Innovating for affordable healthcare

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 14 August 2021

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.

Dear Sir/Ma'am,

Sub: Presentation made to analysts and investors.

Ref: Regulation 30 of the SEBI (Listing Obligations & 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 ended 30 June 2021.

This is for your information and Records.

For Shilpa Medicare Limtied.

SHILPA MEDICARE LTD. RAICHUR

V V Krishna Chaitanya
Company Secretary and Compliance Officer

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Shilpa Medicare Limited (SML)

Q1 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.

Jadcherla Unit, Telangana

Company Overview

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Financial Performance

Abridged P&L Statement - Consolidated

(Rs. In Lakhs)

Particulars	Q1 FY22	Q1 FY21	Change (%)
Total Income (I+II)	23,935	22,835	5
I. Total Revenue from Operations (A+B+C+D)	23,736	22,286	7
•API (A)	12,967	14,708	(12)
•Formulations (B)	9,364	6,208	51
•Service Revenue & Product License Fees (C)	1,021	755	35
•Others (D)	384	616	(38)
II. Other income	199	548	(64)
Total Expenditure	20,547	15,712	31
EBITDA	3,388	7,123	(53)
EBITDA margin (%) to Total Income	14%	31%	-
Share of Profit / (Loss) of Joint Venture and associates, net of tax	(75)	(62)	-
Exceptional (Income)/Expenses	0	(6,084)	-
Finance Costs	1032	400	158
Depreciation and Amortization	1763	1233	43
Tax Expenses	356	2914	(88)
Effective Tax Rate (%)	60%	25%	-
PAT (incl. exceptional item)	161	8598	(98)
PAT Margins (%)	1%	38%	-
Share of Profit /(Loss) JV/ Associated & Non-Controlling Interest (net)	(3)	33	-
PAT (after Share of profit/(loss) of JV/Associate & non controlling interest	159	8,631	(98)
PAT Margins (%)	1%	38%	-

Abridged P&L Statement - Standalone

(Rs. In Lakhs)

Particulars	Q1 FY22	Q1 FY21	Change (%)
Total Income (I+II)	25,012	21,928	14
I. Total Revenue from Operations (A+B+C+D)	24,033	21,664	11
•API (A)	12,967	14,708	(12)
•Formulations (B)	10,274	5,619	83
•Service Revenue & Product License Fees (C)	526	723	(27)
•Others (D)	266	614	(57)
II. Other income	979	264	271
Total Expenditure	19,998	13,905	44
EBITDA	5,013	8,023	(38)
EBITDA margin (%) to Total Income	20%	37%	-
Exceptional (Income)/Expenses	-	(5,295)	-
Finance Costs	699	354	97
Depreciation and Amortization	1,169	991	18
Tax Expenses	631	3,358	(81)
Effective Tax Rate (%)(continued operations)	20%	28%	-
PAT Period/year from continuing operations incl. exceptional item (E)	2,515	8,615	(71)
PAT Margins (%)	10%	39%	-

In relation to the import alert issued by the USFDA for our Jadcherla unit, the Company has initiated extensive remedial measures. The incremental costs incurred on account of the USFDA import alert is Rs.1,821.60 Lakhs in Q1 FY22

Managing Director's Message

Commenting on Q1 FY'22 performance, Mr.Vishnukant Bhutada, Managing Director Shilpa Medicare Limited said

"I am pleased to share we have witnessed a recovery in performance and delivered an encouraging set of results in Q1 even as the macro environment continues to remain volatile. The Company has registered a revenue growth of 5% yoy at Rs. 23,935 lakhs when compared to Rs. 22,835 lakhs in the corresponding period last year. We continue to maintain our focus on improving the core API and Formulations business offerings as we build on newer opportunities in untapped markets. I am glad to share that we recently undertook a vital decision of segregation of API business into a separate subsidiary which will allow us to provide the desired strategic impetus to each business separately and in turn tap their full potential.

A very important development during the quarter, I am pleased to share with you that we are the **Second** Company in India that has received an approval from the **Defence Research & Development Organisation (DRDO)** for the manufacture and sale of **2-Deoxy-D-Glucose (2DG)**. 2DG stops virus growth and is the first medicine in India termed as anti-Covid drug which will treat Covid-19 and its variants.

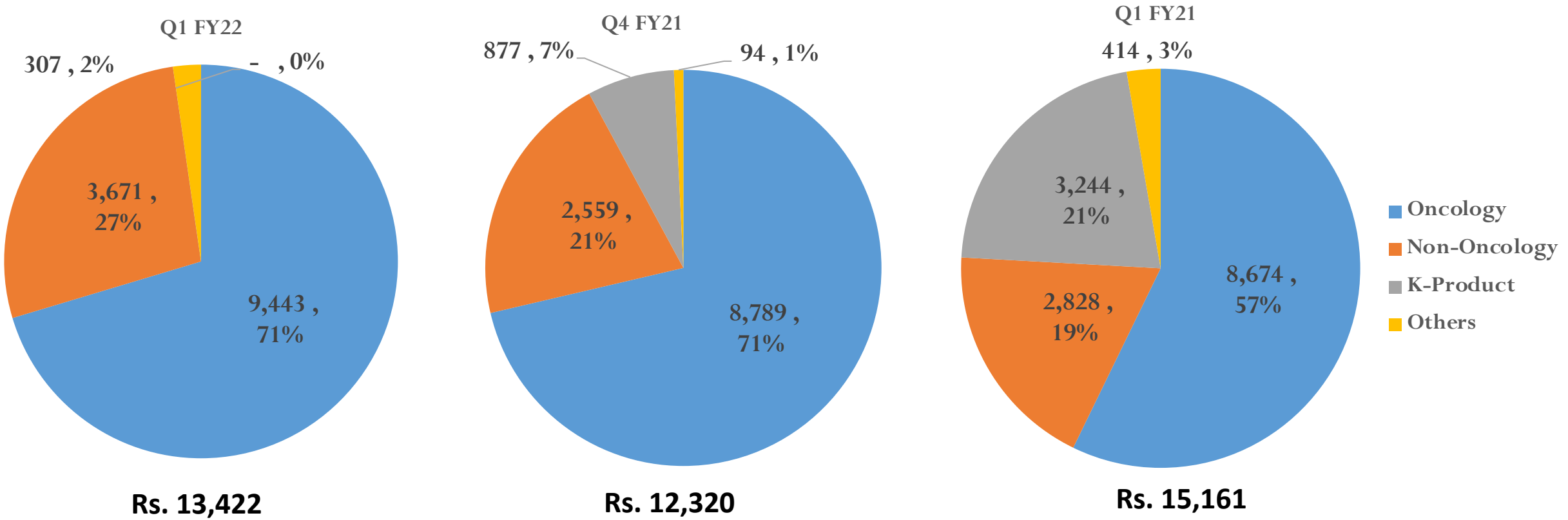
With no end in sight to Covid-19 and its variants, the world has begun to adjust and live with it. It is our earnest endeavor to continue our efforts to combat this disease. In this regard, I am pleased to share that the progress on the production-supply of Sputnik V vaccine is on track and we expect commercial production to commence in Q3FY22. Over the years, we have prudently invested in high-quality human capital and deployed teams across international markets. We believe that our investments in Biologics will act as a strategic growth lever which will enable future growth."

Discussion of Select Business Segments

API - Highlights

Segment wise sales

(Rs. In Lakhs)



- Increased offtake in Japan for Temozomide
- Non Onco Sales driven by UDCA

- Recently received WHO approval for Tenofovir
- Increased production capacity in Tranexamic acid

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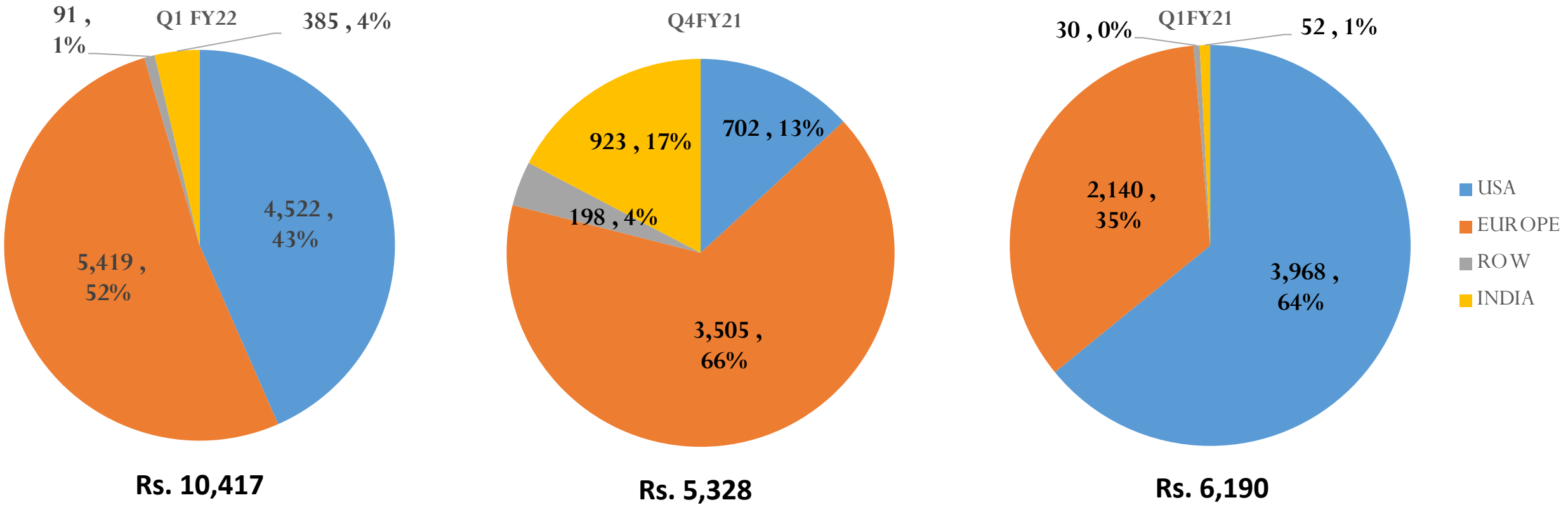
Formulation - Highlights

Revenue Split

(Rs. In Lakhs)



- US business gaining traction again backed by sale of 3 products that have been exempted from the Import Alert
  - Azacitidine for Injection, Cyclophosphamide Capsules and Erlotinib Tablets
- Actively worked on hedging strategy, resulting in significant growth in other international markets as well
  - One Product site transfer successfully completed

Investing in future Growth Businesses – New Launch

Launched fast dissolving oral films of Paracetamol brand name as Molshil®

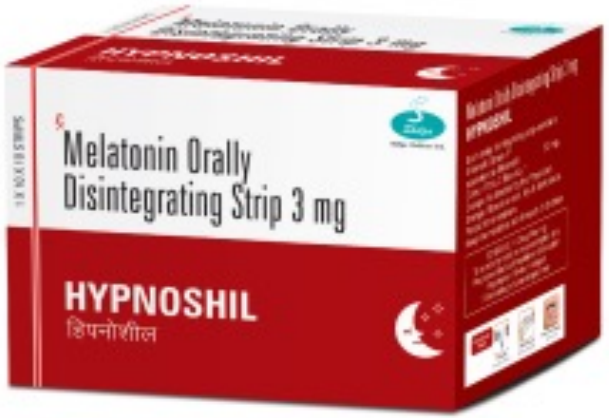
- Shilpa Medicare Ltd. recently announced the launch of Oral Thin Film Formulation, a Infant /pediatric dose of **Paracetamol**, under the Brand name **Molshil®**
- The Company received the approval for Molshil® Oral Thin Films after sufficiently complying with bioequivalence requirements
- These Paracetamol Oral Thin Films are **patent protected** and are **first of its kind in the world**
- The Company has introduced these Paracetamol Oral Thin Films in Orange Flavour in **60 mg and 120 mg** strengths
- The Company is manufacturing these oral films in its own manufacturing facilities

Investing in future Growth Businesses – New Launch

In Insomnia & Sleep Disorders

In Erectile Dysfunction (Majorly through Retail Plan)

In Seasonal Allergic Rhinitis, Asthma, EIB, Perennial Allergic Rhinitis



Other Updates

Contribution towards combating to Covid-19 pandemic

Sputnik V vaccine update

- Shilpa Biologicals Pvt Ltd, (SBPL) the wholly owned subsidiary of Shilpa Medicare Ltd. 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.
- Technology Transfer ongoing currently with commercial production expected to start in Oct-Nov 2021
- 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
- View Biologics as a strategic growth area and made significant investments in setting up a high end, flexible Biologics facility in Dharwad to cater to the requirements of the fast-growing biologics field, that include, the Adenoviral, Subunit & DNA vaccines, Monoclonal antibodies & fusion proteins

Contribution towards combating to Covid-19 pandemic

Received approval from DRDO for the manufacture and sale of 2-Deoxy-D-G1ucose (2DG)

- Recently received an approval from the Defence Research & Development Organization (DRDO) for the manufacture and sale of 2-Deoxy-D-Glucose (2DG).
- Shilpa Medicare is only the second Company in the country to enter in a similar arrangement with DRDO.
- The Drug Controller General of India has given 2DG an emergency approval to treat COVID-19 patients in the country.
- The Company has been continuously striving to contribute towards the fight against COVID-19 and this is yet another step by it after it recently announced the arrangement for manufacture and supply of Sputnik V vaccine.
- Applied another two products for Covid-19 therapy

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 Company already prepared

Planning 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 of FY22

Patents Status as on June 30, 2021

Patents	Filings	Granted	Pending
- API	205	40	165
- Formulation *	179	26	153
- Films Topical & Transdermal	59	6	53
- Biologicals	12	4	8
- Others	22	5	17
TOTAL	**477**	**81**	**396**

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

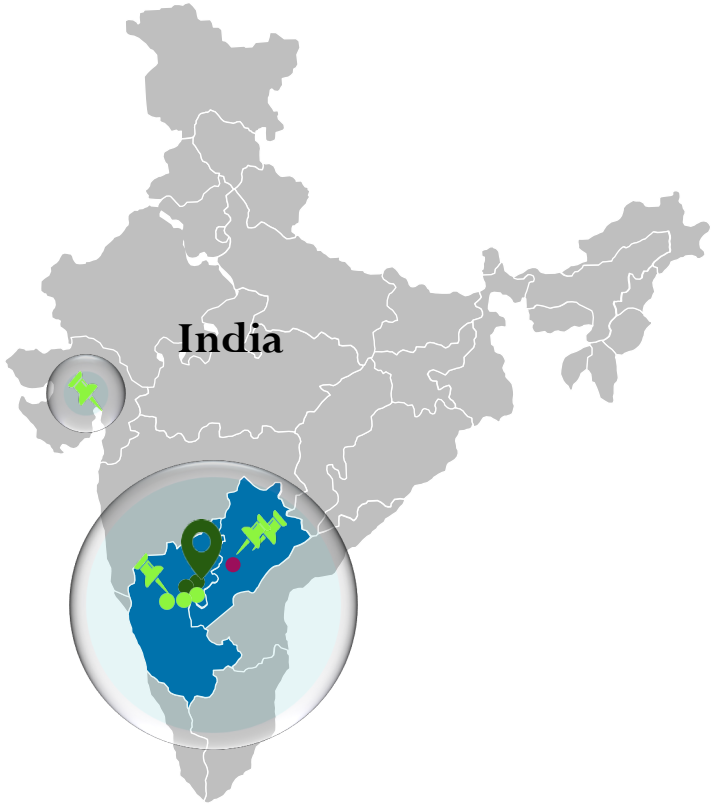
Formulation Product Pipeline as on June 30, 2021

Regulatory Submissions	Filings	Approved (Including Tentative)	Pending
- **US ANDA**: SML	24	13	11
- **US NDA:** SML	03	01	02
- **US ANDA:** Customers	18	12	06
TOTAL (In US)	**45**	**26**	**19**
- EU Filing	24	17	07
- Row Filling	228	65	163
TOTAL (In EU & ROW)	**252**	**82**	**170**
GRAND TOTAL	**297**	**108**	**189**

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 start from Sep-21, 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-21. Further deals being pursued
- Sputnik Vaccine (50m 1st dose + 50m 2nd dose) will be manufactured in tie-up Dr. Reddy's Laboratories – tech transfer ongoing from RDIF, targeting Oct/Nov 21 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 - 6 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
- Site transfer of ODF products from Hyderabad Unit to Bengaluru Unit is planned

Dermatological

- R&D is carried out at Shilpa Medicare's in-house R&D Facility
- Exhibit batches are taken at a Contract Manufacturing Organization

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

Formulations

- Completion of remedial measures towards USFDA import alert by Q2/Q3 of FY22
- 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
- Developing dermatology and ophthalmic pipeline

Biologics

- Focus on turning cash flow positive – capture low hanging fruits
  - Exploring other vaccine manufacturing tie-ups
- Exploring more biologicals to pursue in R&D

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