

Shilpa Medicare Limited

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CIN: L85110KA1987PLC008739

Dated 31.05.2021

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,

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 the Securities and Exchange Board of India (Listing Obligations and Disclosure Requirements) Regulations, 2015 as amended from time to time, please find herewith enclosed copy of 04th Quarter and Financial Year 2020-21 Results presentation made to analysts and Investors.

This is for your information and Records.

For Shilpa Medicare Limited. EDio

William and

V V Krishna Chaitanya

Company Secretary and Compliance Officer



Shilpa Medicare Limited (SML) Q4 & FY21 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.



Corporate Office - 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 Transdermal, Oral Dissolving Films and Dermatological 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





Established Business

API

Formulation

Manufacturing API products with high precision Isolator Technology & operated with zero discharge Portfolio contains technically challenging Oncology and non-Oncology products	Portfolio includes liquid and lyophilized injectable, sterile dry powder injections and oral solids Global reach in the US, EU and the Rest of the
Diversification into Peptide & Polymer products and CDMO	Vertically integrated, with in-house R&D for innovative and cost-effective products
Facility is approved by USFDA, WHO-GMP, EUGMP, TGA, PMDA, KFDA, TPD & Russia	
Certification from ISO & OSHAS	



Growth Business

Biologicals & Biosimilars

Novel Biologic

Company is pursuing a dedicated IP strategy for Biosimilar and NBE assets	Molecule pipeline is patent protected globally
6 of the top 15 Biological products are in the	Clinical trials should start by Jun Sont 21
pipeline	Clinical trials should start by Jun-Sept 21
Ctronathe in the development of continuous	
Strengths in the development of continuous bioprocessing that could disrupt current market	Low risk with diverse applications catering to:
prices	- Low regulatory barrier cell therapy media markets,
	initial customer trials are ongoing
Clinical trials for first 2 Biosimilars should start	- High regulatory barrier drug market with potential to
between June 21 and Sept 21	replace current best-in-class
	 Potential to create targeted chemotherapy drugs, with initial customer trials ongoing



Niche Opportunities

Dermatological

ODF & Transdermal

1 product is ready to be filed in the US market - Niche Generic	Portfolio includes liquid and lyophilized injectable, sterile dry powder injections and oral solids
Swatchshil launched in domestic market in Mar 21 - Additional batch manufacturing in progress	Global reach in the US, EU and the Rest of the World markets
Two new line extensions identified – one in BOV and other in wound healing	Vertically integrated, with in-house R&D for innovative and cost-effective products
2 new niche products are under development	
 One in clinical phase Other has completed the preclinical phase and requesting for clinical waiver with DCGI by June 21 	





SML's Key Strengths





Research & Development



- Pathway Engineering of cells Novel cell lines with novel characteristics, high yield
- HT Biologics characterization Potential to reduce the iterations/cost in the latter stages of development and clinic
- Multi-parallel Bioprocessing platforms with incorporation of continuous bioprocessing Reduces the cost of commercial product with high quality
- Novel Delivery technology platform Marries novel patentable formulations with delivery devices
- Differentiated offering to customers in lifestyle disorders Leading to better patient compliance and outcomes
- Novel biologics media manufacturing platform Leads to complete backward integration Potential to be the lowest cost player in the biologics market with significant competitive moat
- Adenoviral therapy/vaccine based platforms potential to reduce cost of therapies over long term
- R&D lab equipped with State-of-the-art machines and instruments required for pre-formulation and formulation development of Transdermal System (TDS) / Matrix patches and Oral Disintegrating films (ODF) Healthy generic pipeline of projects including Para IV, First to file, 505B2 filing for Global market



Research & Development



- Analytical lab equipped with all sophisticated instruments for analytical development of transdermal patches and oral films as per current US/EU Guidance
- R&D capability to conduct In-Vitro adhesion characterization like Peel, Tack, Shear and Release force; In-Vitro Permeation Test & In-Vitro Release Test studies using Human Cadaver skins to mimic In-Vivo BE studies for PK and adhesion end points
- R&D competency to conduct In-house Extractable and Leachable studies with cGMP compliance
- R&D competency to characterize Pressure sensitive Polymers; Rheological behaviors of Non-Newtonion fluids, quantitively Cold Flow etc.
- SML is delivering end to end Pharmacovigilance activities



Manufacturing Excellence



Facil	ity Location	Facility Type
Dharw	ad	Biologicals Manufacturing plant & R & D Facility
Bengal	uru	TDS & ODF Manufacturing Facility & R & D (All segments except Biologics)
Raichu	ır Unit I	API (Oncology – Non-Oncology)
Raichu	r Unit II	API (Oncology – Non-Oncology) and R & D API
Jadche	erla Unit	Formulations (Onco & Adjuvant Therapy of Onco – Injectable & Oral)
Hydera	abad Unit	Formulations (Oral Dissolving Films)
Hydera	abad	Bio Analytical & Pharmacovigilance R & D
Ahmed	dabad	R&D Formulation



Company's Headquarters at Raichur, Karnataka, India

Manufacturing Facilities

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





Established Business - Capacities

API

Formulation



9 dedicated blocks for Oncology & 4 blocks for Non-Oncology

Multi-product capability for Oncology & Non-Oncology

Expansion of various API capacities

- o Peptide and Polymer divisions added which lends further capacity
- o CDMO introduced to existing business sector to expand capacities

 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 - Capacities



2 independent lines - single use lines (1,000L Bioreactor each) for production of MABS, vaccines and other recombinant proteins from mammalian cells

Biologicals & Biosimilars

- 1 single use line (200L bioreactor) for production of MABS and other recombinant proteins from mammalian cells
- Robotic filling lines for PFS and Vials
- 3rd high speed European vial line that will be commissioned by 4th quarter of FY 22
- CDMO business to kick start from Sep 21

Novel Biologic

- 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
- Sputnik Vaccine will be manufacturing in license with Dr. Reddy's Laboratories
- 100 Million doses in a year



Niche Opportunities - Capacities



Dermatological

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

Dissolving Films & **Transdermal**

Oral

- 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 - 4 products execution completed and few more products in pipeline
- 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



Financial Performance

Abridged P&L Statement - Standalone

(Rs. In Lakhs)

Particulars	Q4 FY21	Q4 FY20	Change (%)	FY21	FY20	Change (%)
Total Income (I+II)	19,485	20,090	(3)	86,422	81,724	6
I. Total Revenue from Operations (A+B+C+D)	17,971	19,793	(9)	83,032	80,598	3
•API (A)	12,226	13,304	(8)	56,319	50,181	12
Formulations (B)	4,856	4,812	1	22,776	19,115	19
Service Revenue & Product License Fees (C)	566	1,054	(46)	2,619	8,968	(71)
•Others (D)	323	624	(48)	1,318	2,334	(44)
II. Other income	1,514	297	410	3,390	1,126	201
Total Expenditure	14,236	14,866	(4)	60,331	56,107	8
EBITDA	5,249	5,225	0	26,091	25,618	2
EBITDA margin (%) to Total Income	27	26	4	30	31	(4)
Exceptional (Income)/Expenses	-	(454)	-	5,295	(454)	(1,266)
Finance Costs	664	129	415	1,747	433	304
Depreciation and Amortization	1,062	916	16	4,085	3,496	17
Tax Expenses	863	1,189	(27)	7,115	4,415	61
Effective Tax Rate (%)(continued operations)	25	32	(23)	28	20	36
PAT Period/year from continuing operations incl. exceptional item (E)	2,659	2,536	5	18,439	16,820	10
PAT Margins (%)	14	13	8	21	21	4
Profit (loss) from discontinued operations (net of tax) (F)	-	3,254	-	-	2,552	-
PAT (E+F)(Continuing & discontinued operation)	2,659	5,790	(54)	18,439	19,373	(5)
PAT Margins (%)	14	29	(53)	21	24	(10)

In relation to the import alert issued by the USFDA for Jadcherla Unit, the Company has initiated extensive remedial measures. The cost towards these measures amounted to Rs.529.44 Lakhs in Q4-FY21 and Rs. 862.51 Lakhs for FY21

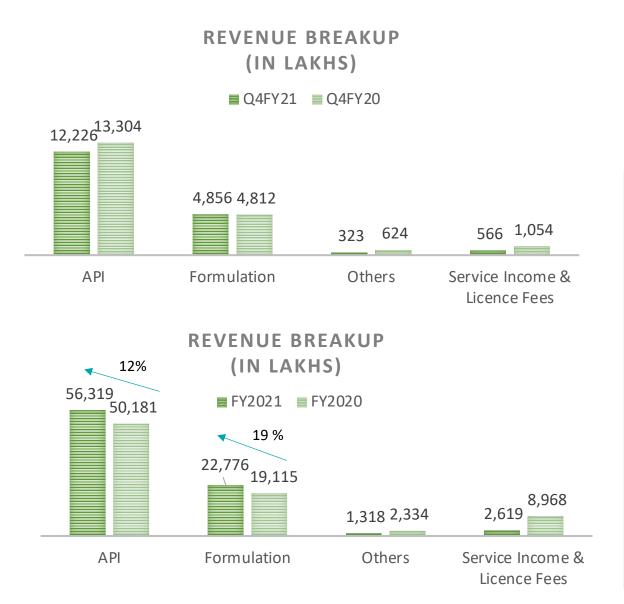


Abridged P&L Statement - Consolidated

Particulars	Q4 FY21	Q4 FY20	Change (%)	FY21	FY20	Change (%)
Total Income (I+II)	21,494	22,890	(6)	93,127	92,485	1
I. Total Revenue from Operations (A+B+C+D)	20,803	21,999	(5)	90,113	90,791	(1)
•API (A)	12,250	15,240	(20)	60,862	55,441	10
Formulations (B)	7,665	5,546	38	25,315	19,429	30
Service Revenue & Product License Fees (C)	566	1,054	(46)	2,619	13,587	(81)
•Others (D)	323	159	103	1,318	2,334	(44)
II. Other income	691	891	(22)	3,014	1,694	78
Total Expenditure	18,182	17,439	4	71,948	68,811	5
EBITDA	3,312	5,450	(39)	21,180	23,674	(11)
EBITDA margin (%) to Total Income	15	24	(35)	23	26	(11)
Exceptional (Income)/Expenses	-	-	-	(6,084)	-	-
Finance Costs	912	101	805	2,187	456	380
Depreciation and Amortization	1,523	1,155	32	5,398	4,378	23
Tax Expenses	80	755	(89)	4,885	3,349	46
Effective Tax Rate (%)	9%	18%	(48)	25	18	39
PAT (incl. exceptional item)	797	3,440	(77)	14,794	15,491	(4)
PAT Margins (%)	4	15	(75)	16	17	(5)
Share of Profit /(Loss) JV/ Associated & Non-Controlling Interest (net)	(14)	17	(181)	(16)	124	(113)
PAT (after Share of profit/(loss) of JV/Associate & non controlling interest	783	3,457	(77)	14,778	15,615	(5)
PAT Margins (%)	4	15	(76)	16	17	(6)



Results Snapshot (Standalone)



Key Highlights

- Despite challenging last 2 quarters, both API & Formulation businesses witnessed robust growth during the year
- Q4 performance across businesses impacted due to:
 - Capacity enhancement in API both Oncology & Non-Oncology
 - Formulation remediation measures have hampered the USA sales, but SML was able to sell in EU Market
 - License income reduced due to USFDA Import Alert



Capital Investment & Debt Details - Standalone

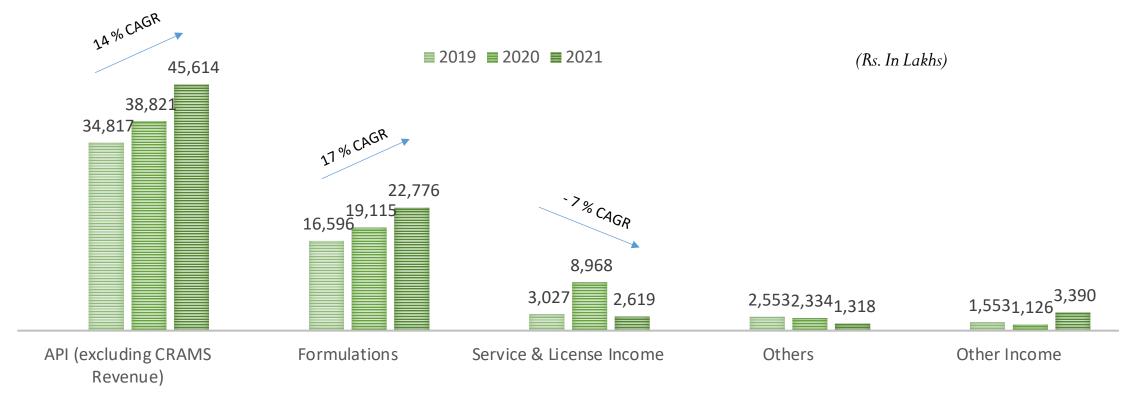
(Rs. In Lakhs)

Particulars	As on 31.03.2021	As on 31.03.2020
Capital Investments		
Fixed Asset Gross Block	89,699	73,392
Tangible Assets (Project Under Progress)	29,719	24,418
Intangible Assets Under Development	18,516	12,863
Total Capital Investment	137,934	110,673
Debt		
Long term	41,152	22,385
Short term	24,190	15,640
Less: Cash & Cash Equivalents	(11,501)	(2,794)
Total Debt	53,841	35,231



Historical Revenue Statement – Standalone





Strong trends in underlying performance ex of CRAMS over the past few years



Historical R&D Expenditure Trends

(Rs. In Lakhs)

Particulars	FY18	FY19	FY20	FY21
Total R&D Expenditure	7,813	8,751	12,883	13,675
R&D Revenue Expenditure	5,386	4,004	6,948	6,836
R&D Intangible Assets(incl. CWIP)	2,427	4,747	5,935	6,839
R&D as a % of Revenue	10%	13%	16%	16%

Strong orientation on R&D to sustain growth performance



Discussion of Select Business Segments



Unique antibacterial as well as fungicide in spray form



	Swatch Shil	Marketed Products
Non-antibiotic bactericide and no drug resistance	~	×
Effective in inhibiting fungi development and growth	~	×
Hands free usage	✓	×
Water required	×	✓
Cleansing spray formulation	~	*
Cleansing liquid	×	✓
Convenient to use	~	×
Ease of carrying	✓	×









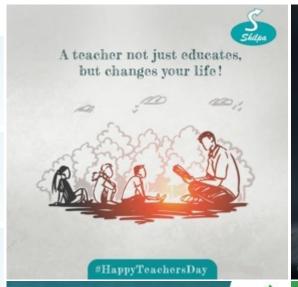
Highlighting the advantages of Shilpa's Green Tea over traditional green tea through communication

Publishing engaging content on social media

Focusing on creating more brand awareness and reaching out to new consumers

Increasing the follower base on social media platforms

Live sessions with renowned dieticians















Vitamin Supplementations

B12 Film – Methyl Cobalamin 1500 mcg

Cholcal – Vitamin D3 2000 IU





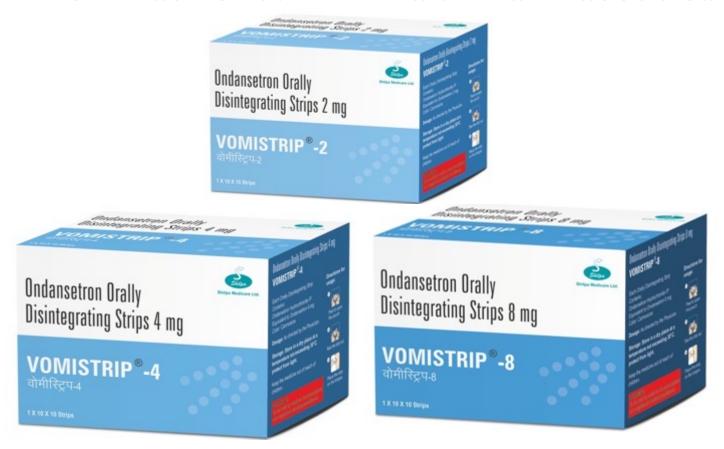


PDE Inhibitor

TFL – Tadalafil 5mg, 10mg, 20mg









Ondansetron

Vomistrip – 2mg, 4mg, 8mg

Simethicone 62.5mg

Gastrip



API Progress in FY 2021

New Products Introduced

Business Segment	Name of the Product	Therapeutic Area	Geography	Total Market Size
	Nilotinib *	Oncology	Global	\$ 1.64 Billion
	Pazopinib HCL *	Oncology	Global	\$ 568 Million
API	Phenylephrine HCL	Non-Oncology	Global	\$ 1.72 Billion (Single and in combination with other Drugs
	Citicholine Sodium	Non-Oncology	Global	\$ 448 Million (Single and in combination with other Drugs

*Patented Products: Shilpa shall supply APIs for research and/or regulatory submissions as per individual Country Laws during the valid term of Patent in specific Country

- Added two new US based innovators to CDMO-API business for late phase clinical development
- o Expanded to 1 dedicated blocks for Oncology and 2 blocks for Non-Oncology and created bay within the block to operate multiple products
 - Expansion of various API capacities
 - Multi-product capability for Oncology & Non-Oncology
- o 1 product is approved by WHO and another product approval is expected by June 21
- Peptide Block commissioned
- o Tranexamic acid production block capacity expanded from 5.5 MT to 15 MT
- Dedicated Peptide and Polymer R&D nearing completion



Formulation Progress in FY 2021

Products launched

Business Segment	Name	Shilpa's Brand Name	Therapeutic Area	Geography	Total Market Size
	Lenvatinib	Lenshil	Oncology	India	\$ 777 K
	Dastinib	Dasashil	Oncology	India	\$ 1.8 Million
	Sunitinib	Sunishil	Oncology	India	\$ 1.3 Million
	Axitinib	Axishil	Oncology	India	-
	Dimethyl Fumarate	Dmfshil	Oncology	India	\$ 696 K
	Simethicone	Gastrip	Anti-Flatulence	India	-
Formulations	Ondansetron	Vomistrip	Anti-Emetic	India	\$ 41 Million
	Tadalafil	TFL	PDE Inhibitor	India	\$ 16 Million
	Methyl Cobalamin	B 12 Film	Vitamin Supplementation	India	\$ 18.2 Million
	Cholecalciferol	Cholcal	Vitamin Supplementation	India	\$ 87.9 Million
	Anti Bacterial , Anti fungal	SwatchShil	Intimate Hygiene for women	India	-
	Green Tea	Green Tea Film	Antioxidant/wt loss.	India	-

Note: Total Market Size data is extracted from IQVIA MAT Q4 2020

- o Lenvatinib: Lenshil was the first generic brand of Lenvatinib in India
- O Anti Bacterial, Anti fungal: Swatchshil is first of its kind for intimate cleansing spray for women
- o Green Tea: First of its kind a Green Tea film in a form of Oral disintegrating film
- o Commercial supplies of Azacitidine Inj to 2 customers in Europe
- Additional variants of Green T Film launched in Indian market



Investing in future Growth Businesses

Recently tied up with Dr. Reddy's Laboratories for the production of Sputnik V vaccine

- 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 at Dharwad,
 Karnataka
- As per the terms of the agreement, SBPL will be responsible for the manufacture of the vaccine while DRL will be responsible for its distribution
- 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



Managing Director's Message

Commenting on Q4 & FY'21 performance, Mr. Vishnukant Bhutada, Managing Director Shilpa Medicare Limited said

"I am pleased to share with you that we have been able to maintain our revenues during the year despite facing a volatile macro environment and other regulatory challenges. We continue to focus on improving the core API and enhance our Formulations business as we look for newer opportunities in untapped markets. Over the past few years, we have judiciously invested in top quality human capital. The teams we have deployed in our international markets have helped us grow our presence and we hope to capitalize there. Furthermore, we are building a strong product pipeline which will translate to healthy growth in the years ahead.

Our focus on the diversification in newer areas like Biologics, portfolio expansion in Transdermal Dosage Forms and Oral Thin Films formulations, CDMO business will gain traction in FY22 and we believe that investing in these areas will benefit the Company in the years to come.

Very recently we tied up for production of Sputnik V, at our Biologics facility, Dharwad, further augmenting the availability of life-savings vaccines in the country."



Business Update

Current Status on USFDA Warning Letter

- o SML's Jadcherla Unit received the Import Alert in Feb 2021
- After the Warning Letter in October 2020, the Company has undertaken a systematic and wholesome remediation plan with the help of a Third-Party Consultant to address the concerns of the Agency
- The Company remains committed to work towards resolving all the concerns cited by the Agency. Company plans to seek a meeting with USFDA in the near future
- Continuing to supply 3 products to the US market in accordance with conditions set forth in Import Alert.
 Commercial supplies to Europe and other countries are being done regularly
- Company continues to file new ANDA/NDA applications and the review from Agency is ongoing
- o Adding 3rd party manufacturing facilities of Oral & Injectable as a risk hedging strategy

Update on European Market:

The unit has maintained uninterrupted supply of approved products to European markets





USFDA Exempted Formulation Sales - Largest Revenue Source

(Rs. In Lakhs)

Year	FY21	FY20	FY19
Total Formulation Sales	21,308	19,436	17,104
Exempted Formulation Sales*	18,608	13,426	14,467
% of total Formulation Sales	87%	69%	85%

^{*} Includes all products permitted for sales in the US

Exempted Formulations Sales – Geographical Breakup

(Rs. in Lakhs)

Geography	FY21	%	FY20	%	FY19	%
US	6,294	34	13,280	99	14,387	99
Europe & Other	12,314	66	146	1	80	1
TOTAL	18,608	100	13,426	100	14,467	100

- 3 products have been exempted from the Import Alert Azacitidine for Injection, Cyclophosphamide Capsules and Erlotinib Tablets, subject to certain conditions which are 3rd Party Certified
- Actively worked on hedging strategy, resulting in significant growth in other international markets



Patents Status as on March 31, 2021

Patents	Filings	Granted	Pending
- API	204	40	164
- Formulation *	168	21	147
- Films Topical & Transdermal	57	5	52
- Biologicals	11	3	8
- Others	22	5	17
TOTAL	462	74	388

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



Formulation Product Pipeline as on March 31, 2021

Regulatory Submissions	Filings	Filings (Including Tentative)	
- US ANDA: SML	23	13	10
- US NDA: SML	2	0	2
- US ANDA: Customers	18	12	6
TOTAL (In US)	43	25	1 8
- EU Filing	21	<mark>16</mark>	5
- Row Filling	209	52	147
TOTAL (In EU & ROW)	230	68	152
GRAND TOTAL	273	93	170



Way Forward

Way Forward





- Completed debottlenecking of 1 Oncology block & 1 Non-Oncology started the manufacturing the product
- Initiated debottlenecking of all the production blocks
- o 2 major Oncology products batch size increased by 5 times and 7 times respectively
- New Tranexamic block commissioned which is an expansion block
- One new Oncology intermediate block commissioned and taken one product validation in the same

Formulations



- Expanding reach by entering different geographies/markets
- Maintain regulatory compliance in Europe and other countries
- o Resolve the GMP concerns raised in Warning Letter and Import Alert
- Mitigate risk in US market by alternate ways like site transfer of products, new QC laboratory, etc.



Future Growth Businesses



- Diversification in other therapeutic areas like Biologics, portfolio expansion to Transdermal Dosage Forms and Oral thin films formulations. The manufacturing unit at Bengaluru has delivered exhibit batches for additional products
- Launch of Shilpa's branded products for ODF in the domestic market
- o Markets in addition to US may drive the business going forward. Received approvals for products in ROW markets
- In Formulations, developing other therapeutic areas like Dermatology and Ophthalmology
 - To support the above, the marketing team has been strengthened both in India and overseas, particularly South Africa, Canada, South America and Russia
- Vaccines against viruses/adventitious agents recombinant, viral vaccines to emerge as significant areas of opportunities for the company over short to medium term
 - o The Company has recently tied up with Dr. Reddy's Laboratories for the production of Sputnik V vaccine
- o Production platforms and formulation, logistics competencies in the area being built via emerging CDMO opportunities now
- R&D facility at Bengaluru is now complemented with a Pilot Plant and an extractable/leachable lab



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 today is the result of their constant endeavors for more than three decades.



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Biological Facility Temple - Dharwad





Thank You

