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

Dated: 29th October, 2021

To
Corporate Relationship Department
BSE Limited
01st Floor, Routunda Building,
PJ Towers, Dalal Street,
Mumbai – 400001

To
National Stock Exchange of India Limited.
Exchange Plaza, 05th Floor,
Plot No: C/1, G Block,
Bandra Kurla Complex, Bandra €
Mumbai - 400051

Dear Sir/Madam

Sub: Presentation made to analysts and investors.
Reg: Regulation 30 of the SEBI (Listing Obligations and Disclosure Requirements) Regulations, 2015

Scrip Code: BSE: 530549
Stock Symbol: NSE: Shilpamed

Pursuant to Regulation 30 of Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015, please find enclosed herewith the copy of presentation made to analysts and investors in connection with Un-Audited Standalone & Consolidated Financial Results for quarter and half year ended 30th September, 2021.

Kindly take the same into your records.

For Shilpa Medicare Limited.

V V Krishna Chaitanya
Digitally signed by V V Krishna Chaitanya
Date: 2021.10.29 21:05:38 +05'30'

V V Krishna Chaitanya
Company Secretary & Compliance Officer.

Innovating for affordable healthcare

Shilpa Medicare Limited (SML)

Q2 FY22 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 Unit, Raichur

Company Overview

Table of Contents

Financial Performance

Abridged P&L Statement - Consolidated

(Rs. In Lakhs)

Particulars	Q2 FY22	Q2 FY21	Change (%)	H1 FY22	H1 FY21	Change (%)
Total Income (I+II)	29,655	28,814	3	53,590	51,648	4
I. Total Revenue from Operations (A+B+C+D)	29,527	27,894	6	53,263	50,180	6
•API (A)	19,055	16,508	15	32,170	32,556	(1)
•Formulations (B)	9,105	10,119	(10)	18,510	15,221	22
•Service Revenue & Product License Fees (C)	1,144	1,073	7	2,165	1,827	18
•Others (D)	223	194	15	417	576	(28)
II. Other income	128	920	(86)	327	1,468	(78)
Total Expenditure	24,211	21,025	15	44,759	36,737	22
EBITDA	5,444	7,789	(30)	8,831	14,911	(41)
EBITDA margin (%) to Total Income	18%	27%	-	16%	29%	-
Exceptional (Income)/Expenses (Net of Taxes)	(891)	-	-	(891)	(6,084)	(85)
Finance Costs	1,158	395	193	2,190	796	175
Depreciation and Amortization	1,918	1,270	51	3,681	2,502	47
Tax Expenses	1,156	1,599	(28)	1,512	4,514	(67)
Effective Tax Rate (%)	35%	26%	-	39%	26%	-
PAT (incl. exceptional item & before Non - Controlling Interest (net))	1,989	4,521	(56)	2,150	13,119	(84)
PAT Margins (%)	7%	16%	-	4%	25%	-
Share of Profit/(Loss) of Non-Controlling Interest (net)	(7)	(17)	(57)	(5)	(50)	(91)
PAT after Share of profit/(loss) of JV/Associates & Non controlling interest	1,996	4,538	(56)	2,155	13,169	(84)
PAT Margins (%)	7%	16%	-	4%	25%	-

Abridged P&L Statement - Standalone

(Rs. In Lakhs)

Particulars	Q2 FY22	Q2 FY21	Change (%)	H1 FY22	H1 FY21	Change (%)
Total Income (I+II)	29,498	27,020	9	54,512	48,947	11
I. Total Revenue from Operations (A+B+C+D)	28,587	26,268	9	52,620	47,931	10
•API (A)	19,055	16,508	15	32,170	31,216	3
•Formulations (B)	8,732	8,641	1	18,930	14,727	29
•Service Revenue & Product License Fees (C)	577	925	(38)	1,103	1,551	(29)
•Others (D)	223	194	15	417	437	(5)
II. Other income	911	752	21	1,892	1,016	86
Total Expenditure	22,194	18,130	22	42,194	32,035	32
EBITDA	7,304	8,890	(18)	12,318	16,912	(27)
EBITDA margin (%) to Total Income	25%	33%	(25)	23%	35%	(35)
Exceptional (Income)/Expenses (Net of Taxes)	(891)	-	-	(891)	(5,295)	(83)
Finance Costs	785	334	135	1,484	688	116
Depreciation and Amortization	1,313	984	33	2,481	1,975	26
Tax Expenses	1,736	2,095	(17)	2,367	5,452	(57)
Effective Tax Rate (%)	28%	28%	3	26%	28%	(8)
PAT Period/year from continuing operations incl. exceptional item	4,362	5,478	(20)	6,877	14,092	(51)
PAT Margins (%)	15%	20%	(27)	13%	29%	(56)

In relation to the import alert issued by the USFDA for the Jadcherla unit, the Company has initiated extensive remedial measures. The incremental costs incurred on account of the USFDA import alert is Rs.465.02 Lakhs in Q2 FY22

Managing Director's Message

Commenting on Q2 FY'22 performance, Mr.Vishnukant Bhutada, Managing Director Shilpa Medicare Limited said

"I am pleased to share we have improved our growth trajectory over the past quarters with a growth of 3%. Revenues for the quarter stood at Rs. 29,655 lakhs as against Rs. 28,814 lakh in the corresponding period last year. APIs continues to be the backbone of our business and our strategy of focusing on long-term opportunities through niche business of peptides, polymers & CDMO services will bear fruit in the coming periods. Formulation sales sustained momentum given higher traction in EU and rest of the world markets in addition to the sale of exempted products into the US.

I am furthermore happy to share that through SML's wholly owned subsidiary, Shilpa Biologicals entered into a definitive agreement with Cadila Healthcare Ltd (CHL) for production and supply of the ZyCov-D, a vaccine drug substance. ZyCov-D is the first DNA plasmid vaccine in the world for human use developed indigenously by CHL against the Covid-19 virus. It is also the first COVID-19 vaccine for adolescents in the 12-18 age group. SML has taken another step towards supporting the nation battle the pandemic.

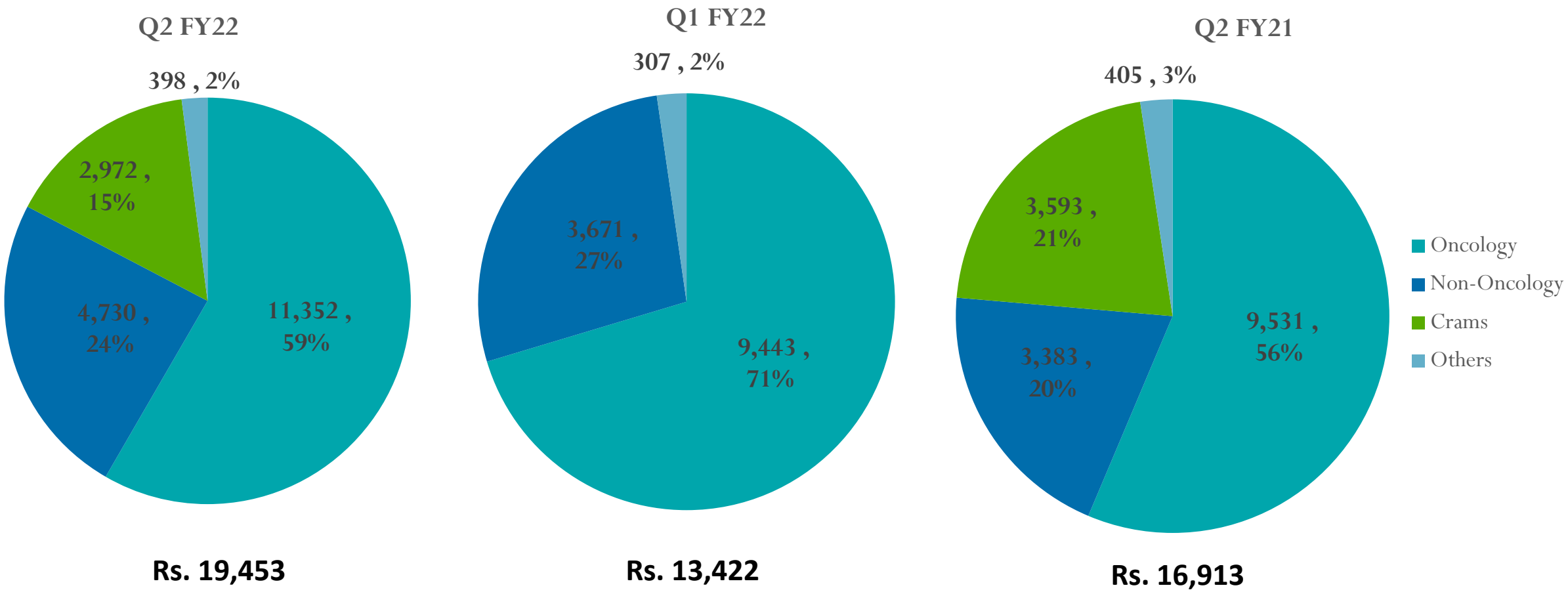
We believe that our attractive pipeline in formulations and investments in Biologics including our potential technology product of recombinant albumin will serve as a strategic growth lever, allowing us to expand meaningfully in the future."

Discussion of Select Business Segments

API - Highlights

Segment wise sales (including service revenue)

(Rs. In Lakhs)



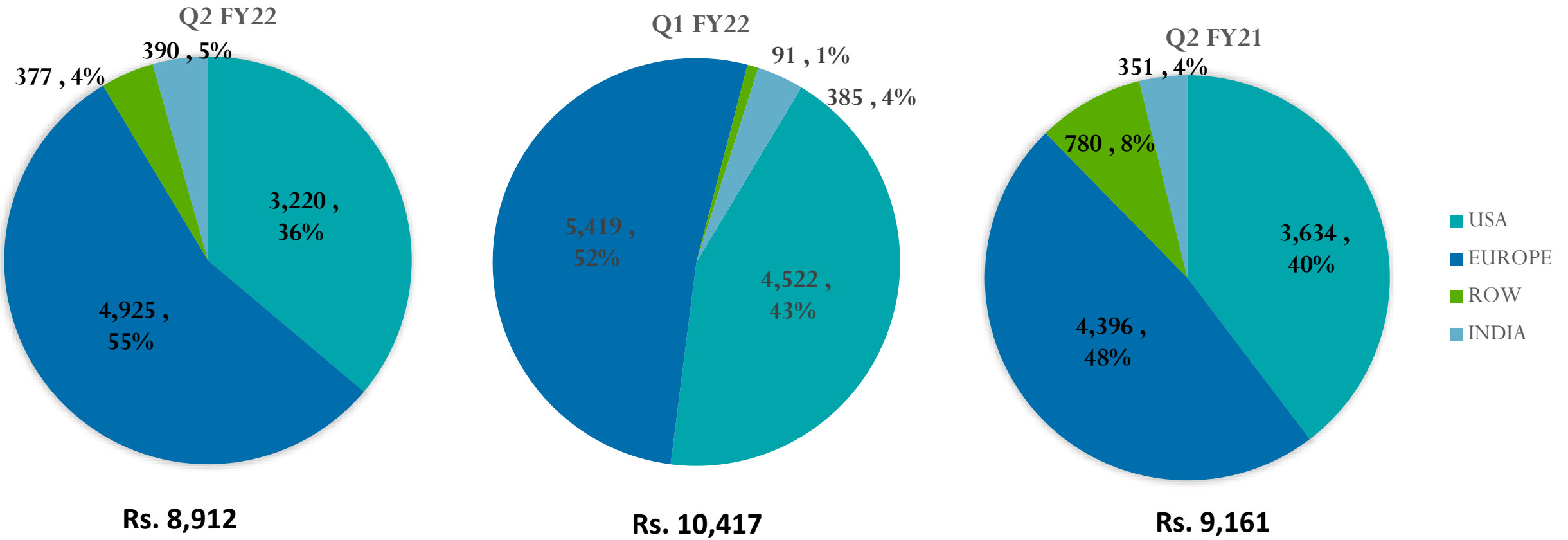
- Growth of 45% over Q1'FY22
  - Including CRAMS business of Rs. 2,972 lakh
  - Excluding CRAMS business – growth of 23%

- Capacity enhancements have resulted in incremental sales in Q2 FY22
- Gemcitabine supplies for Phase III clinical trials commenced

Formulation - Highlights

Revenue Split (including service revenue)

(Rs. In Lakhs)



- Actively worked on hedging strategy to de-risk the current USDFA challenges
  - Out of six product site transfer, one product successfully completed
- Requesting a meeting with USFDA in Q3 FY22

Shilpa | Innovating for affordable healthcare

Other Updates

Contribution towards combating to Covid-19 pandemic

Entered in an agreement with Cadila Healthcare Ltd (CHL) for production-supply of the ZyCov-D vaccine drug substance

- The Company will manufacture the drug in its integrated Biologics R&D cum Manufacturing center at Dharwad, Karnataka through its wholly owned subsidiary Shilpa Biologicals
- The targeted production of the ZyCoV-D vaccine from this facility will be mutually agreed upon by both parties
- ZyCoV-D is the first DNA plasmid vaccine in the world for human use which was developed by CHL and is also the first COVID-19 vaccine for adolescents in the 12-18 age group
- SML has identified the biologics business as a key strategic growth lever and continues to make significant investments in Shilpa Biologics

Contribution towards combating to Covid-19 pandemic

Sputnik V vaccine update

- Shilpa Biologicals Pvt Ltd, (SBPL) has entered in a 3-year definitive agreement with Dr. Reddy's Laboratories for the production-supply of Sputnik V vaccine from its integrated Biologics R&D cum manufacturing center
- The targeted production of the dual vector Sputnik V for the first 12 months is 50 million doses (50 million of dose 1 and 50 million of dose 2), from the start date of commercial production
- DRL conducting Bridging studies for India for Sputnik Light in Q3 FY22 which would include product manufacturing by SBPL

Current Status on USFDA Warning Letter

USFDA updates on formulation facility

- Completed gap assessment and ongoing remediation in place for the two major areas of concern cited by the USFDA
  - Handling of complaints and
  - Handling of laboratory investigations
- A Master Compliance Action Plan will be submitted to FDA in Q3FY22
- Requesting a meeting with USFDA in Q3FY22
- Filing of new ANDA/NDA applications continues and the review from Agency is ongoing
- Site transfer batches of one product have been successfully made at a CMO and shall be filed in the Q3/Q4 FY22
- Remedial actions in various areas are in full swing with the help of 3rd party consultants

Patents Status as on September30, 2021

Patents	Filings	Granted	Pending
- API	207	43	164
- Formulation *	182	28	154
- Films Topical & Transdermal	61	6	55
- Biologicals	12	4	8
- Others	22	5	17
TOTAL	**484**	**86**	**398**

* Formulation numbers includes the Patents of FTF Pharma Pvt Ltd Ahmedabad, a wholly owned subsidiary of Shilpa Medicare Ltd

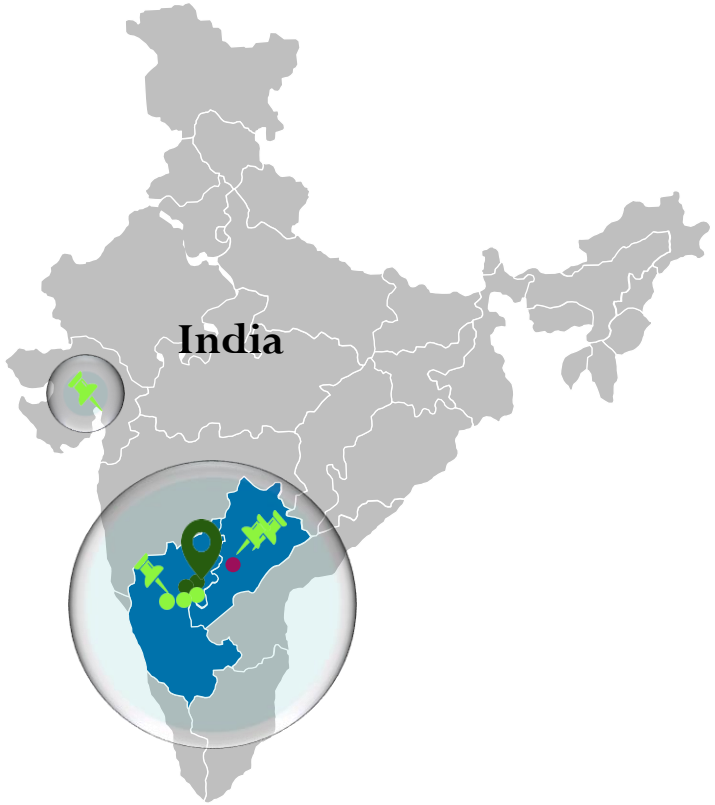
Formulation Product Pipeline as on September 30, 2021

Regulatory Submissions	Filings	Approved (Including Tentative)	Pending
- **US ANDA**: SML	25	13	12
- **US NDA:** SML	03	01	02
- **US ANDA:** Customers	18	13	05
TOTAL (In US)	46	27	19
- EU Filing	25	18	07
- Row Filling	254	79	175
TOTAL (In EU & ROW)	279	97	182
GRAND TOTAL	325	124	201

Manufacturing Excellence

India

Facility Location	Facility Type
Dharwad	Biologicals Manufacturing plant & R & D Facility
Bengaluru Unit	TDS & ODF Manufacturing Facility & Formulation R & D
Raichur Unit I	API (Oncology – Non-Oncology)
Raichur Unit II	API (Oncology – Non-Oncology) and R & D API
Jadcherla Unit	Formulations (Onco & Adjuvant Therapy of Onco – Injectable & Oral)
Hyderabad Unit	Formulations (Oral Dissolving Films)
Hyderabad	Bio Analytical Lab, Pharmacovigilance Lab & Quality control lab
Ahmedabad	R & D Formulation



Company's Headquarters at Raichur, Karnataka, India

Manufacturing Facilities

- 2 API plants at Raichur, India
- 4 R & D units (Bengaluru, Dharwad, Raichur and Ahmedabad, India)
- 1 Manufacturing site for Biologicals at Dharwad, India
- 3 Formulation plants at Jadcherla, Hyderabad and Bengaluru, India

Ramping Up Capacities

Established Business

API

- 9 dedicated blocks for Oncology & 4 blocks for Non-Oncology
- Multi-product capability for Oncology & Non-Oncology
- Expansion of various API capacities
- Peptide and Polymer divisions added which lends further capacity
- CDMO introduced to existing business sector to expand capacities

Formulation

- 2 self contained Oncology & Adjuvant Therapy Manufacturing lines for Oral Solids products
- 3 self Isolated Oncology & Adjuvant Therapy manufacturing lines for Injectable products (Liquid & Lyophilized)
- New centralized QC laboratory and Bio-Analytical labs in Hyderabad

Growth Business

Biologicals & Biosimilars

- 2 independent lines - single use lines (Expanded to 4000L each) for production of MABS, vaccines and other recombinant proteins from mammalian cells
- 1 single use line (200L bioreactor) pilot scale – for clinical material production of MABS and other recombinant proteins from mammalian cells
- Currently 2 nos Robotic filling lines for PFS and Vials, 3rd , 4th high speed vial and PFS line will be commissioned by 4th quarter of FY 22
- CDMO business to kick started from Sep-21 with ZyCov-D deal, Biosimilar out licensing opportunities being pursued

Novel Biologics

- 2 lines each of 1,000L fermentation capacity for production of the NBE to cater to clinical trial material and formulation grade material was commissioned in April-21
- CDMO opportunities in production of vaccines being pursued and completed a deal in May-21and Sep-21. Further deals being pursued
- Sputnik Vaccine (100 m doses pa) will be manufactured in tie-up Dr. Reddy's Laboratories – tech transfer ongoing from RDIF, targeting Dec 21/Jan 22 production

Niche Opportunities

ODF & Transdermal

- State-of-art mfg. facility to develop and manufacture novel tech-based products at Bengaluru facility for global market
- Combo line for ODF/TDS has been commissioned and exhibit batches of ODF Products have been initiated - 7 products execution completed and few more products in pipeline. Nutraceutical products introduction under planning
- Complete in-house characterisation of TDS and ODF formulations using validated methods and high-end analytical instrumentations
- 2 dedicated lines for ODF formulations at Hyderabad facility to cater Domestic and ROW market
- Optimal use of both Sites depending on product and market is being done

Dermatological

- R&D is carried out at Shilpa Medicare's in-house R&D Facility
- Exhibit batches are taken at a Contract Manufacturing Organization
- One ANDA filed in US market and one product clinical phase 1 studies in progress.

Way Forward

Way Forward…

API

- Separate business under Shilpa Lifesciences Pvt. Ltd to provide focused approach resulting in better operating efficiency
- Greater impetus to specialty areas of CDMO, Peptides & Polymers
- One Production block likely to get commissioned in next quarter and also planning to increase the batch size of various products to improve efficiency

Formulations

- Partial completion of major remedial measures towards USFDA import alert by Q3 of FY22
- Submission of MCAP (Compliance Plan) to FDA by Q3 of FY 22
- Continue the hedging strategy to de-risk against single site operations
- Focus on niche and value-added products portfolio
- Expand transdermal patches & thin film portfolio – increase geographic reach

Biologics

- Focus on turning cash flow positive – capture low hanging fruits
  - Exploring other vaccine / MAbs manufacturing tie-ups
- Completion of clinical trials for Adalimumab & Human Recombinant Albumin

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
Karl H Kolah

CDR India

+91 22 6645 1209 / 1220

siddharth@cdr-india.com
karl@cdr-india.com

Thank You