Shilpa Medicare Limited
Corporate & Admin Office:
"Shilpa House", # 12-6-214/A-1, Hyderabad Road,
Raichur – 584 135, Karnataka, India
Tel: +91-8532-238704, Fax: +91-8532-238876
Email: info@vbshilpa.com, Web: www.vbshilpa.com
CIN: L85110KA1987PLC008739

Date: 10 February, 2025

To
Corporate Relationship Department
BSE Limited,
1st Floor, Rotunda Building,
P.J. Towers, Dalal Street,
Mumbai – 400 001.

To
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 Sir/Madam,

Sub: Investor Presentation of the Company for the quarter ended 31 December, 2024
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 31 December, 2024, on Company Overview, Business highlights, financial performance and other updates is enclosed herewith for your consideration.

This is for your information and necessary records.

For Shilpa Medicare Limited,

Ritu Tiwary
Digitally signed by Ritu Tiwary
Date: 2025.02.10 14:47:30 +05'30'

Ritu Tiwary
Company Secretary & Compliance Officer

Innovating for affordable healthcare

Shilpa Medicare Ltd

3QFY25 Earnings Presentation

Date: 10th Feb 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

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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 **30+** countries

9MFY25 Financials

Revenue **INR 971 crores (+12% YoY)**

EBITDA **INR 256 crores (+42% YoY)**

Key operating verticals

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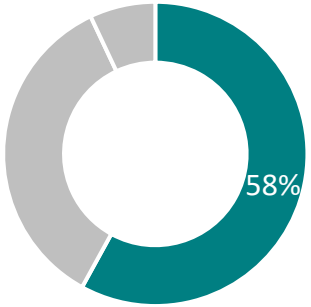
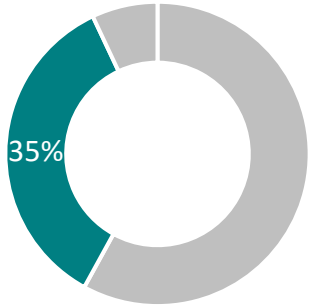
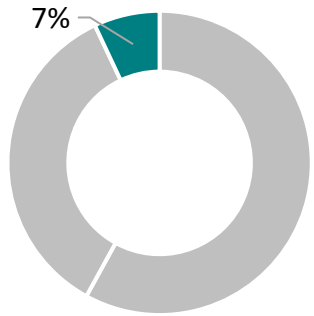
	API	Formulations	Biologics
9MFY25 Revenue contribution			
Legal Entities	▪ Shilpa Pharma Lifesciences	▪ Shilpa Medicare ▪ Shilpa Therapeutics ▪ FTF Pharma	▪ Shilpa Biologicals ▪ Shilpa Biocare
Areas of Operation	▪ Oncology ▪ Non-Oncology ▪ HpAPI ▪ Peptides ▪ Polymers ▪ CDMO	▪ Tablets/Capsules ▪ Injectables ▪ Oral Dissolving Films ▪ Transdermal patches ▪ CDMO	▪ NBE ▪ Microbials Products ▪ Mammalian Products ▪ GLP-1 ▪ CDMO

API Includes others

CDMO – Strong capabilities in various technologies

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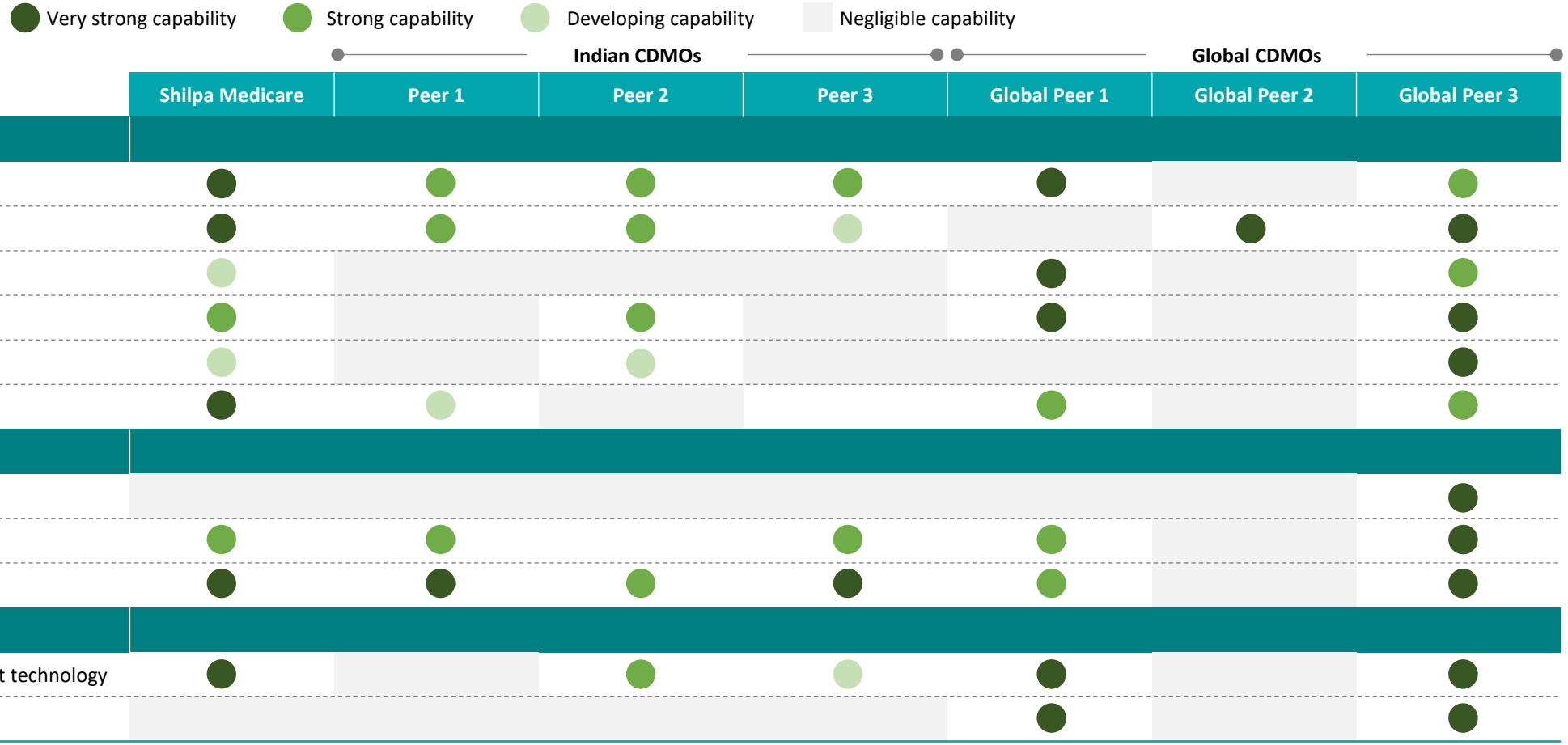

Shilpa's CDMO offerings are a One – Stop – Shop covering various aspects including Biologics

3Q & 9MFY25 Performance

Management Commentary

Our 3QFY25 performance reflects robust growth in profitability driven by improved business mix. The quarter witnessed healthy YoY growth in our key verticals of FDF & Biologics, which was partially offset by muted API performance.

As we focus on achieving significant milestones in all our verticals, our efforts remain towards monetizing existing key assets. During the quarter we have launched Nilotinib in EU region where we are a sole generic, on the Biologics front we have initiated Ph3 trials for Aflibercept, and we have initiated commercial launch quantities for OLC – a US CDMO opportunity. I am also highly optimistic on receiving approval for our NCE – NorUDCA in this financial year.

With positive traction on our new product launches in coming quarters I am confident of delivering strong revenue growth in each business vertical.

Going forward, our focus remains on scaling up API business, launch of approved NDAs in regulated markets and getting timely approvals on filed products. We continue to invest in future pipeline as well as focusing on resolutions on the regulatory front.

— Mr. Vishnukant Bhutada
Managing Director

3Q FY25 – Financial Performance

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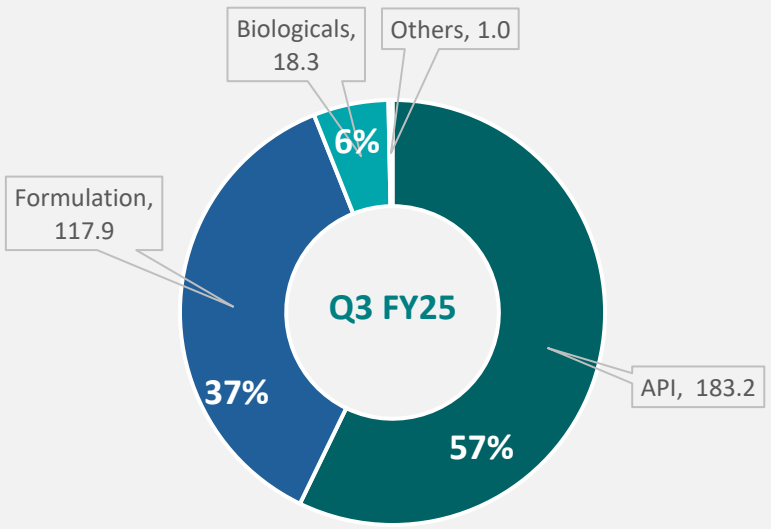
3Q FY25 (Consolidated)					
Particulars (INR cr)	**3QFY25**	**3QFY24**	**YoY**	**2QFY25**	**QoQ**
Total Revenue	**320**	**289**	***11%***	**349**	***-8%***
Gross Profit	229	192	*19%*	227	*1%*
GP Margin	*72%*	*67%*	*500 bps*	*65%*	*700 bps*
EBITDA	**82**	**68**	***20%***	**91**	***-10%***
EBITDA Margin	*26%*	*24%*	*200bps*	*26%*	*-*
PAT	**32**	**5**	***588%***	**18**	***76%***
PAT Margin	10%	2%	*800 bps*	5%	*500 bps*

Revenue Break-up (INR in cr.)



Result commentary

- Revenue growth came in at 11% on YoY basis, driven by healthy performance in our fast-growing verticals viz. FDF and Biologics.
- Gross margins for the quarter came in at 72%, driven by healthy product mix
- PAT at INR 32crs showed a robust growth of ~588% YoY

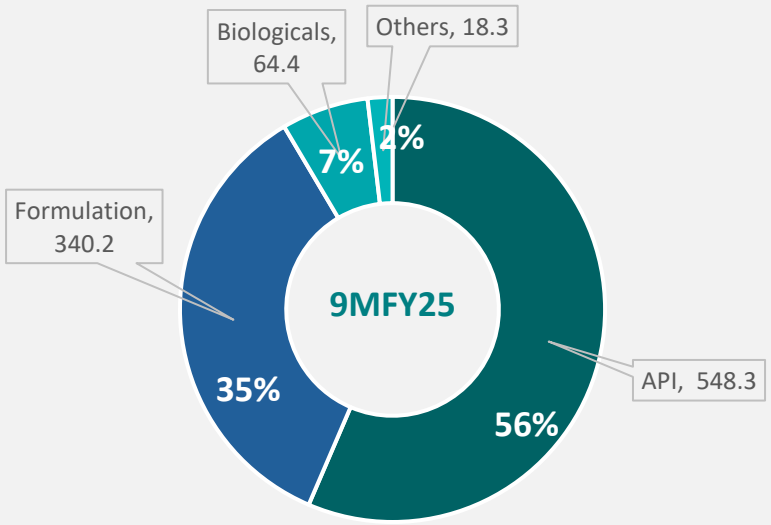
All numbers are rounded off to nearest one

9M FY25 – Financial Performance

Innovating for affordable healthcare

9M FY25 (Consolidated)			
Particulars (INR cr)	**9MFY25**	**9MFY24**	**YoY (%)**
Total Revenue	**971**	**866**	***12%***
Gross Profit	665	555	*20%*
GP Margin	*69%*	*64%*	*500bps*
EBITDA	**256**	**180**	***42%***
EBITDA Margin	*26%*	*21%*	*500bps*
PAT	**64**	**7**	***760%***
PAT Margin	7%	1%	*600bps*

Revenue Break-up (INR in cr.)



Result commentary

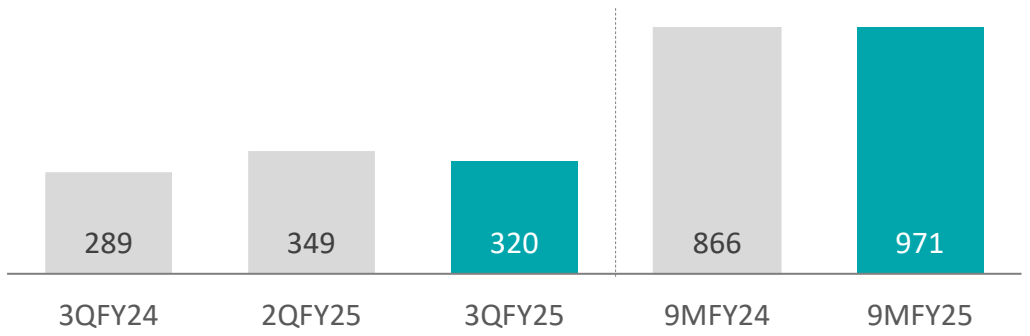
- Revenue growth came in at 12% on YoY basis, driven by healthy performance across our key verticals.
- Gross margins continue to improve at 69%, driven by better product mix
- EBITDA for 9MFY25 at INR 256crs is higher than the EBITDA of FY24, with EBITDA Margins of ~26%
- PAT stood INR 64crs, has nearly doubled of FY24 PAT of INR 32crs

All numbers are rounded off to nearest one

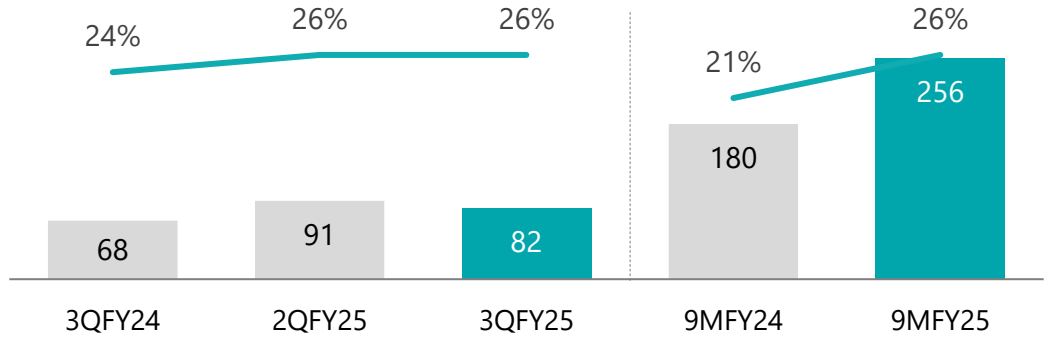
Consolidated Performance

(INR in Cr.)

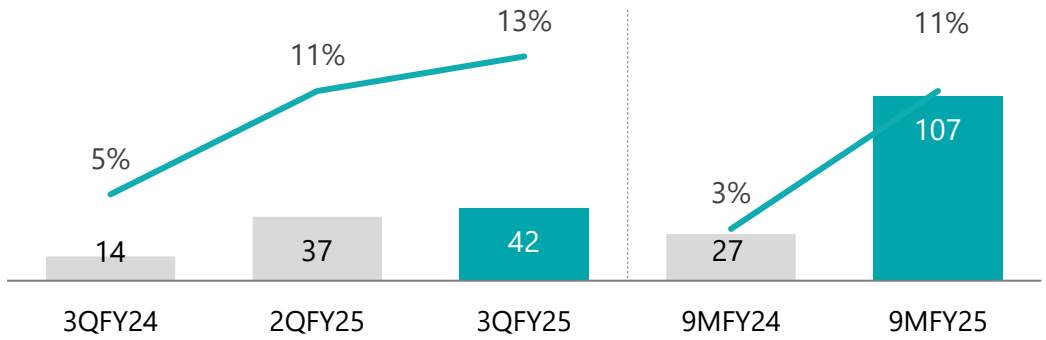
Revenues



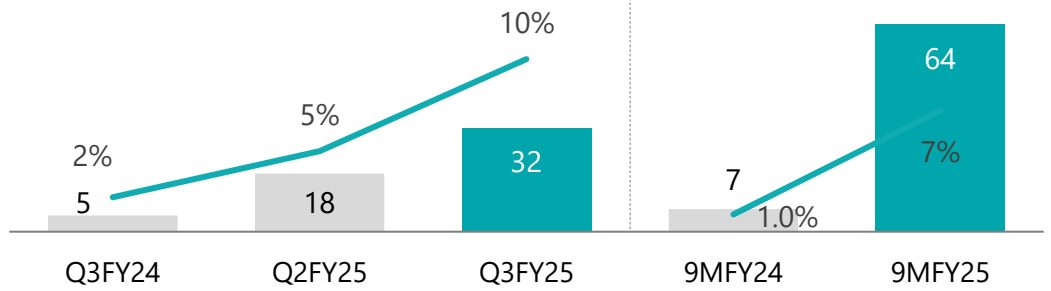
EBITDA and Margins



PBT and Margins



PAT and Margins



Financial Summary

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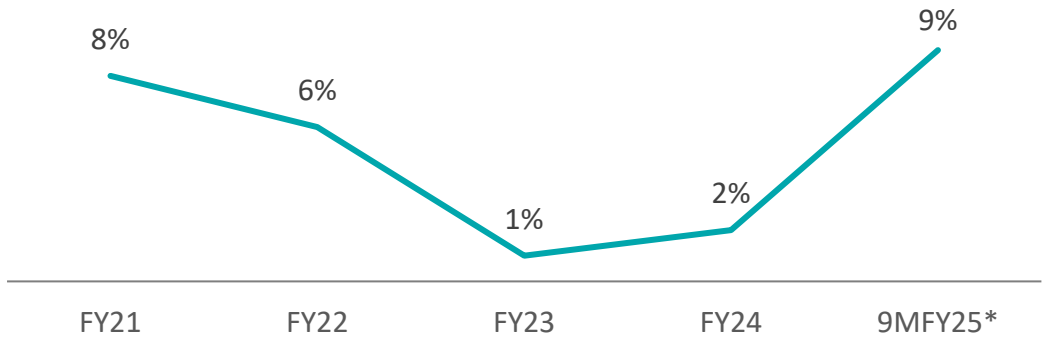
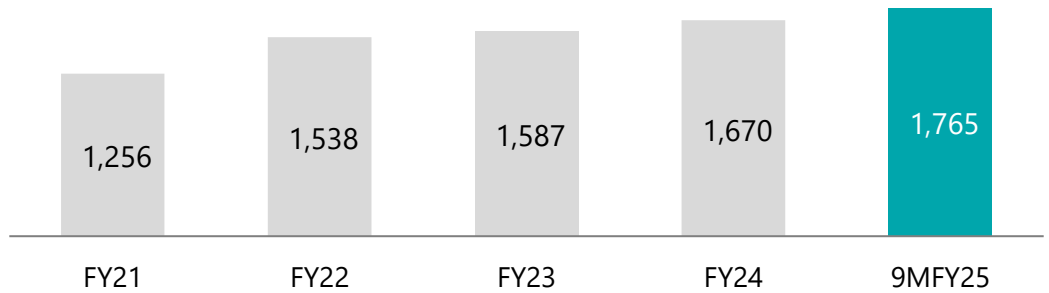
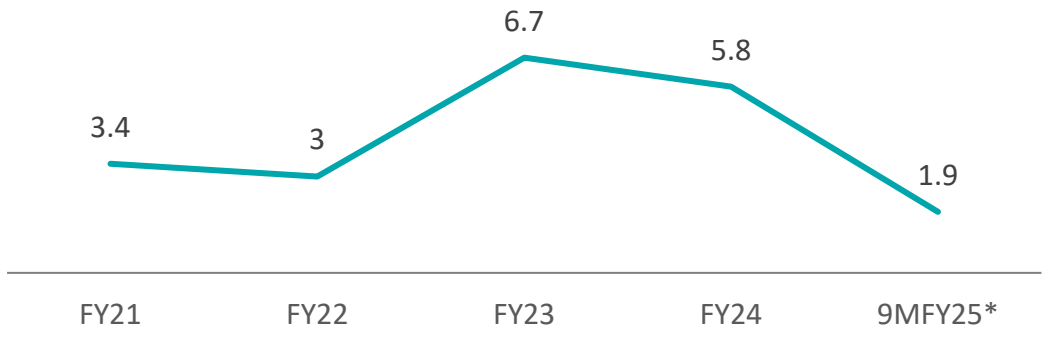
ROCE



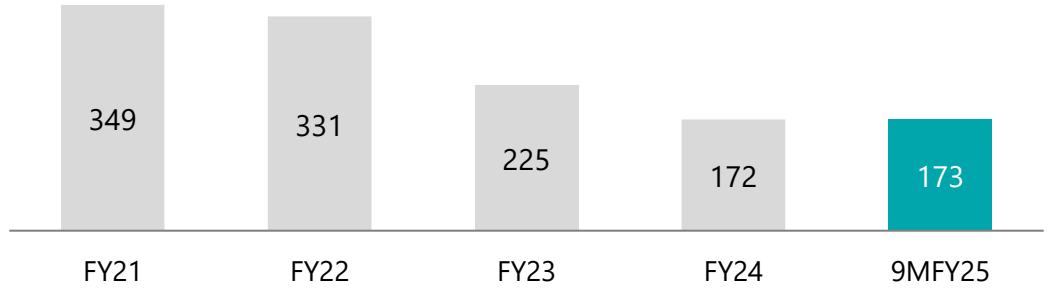
Gross Block (INR crs)



Net Debt to EBITDA (x)



Capex (INR crs)



Note: 9MFY25 Annualized *

API Business

API – Muted growth; order book remains healthy

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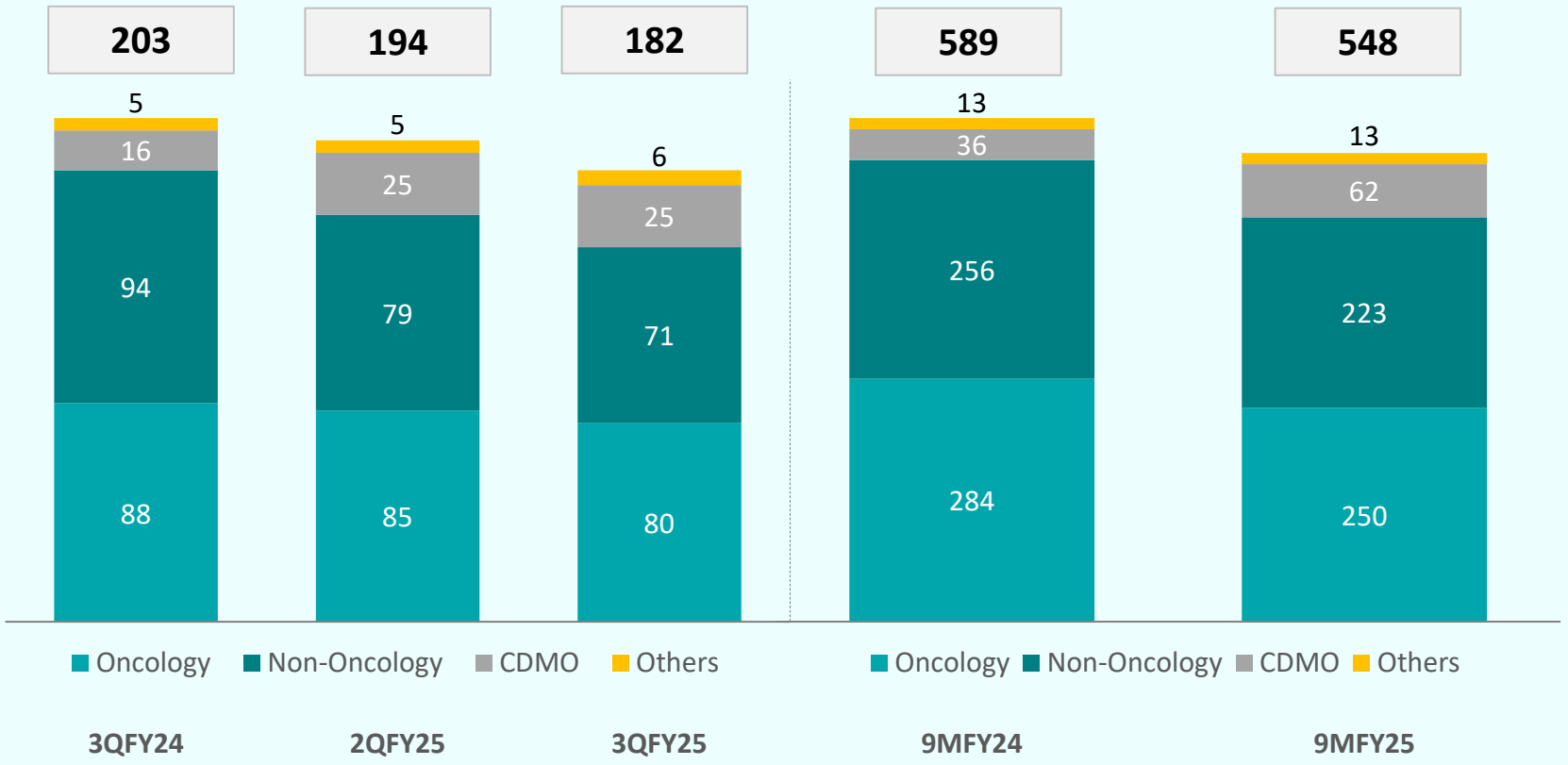
(INR in Cr.)



- 3QFY25 Revenue remained muted on account of lumpiness in client buying pattern.
- Completed capacity expansion for key products viz. UDCA, Tranexamic Acid, Palbociclib and Nilotinib. Likely to drive incremental growth from 1QFY26 onwards
- Expanding product portfolio with launches in multiple complex APIs and Specialty portfolio
- Added new clients in various geographies

API – Ongoing Developments

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API Molecules

- Increased capacity for key products viz. Nor UDCA, Palbociclib and Nilotinib. Commercialized expanded capacities of Tranexamic Acid
- Non-Infringing API of Nilotinib and Axitinib approved in EU market
- CEP filed for Methotrexate – an import substitute molecule
- Olaparib validation is expected to be complete in 4QFY25
- Successfully completed Mexican regulatory authority audit for both units, for 7 products.

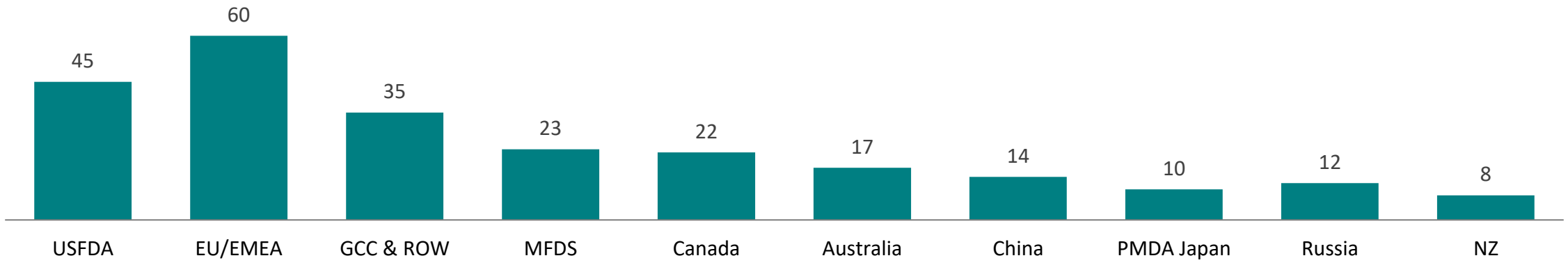
CDMO

- Successfully Completed Phase II supply for a multi-step complex chemistry project, offering One-Stop-Solution for drug substance and drug product development for US client.
- Commenced commercial production for launch quantities of OLC
- Started plant scaleup of 2 ongoing CDMO programs.
- In our ongoing NDA program, where we serve as our partner's CDMO, has been given fast track classification
- Increase in number of RFQs received from various global biotech companies

Polymer and Peptide

- 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.
- Developed a process for synthesizing polymer with varying molecular weights, widely used in biomedical applications, including drug delivery and tissue engineering
- GLP 1 - Liraglutide dossier readied by 4QFY25 and Semaglutide plant scaleup planned in 1QFY26.

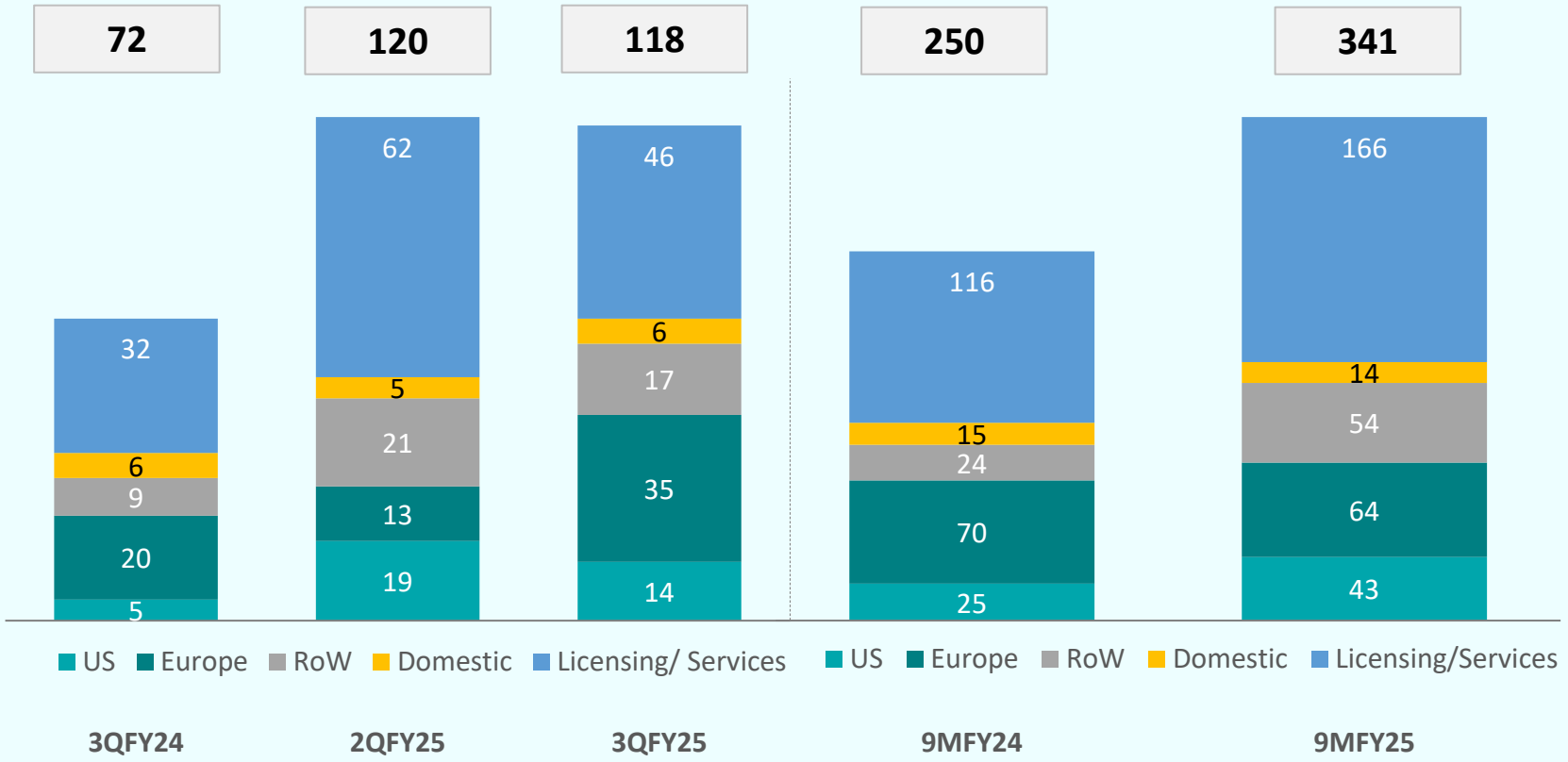
API – DMF Filings



New product introduction and increase in geographical coverage replicated with **246 DMF filings** with major regulatory authorities

Formulations Business

New product launches drive FDF revenue growth



(INR in Cr.)

- For the quarter, the division reported robust revenue growth of 64% on YoY basis
- Nilotinib Launch in EU region drove strong EU growth
- Received approval of our first ODF in EU region
- Scale up in pemetrexed on expected lines. Faster pick up expected in FY26
- Submitted remediation work with the US FDA for re-inspection of Jadcherla Unit
- 3 approved NDAs have limited competition. More NDAs will be filed in coming quarters

FDF – Update on key assets

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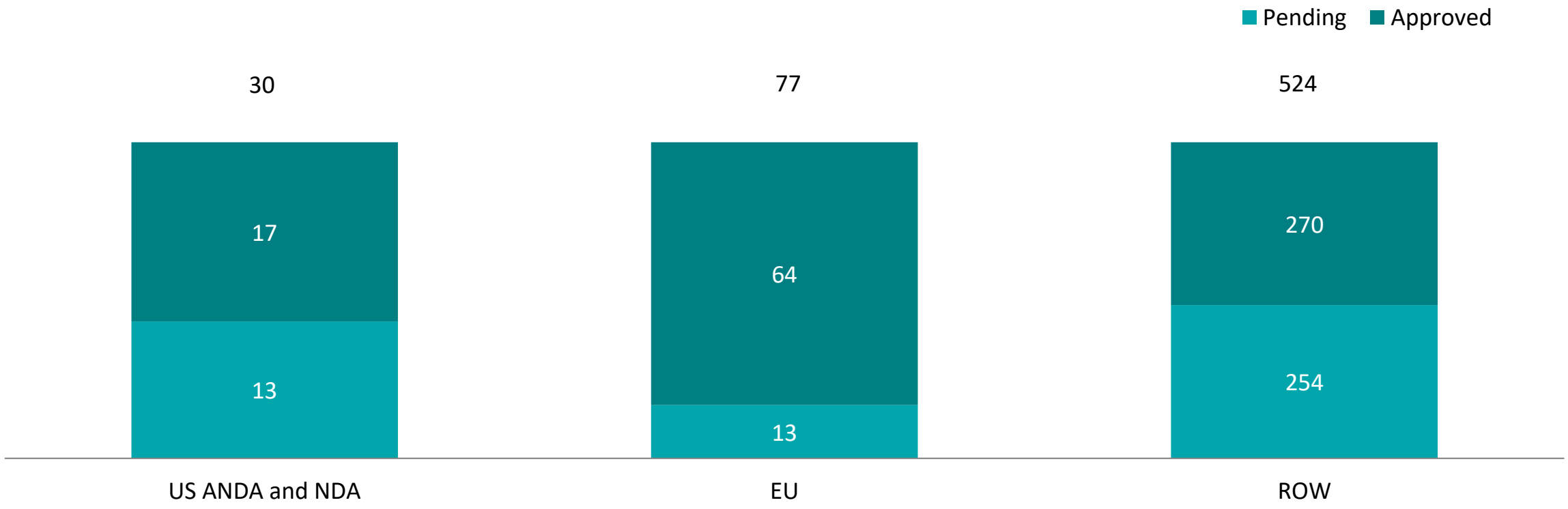
NorUDCA SMLNUD07	SMLTDP08	SMLTOP09	SMLODF010	SMLINJ011	ODF & TDS
▪ Phase III Studies for NAFLD completed and dossier submitted to Indian regulatory body ▪ Approval expected in FY25, with launch planned in 1HFY26. The product will be first NCE launch for NAFLD disease treatment for company.	▪ Transdermal Patch for treatment of Parkinson's disease ▪ US Study planned to initiate in 4QFY25 ▪ Europe submission completed in 2Q FY25 by our partner and expecting a limited competition launch in FY26.	▪ Topical lotion for treatment of Androgenic Alopecia ▪ Phase II completed and submitted to Indian regulatory body; Phase III study to start post approval ▪ EU Scientific advice filed.	▪ European market launch expected in FY26 ▪ Clinical trials for US will be initiated in 4QFY25	▪ Injection for prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer chemotherapy, radiotherapy and other associated medication. Market Size is ~$931 mn (Global) ▪ Phase I study completed; Approval received for initiating Phase III studies ▪ EU Scientific advise filed; US Pre-IND filed and expect response in 4QFY25	▪ Two new transdermal patch product development completed. Initiating human pilot study in 4QFY25 for our EU partner. The product is complex and uniquely positioned with no generic expected. ▪ Tadalafil ODF approved in EU market and expected to launch in FY26

*Source: IQVIA – MAT-June 24

Filings – Formulations



Robust regulatory filings to strengthen the base for growth in the formulation segment

As on 31st Dec 2024

Comprehensive CDMO Development Needs to be updated

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 with potential approval FY26

Long term manufacturing and supply agreement with SML.

Binding purchase order for supply of OLC tablets by 1QFY26; Additional tablets to be delivered from 3QFY26 onwards

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[1]

- 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
- Initial launch quantities to be delivered in 1QFY26
- Unicycive announced successful trial results and FDA acceptance of its New Drug Application for OLC, with a target decision date of June 28, 2025, potentially easing treatment for hyperphosphatemia in CKD dialysis patients.

1. Source: Unicycive Presentation

Biologics

Biologics – Growth envisioned on 4 pillars

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Biologics

- Adalimumab: India market growth based on approval of additional indications (Crohn's disease and Ulcerative colitis in adults) from Indian agency
- Aflibercept: Ophthalmic biologic with a global market size of ~$9 bn[1] initiated into ph3. Expected launch in FY26. Two other Indian players (vial only) at launch.

Novel Biologics

- Albumin India: Permission for India Phase III study received, trial starting in 1QFY26.
- Albumin Global: EU scientific advice for ph3 filed, expected feedback by 4QFY25; US advice to be filed subsequently, with feedback expected by 1HFY26.
- NBE asset in-licensing opportunities under evaluation

Integrated CDMO @Dharwad

- 3 CDMO projects in pharmaceutical segment are ongoing.
- 1 large microbial-based project under advanced discussions.
- 1 New project in food sector signed in Dec 2024.
- Extensive BD efforts are planned for expanding business in this segment.

Additional Products

- Nivolumab ~($10 bn)[1] , Pembrolizumab ~($26 bn)[1] , Abatacept ~($4 bn)[1] R&D initiated, PCT planned for all in 4QFY25 and target to start human studies in FY26.
- Wave 2 portfolio - 3 new blockbusters added and PCT planned 2025-26.
- With this there are 6 biosimilars in total at various stages of development and pipeline, having multi billion dollars of cumulative market size.

1. Global Market share, Source: IQVIA – MAT-June 24

Outlook FY26 and beyond

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FDF
6 key products (NDA-Pemetrexed, NDA – Bortezomib, Nilotinib, Axitinib, Rotigotine and NorUDCA) launches/Scale up to drive revenue materially

CDMO
Commercial launch of OLC in US to kick start significant revenue from CDMO division

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

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

Recombinant Albumin
The product has moved to Ph3 trials for India and filed for EU advice on Ph3 trials. The non – therapeutic usage is also being explored with large vol clients

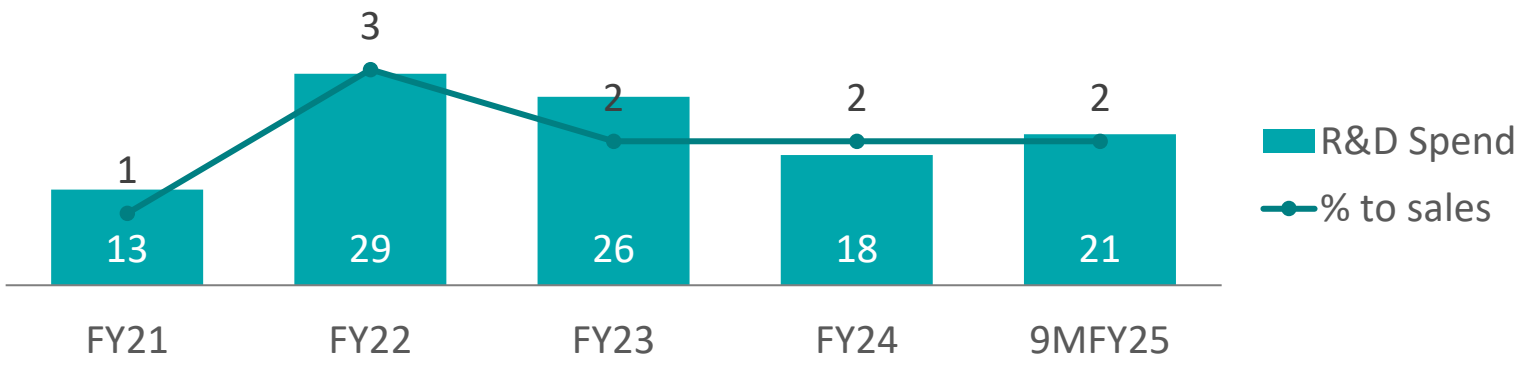
Licensing income
Various assets where licensing income was received are moving towards commercial long term supply agreements

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

R&D Capabilities

R&D Spend (INR crs)



Regulatory Filings	
API	246
Biologicals	10
Formulation	524
Total	**780**
No. of Scientists	**400+**

- 5 R&D sites across major cities in India
- Carefully crafted IP strategy for patent challenges and 505(b)(2) filings
- **API -** Developed capabilities in peptide, specialty and bio polymers manufacturing
- **FDF-** Differentiated Portfolio comprising of Onco and Non-Onco 505(b)(2) products. With key focus on ease of administration
  - Developed products in difficult to manufacture dosage forms viz. ODF & TDF
- **Biosimilar –** Capabilities to design and develop complex biologics with speed, quality, and innovation
  - Developed molecule viz. recombinant human albumin, an NBE, biosimilars product as well as vaccines
- Clone-to-Vial capabilities
- End-to-end biologics CDMO services for drug substances (mammalian and microbial) and drug products
- Capabilities in high density fermentation process development.

Manufacturing Capabilities – API & Biocare

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	API Unit 1 - Raichur	API Unit 2 - Raichur	Biocare - Kadechur
			
Capabilities	Onco, Non-Onco APIs and peptide, having competence for gram-to-kilo scale synthesis	• Isolation, purification, separation techniques. • Asymmetric synthesis. • Chiral technology. • CDMO	• Fully automated integrated facility with DCS control system • Filtration system for protein separation
Capacities	• 11 mfg blocks (4 onco and 7 non-onco) • Total reactor capacity of 650 KL	• 10 mfg blocks (5 onco and 5 non onco) • Total reactor capacity of 510 KL	• 200KL+ Fermentation capacity • Capacities ranging from 5 KL to 50 KL for product vessels and 5 KL to 15 KL for buffer vessels
Regulatory Accreditation	• USFDA • EUGMP • TGA • PMFDA • KFDA • WHO-GMP • TPD	• USFDA • EUGMP • TGA • PMFDA • KFDA • WHO-GMP • TPD	• Audit ready

Manufacturing Capabilities – Formulations & Biologics

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	Formulations - Jadcherla	Formulations - Bangalore	Biologics - Dharwad
Capabilities	OSD tablets and capsules; Injectables – dry powder and liquid lyophilization	Fully automated facility for Transdermal patches and Oral Thin Films	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
Capacities	Injectable - ~3mn Liquid Vials Lyophilized - ~2mn Vials OSD – 25mn Tablets Capsules – 4mn Hard Capsules	ODF - ~50mn Units TDF - ~30mn Units	Upstream – 4000LX2 Microbial Suite – SS 1000LX2 PFS – 80 units/min
Regulatory Accreditation	EU GMP, ANVISA, COFEPRIS, TGA, WHO-GMP, SHAPRA, Health Canada	WHO-GMP, UK-MHRA	• DSIR Approved facility

Financials

Profit & Loss Consolidated

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Particulars (INR cr)	3Q FY25	3Q FY24	YoY	2Q FY25	QoQ	9M FY25	9M FY24	YoY
Revenues	**320**	**289**	***11%***	**349**	***-8%***	**971**	**866**	***12%***
Gross Profit	229	192	*19%*	227	*1%*	665	555	*20%*
Gross Margin %	72%	67%		65%		69%	64%	
Employee Cost	74	69	*6%*	76	*-4%*	222	215	*3%*
Other Expenses	74	55	*35%*	60	*24%*	188	160	*17%*
EBITDA	**82**	**68**	***20%***	**91**	***-10%***	**256**	**180**	***42%***
EBITDA Margin %	26%	24%		26%		26%	21%	
Finance Cost	12	26	*-55%*	26	*-54%*	61	68	*-10%*
Depreciation	29	27	*8%*	28	*2%*	84	81	*4%*
PBT	**42**	**14**		**37**		**107**	**27**	
PAT	**32**	**5**		**18**		**64**	**7**	

All numbers are rounded off to nearest one

Earnings call Details

Shilpa Medicare 3Q and 9MFY25 Results Conference Call to be held
February 11, 2025, Tuesday at 11:00 AM

Details of Earnings Conference Call	
Universal Access	+91 22 6280 1107 +91 22 7115 8008
The number listed above is universally accessible from all networks and all countries	
International Toll-Free Numbers	
USA	18667462133
UK	08081011573
Singapore	8001012045
Hong Kong	800964448
DiamondPass™ Link	Click Here to join with DiamondPass™ (No Wait Time)

THANK YOU!

Shilpa Medicare

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Ernst & Young IR

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sneha2.salian@in.ey.com