

#### 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

#### 10 November 2023

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

Dear Sir/Ma'am,

Scrip Code: BSE - 530549/Stock Symbol: NSE - SHILPAMED

Sub: Investor Presentation of the Company for the Quarter ended 30 September 2023

Ref: Disclosure under Regulation 30 of SEBI (Listing Obligations and Disclosure Requirements)
Regulations, 2015

With reference to the captioned subject, the Investor Presentation of the Company for the Quarter & Half year ended 30 September 2023 on Business highlights, financial performance and other updates is enclosed herewith for your consideration.

We request you to take the same on record.

Thanking you.

Yours faithfully,
For **Shilpa Medicare Limited** 

RITU TIWARY
Date: 2023.11.10 19:48:45

Ritu Tiwary
Company Secretary & Compliance Officer



## Shilpa Medicare Limited (SML)

Q2 & H1 FY24 Results Presentation

### **Disclaimer**

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.



API Units, Raichur





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## Company Overview

## Company Overview







Established presence in **Active Pharmaceutical** Ingredients (APIs) and Formulations for domestic & international markets

Pursuing niche growth businesses like Biologics, Transdermal & Oral **Dissolving Films Formulations** 

Affordable & **Effective Pharmaceutical Solutions** 

Robust research orientation resulting in innovative products





Very strong R&D background including development, pathway engineering and characterization of biologics

Best in class manufacturing and supply of high-quality affordable drugs





## Managing Director's Message

#### Commenting on Q2 FY 24 performance, Mr. Vishnukant Bhutada, Managing Director Shilpa Medicare Limited said

"I am pleased to inform you that our relentless efforts on bringing operational efficiencies and strengthening our business is getting reflected in continuous improvement in our performance quarter after quarter. On the regulatory front, we have received approval for Betahistine Oral dispersible film for the UK market – our first product approval from our Bangalore Oral films plant and various other products are under filling. We have also received 3 product approvals for the Mexican market including the first generic approval of Axitinib. The launches in Mexico are planned in coming quarters.

Our Jadcherla facility recently received UAE GMP approval, Australia GMP approval and ANVISA Brazil approval with Nil observations. We have also concluded USFDA "for cause" inspection of our facility on 9<sup>th</sup> November with 10 observations. I would like to inform you that none of the observations relate to 'data integrity' or has been listed as 'repeat observation'.

For API business, we have successfully completed PMDA Japan regulatory audit without any major or critical observations for our API facility. Our CDMO business has been receiving positive responses from customers and is on growing path. Additionally, in the non-oncology API segment we are exploring products which have high growth potential or can serve as an import substitute.

As an organization we are committed to facilitating successful introduction of novel products within APIs and Formulations, ensuring predictable cash flows. As previously mentioned, we are actively streamlining our R&D spends and expediting the monetization process. By concentrating our efforts there, we aim to consistently lower R&D costs, resulting in substantial savings that will positively impact our cash flow without affecting the niche product developments

On biological front, we have launched **High concentration Adalimumab** in India under the brand name "**ORIADALI™**" which is a crucial step into the realm of our biological offerings, aimed at enhancing patient comfort in treating Rheumatoid Arthritis. Piggybacking on India approval and launch, our strategy extends to tapping into various international markets with this product. I am happy to inform you that we have also commenced phase 1 trials for **recombinant Albumin**, which is a pivotal move for this niche opportunity. Our large-scale fermenting facility is under erection and we expect the same to be completed by March 2024".



## Formulation update - Topical

#### **Topical Lotion (SMLTOP09) for the Treatment of Androgenic Alopecia**

- Phase II trial completed
- Phase III will be planned to be initiated in Q3 FY24
- Covered by granted patents in India, USA, China, Japan, Korea till June 2038
- Patent pending in Europe
- The global alopecia market is valued at \$8.2 billion in 2022 and is expected to grow at the CAGR of 9% from 2023 to 2030
- Alopecia Disease Types:

| Disease Subtype   | % of Market | Value in \$billion (2022) |
|---|-------------|---------------------------|
| Alopecia Areata   | 34.3%       | \$2.8 billion             |
| Androgenic  | 31.1%       | \$2.5 billion             |
| Alopecia  |             |                           |
| Cicatricial Alopecia, Traction Alopecia<br>Alopecia Totalis, Alopecia Universalis<br>And others | 34.5%       | \$2.8 billion             |

Scientific advice for EU successfully submitted and awaiting feedback in Q4 FY24



#### **SMLNUD07**:

- Received approval from CDSCO for proceeding further for Phase III studies of oral product SMLNUD07
- Phase III studies have been initiated for the indication of NAFLD (Non-alcoholic fatty liver disease)
- Tentative completion of the study Q1/Q2 FY25
- About NAFLD
  - Most common liver disease and it is estimated to affect up to 15% of the population in World (approx. 1.2 billion)
    - About 188 Million people suffer from develop NAFLD in India
  - The main characteristic of NAFLD is excessive accumulation of fat in hepatocytes
  - In first stage NAFLD is characterized by simple hepatic steatosis (NAFL, non-alcoholic fatty liver)



## Formulation update – Oral Films and Patches

#### Betahistine Dihydrochloride Orodispersible Films, 24 mg

- First company to receive approval for the 24 mg strength as a Film formulation in the UK
- Approval is a hybrid product application, which is bioequivalent to the reference product
- Indicated for the treatment of vertigo, tinnitus, hearing loss and nausea associated with Meniere's syndrome
- Available in the form of tablets and oral liquid dosage forms in various strengths across UK, Europe
- The ODF formulation offers benefits with respect to patient compliance and ease of administration
- Approval from own manufacturing facility at Dabaspet, Bengaluru



## Biosimilar update

#### Launch of High Concentration Adalimumab injection in India

- Used for the treatment of Rheumatoid Arthritis (moderate to severe active RA & severe active and progressive RA)
- Increased patient comfort based on reduced injection volume
- Launched Adalimumab under Shilpa own brand ("Oriadali™") in Aug 2023
- Other marketing partner expected to launch in Q3 FY24

#### **Recombinant Albumin**

- Phase I initiated for the product
- Product has been granted NBE(New Biological Entity) status

#### Aflibercept

Phase III approval received from CDSCO and plans to initiate a Phase 3 clinical trial in Q3FY24

#### **CDMO**

First CDMO project for microbial fermentation from a client for the Korea Market



## Financial Performance

### Financial Performance – SML Standalone

| Particulars                    | Q2 FY24 | Q1 FY24 | %<br>change | Q2 FY23     | %<br>change |
|--------------------------------|---------|---------|-------------|-------------|-------------|
| Revenues                       | 97.4    | 104.5   | -7%         | 86.8        | 12%         |
| Gross Margin                   | 78.7    | 84.9    | -7%         | 54.1        | 46%         |
| Gross Margin %                 | 81%     | 81%     | 0%          | 62%         | 30%         |
| Employee Cost                  | 26.3    | 27.8    | -5%         | 29.6        | -11%        |
| Other Expenses                 | 22.4    | 21.0    | 7%          | 30.8        | -27%        |
| EBITDA                         | 30.0    | 36.1    | -17%        | -6.4        | 570%        |
| EBITDA %                       | 31%     | 35%     |             | <b>-7</b> % |             |
| Finance Cost                   | 5.2     | 6.8     | -23%        | 4.9         | 5%          |
| Depreciation                   | 12.7    | 12.3    | 3%          | 11.9        | 6%          |
| PBT                            | 12.2    | 17.1    | -29%        | -23.2       | 153%        |
| Execeptional Item-(Income)/Exp | 0.2     | 6.3     | -97%        | 0.6         | -64%        |
| PAT                            | 6.6     | 7.9     | -16%        | -17.2       |             |



### Balance Sheet — SML Standalone



| Particulars                         | 30-Sep-23 | 30-Jun-23    | 30-Sep-22 |
|-------------------------------------|-----------|--------------|-----------|
| Fixed Assets                        | 598.9     | <i>598.3</i> | 603.0     |
| Tangible Assets                     | 512.5     | 509.1        | 529.8     |
| Intangible Assets                   | 86.4      | 89.2         | 73.2      |
| Capital WIP                         | 227.4     | 230.5        | 251.5     |
| Tangible Assets                     | 27.1      | 38.7         | 54.1      |
| Intangible Assets                   | 200.3     | 191.8        | 197.4     |
| Slump Sale Consideration Receivable | 0.0       | 249.0        | 435.3     |
| Other Non-current Assets            | 1188.8    | 1122.8       | 960.7     |
| Net Working Capital                 | 260.7     | 228.8        | 251.1     |
| Current Assets                      | 329.6     | 300.7        | 305.6     |
| Cash and cash equivalents           | 6.7       | 11.8         | 36.4      |
| Current Liabilities                 | -75.6     | -83.7        | -90.9     |
| Total Assets ( Net)                 | 2275.8    | 2429.4       | 2501.7    |
| Equity                              | 2131.9    | 2125.3       | 2148.5    |
| Borrowings (Current & Non current)  | 108.5     | 271.8        | 312.1     |
| Other Non Current Liabilities       | 35.4      | 32.3         | 41.2      |
| Total Liabilities                   | 2275.8    | 2429.4       | 2501.7    |



| Particulars    | Q2 FY24 | Q1 FY24 | % change | Q2 FY23 | % change |
|----------------|---------|---------|----------|---------|----------|
| Revenues       | 314.8   | 262.1   | 20%      | 267.3   | 18%      |
| Gross Margin   | 189.0   | 173.9   | 9%       | 150.8   | 25%      |
| Gross Margin % | 60%     | 66%     |          | 56%     |          |
| Employee Cost  | 73.1    | 72.9    | 0%       | 73.6    |          |
| Other Expenses | 53.8    | 51.2    | 5%       | 60.7    | -11%     |
| EBITDA         | 62.1    | 49.8    | 25%      | 16.5    | 275.7    |
| EBITDA %       | 20%     | 19%     |          | 6%      |          |
| Finance Cost   | 23.2    | 18.2    | 28%      | 13.5    | 72%      |
| Depreciation   | 27.8    | 26.7    | 4%       | 23.3    | 19%      |
| PBT            | 11.1    | 5.0     | 124%     | -20.2   | -155%    |
| PAT            | 1.6     | 1.2     | 37%      | -18.6   | -109%    |



### **Balance Sheet Consolidated**

(INR in Cr.)

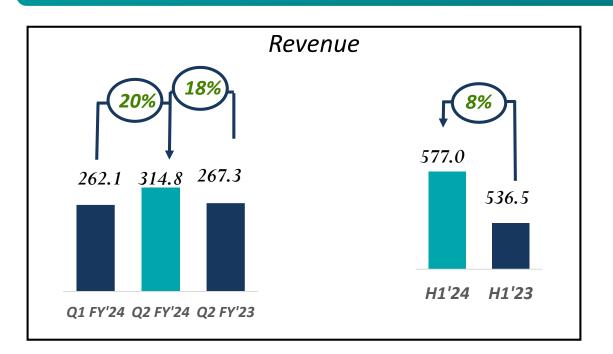
|                                    | Consolidated |           |              |  |  |
|------------------------------------|--------------|-----------|--------------|--|--|
| Particulars                        | 30-Sep-23    | 30-Jun-23 | 30-Sep-22    |  |  |
| Fixed Assets                       | 1,361.0      | 1,371.6   | 1,353.7      |  |  |
| Tangible Assets                    | 1,160.0      | 1,163.7   | 1181.8       |  |  |
| Intangible Assets                  | 201.0        | 208.0     | 171.9        |  |  |
| Capital WIP                        | 681.2        | 657.1     | 602.9        |  |  |
| Tangible Assets                    | 389.1        | 377.7     | 302.3        |  |  |
| Intangible Assets                  | 292.1        | 279.3     | 300.6        |  |  |
| Other Non-current Assets           | 136.8        | 123.8     | 117.3        |  |  |
| Net Working Capital                | 501.6        | 454.8     | <i>587.6</i> |  |  |
| Current Assets                     | 801.4        | 732.0     | 851.7        |  |  |
| Cash and cash equivalents          | 23.7         | 33.0      | 57.2         |  |  |
| Current Liabilities                | -323.5       | -310.2    | -321.3       |  |  |
| Total Assets ( Net)                | 2,680.5      | 2,607.2   | 2,661.5      |  |  |
| Equity                             | 1,774.6      | 1,772.9   | 1787.9       |  |  |
| Borrowings (Current & Non current) | 863.5        | 789.0     | 800.9        |  |  |
| Other Non Current Liabilities      | 42.4         | 45.3      | 72.8         |  |  |
| Total Liabilities                  | 2,680.5      | 2,607.2   | 2,661.5      |  |  |

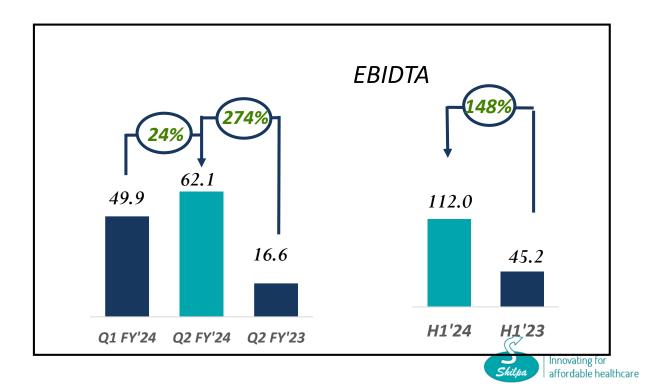


## **Business Highlights**

(INR in Cr.)

#### H1 FY 24 Consolidated Performance

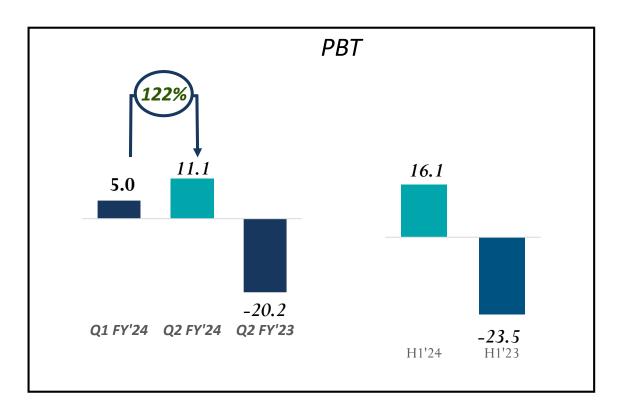


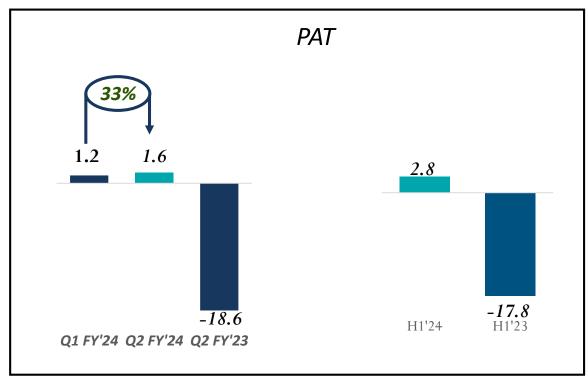


#### H1 FY 24 Consolidated Performance



(INR in Cr.)



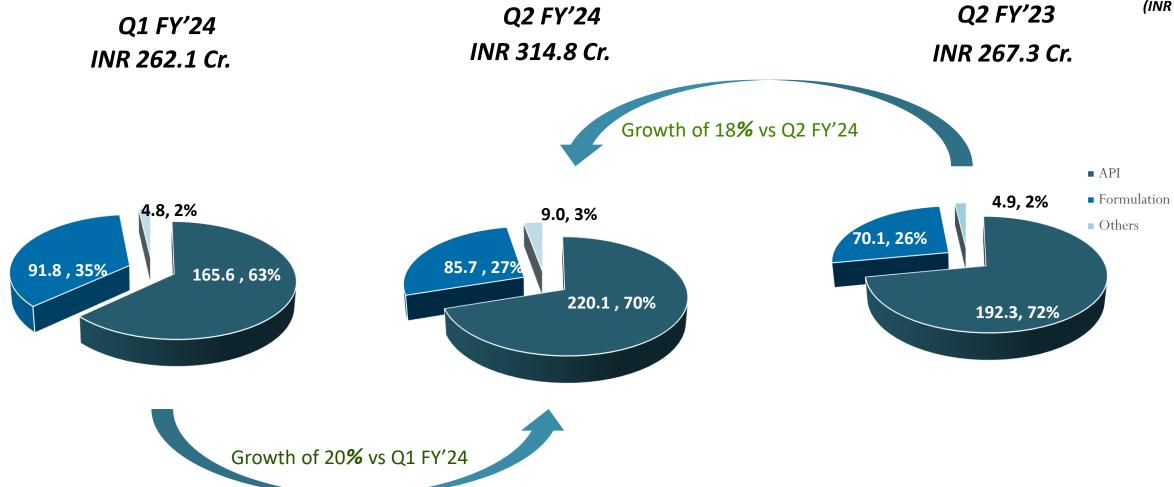


- ❖ PBT excluding share of loss in JV/Associates
- Excluding exceptional items

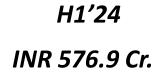


### Consolidated Revenue Break-up – Q2 24









H1'23 INR 536.6 Cr.





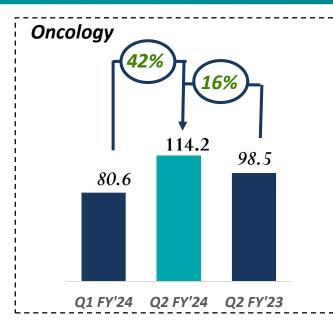
## API Business



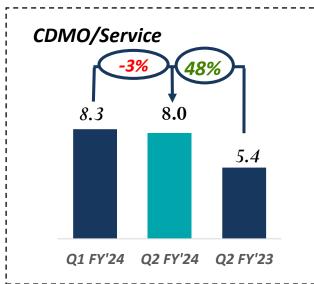
#### API Business-Highlights Q2 FY 24

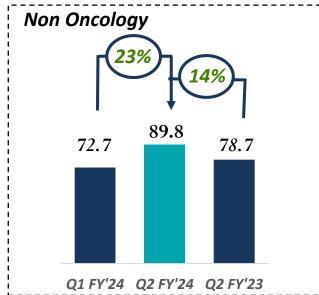


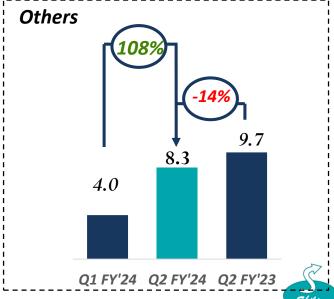
affordable healthcare









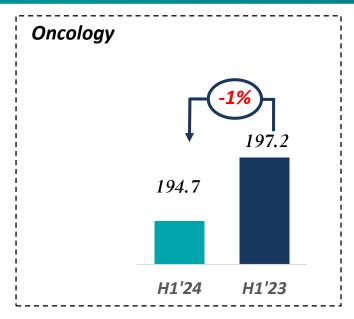


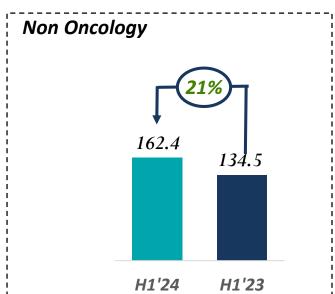
\*Numbers are excluding captive consumptions

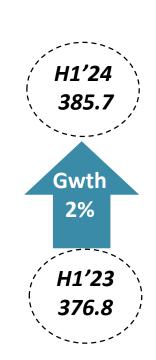
### API Business-Highlights H1 FY 24

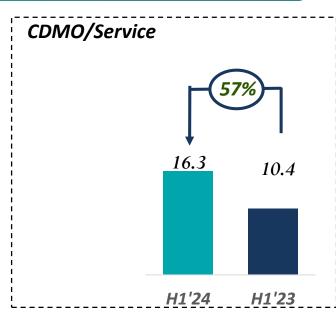


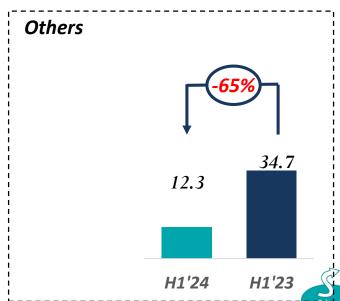
Innovating for affordable healthcare







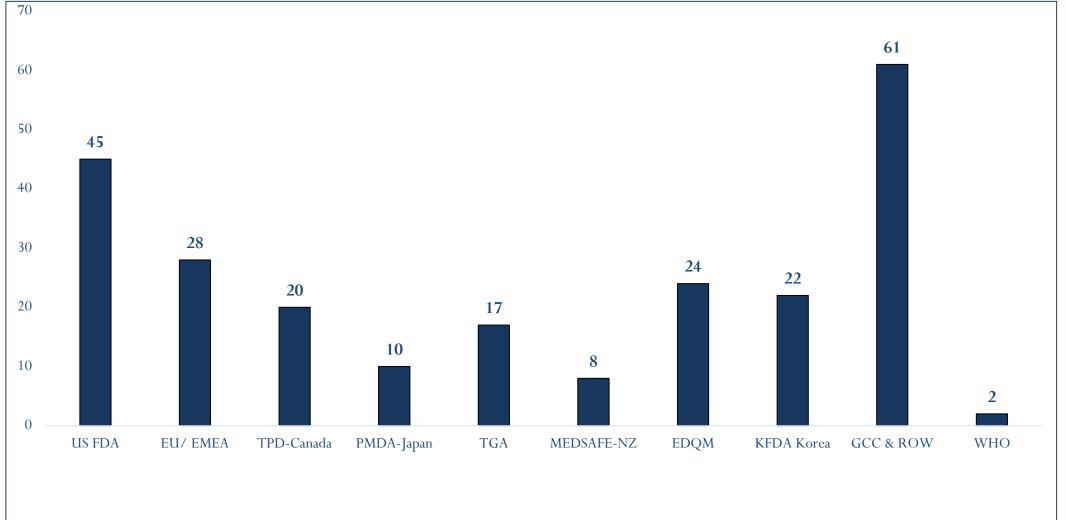




\*Numbers are excluding captive consumptions

## DMF Filing update

New product introduction and increase in geographical coverage replicated with **237** number of **DMF filings** done with major regulatory authorities





## Formulation Business

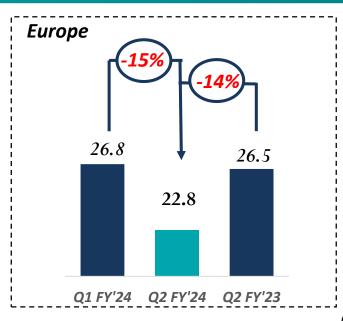


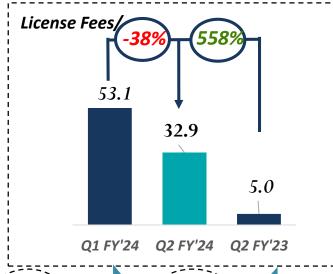
#### Formulation Business- Highlights Q2 FY 24

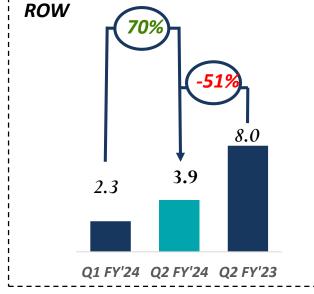


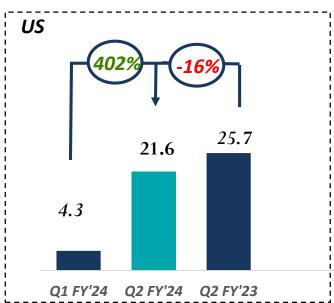
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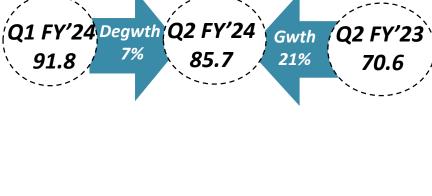
affordable healthcare

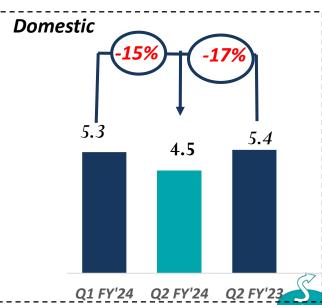










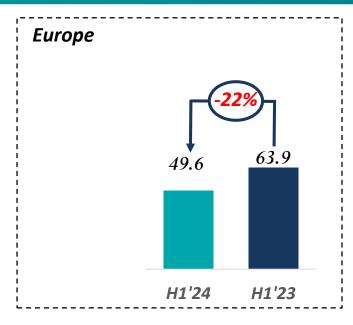


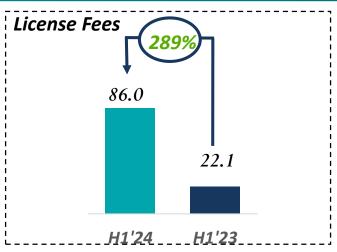
#### Formulation Business-Highlights H1 FY 24



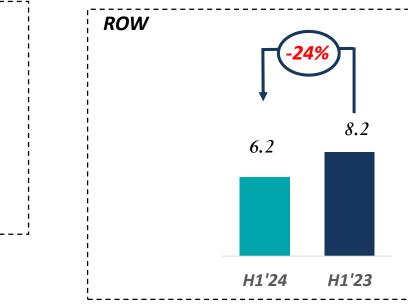
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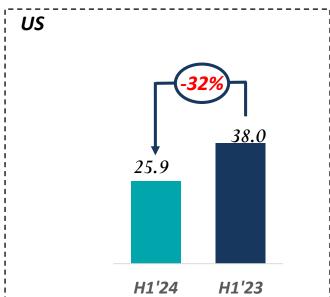
Innovating for affordable healthcare

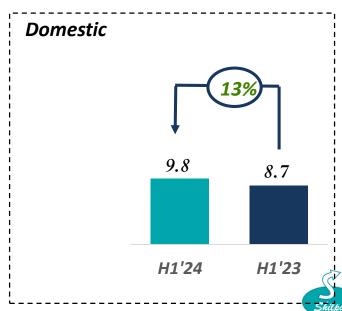








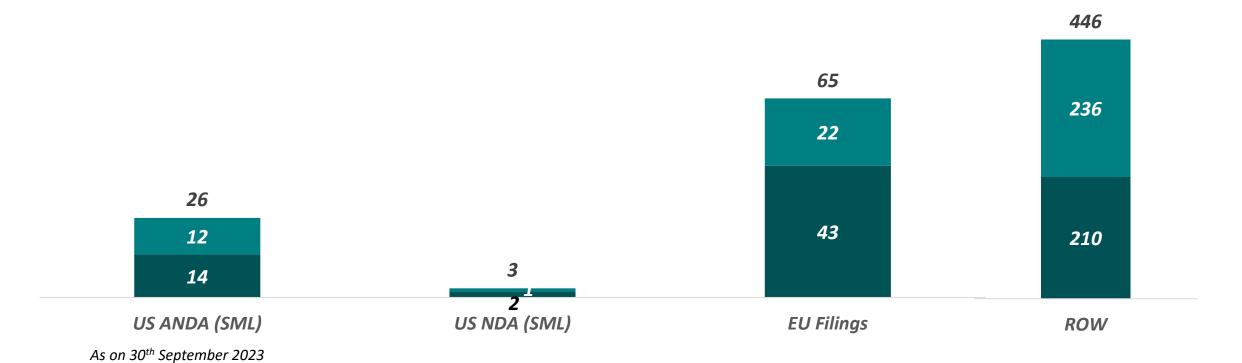




## Regulatory Filings

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

■ Approved ■ Pending





## Annexures

## Manufacturing Excellence

#### **Dharwad**



Biologicals Manufacturing plant & R&D Facility

#### **Bengaluru Unit**



 TDS & ODF Manufacturing Facility & Formulation R&D

#### Raichur Unit I & II



- API (Oncology Non-Oncology)
- API (Oncology Non-Oncology) and R&D API
- CRAMS
- Peptide
- Polymer

#### **Jadcherla Unit**



 Formulations (Onco & Adjuvant Therapy of Onco – Injectable & Oral)

#### **Hyderabad**



- Formulations (Oral Dissolving Films)
- Bio Analytical Lab, Pharmacovigilance Lab & Quality control lab

#### **Ahmedabad**



- CRO & CDMO
- R&D Formulation



## About Shilpa Medicare Ltd.

Shilpa Medicare Limited (SML) started its operations as API manufacturer way back in 1989 at Raichur, Karnataka-India. Today Shilpa Medicare Limited is a global brand in manufacturing and supplying of affordable API and Formulation globally in different regulated markets.

Shilpa Medicare has been on path of expansion ever since its inception. With a regulatory recognized manufacturing set up and excellent scientific expert team in place, Shilpa Medicare has since been on a steady growth path. Currently they are one of the leaders in the Oncology market and offer a complete range of products in this segment spanning across APIs, formulations both in terms of R&D and manufacturing capabilities. Further to consolidate in field of Oncology, API and formulations, they are striving to put in efforts in field of novel drug delivery systems and biotech products along with widening their focus to other therapy areas. Where Shilpa Medicare Ltd is today is the result of their constant endeavors for more than three decades.



**Siddharth Rangnekar** Mit Shah





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# Thank You

