## Shilpa Medicare Limited



Innovating for affordable healthcare

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CIN No. L85110KA1987PLC008739

Dated 18<sup>th</sup> June, 2020

To Corporate Relationship Department BSE Limited, 1<sup>st</sup> Floor, Rotunda Building, P.J. Towers, Dalal Street, . **Mumbai – 400 001.**  To National Stock Exchange of India Limited Exchange Plaza, 5<sup>th</sup> Floor, Plot No.C/1, G Block Bandra Kurla Complex, Bandra (E) **MUMBAI – 400 051**.

Dear Sir,

Sub: Updated 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 updated copy of 04<sup>th</sup> Quarter and Financial Year 2019-20 Results presentation made to analysts and Investors.

This is for your information and Records.

For Shilpa Medicare Limtied.

V V Krishna Chaitanya<sup>k</sup> Company Secretary and Compliance Officer

#### Q4 & FY20 Results Presentation

# Shilpa Medicare Limited (SML)





#### 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 forwardlooking statements to reflect subsequent events or circumstances.







#### **Company Overview**



Established presence in Active Pharmaceutical Ingredients (APIs) and Formulations for domestic & international markets

> Pursuing niche growth businesses like Biologics, Transdermal, Oral Dissolving Films and Dermatological Formulations

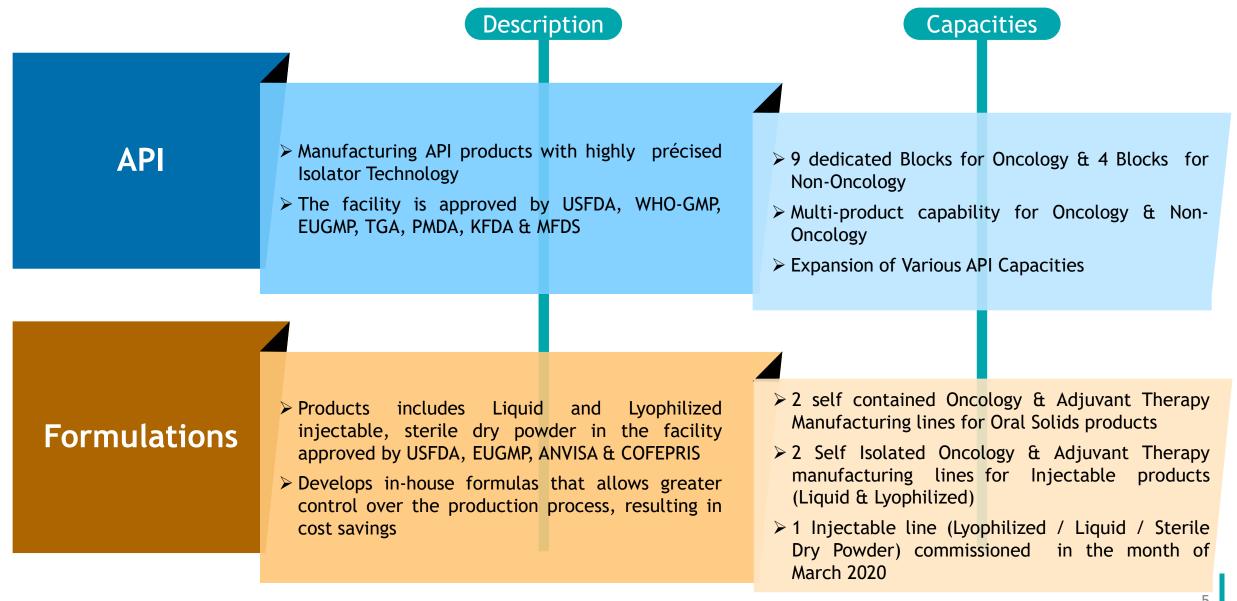
Specialized in Oncology and Non-Oncology Therapeutic areas, supported by strong R&D capability

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

Robust research orientation resulting in innovative products Affordable & Effective Pharmaceutical Solutions

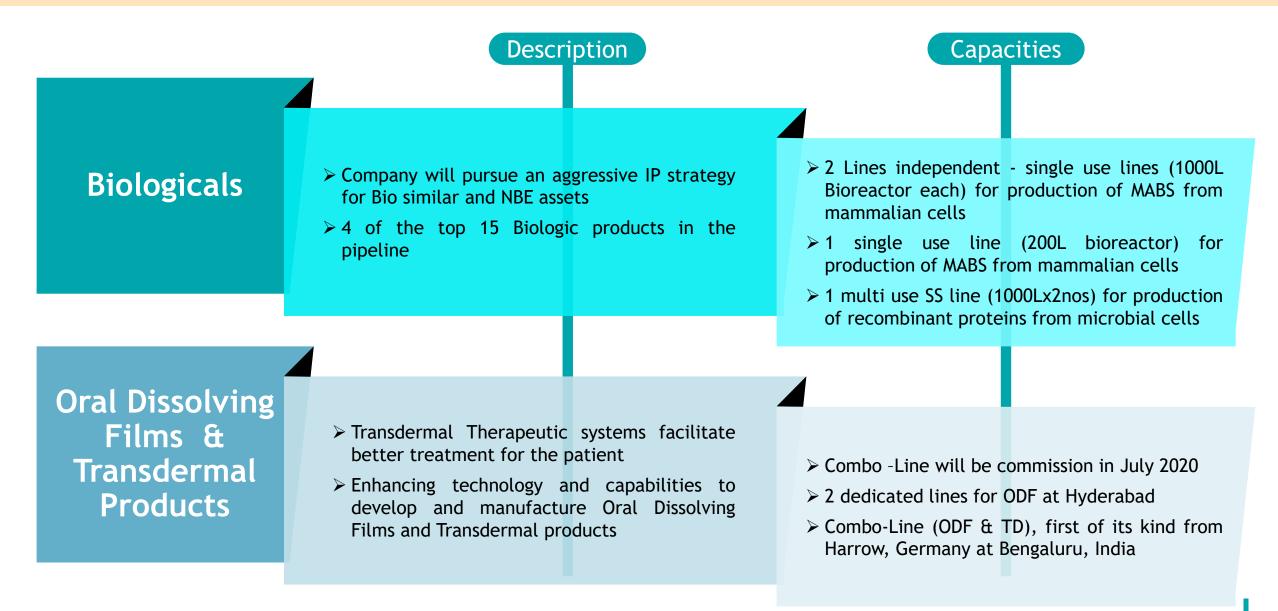
#### **Established Business Segments**





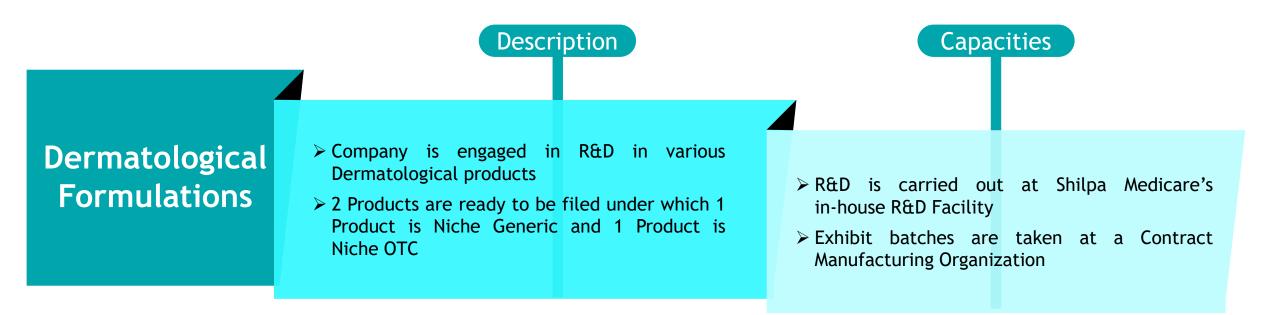
#### **Growth Business Segments**

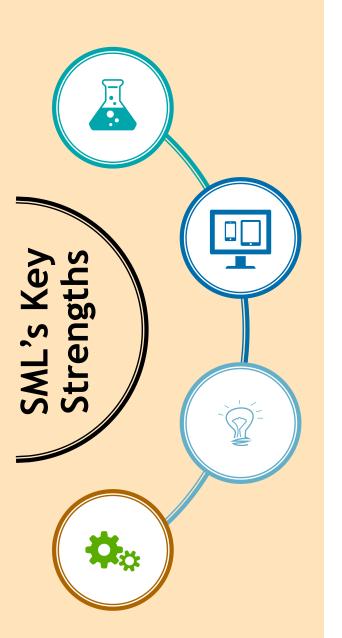




#### **Growth Business Segments**







## **R&D** Competence

## **Technology Edge**

## **Rich Scientific Talent**

Manufacturing Excellence

Research & Development Competence



API R&D Centre aids the development of Generics which meet international development standards

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



Formulation R&D centre develops Generic equivalents and super Generics for global markets of Injectable and Oral Formulations which are primarily used for the treatment of cancer & adjuvant therapy



Upcoming state of the art centralized R&D center at Bengaluru for the development of Formulation, will be fully commissioned by September 2020

#### Technology Edge API



X-Ray Diffraction for Polymorphic Identification Instrument

- Improved safety in the process
- Reduced pain points in the process
- Reduced manual intervention which improves effluent quality
- Flexibility to use the equipment in multiple processes (with similar chemistries)
- The Company has made progress in the field of 'Targeted Therapy,' which has enabled the identification of neoplastic cells and the development of novel targeted therapies
- The Company constantly works on reducing the prices of medicines by developing Generic versions of off-patented drugs

#### **Rich Scientific Talent API**



Devise new processes, or validate new processes, or refine existing ones, to optimize the manufacturing process

Improve the yields by reducing costs, e.g. investigating alternative materials or new machinery to improve efficiency and quality in bottleneck areas

Implement product protocols and procedures and product evaluation Transfer new technologies across a range of product categories

Oversee the integration of new products with other commercial areas, including brand development, sales strategy, quality assurance, legal, marketing and manufacturing

125+ Scientists

200+ Patents filed

44+

High quality products



Patents	Filings	Granted	Pending
- API	200	34	166
- Formulation	83	8	75
- Films Topical & Transdermal	46	2	44
- Biologicals	6	2	4
- Others	22	1	21
TOTAL	357	47	310

### Product wise DMF filings as on March 31, 2020

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Name of the API	US FDA	EU/ EMEA	TPD-Canada	PMDA Japan	TGA & Medsafe-NZ	EDQM	KFDA Korea	GCC & ROW	WHO Market
Ambroxol HCl						$\checkmark$	$\checkmark$	$\checkmark$	
Azacitidine	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$			$\checkmark$	$\checkmark$	
Bicalutamide	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$				$\checkmark$	
Bendamustine HCl	$\checkmark$	$\checkmark$	$\checkmark$		$\checkmark$		$\checkmark$	$\checkmark$	
Bortezomib	$\checkmark$	$\checkmark$	$\checkmark$				$\checkmark$	$\checkmark$	
Busulfan	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
Capecitabine	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$		$\checkmark$	
Decitabine	$\checkmark$		$\checkmark$				$\checkmark$	$\checkmark$	
Erlotinib HCl	$\checkmark$	$\checkmark$					$\checkmark$		
Fingolimod HCl	$\checkmark$	$\checkmark$	$\checkmark$			$\checkmark$			
Gemcitabine HCl	$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
Imatinib Mesylate	$\checkmark$	$\checkmark$			$\checkmark$	$\checkmark$	$\checkmark$		
Letrozole	$\checkmark$			$\checkmark$		$\checkmark$			
Irinotecan HCl	$\checkmark$	$\checkmark$	$\checkmark$		$\checkmark$	$\checkmark$		$\checkmark$	
Irinotecan HCl (Process-2)						$\checkmark$			
Melphalan HCl	$\checkmark$	$\checkmark$	$\checkmark$						
Oxaliplatin	$\checkmark$		$\checkmark$		$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
Pemetrexed Disodium	$\checkmark$	$\checkmark$	$\checkmark$		$\checkmark$		$\checkmark$	$\checkmark$	
Temozolomide	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$	
Zoledronic Acid	$\checkmark$	$\checkmark$							
Pemetrexed Dipotassium (Nonahydrate)	$\checkmark$	~			✓				
Anastrozole	$\checkmark$								

### Product wise DMF filings as on March 31, 2020

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Name of the API	US FDA	EU/ EMEA	TPD-Canada	PMDA Japan	TGA & Medsafe-NZ	EDQM	KFDA Korea	GCC & ROW	WHO Market
Clofarabine	$\checkmark$	✓							
Dimethyl Fumarate	$\checkmark$								
Axitinib	$\checkmark$								
Enzalutamide	$\checkmark$								
Pirfenidone	$\checkmark$					$\checkmark$			
Gemcitabine Hydrochloride (Process-2)	$\checkmark$	$\checkmark$	$\checkmark$			~			
Ibrutinib	$\checkmark$								
Teriflunomide	$\checkmark$								
Pomalidomide	$\checkmark$								
Tranexamic Acid	$\checkmark$					$\checkmark$			
Thalidomide	$\checkmark$	$\checkmark$						$\checkmark$	
Sunitinib Malate	$\checkmark$	$\checkmark$							
Lenvatinib Mesylate	$\checkmark$								
Tenofovir Alafenamide Fumarate	$\checkmark$								
Praziquantel						$\checkmark$			$\checkmark$
Tenofovir Disoproxil Fumarate									✓
Cyclophosphonamide	$\checkmark$					$\checkmark$			
Prucalopride succinate		$\checkmark$					$\checkmark$		
Lenalidomide	$\checkmark$								
Acebrophylline							$\checkmark$		
Sorafenib (Base)							$\checkmark$		
Sunitinib (Base)							$\checkmark$		



Patents	Filings	Approved (Including Tentative)	Pending
US ANDA			
- On SML's Name	22	13	9
- On Customer's Name	20	12	8
TOTAL (In US)	42	25	17
- EU Filing	19	13	6
TOTAL (In US & EU)	61	38	23

### Manufacturing Excellence



Facility Location	Facility Type
Dharwad	R & D Biologicals
Bengaluru	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)
Hubli	Biologicals Manufacturing Site and R & D
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 inAustria
- 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

Ompany'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

#### Filtration, Milling, Sieving & Packing Isolator





### **Financial Performance**

#### Covid19



As per guidelines issued by the Government on March 24, 2020 the Company has been following all standard operating procedures at its Manufacturing, Research and Office sites

- The COVID-19 pandemic outbreak is impacting the global economy in multiple ways and also impacted on the pharmaceuticals industry. During the quarter ended March, 31 2020 the Company had moderate impact on the revenue due to disruption in the manpower, supply chain, and increase in working capital due to slowing down in the receivables. The COVID-19 Pandemic outbreak for a medium/large span of time may impact the supply of key material import/export of the product. There will also be low impact on the R&D activity due to deferment in project timeline
- The Company continues to undertake Corporate Social Responsibility initiatives in various part of the society, helping farmers through Water conservation, Environment, Animal welfare etc. Due to impact of COVID-19 and increase in unemployment of daily wages worker, the Company supported the under-privileged people by distributing groceries, food to quarantined migrants, undertook distribution of masks, sanitizers and temperature reading equipment. Donation was made to PM Cares fund. Amount of Rs. 75.00 Lakhs has been utilized on the above



### Abridged P&L Statement -Standalone



(Rs. In Lakhs)

Particulars	Q4 FY20	Q4 FY19	Q-o-Q Change (%)	FY20	FY19	Y-o-Y Change (%)
Total Income (A+B+C+D+E)	20090	17450	15%	81723	67941	20%
Total Revenue from Operations (A+B+C+D)	19793	17102	16%	80597	66388	21%
•API (A)	13304	10988	21%	50181	44212	14%
•Formulations (B)	4812	3784	27%	19115	16596	15%
• Service &License Income (C)	1054	1818	-42%	8968	3027	196%
•Others ( D)	624	512	22%	2334	2553	<b>-9</b> %
•Other Income (E)	297	349	-15%	1126	1553	-27%
Total Expenditure	14866	12869	16%	56107	47533	18%
EBITDA	5225	4581	14%	25617	20408	26%
EBITDA margin (%) to Total Income	26%	26%		31%	30%	4%
Exceptional items- (Income)/Expenses	454	798	-43%	454	(622)	-
Finance Costs	129	100	28%	433	279	55%
Depreciation and Amortization	916	845	8%	3496	3401	3%
PAT Period/year from continuing operations (A)	2536	1964	29%	16819	13575	24%
PAT Margins (%)	13%	11%	12%	21%	20%	3%
PAT Period/year from discontinued operations (B)	3254	(293)	-	2552	(1164)	-
Other comprehensive income (C)	(150)	(52)	-	(120)	46	-
PAT (A+B+C)	5641	1618	<b>249</b> %	19252	12457	55%

#### Abridged P&L Statement - Consolidated

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Particulars	Q4 FY20	Q4 FY19	Q-o-Q Change (%)	FY20	FY19	Y-o-Y Change (%)
Total Income (A+B+C)	22890	20261	13%	92485	74711	24%
Revenue from operations (A)	20547	18134	13%	77204	70147	10%
Service Income and License fees (B)	1452	1817	-20%	13587	3192	326%
Other Income (C)	891	309	188%	1694	1372	23%
Total Expenditure	17439	16211	8%	68811	57755	<b>19</b> %
EBITDA	5451	4050	35%	23674	16956	40%
EBITDA margin (%)	24%	20%	<b>19</b> %	26%	23%	13%
Exceptional items- (Income)/Expenses		46			(1987)	
Finance Costs	101	141	-28%	456	368	24%
Depreciation and Amortization	1155	1054	10%	4378	4206	4%
PAT attributable to owners of the Parent Company	3457	2388	45%	15615	11226	39%
PAT Margins (%)	15%	12%	28%	17%	15%	12%
PAT (including comprehensive income)	3323	2333	42%	15511	11269	38%

### **Consolidated Balance Sheet**

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Assets	As at 31.03.2020	As at 31.03.2019
	Audited	Audited
(1) NON- CURRENT ASSETS		
(a) Property , plant & equipment.	55,737.28	49,450.48
(b) Capital work -in-progress	48,208.23	30,446.01
(c) Goodwill	3,700.08	3,675.26
(d) Right-of-use asset	2,639.19	0.00
(e) Intangible assets	3,232.66	2,840.97
(f) Intangible assets under development	18,152.28	12,300.00
(g) Financial assets		
i) Investments	1,045.11	225.45
ii) Loans	(0.00)	0.00
iii) Others financial assets	1,147.37	803.58
(h) Other non- current assets	2,672.83	6,754.72
Total non-current assets	136,535.04	106,496.48
(2) CURRENT ASSETS		
(a) Inventories	22,643.36	18,766.94
(b) Financial assets		
i) Investment	0.00	0.12
ii) Trade receivables	24,372.12	20,372.82
iii) Cash and cash equivalents	4,431.43	3,427.15
iv) Other bank balance	24.85	6,026.65
v) Loans	(0.00)	62.76
vi) Other financials assets	644.79	962.48
(c) Other current assets	9,337.17	4,495.16
(d) Current tax assets (net)	624.17	391.79
Total current assets	62,077.89	54,505.87
TOTAL ASSETS	198,612.93	161,002.35

Equity & Liabilities	As at 31.03.2020	As at 31.03.2019
	Audited	Audited
(1) EQUITY		
(a) Equity share capital	815.27	815.27
(b) Other equity	132,121.00	118,943.06
Equity attributable to owners of the Company	132,936.27	119,758.32
(c) Non-controlling interest	(791.13)	(761.94)
Total equity	132,145.14	118,996.38
LIABILITIES		
(2) NON- CURRENT LIABILITIES		
(a) Financial liabilities		
i) Borrowings	16,501.84	8,109.56
(b) Provisions	2,616.88	2,177.16
(c) Deferred tax liabilities (net)	4,198.46	4,767.32
(d) Other non-current liabilities	2,376.38	1,607.66
Total non-current liabilities	25,693.56	16,661.70
(3) CURRENT LIABILITIES		
(a) Financial liabilities		
i) Borrowings	16,527.34	8,657.99
ii) Trade payables		
-Total outstanding dues of Micro Enterprises	1 076 79	922 57
and Small Enterprises -Total outstanding dues of creditors other	1,076.78	832.57
than Micro Entrerprises and Small Enterprises	7,869.12	7,239.73
iii) Other financial liabilities	11,977.92	6,656.63
(b) Other current liabilities	2,233.45	1,505.27
(c) Provisions	1,089.63	452.06
Total current liabilities	40,774.23	25,344.26
TOTAL EQUITY & LIABILITIES	198,612.93	161,002.35

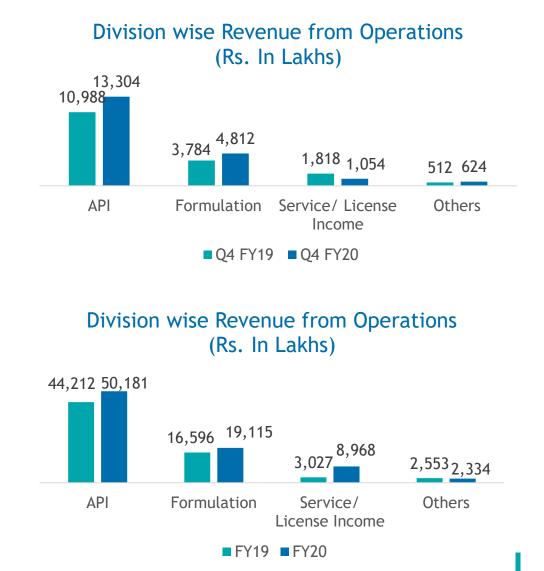
### Results Snapshot (Standalone)



#### Key Highlights

- Formulations' revenues were higher backed by the launch of new products in the US
- API revenues were higher on account of delivering a better growth in the Oncology API Business
- CRAMS revenue declined as the Company exited the JV



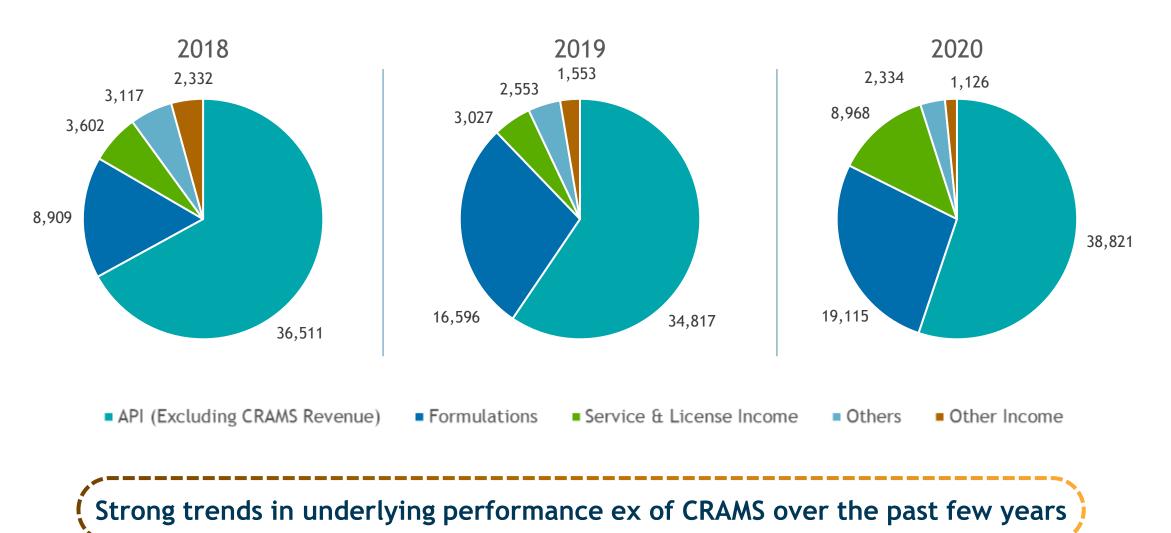


#### Historical Revenue Statement - Standalone



#### Total Revenue (ex-CRAMS): 13.66% CAGR since 2018

(Rs. In Lakhs)



#### Corporate updates





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#### API

> SML received an Establishment Inspection Report (EIR) from USFDA ZERO 483 with observations for the inspection conducted between 03 and 07 February 2020 at the **Raichur API facility** 

> The inspection classification of this facility is NO ACTION INDICATED (NAI)

#### **Formulations**

- USFDA held an audit from 13 February to 25 February at its finished Dosage Formulation Facility in Jadcherla, Form 483 issued with 15 observations, SML working with USFDA to address the observations in a comprehensive manner
- SML was issued EU GMP by Austrian Authority (AGES) for inspection held during 13th to 17th Jan 2020. SML's affiliates have registered its products (Oral solids & Injections) with European authorities for commercial distribution
  - The renewed EU GMP facilitates continued supply of products to European union
- SML launched its first branded Generic version for Lenvatinib Mesylates, an anti-cancer drug with a brand name 'LENSHIL'
  - These 4 mg & 10 mg capsules will be used for the treatment of Thyroid & Hepatocellular and potentially for other cancers (renal & endometrium) as well
  - LENSHIL will drastically reduce the treatment cost, more than the 50% when compared to cost of other innovator drug
  - These products are being manufactured and supplied from the state-of-the-art USFDA approved manufacturing facility

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#### **Future Growth Businesses**

- The Biologicals unit of SML was transferred to Shilpa Biologicals Pvt. Ltd., a wholly owned subsidiary of SML, which would result in :-
  - Operational synergies which would lead to cost optimization
  - Sector focused company which will facilitate Strategic Investment
  - Facilitates the creation of a Biological Business with a separate focused management that would provide with a greater flexibility in pursuing long-term growth plans and strategies

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#### Managing Director's Message



#### Commenting on Q4 & FY'20 performance, Mr. Vishnukanth Chaturbhuj Bhutada, Managing Director Shilpa Medicare Limited said

"We are pleased with the operating trends shown by the business during the year. Performance is tracking the expected milestones with 24% growth in overall revenues and 38% gains in net profits.

Strategic focus on driving Formulations has resulted in healthy income from introduced and licensed products, and we are also developing a marketing team especially across Russia, Europe, Brazil, and other geographies. Consequently our margins are also showing improvement YoY owing to vertical integration benefits. Further a strong pipeline of products will aid our momentum. This will balance out the reduction in CRAMS business given our exit of the JV. Our Oncology APIs segment has delivered as per plan and will continue to progress well based on an attractive pipeline and diversified base of intermediates.

Our investments in Biologicals will start showing results in the coming quarters where as an enabling measure we have housed the segment under a wholly owned subsidiary so that it can be scaled up to potential. Further our interest in other growth segments will support the enhancement in earnings as we go forward."



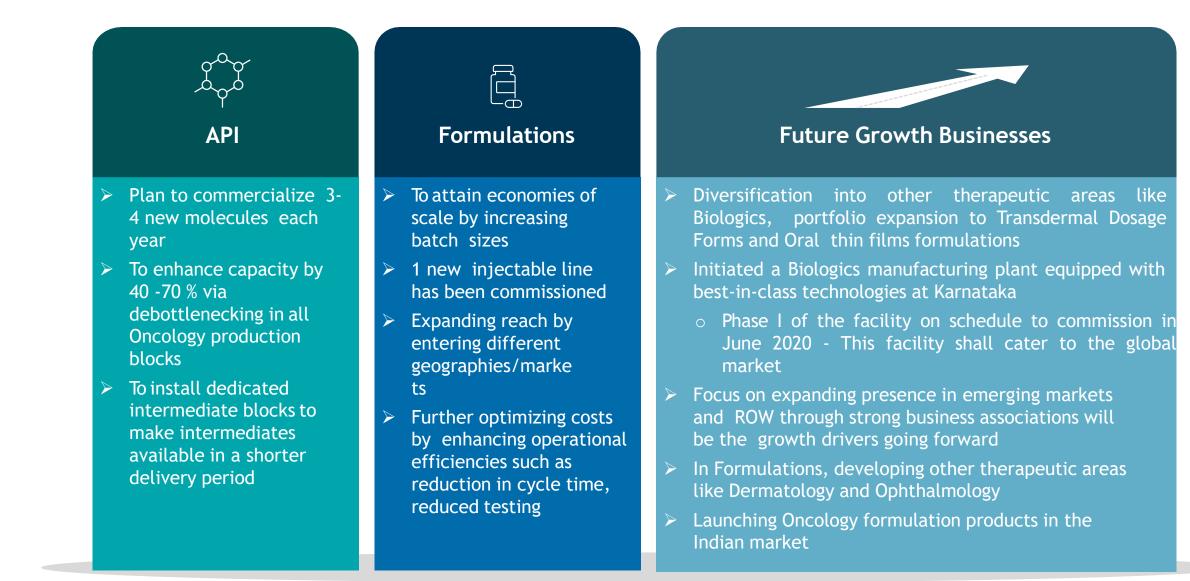


## Way Forward



#### Way Forward







#### Glass Lined Reactors in Intermediate Area





#### Annexures

### API Key Highlights :





Increased the capacity of **Tranexamic Acid** by nearly about 100% from the pervious capacity & upgradation of existing API

### Successful Regulatory Record



Segment	Facility	Audit Date and Agency	Resolution
API Site	API Unit-1 & Unit-2, Raichur	USFDA inspection between Feb 3-7, 2020	EIR Received
	API Unit-1 & Unit-2, Raichur	USFDA inspection between July 22-26, 2019	EIR Received
	API Unit-1	GMP inspection by COFEPRIS-Mexico between April 15-19, 2019	GMP certificate received
	API Unit-2	GMP inspection by COFEPRIS-Mexico between April 22-26, 2019	GMP Certificate received
	API Unit-1	EU-GMP from AGES-Austria between Jan 16-18 & 24, 2018	EU-GMP certificate received
	API Unit-2	EU-GMP from AGES-Austria between Jan 19-24, 2018	EU-GMP certificate received
Formulation Site	SEZ Jadcerla Facility	FDA, USA 29 Aug 2019 to 06 Sep 2019	EIR Received
		FDA, USA 13 Feb 2020 - 25 Feb 2020	Awaited Response form USFDA
		JAZMP, Slovenia (EU) 12 to 19 Nov 2014	GMP Certificate received
		AGES, Austria (EU) 25 to 30-01-2018	EU-GMP certificate received
		AGES, Austria (EU) 13 to 17 Jan 2020	EU-GMP certificate received

- SML continues to observe the highest standards of regulatory compliance. Its systems and processes are attuned to adhere to the evolving requirements of regulators in the geographies where it operates
- > Past instances of regulatory observations have all be successfully closed with favorable outcome

Shilpa

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 two decades.



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### Temple - API Plant- Raichur



## **Thank You**