncology): Term sheet signed with mAbTree; cell line received and process development underway. Targeting investigator-led trials by late FY26.
- Novel Live Biotherapeutic
   Product (LBP) Development &
   manufacturing contract signed
   with Alveolus Bio
- Alveolus and mAbTree NBE projects are expected to enter Phase I studies in FY27
- Albumin Global clinical trial protocol submitted, aligned with EMA guidance

### Integrated CDMO @Dharwad

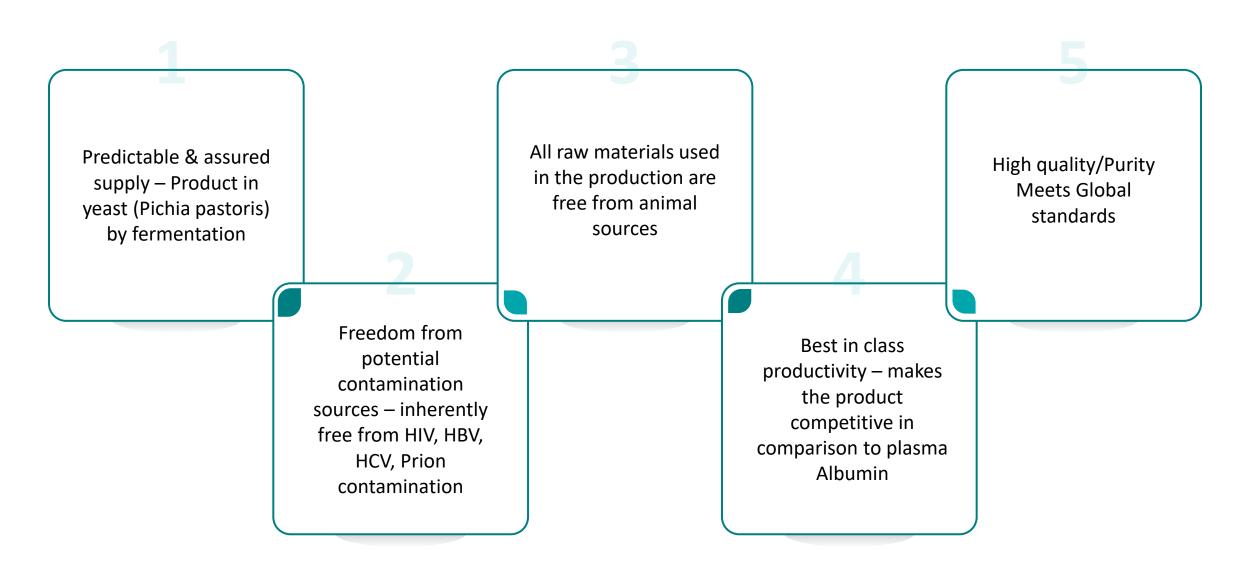
- Five active Novel Biologic Entity (NBE) programs advancing for multiple partners
- Increase in number of RFQs received from various global biotech

#### **ADC Platform**

- Shilpa's First ADC biosimilar is expected to enter human studies in FY27
- Dual-capability platform in both small molecules and biologics manufacturing provides global pharma partners with unmatched integration, simplifying their supply chain and development needs

### Why Recombinant Human Albumin?





### Shilpa's Recombinant Human Albumin



### **Key highlights**



Shilpa's novel rHA (Recombinant Human Albumin)

- Entered into a strategic partnership with Orion Corporation for commercialization in Europe region for therapeutic use
- Under this agreement, Orion will be the exclusive partner for the distribution, marketing, and sales of Shilpa's Recombinant Human Albumin for therapeutic use in Europe
- Shilpa is entitled to receive from Orion certain development and regulatory milestone payments
- Shilpa has been investing in the development of this novel product for about 8 years and has also set-up a large-scale fermentation facility for manufacturing



Regulatory filing status

- India Initiating Ph3 trials in FY26
- **EU** Initiating Ph3 trials in FY26
- US Pre IND to be filed 2QFY26
- Non-Therapeutic Samples shared with few clients in US



Addressing the global unmet need

- Shilpa has developed recombinant Human Albumin (rHA)
- Targets to fulfil growing demand of human serum albumin
- All the raw materials used in manufacturing are animal origin free (AOF)



**IP Positioning** 

 Shilpa's Recombinant Human Albumin production technology is covered by patents in developed markets viz. US & Europe

### Outlook





#### **FDF**

NDA – Pemetrexed and Bortezomib

Hybrid – Nilotinib (limited competition), Axitinib & Rotigotine

**NorUDCA** – First-In-Class for NAFLD in India, followed by launches in RoW



#### **CDMO**

Two NCE projects to commercialize in FY27

Two NBE projects expected to enter human studies in FY27



#### API

Multiple complex API launches, growth in Specialty portfolio, coupled with capacity expansion for existing key products to drive API growth



#### **Biologic**

Strong Biosimilar pipeline with various large assets completing clinical trails, coupled with niche CDMO Biologic offerings to drive Biosimilar revenue growth in significant manner from late FY26



#### **Recombinant Albumin**

Ph3 trials for India and Europe to start in FY26

Strategic tie up with Orion Corporation for therapeutic use

Non – Therapeutic usage is being explored



#### **Licensing income**

Various assets where licensing income was received are moving towards commercial long term supply agreements



#### **Impending Operating Leverage**

Substantial portion of current gross block remains under utilized having spread across high margin divisions viz.

Biosimilar, CDMO and NDDS



#### **Margin Improvement**

Improved utilization is likely to drive meaningful improvement in revenue and EBITDA margins

### Manufacturing Capabilities – API & Biocare









### **Capabilities**

Onco, Non-Onco NCE, APIs, Peptide and Polymers, Manufacturing proficiencies at gramto-multi kilo and ton scales

### **Capacities**

- 11 mfg blocks (4 onco and 7 non-onco)
- Total reactor capacity of 650 KL

### Regulatory Accreditation

- US FDA
- PMDA
- EU GMP
- Russian GMP
- ANVISA
- WHO-GMP
- COFEPRIS
- KFDA
- TGA
- TPD

- Manufacturing and R&D Centre
- Small molecule development, Linker, GalNAc Chemistry, Asymmetric synthesis, Chiral Chemistry, Peptides, Polymers, Enzymes, Purification, RP-separations CDMO services
- 10 mfg blocks (5 onco and 5 non onco)
- Total reactor capacity of 510 KL
- US FDA
- PMDA
- EU GMP
- Russian GMP
- ANVISA
- TDP
- COFEPRIS
- WHO-GMP
- TGA
- KFDA

- Fully automated integrated facility with DCS control system
- Filtration system for protein separation
- 200KL+ Fermentation capacity
- Capacities ranging from 5 KL to 50 KL for product vessels and 5 KL to 15 KL for buffer vessels
- Audit ready

# Manufacturing Capabilities – Formulations & Biologics









**Capabilities** 

OSD tablets and capsules; Injectables – dry

**Capacities** 

Injectable - ~3mn Liquid Vials Lyophilized - ~2mn Vials OSD - 25mn Tablets

Regulatory **Accreditation** 

powder and liquid lyophilization

Capsules – 4mn Hard Capsules

EU GMP, ANVISA, COFEPRIS, TGA, WHO-GMP, SHAPRA, Health Canada, GHC

Fully automated facility for Transdermal patches and Oral Thin Films

ODF - ~50mn Units TDF - ~30mn Units

US FDA, WHO-GMP, UK-MHRA, EU GMP, TGA, SFDA

End-to-end services, from development to commercial manufacturing of microbial & mammalian-based drug substance and drug products. Having expertise in complex technologies viz. ADC, peptides and conjugated proteins

Upstream – 4,000LX2 Microbial Suite – SS 1,000LX2 PFS – 80 units/min

• EU GMP, DSIR Approved facility





### Profit & Loss Consolidated



Particulars (INR cr)	1QFY26	1QFY25	YoY	4QFY25	QoQ
Revenues	328	302	9%	338	(3%)
Gross Profit	248	209	19%	234	6%
Gross Margin %	76%	69%		69%	
Employee Cost	82	72	14%	71	15%
Other Expenses	68	54	26%	79	-14%
EBITDA	98	83	18%	84	17%
EBITDA Margin %	30%	27%		25%	
Finance Cost	19	24	-21%	15	27%
Depreciation	29	27	7%	29	<del>-</del>
PBT	50	29	72%	43*	16%
PAT	47	14	236%	33*	42%

<sup>\* 4</sup>QFY25 PBT & PAT are adjusted to Exceptional item All numbers are rounded off to nearest one

### Earnings call Details



Shilpa Medicare 1QFY26 Results Conference Call to be held

August 13, 2025, Wednesday at 17:00 IST

### **Details of Earnings Conference Call**

+91 22 6280 1130 +91 22 7115 8031

The number listed above is universally accessible from all networks and all countries

### **International Toll-Free Numbers**

 USA
 18667462133

 UK
 08081011573

 Singapore
 8001012045

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 800964448

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