



Innovating for
affordable healthcare

Shilpa Medicare Limited

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CIN: L85110KA1987PLC008739

Dated 13th February, 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 03rd Quarter of Financial Year 2020-21 Results presentation made to analysts and Investors.

This is for your information and Records.

For Shilpa Medicare Limited.

V V Krishna Chaitanya
Company Secretary and Compliance Officer





Innovating for
affordable healthcare

Shilpa Medicare Limited (SML)

Q3 & 9M 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



Established Business Segments

Description

APIs

- Manufacturing API products with highly précised Isolator Technology
- Facility is approved by USFDA, WHO-GMP, EUGMP, TGA, PMDA, KFDA, TPD

Formulations

- Products include liquid and lyophilized injectable, sterile dry powder in the facility approved by USFDA & EUGMP
- Develops in-house formulae that allow greater control over the production process, resulting in cost savings

Capacities

- 9 dedicated blocks for Oncology & 4 blocks for Non-Oncology
- Multi-product capability for Oncology & Non-Oncology
- Expansion of various API 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)
- Extension of new QC laboratory in Hyderabad

Established Business Segments

Description

Biologicals & Biosimilars

- Company is pursuing a dedicated IP strategy for Biosimilar and NBE assets
- 6 of the top 15 Biological products are in the pipeline
- Strengths in the development of continuous bioprocessing that could disrupt current market prices
- Clinical trials for first 2 Biosimilars should start by June-21

Novel Biologic

- Molecule pipeline is patent protected globally
- Clinical trials should start by June-21
- Low risk with diverse applications catering to
 - Low regulatory barrier cell therapy media markets
 - High regulatory barrier drug market with potential to replace current best in class
 - Potential to create targeted chemotherapy drugs

Capacities

- 2 independent lines - single use lines (1,000L Bioreactor each) for production of MABS and other recombinant proteins from mammalian cells
- 1 single use line (200L bioreactor) for production of MABS and other recombinant proteins from mammalian cells
- Robotic filling lines for PFS and Vials
- CDMO business to kick start from June-21

- 2 lines each of 1,000L fermentation capacity for production of the NBE to cater to clinical trial material and formulation grade material
 - Will get commissioned in Q4 FY21
- CDMO opportunities in production of vaccines being pursued

Established Business Segments

Description

Dermatological

- Company engaged in R&D in various Dermatological products
- 2 products are ready to be filed under which 1 product is Niche Generic and 1 product is Niche OTC
- To launch 1 product in the domestic market by Feb 2021. Commercial batch manufacturing in CMO in progress.
- 2 new niche products are under development in which 1 product is in clinical phase and 1 product is in preclinical phase

Oral Dissolving Films & Transdermal

- Transdermal Therapeutic systems facilitate better treatment for the patient
- Enhancing technology and capabilities to develop and manufacture Oral Dissolving Films and Transdermal products
- Launched green tea films in the domestic market which is the first of its kind in the world and will change the dynamic of green tea consumers
- Local cGMP inspection planned in March 2021

Capacities

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

- Combo - line has been commissioned and exhibit batches for the products ODF Products have been initiated. One product execution has been completed
- 2 dedicated lines for ODF at Hyderabad
- Combo-line (ODF & TD), first of its kind from Germany to Bengaluru, India



R&D

SML's Key Strengths



Manufacturing Excellence



- Qualified, experienced and well-trained staff for the design of clinical studies & quality control
- Therapeutic expertise in the conduct of patient-based studies in Oncology, Dermatology, Ophthalmology and Biologics
- Expertise in performing method validation, method transfer in quality control for various dosage forms such as oral solids and parenteral drugs

Experienced in:

- Bioequivalence / Bioavailability
- Phase II- IV trials
- PK / PD studies in patients
- Feasibility studies
- Project planning and setup
- Project management
- Study designs & strategies
- Analytical method validation
- Analytical method transfer
- Regulatory query responses and analysis
- Diluent compatibility studies
- Stability analysis
- Multi media dissolution profile

- Core medical team comprises physicians and pharmacologists involved in the design of clinical studies and the preparation of scientific documents such as pre-INDs, EMEA scientific advice, an integrated summary of efficacy and safety reports, a clinical and non-clinical overview and clinical study reports
- Qualified persons with experience in different formulation dosage forms & Targeting 100+ Manpower in QC

Research & Development – Bio Analytical at Hyderabad



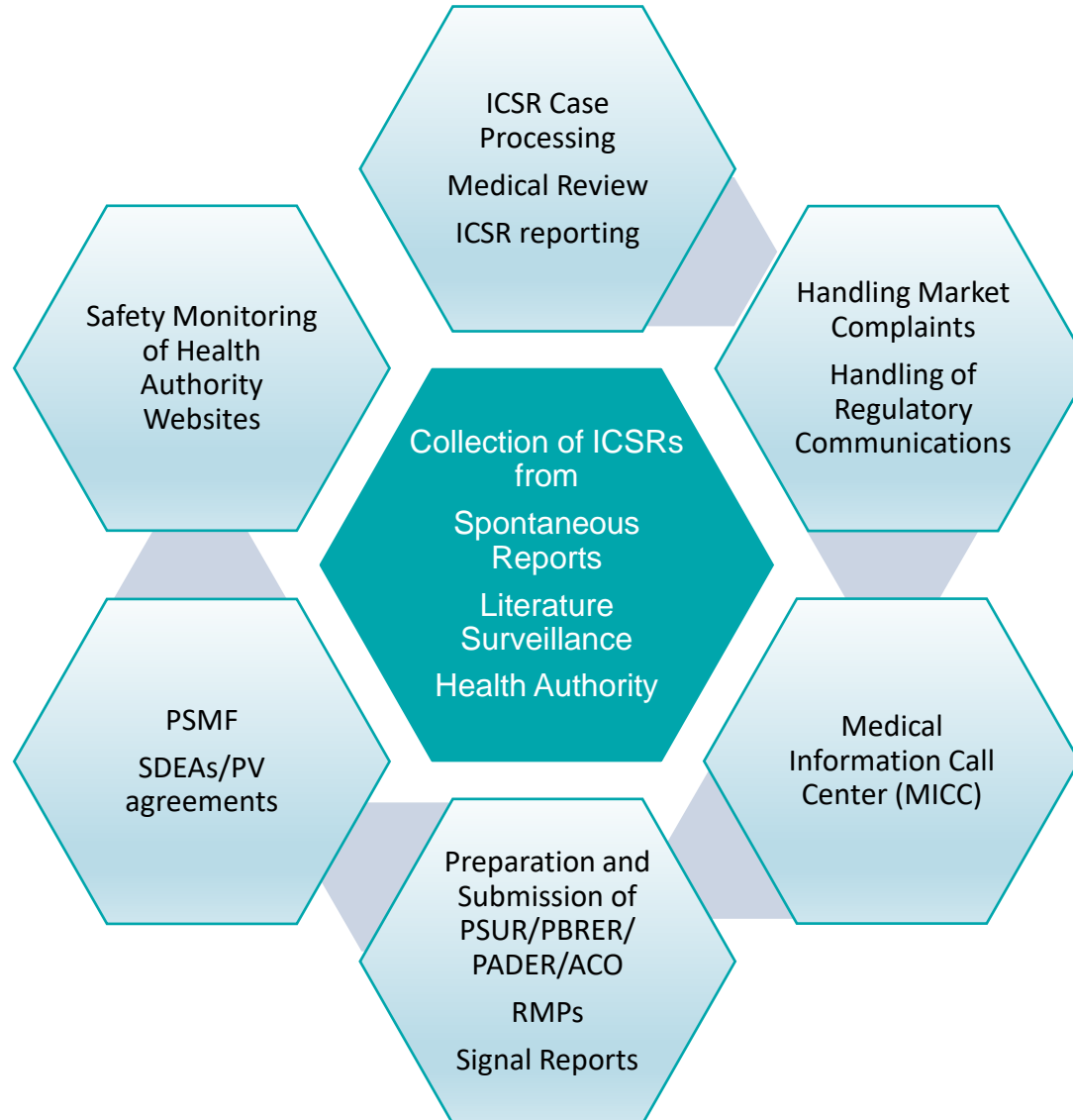
- The Bio Analytical Laboratory is equipped with the state-of-the-art equipment and tools required for analysis in the biological matrix of the subject samples
- Therapeutic expertise in conducting patient-based studies in Oncology, Dermatology, Ophthalmology and Biologics

- Can handle liquid-liquid extractions, solid-phase extractions & protein precipitation techniques
- Can handle pre-column / post-column derivatization procedures, Chiral separation of optical isomers as well as conjugate and non-conjugate drug level estimation

- Team of qualified and experienced researchers with experience in method development, validation and regulated bioanalysis for a wide range of chemically diverse drug molecules



SML delivering end to end Global Pharmacovigilance Activities





India

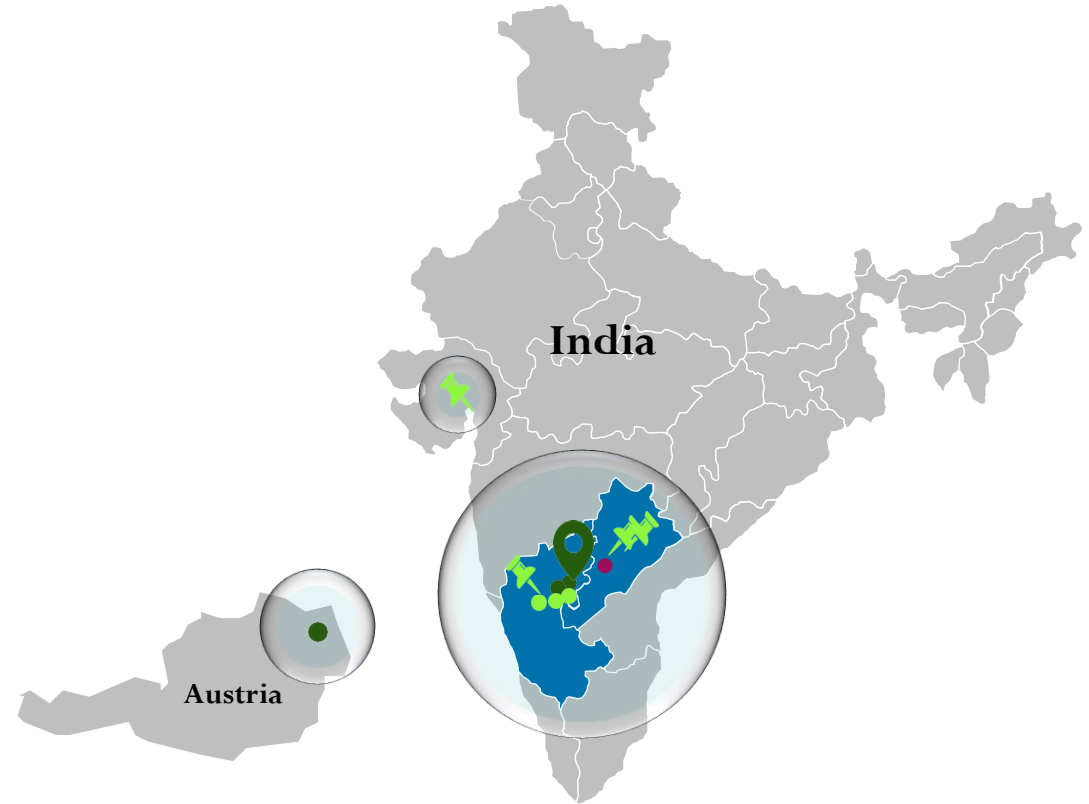
Facility Location	Facility Type
Dharwad	Biologicals Manufacturing plant & R & D Facility
Bengaluru	TDS & ODF Manufacturing Facility & R & D (All segments except Biologics)
Raichur Unit I	API (Onco – Non-Oncology)
Raichur Unit II	API (Onco – Non-Oncology) and R & D API
Jadcherla Unit	Formulations (Onco & Adjuvant Therapy of Onco – Injectable & Oral)
Hyderabad Unit	Formulations (Oral Dissolving Films)
Hyderabad	Bio Analytical & Pharmacovigilance R & D
Ahmedabad	R&D Formulation
Austria (Overseas)	API Manufacturing

Currently 6 manufacturing facilities for API & Formulation products in India & 1 manufacturing facility for API in Austria

World-class manufacturing unit of Transdermal Patch and Oral Films at Bengaluru, Karnataka

The manufacturing equipment is state of the art and with all necessary machine controls to maintain quality and consistency

Four single use and one multi use best in class Bio reactors



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
- 1 API plant at Austria



Discussion of Select Business Segment

Shilpa's GREEN T FILM

Your health boost on-the-go!
Travel friendly, easy to use Green T Films

Have you tried yet?

BUY NOW
For Order visit www.shilpaote.com #ReinventGreenT



Move over messy Tea bags
Get the convenience of Novel T
with our Green T Film

Shilpa's GREEN T FILM

Like us on Facebook to know more

Shilpa's GREEN T FILM

Move over your caffeine based life form!

CAFFEINE CONTENT

BUY NOW
For Order visit www.shilpaote.com

Shilpa's GREEN T FILM™

ENJOY EVERY SIP WITH CONSISTENCY

ORDER YOUR PACK TODAY!

WE ARE NOW AVAILABLE ON Facebook

Shilpa's GREEN T FILM

Goodbye, messy teabags!

There's a new Green Tea in town with no teabags...

Stay tuned!

Shilpa's GREEN T FILM Is now available on **amazon** for online orders.

Refreshment for the moment?

Refreshment for Lifetime

To order, visit www.shilpaote.com

TAKE THE SIP OF CHANGE FOR A HEALTHIER LIFE

Top Reviews from India

Great for weight loss and immunity boosting

Reviewed in India on 23 October 2020

Some great stuff here. This is one of the best products I have ever seen. No mess and easy to use. Good certainly better!

CONTAINS EGCG
RICH IN ANTIOXIDANTS
HELPS BURN FAT
ENERGY BOOSTER

GOOD FOR SKIN

HEALTHY REPLACEMENT
PLASTIC FREE
GOOD FOR HAIR

Green Tea Vs Black Tea - Which is Healthier? - Shilpa Medicare Ltd

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nonavalla - Follow

nonavalla Enjoyn the winter shooop ☺️ and warmth of Green Tea ☺️ with latest technology. No tea leaves just a soluble natural film that get dissolved in warm water.

☺️Shilpa greenTfilmagic has come up innovative Green Tea strips, making it easy to have tea on the go. No messy tea bags. A perfect immunity booster shot for your wellbeing.

To get that winter glow make healthy lifestyle choices. Let the sunshine energize you.

Pharmashil New Launches in India's Pharmaceutical Market





Financial Performance

Abridged P&L Statement - Standalone

(Rs. In Lakhs)

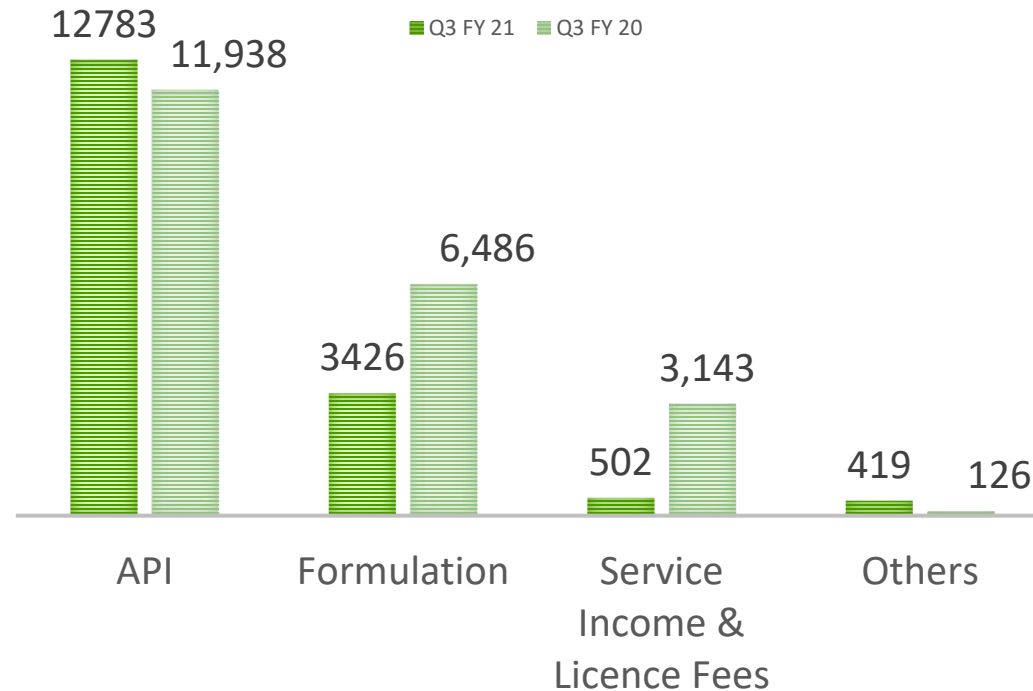
Particulars	Q3 FY21	Q3 FY20	Change (%)	9M FY21	9M FY20	Change (%)	F.Y 2019-20
Total Income (I+II)	17,991	21,936	(18)	66,938	61,633	9	81,724
I. Total Revenue from Operations (A+B+C+D)	17,130	21,693	(21)	65,061	60,804	7	80,598
•API (A)	12,783	11,938	7	44,095	37,554	17	50,181
•Formulations (B)	3,426	6,486	(47)	17,919	14,499	24	19,549
•Service Revenue & Product License Fees (C)	502	3,143	(84)	2,053	7,915	(74)	9,872
•Others (D)	419	126	234	995	837	19	996
II. Other income	861	243	254	1,876	829	126	1,126
Total Expenditure	14,061	13,960	1	46,095	41,241	12	56,109
EBITDA	3,930	7,976	(51)	20,842	20,392	2	25,615
EBITDA margin (%) to Total Income	22	36	(40)	31	33	(6)	31
Exceptional (Income)/Expenses	-	-	-	(5,295)	-	-	454
Finance Costs	395	109	261	1,083	304	256	433
Depreciation and Amortization	1,048	862	22	3,023	2,580	17	3,495
Tax Expenses	799	1,278	(37)	6,252	3,384	85	4,414
Effective Tax Rate %)(continued operations)	32	18	76	28	19	47	21
PAT Period/year from continuing operations incl exceptional item (E)	1,688	5,727	(71)	15,780	14,124	12	16,819
PAT Margins (%)	9	26	(64)	24	23	3	21
Profit (loss) from discontinued operations (net of tax) (F)	-	(66)	(100)	-	(543)	(100)	2,553
PAT (E+F)(Continuing & discontinued operation)	1,688	5,661	(70)	15,780	13,581	16	19,372
PAT Margins (%)	9	26	(64)	24	22	7	24

Abridged P&L Statement - Consolidated

(Rs. In Lakhs)

Particulars	Q3 FY21	Q3 FY20	Change (%)	9M FY21	9M FY20	Change (%)	F.Y 2019-20
Total Income (I+II)	19,985	24,011	(17)	71,634	69,882	3	92,485
I. Total Revenue from Operations (A+B+C+D)	19,125	23,685	(19)	69,305	68,776	1	90,791
•API (A)	13,534	13,644	(1)	46,225	40,760	13	55,441
•Formulations (B)	3,986	3,035	31	19,073	15,281	25	19,429
•Service Revenue & Product License Fees (C)	1,185	6,880	(83)	3,012	11,898	(75)	13,587
•Others (D)	419	126	234	995	837	19	2,334
II. Other income	861	325	165	2,329	1,106	111	1,694
Total Expenditure	17,028	16,311	4	53,765	51,722	4	68,811
EBITDA	2,958	7,700	(62)	17,869	18,160	(2)	23,674
EBITDA margin (%) to Total Income	15	32	(54)	25	26	(4)	26
Exceptional (Income)/Expenses	-	-	-	(6,084)	-	-	-
Finance Costs	480	127	278	1,276	355	259	456
Depreciation and Amortization	1,372	1,097	25	3,875	3,228	20	4,378
Tax Expenses	291	1,053	(72)	4,805	2,577	86	3,349
Effective Tax Rate (%)	28	16	71	26	18	46	21
PAT (incl exceptional item)	814	5,424	(85)	13,998	12,000	17	15,491
PAT Margins (%)	4	23	(82)	20	17	14	17
Share of Profit /(Loss) JV/ Associated & Non-Controlling Interest (net)	(47)	83	(157)	(62)	158	(139)	124
PAT (after Share of profit/(loss) of JV/Associate & non controlling interest)	767	5,506	(86)	13,936	12,158	15	15,615
PAT Margins (%)	4	23	(83)	19	17	12	17

REVENUE BREAKUP (IN LAKHS)



Key Highlights

- Decrease in Formulation revenue in Y-o-Y i.e., Q3 FY21 V/s Q3 FY20 due to WL from USFDA & commitment given to FDA for remediation measures, commercial production was delayed/temporarily stopped
- Service income in Q3 FY20 includes one time license revenue of Rs.2,680 Lakhs

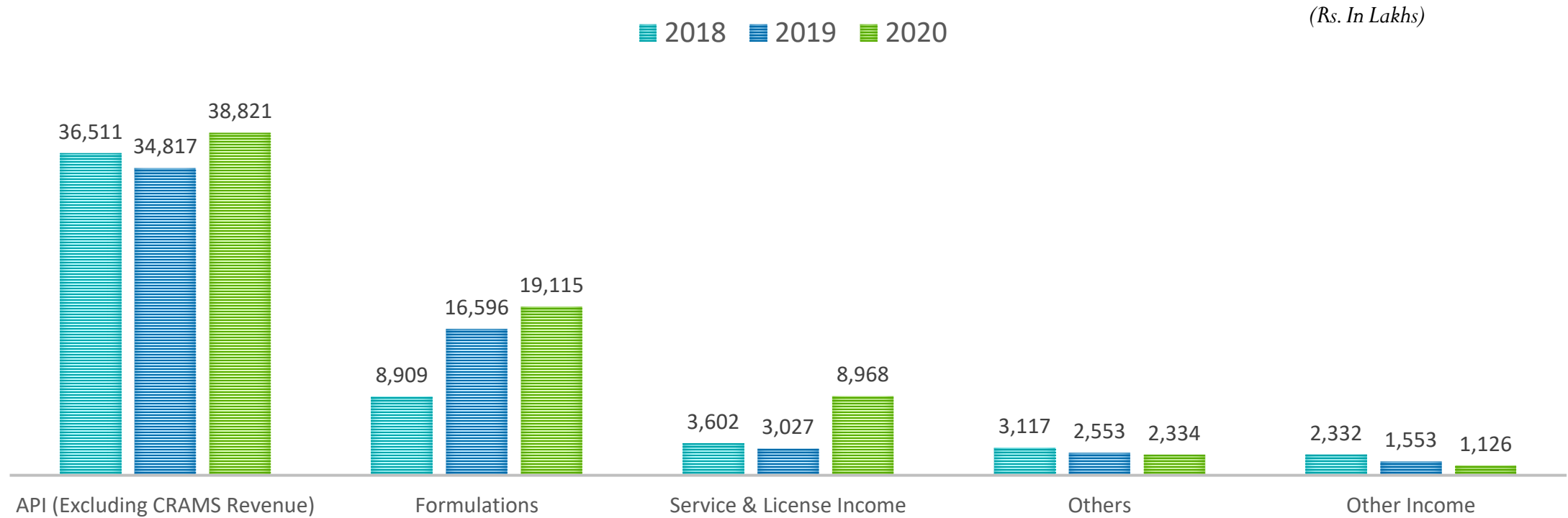
Capital Investment & Debt Details - Standalone

(Rs. In Lakhs)

Particulars	As on 31.12.2020	As on 31.03.2020
Capital Investments		
Fixed Asset Gross Block	78,439	73,392
Tangible Assets (Project Under Progress)	36,112	24,418
Intangible Assets Under Development	16,625	12,863
Total Capital Investment	131,176	110,673
Debt		
Long term	30,458	22,385
Short term	20,249	15,640
Less: Cash & Cash Equivalents	(7,969)	(2,794)
Total Debt	42,738	35,231

Historical Revenue Statement – Standalone

Total Revenue –13.66% CAGR in last 3 years



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



Business Update

API

- Stringently adhering and complying with global safety guidelines across all API facilities
- 2 Products are in review with WHO and expected approval by Mar-21
- Completion of Russian GMP audit successfully in Dec-20



Formulations

- Following products were commercialized
 - Axitinib Tablets - Domestic market
 - Commercial supplies of Azacitidine Inj to two customers in Europe from Jadcherla Unit
 - Additional variants of Green T Film launched in Indian market
- Gearing up to launch Green T Film in export market in 2021
- Exhibit batches to be submitted to the Bengaluru Unit for ODF products



Future Growth Businesses

- R&D facility at Bengaluru is now complemented with a Pilot Plant and an Extractable/Leachable Lab
- Clinical/Bio analytical centre in Hyderabad has been commissioned
- Additionally, the project work for Ophthalmic Line is under discussion
- New QC Laboratory is commissioned at Hyderabad
- CDMO opportunities in production of vaccines being pursued
- Vaccine technologies as a production platform for biopharmaceuticals is a strategic, emerging area of development
 - Capacity for production is now in place, analytical capacity is being built to cater to this market



Current Status on USFDA Warning Letter

- SML's Jadcherla Unit was served a Warning Letter from USFDA in Oct-2020
- The Company has undertaken a systematic remediation plan with the help of a Third-Party Consultant to address the concerns of the Agency
- SML has regularly updated the Agency's status of remediation activities in the form of monthly updates
- Due to remediation measures and upgradation of facility, commercial production was delayed/temporarily stopped
- Continuing to supply three products to the US market as per the commitments made to the USFDA from Q4 F.Y 2020-21
- The Company remains committed to work towards resolving all the concerns cited by the Agency

Update on European Market:

- The unit has maintained uninterrupted supply of Azacitidine products to European markets





Marketing Updates

Proficient Marketing Team Across Geographies - API

V. Prakash



Rajkumar Somani



Janak Kastia



Dilip Chavan



Guruprasad



Anna Chaturvedi



- 29+ years of overall work experience
- Designation: **Global Head for API**
- Previously worked with Sun Pharma as Sr. Vice President

- 29+ years of overall work experience
- Working with SML for 12+ years
- Designation: **Vice President - Marketing**
- Region: **India and Europe**
- Previously worked with Khandelwal Laboratories Pvt. Ltd. as Vice President - Operations

- 30+ years of overall work experience
- Working with SML for 11+ years
- Designation: **Sr. GM – Marketing & Business Development**
- Region: **USA**
- Previously worked with Zydus-Cadila Healthcare as GM–International Business

- 24+ years of overall work experience
- Working with SML for 13+ years
- Designation: **Sr. General Manager – International Business**
- Region: **Emerging ROW market**
- Previously worked with Naprod Group as Sr. Marketing Manager

- 24+ years of work experience
- Designation: **Head - Business Development - API**
- Region: **China**
- Previously worked with Nanjing Dorra Pharmaceutical, China as Head Business Development

- 8+ years of work experience
- Region: **Russia & CIS markets**
- Previously worked with JSC "Rafarma"

Proficient Marketing Team Across Geographies - Formulation

Sundeip Bhatia



- 34+ years of overall work experience
- Designation: **Business Head – Formulation**
- Region: **India**
- Previously worked with Dr. Reddy's Laboratories as Cluster Head - India

Shankar Ramakrishna Iyer



- 32+ years of overall work experience
- Working with SML for 4+ years
- Designation **General Manager – Business Development**
- Region: **MENA & Asia (excl. India)**
- Previously worked with Gland Pharma Limited as GM – International Business

Michel Roy



- 25+ years of overall work experience
- Designation **President – Formulation for Canada**
- Region: **Canada**
- Previously worked with Intas Pharmaceuticals as Vice President of Business Development & Licensing (Canada)

Pramod Pandey



- 22+ years of overall work experience
- Designation: **President – Formulation for South Africa**
- Region: **South Africa**
- Previously worked with Piramal Healthcare as a Sales & Marketing Director

Proficient Marketing Team Across Geographies - Formulation

Harco Giling



- 11+ Years of overall work experience
- Designation: **Vice President – Licensing and Third Party Sales - Formulations**
- Region: **Europe**
- Previously worked with Intas Pharmaceuticals as Global Licensing Business Development and Generic Portfolio Manager

Adam Levitt



- 30+ years of overall work experience
- Working with the SML for 3+ years
- Designation: **CEO of Shilpa Pharma Inc**, a wholly owned subsidiary of SML
- Region: **USA**
- Previously worked with Teva Pharmaceuticals as Sr. VP - Global Commercial Operations

Abhishek Banerjee



- 20+ years of overall work experience
- Region: **Latin America**
- Previously worked with Accord Farmaceutica Ltda as Regional Director Latin America & the Caribbean

Rajeev Kumar



- 14+ years of overall work experience
- Designation: **Head Formulation Business – Russia & CIS**
- Region: **Russia & CIS markets**
- Previously worked with Routek Ltd as Head of Representative Office of Formulation Business Marketing and Sales

Product Dossier submissions in ROW Market

Region	Products Submitted to MOH	Products Approved	Products Under Assessment with Customer
Australia	9	--	2
MENA	26	1	20
LATAM	94	26	29
Asia	43	8	46
CIS	6	2	18
Africa	25	5	24
Total	203	42	139

Patents Status as on December 31, 2020

Patents	Filings	Granted	Pending
- API	203	37	166
- Formulation *	166	15	151
- Films Topical & Transdermal	49	2	47
- Biologicals	10	2	8
- Others	22	4	18
TOTAL	450	60	390

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

Formulation Product Pipeline as on December 31, 2020

Regulatory Submissions	Filings	Approved (Including Tentative)	Pending
- US ANDA: SML	23	13	10
- US NDA: SML	2	0	2
- US ANDA: Customers	18	12	6
TOTAL (In US)	43	25	18
- EU Filing	21	13	8
- Canada Filing	1	0	1
TOTAL	65	38	27



Way Forward

API



- Plan to commercialize 3-4 molecules each year
- Completed debottlenecking of one Oncology block & started the manufacturing the product
- Initiated debottlenecking of two Oncology blocks
- New Tranexamic block commissioned which is an expansion block

Formulations



- Expanding reach by entering different geographies/markets
- Risk mitigation strategy to minimize the impact of 483's on business has worked out – for eg: Alternate testing lab, alternate manufacturing site, engagement of external consultants for remediation and reorganizing and strengthening the quality structure

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 further products
- Launch of Shilpa's branded products for ODF in the domestic market
- 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 all 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. Such partnering opportunities are being pursued now
- Production platforms and formulation, logistics competencies in the area being built via emerging CDMO opportunities now



Key addition to the CDMO team

- **Dr. Vishal Rajput** joined the CDMO team as **General Manager – Head CDMO Business** (SML Group Services) and will be in charge of the CDMO Business
- Dr. Rajput has 11+ years of overall work experience and previously worked with Syngene International Ltd



Annexure

Historical R&D Expenditure Trends

(Rs. In Lakhs)

Particulars	FY18	FY19	FY20	9M-FY21
Total R&D Expenditure	7,813	8,751	12,883	10,793
R&D Revenue Expenditure	5,386	4,004	6,948	5,870
R&D Intangible Assets(incl. CWIP)	2,427	4,747	5,935	4,923
R&D as a % of Revenue	10%	13%	16%	17%

Strong orientation on R&D to sustain growth performance

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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Thank You



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