



Innovating for
affordable healthcare

Shilpa Medicare Limited

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CIN: L85110KA1987PLC008739

Dated 02nd November, 2020

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 02nd 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



Q2 & H1 FY21
Results Presentation

Shilpa Medicare Limited (SML)



Innovating for
affordable healthcare

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.

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Way Forward



Annexure



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

Robust research orientation resulting in innovative products

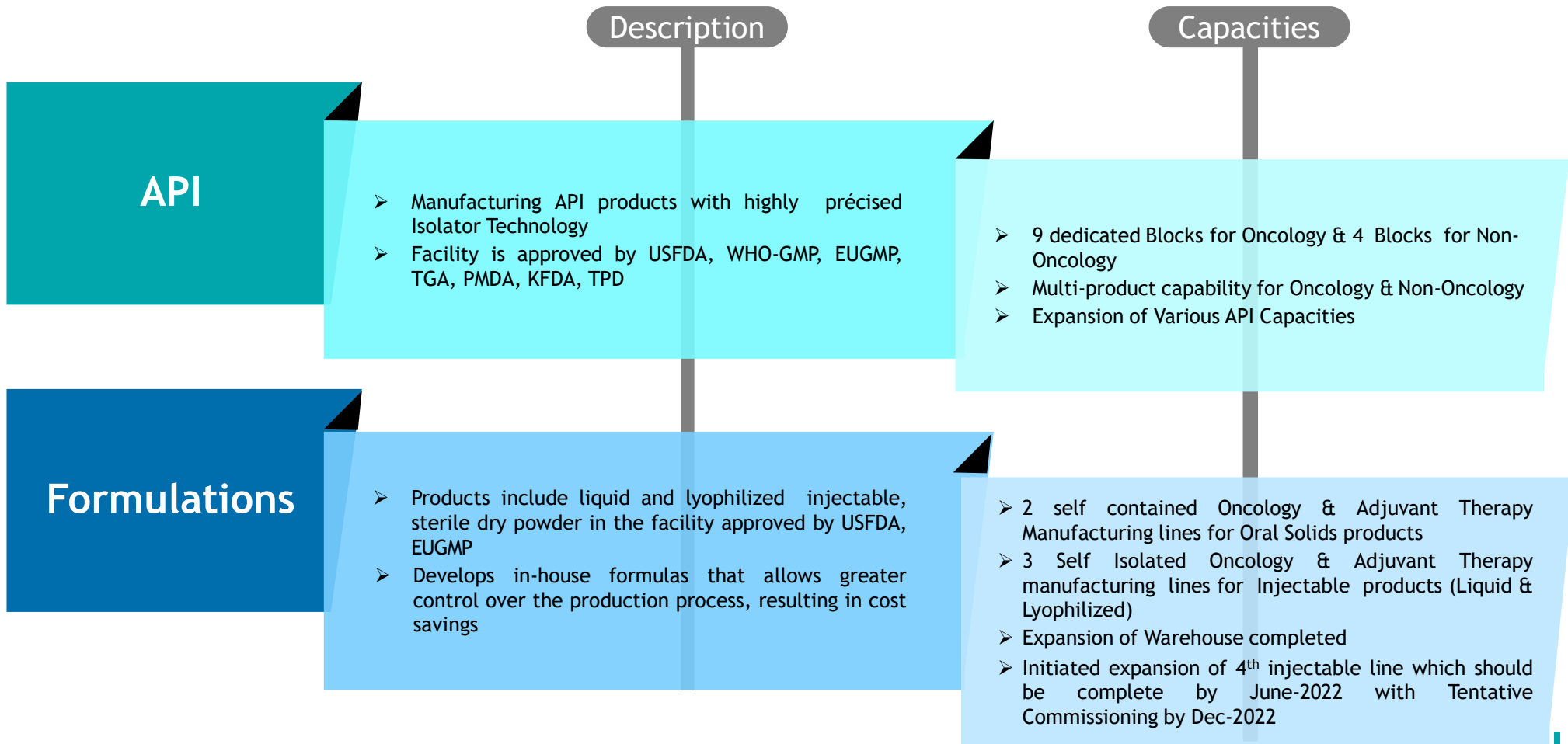
Very strong R&D background in biologics development, pathway engineering and characterization of biologics

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

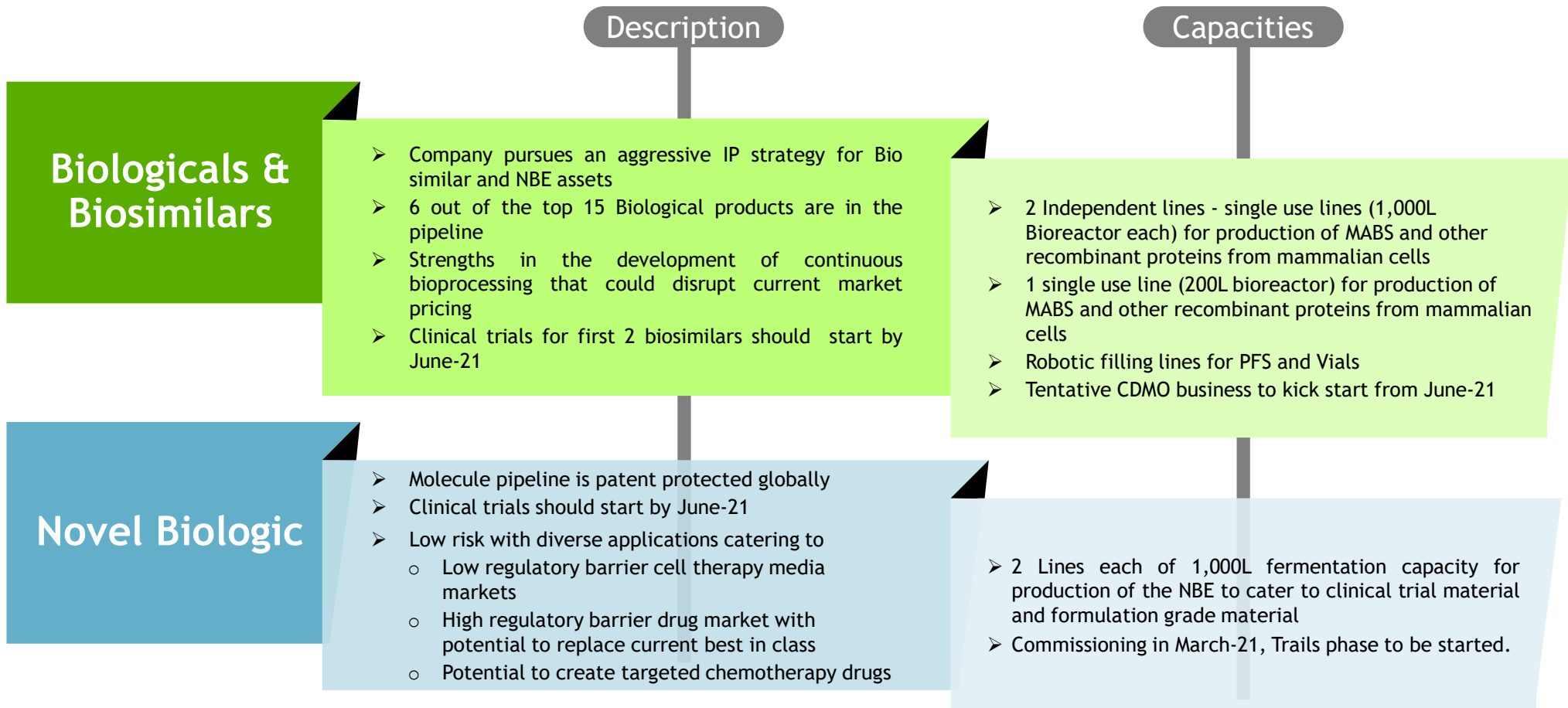
Affordable & Effective Pharmaceutical Solutions



Established Business Segments



Established Business Segments



Growth Business Segments



Description

Capacities

Dermatological Formulations

- Company is 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
- Plan to launch 1 product in domestic market by June-2022
- 2 niche new products are under development in which 1 product is in clinical phase and 1 product in preclinical phase

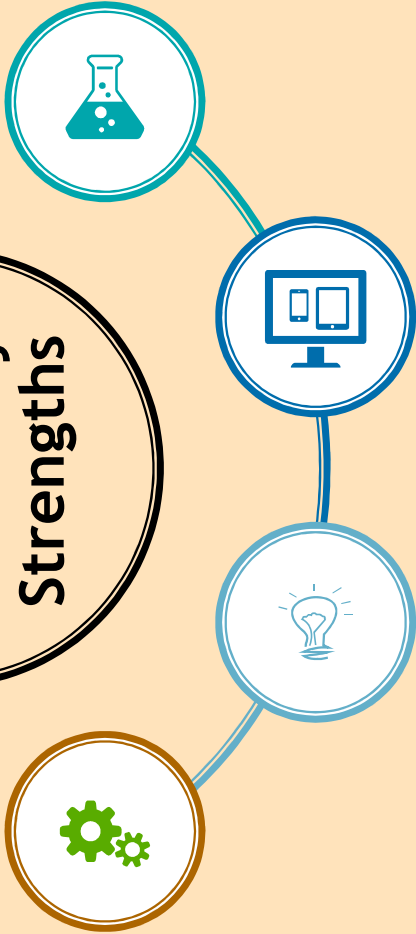
- R&D is carried out at Shilpa Medicare's in-house R&D Facility
- Exhibit batches are taken at a Contract Manufacturing Organization

Oral Dissolving Films & Transdermal Products

- 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 film in the domestic market which is first of its kind in the world & will change the dynamics of green tea consumers

- Combo - Line has been commissioned and exhibit batches for the products ODF Products initiated. One Product execution initiated. Will be completed by Dec-20 Bangalore.
- 2 dedicated lines for ODF at Hyderabad
- Combo-Line (ODF & TD), first of its kind from Germany at Bengaluru, India

SML's Key Strengths



R&D Competence

Technology Edge

Rich Scientific Talent

Manufacturing Excellence

TD and ODF Research & Development Competence

R&D
capabilities, a
vital component
providing a
sustainable,
long-term
competitive
advantage



- 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



- 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-Newtonian fluids, quantitative Cold Flow etc.

Technology Edge



Coating Machine



Converting Machine



- State of the art machines and equipment for TDS and ODF dosage forms
- Fully automated world class ODF and TDS manufacturing Combo facility at Bengaluru based to produce high quality products with German equipments
- Low waste leading to low COGS
- Flexibility to incorporate continuous batch process

- Environment friendly manufacturing facility
- Multiproduct capability and capacity
- Complete in-house characterisation of Transdermal patches and Oral films with high end, high throughput analytical instrumentation and validated methods
- Experienced R&D, Scale-up and Manufacturing / Regulatory / Quality team

Rich Scientific Talent (TDS & ODF)

40+

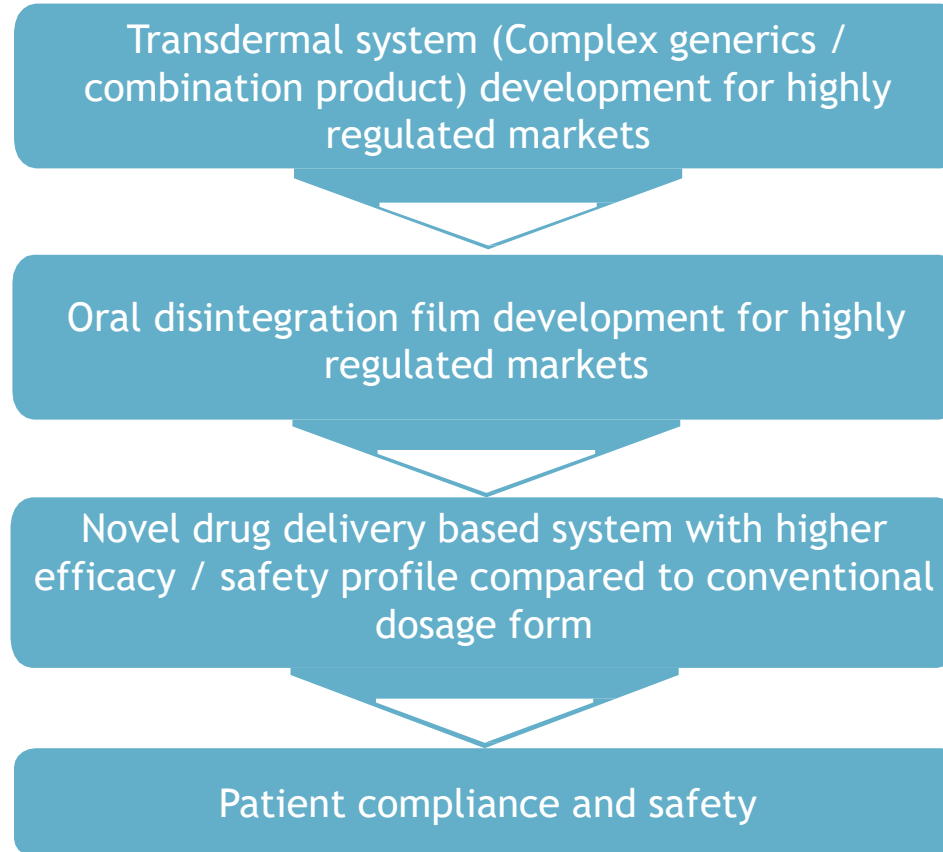
Scientists

48

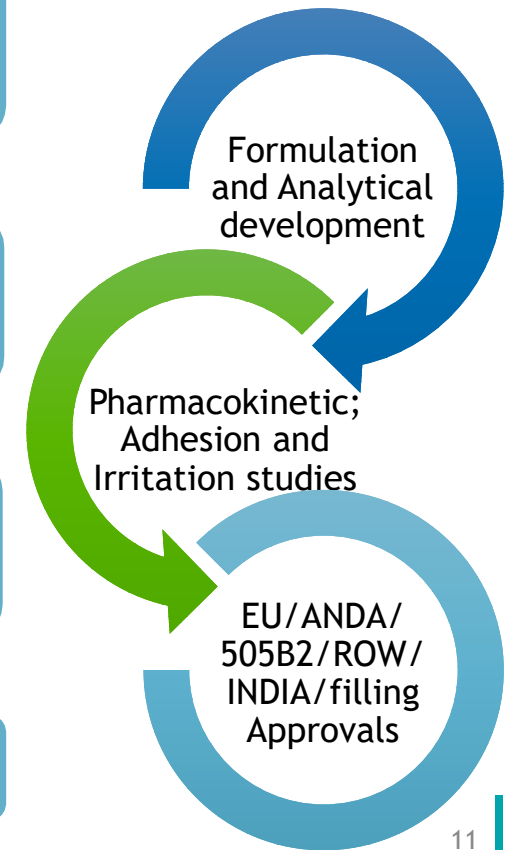
Patents filed

2

Patents Granted



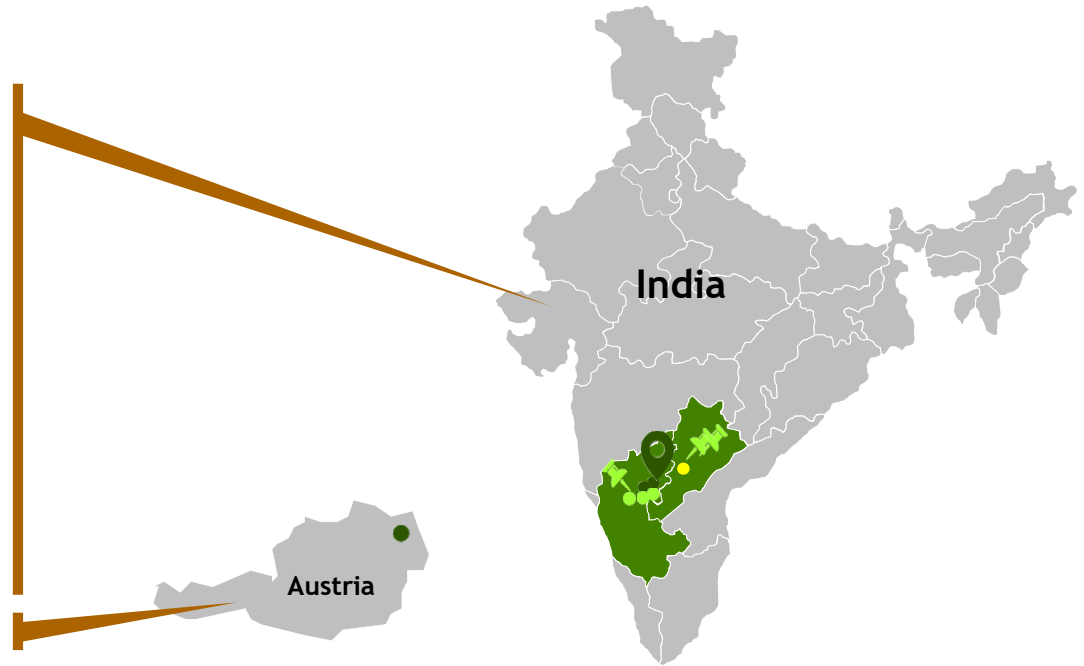
Current pipe line projects for TDS/ODF for Global market



Manufacturing Excellence



Facility Location	Facility Type
Dharwad	Biologicals Manufacturing plant & R&D Facility
Bengaluru	TDS & ODF Manufacturing Facility & R & D (All segments except Biologicals)
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
Austria	API Manufacturing



- Currently 5 manufacturing facilities for API's & Formulations 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 are 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 reactor

Company's Headquarters at Raichur, Karnataka, India

Manufacturing Facilities

- 2 API plants at Raichur, India
- ✦ 4 R&D units. (Bangalore, Dharwad Hubli and Raichur, India)
- 1 Manufacturing site for Biologicals at Hubli, India
- 2 Formulation plants at Jadcherla and Hyderabad, India
- 1 API plant at Austria

Coating Machine



Discussion of Select Business Segment

Film Formulation - Under Shilpa's Brand



Methylcobalamin Orally Disintegrating Strips 1500 mcg



Tadalafil Orally Disintegrating Strips 5 mg, 10 mg and 20 mg



Simethicone Orally Disintegrating Strips 62.5 mg



Ondansetron Orally Disintegrating Strips 2 mg, 4 mg and 8 mg



Green T Film



Smart brews for
THE SMART GENERATION

Order Now
www.shilpaotc.com

Ginger
lemon flavor

Available
at **AMAZON**

- With the launch of ready to dissolve Green Tea, SML forayed into the niche OTC segment
- SML's Green T films are patent protected and first of this kind in the world
- These Green T Films are currently available in Ginger and Lemon flavors
- SML's Green T Films are an innovative product which enables easier and no-mess preparation of green tea



BENEFITS OF SHILPA'S GREEN TEA FILM

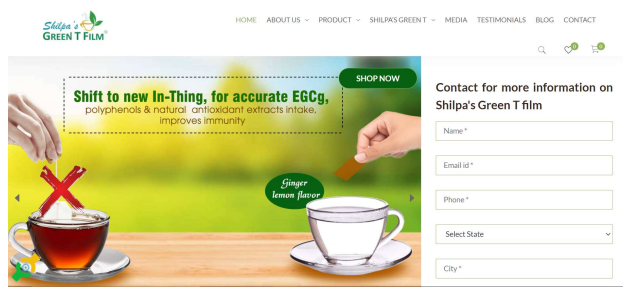
- Fat burning properties assisting in weight loss
- Free Radical Scavengers in the Green tea reduces the chances of cancer occurrence
- Boosts metabolism
- Reduces hunger
- Improves physical performance
- Green tea catechin may improve brain function
- Green tea EGCG is beneficial for skin and hair
- Green tea antioxidants may reduce PCOS (polycystic ovarian syndrome) risk, a hormonal disorder in women
- Green tea catechin may reduce high blood pressure, inflammation & arthritis
- Green tea may boost immunity and increase longevity

Green T Films Vs Green Tea Bag



Advantages of Green Tea Film	Disadvantages of Green Tea Bag
<ul style="list-style-type: none">➤ Completely disintegrates in hot water and does not leave any residues behind	<ul style="list-style-type: none">➤ Do not dissolve or disintegrate in hot water and leaves residues behind
<ul style="list-style-type: none">➤ Gives accurate dose as per the label claim	<ul style="list-style-type: none">➤ Dose may variable based on dipping time
<ul style="list-style-type: none">➤ Contains accurate Polyphenol Content (120mg) and EGCG content (54mg) which has antioxidant properties	<ul style="list-style-type: none">➤ Does not provide the content of Polyphenol and EGCG
<ul style="list-style-type: none">➤ Does not lose nutrients, aroma, essential oils and flavour thus giving the intended effect of the green tea	<ul style="list-style-type: none">➤ Tea bags often contain dust & fanning's➤ The tea bags loses its nutrients, aroma, essential oils and flavour
<ul style="list-style-type: none">➤ No contact with the packing material during preparation and no chance of leachable and extractables	<ul style="list-style-type: none">➤ Study finds that Tea bags release millions of microscopic plastic particles into your drink➤ Electron microscopy shows that a single plastic teabag at brewing temperature released about 11.6bn microplastic and 3.1bn Nano plastic particles into the water* https://pubs.acs.org/doi/abs/10.1021/acs.est.9b02540

Green T Film - Social Media Presence



shilpaotc.com



[Amazon page](#)

Shilpa's Green T Film Natural Green Tea
(Pack of 30Pcs)

Brand: Shilpa's
★★★★★ 2 ratings

Price: ₹ 285.00 (₹ 9.50 / count)
Inclusive of all taxes

FREE delivery: Monday, Nov 2 Details

No-Contact Delivery Non-Returnable Amazon Delivered

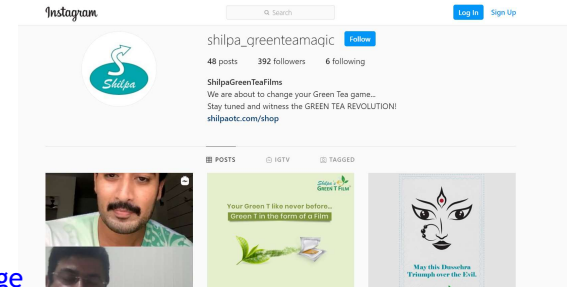
In stock.
Sold by Shilpa Medicare.
Size: Pack of 30Pcs

Pack of 30Pcs ₹ 285.00 (₹ 9.50 / count) Pack of 60Pcs ₹ 530.00 (₹ 8.83 / count)

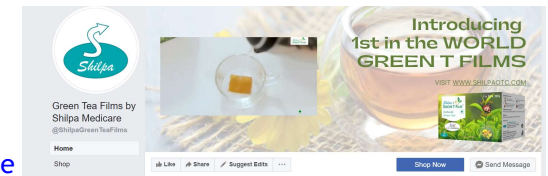
Pack of 100Pcs ₹ 950.00 (₹ 9.50 / count)



[Shilpa's Green Tea Insta Page](#)



[Shilpa's Green T Film FB page](#)



[Shilpa's Green Tea Twitter Page](#)



TDS & ODF Key Highlights :



Manufacturing Vessels

- 08 Oral Film Products are in pipeline for Global and Domestic Market
- 02 Transdermal Patch Products are in pipeline for Global and Domestic Market
- High Standard Regulatory Compliant facility for Manufacturing of Oral Films and Transdermal Patches
- Experienced team with global exposure

Slitting Machine



Financial Performance

Abridged P&L Statement -Standalone



(Rs. In Lakhs)

Particulars	Q2 FY21	Q2 FY20	Change (%)	H1FY21	H1FY20	Change (%)	F.Y 2019-20
Total Income (A+B+C+D)	26,269	23,653	11	47,933	39,110	23	80,598
Normalised Total Income (A+B+C+D+E)	27,021	23,897	13	48,949	39,696	23	81,724
Total Revenue from Operations (A+B+C+D+E)	27,021	23,897	13	48,949	39,696	23	81,724
•API (A)	16,510	14,120	17	31,218	25,168	24	50,181
•Formulations (B)	8,190	4,747	73	13,809	7,897	75	19,115
•Service Revenue & Product License Fees (C)	925	4,072	(77)	1,551	4,772	(67)	8,969
•Others (D)	644	714	(10)	1,355	1,273	6	2,333
•Other Income (E)	752	244	208	1,016	586	73	1,126
Total Expenditure	18,130	16,124	12	32,035	27,281	17	56,109
EBITDA	8,891	7,773	14	16,914	12,415	36	25,615
EBITDA margin (%) to Total Income	33	33	1	35	31	10	31
Normalised EBITDA	8,891	7,773	14	16,914	12,415	36	25,615
EBITDA margin (%) to Total Income	33	33	1	35	31	10	31
Exceptional (Income) Expenses	-	-	-	(5,294)	0	100	454
Finance Costs	334	63	430	688	195	253	433
Depreciation and Amortization	984	861	14	1,975	1,718	15	3,495
Tax Expenses	2,095	1,294	62	5,453	2,107	159	4,414
Effective Tax Rate (%)	28	16	75	28	17	65	21
PAT Period/year from continuing operations (A)	5,478	5,555	(1)	14,092	8,395	68	16,819
PAT Margins (%)	20	23	(13)	29	21	36	21
Profit (loss) from discontinued operations (B) (net of tax)		(246)			(476)		2,553
Normalised PAT (A+B)	5,478	5,309	3	14,092	7,919	78	19,372
PAT Margins (%)	20	22	(9)	29	20	44	24

Abridged P&L Statement - Consolidated



(Rs. In Lakhs)

Particulars	Q2 FY21	Q2 FY20	Change (%)	H1FY21	H1FY20	Change (%)	F.Y 2019-20
Total Income (A+B+C+D)	27,934	28,992	(4)	50,181	45,091	11	90,791
Normalised Total Income (A+B+C+D+E)	28,854	29,574	(2)	51,649	45,871	13	92,485
Total Revenue from Operations (A+B+C+D+E)	28,854	29,574	(2)	51,649	45,871	13	92,485
•API (A)	17,412	15,083	15	32,556	26,669	22	55,441
•Formulations (B)	8,796	5,095	73	14,448	8,042	80	19,429
•Service Revenue & Product License Fees (C)	1,073	8,015	(87)	1,827	8,715	(79)	13,587
•Others (D)	653	799	(18)	1,350	1,665	(19)	2,334
•Other Income (E)	920	582	58	1,468	780	88	1,694
Total Expenditure	21,066	22,191	(5)	36,738	35,410	4	68,811
EBITDA	7,788	7,383	5	14,911	10,461	43	23,674
EBITDA margin (%) to Total Income	27	25	8	29	23	27	26
Normalised EBITDA	7,788	7,383	5	14,911	10,461	43	23,674
EBITDA margin (%) to Total Income	27	25	8	29	23	27	26
Exceptional (Income) Expenses	-	-	-	(6,084)	-	100	-
Finance Costs	395	82	382	795	228	249	456
Depreciation and Amortization	1,270	1,066	19	2,502	2,132	17	4,378
Tax Expenses	1,600	1,119	43	4,514	1,524	196	3,349
Effective Tax Rate (%)	26	18	44	26	19	37	21
PAT	4,523	5,116	(12)	13,184	6,577	100	15,491
PAT Margins (%)	16	17	(9)	26	14	78	17
Share of Profit /(Loss) JV/ Associated & Non-Controlling Interest (net)	14	(38)		(15)	(75)		124
Normalised PAT	4,537	5,078	(11)	13,169	6,652	98	15,615
PAT Margins (%)	16	17	(9)	26	14	78	17

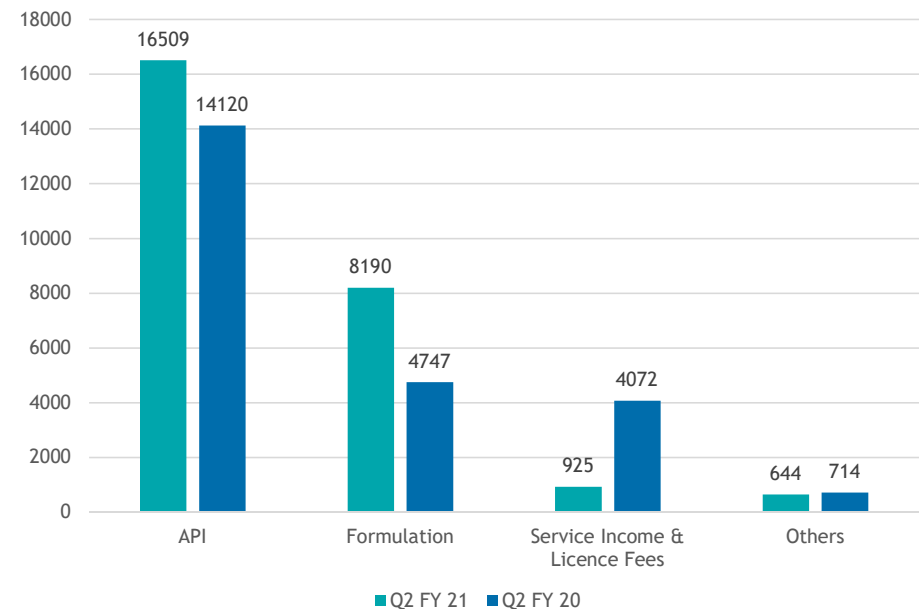
Results Snapshot (Standalone)



Key Highlights

- API & Formulation revenue growth Y-o-Y i.e Q2 FY21 v/s Q2 FY20 are 17% and 73% respectively.
- Service Income in Q2 FY20 includes one time License revenue of Rs.3525 lakhs.

Revenue Breakup (In Lakhs)



Capital Investment & Debt Details - Standalone



(Rs. In Lakhs)

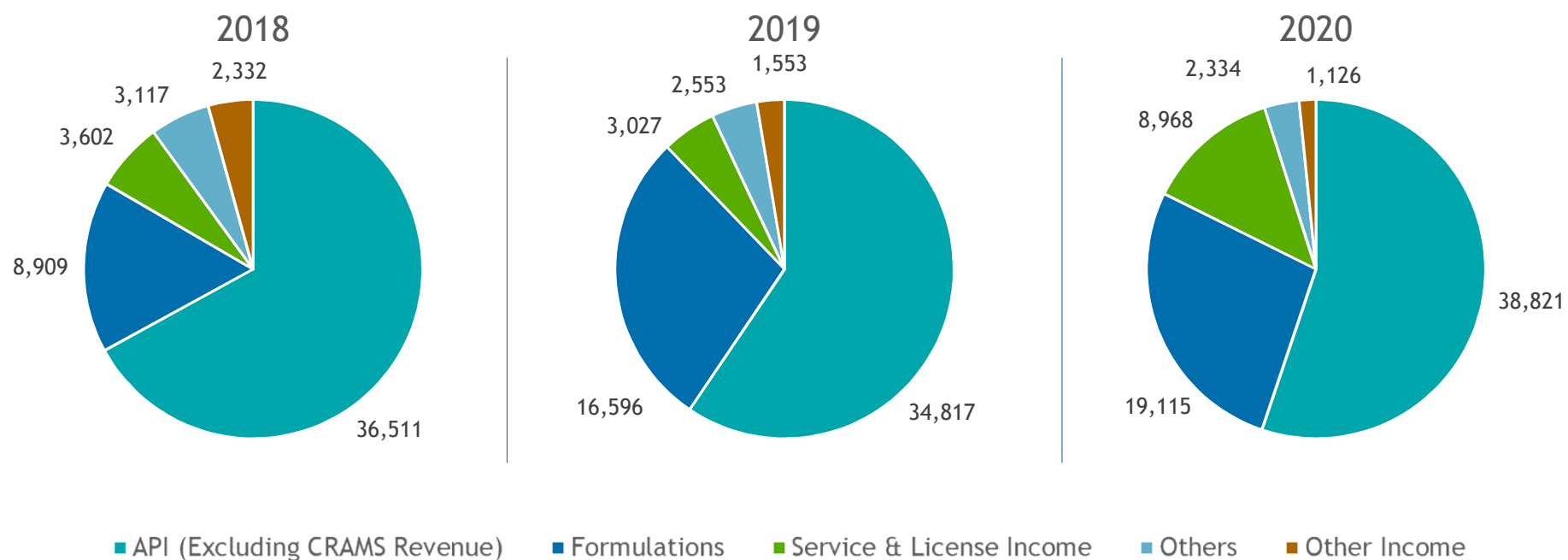
Particulars	As on 30.09.2020	As on 31.03.2020
Capital Investments		
Fixed Asset Gross Block	77,931	73,392
Tangible Assets (Project Under Progress)	31,647	24,418
Intangible Assets Under Development	14,050	12,863
Total Capital Investment	123,628	110,672
Debt		
Long term	29,953	16,448
Short term	21,932	15,640
Less: Cash & Cash Equivalents	(17,677)	(2,794)
Total Debt	34,208	29,295

Historical Revenue Statement - Standalone



Total Revenue -13.66% CAGR in last 3 years

(Rs. In Lakhs)



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

Converting Machine



Business Update



API

- Stringently adhering and complying to Global safety guidelines across all API facilities
- 2 Products are in review with WHO and expected approval by Mar-2021



Formulations

- Following products were commercialized
 - Green Tea Film launched in Domestic market from Hyderabad Unit
 - Commercial supplies of Azacitidine Inj to two customers in Europe from Jadcherla Unit
 - Betahistine ODF for Abbott launched in Indian market
- Gearing up to launch Green T Film in Export market in 2021



Future Growth Businesses

- R&D Facility at Bengaluru is now fully operational
- Additionally, the Project work for Ophthalmic Line and Pilot Plant is underway
- The Bengaluru center also has state of art facility for manufacturing pilot cGMP batches at low batch sizes for BA/BE and clinical supplies, which helps companies to extend their research at lower cost
 - This facility has the capacity of catering to complex products in injectable and solid oral in Non-Oncology segment and solid orals in the Oncology segment
- 2-3 Biosimilars to launch in India/RoW markets by June-2022
- Cell banking and Virus testing/Virus clearance services - Test runs phase
- Fully integrated offerings in CDMO - Cell line development to DP Production will be on offer from June-21- A first from India

Current Status on USFDA Warning Letter



- Shilpa's Jadcherla Unit was served a Warning Letter from USFDA
- The Warning Letter acknowledges Shilpa's responses to the 15 observations listed in Form 483, as well as some of the measures taken by Shilpa to address the concerns raised in the Form 483
- As compared to the 15 observations in the 483 Form, the Warning Letter has two citations
- Shilpa has responded to the Warning Letter within the stipulated time. Shilpa has already sent out appropriate communication to all concerned about the receipt of Letter
- In the response, Shilpa will be clearly stating the strategy for remediation of the specific two citations in the Letter, as well as overall cGMP review and overall compliance status of the Plant
- Strongly committed towards resolving all the observations cited by the Agency

Message by Dr. Jayant Karajgi - COO (Formulation)



Commenting on the performance for Q2 FY2021, Dr. Jayant Karajgi , COO (Formulation), Shilpa Medicare Limited (SML), said:

“We are pleased to have continued the steady performance and growth in this quarter despite the challenges of working under constraints of compliance at Jadcherla Unit, where significant resources were spent for response and remediation of 483 observations. This quarter saw the Project of Corporate hub, Quality Control and Bioanalytical Labs at Hyderabad nearing completion. It is expected to get operational in Q3.

Bengaluru Unit witnessed kick start of the first product exhibit batches for regulated markets. R&D continues to develop and deliver exciting new niche products. Product approvals gained steam, particularly for rest of world markets. Key ROW markets will witness increased thrust, being supported from the front end by aggressive newly recruited Marketing Heads.

Development of alternate sites and laboratories for any perceived risk mitigation is ongoing. The key is the relentless and quick execution of the excellent ideas and concepts on which we are working and translate them into product filings and approvals.”

Patents Status as on September 30, 2020



Patents	Filings	Granted	Pending
- API	201	37	164
- Formulation	110	14	96
- Films Topical & Transdermal	48	2	46
- Biologicals	8	2	6
- Others	22	1	21
TOTAL	389	56	333

Formulation Product Pipeline as on September 30, 2020



Patents	Filings	Approved (Including Tentative)	Pending
US ANDA/NDA			
- On SML's Name	25	13	12
- On Customer's Name	18	12	6
TOTAL (In US)	43	25	18
- EU Filing	20	14	6
TOTAL (In US & EU)	63	39	24

Quality Control Lab



Way Forward

Way Forward



API

- Plans to commercialize 3-4 molecules each year
- Debottlenecking initiated and will be completely executed by March 2021
- Commenced Dedicated block work



Formulations

- Achieved significant progress in two of the goals stated in Q1 (expanded geographies & economies of scale)
- Expanding reach by entering different geographies/markets
- Significant work ongoing for the third point(operational excellence)
- Risk mitigation strategy to minimize the impact of 483's on business has been 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 Unit 6 will take exhibit batches for further two products
- Launch of Shilpa's branded products for ODF in the domestic market i.e about 6-7 products
- Markets besides US may be the business drivers going forward
- 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)
- Patient compliance/ease of use - will drive markets in biologics for lifestyle disorders
 - Novel formulations in biosimilars integrated with novel delivery devices being developed, with focus on lifestyle related diseases

Packaging Machine



Annexures

Historical R&D Expenditure Trends



(Rs. In Lakhs)

Particulars	FY18	FY19	FY20	H1-FY21
Total R&D Expenditure	7,813	8,751	12,883	5,556
R&D Revenue Expenditure	5,386	4,004	6,948	3,643
R&D Intangible Assets (incl. CWIP)	2,427	4,747	5,935	1,914
R&D as a % of Revenue	10%	13%	16%	12%

Strong orientation on R&D to sustain growth performance

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

 **Siddharth Rangnekar/ Karl Kolah**

 **CDR India**

 **+91 22 6645 1209 / 1220**

 siddharth@cdr-india.com

karl@cdr-india.com

API Facility Temple Photo - Raichur



Thank You