



Innovating for
affordable healthcare

Shilpa Medicare Limited



Healthy Progress

35th Annual Report 2021-22

TABLE OF CONTENTS

Management Review

About Shilpa Medicare Limited	2
Chairman's Message	4
Review by Managing Director	6
Key Differentiators	8
Consolidated Financial Highlight	10
Standalone Ratios	11
Active Pharma Ingredients	12
Formulation Facility	14
Board of Directors	16
Corporate Information	18
Intellectual Property Management	20
Biologicals	22
Transdermal Patches and Oral Films	24
Polymers Research and Technology	25
Peptide Department	26
Contract Development & Manufacturing Organization	27
Reserch & Manufacturing Capabilities	28
Environment	29
CSR	30

Statutory Reports

Management Discussion & Analysis	31
Directors' Report	40
Secretarial Audit Report	65
Annual Report on CSR Activities	72
Corporate Governance Report	75
Business Responsibility Report	101
Notice	248

Financial Statements

Independent Auditor's Report	116
Standalone Balance Sheet	126
Standalone Statement of Profit and Loss	127
Standalone Statement of Changes in Equity	128
Standalone Statement of Cash Flow	129
Notes Forming Part of Standalone Financial Statement	131
Independent Auditor's Report	188
Consolidated Balance Sheet	196
Consolidated Statement of Profit and Loss	197
Consolidated Statement of Changes in Equity	198
Consolidated Statement of Cash Flow	199
Notes Forming Part of Consolidated Financial Statement	201

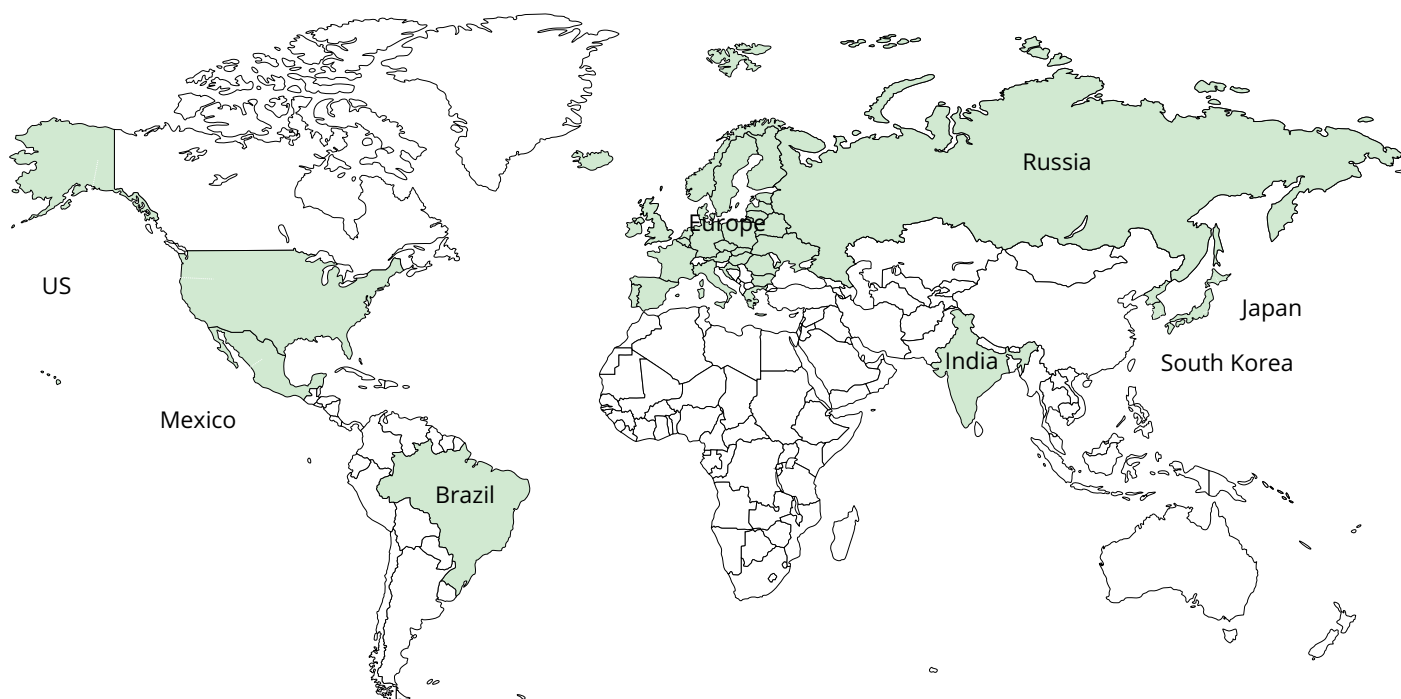
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Statements in this report that describe the Company's objectives, projections, estimates, expectations or predictions of the future may be 'forward-looking statements' within the meaning of the applicable securities laws and regulations. The Company cautions that such statements involve risks and uncertainty and that actual results could differ materially from those expressed or implied. Important factors that could cause differences include raw materials' cost or availability, cyclical demand and pricing in the Company's principal markets, changes in government regulations, economic developments within the countries in which the Company conducts business, and other factors relating to the Company's operations, such as litigation, labour negotiations and fiscal regimes. Some of the images used in this report are purely for illustrative purposes only and hence they are not the photos/images of our facilities, products or of any such nature/kind.

We continue to pursue the path of innovation for making healthcare affordable. In FY22 the company made significant progress with respect to research, increasing manufacturing capabilities, product development and revenue. Stepping into FY23 we are sustaining the healthy progress by expanding our product offerings of generics and focusing on increasing access to products with significant barriers to entry. We will also continue to look for new opportunities to take generics to more patients, in collaboration with our peer pharmaceutical companies.

ABOUT SHILPA MEDICARE LIMITED

SML was incorporated in 1987 at Raichur, Karnataka, India. SML is one of the leading API and formulations manufacturers with strong capabilities in the therapeutic area of oncology. SML supplies more than 30 oncology APIs including key products such as Capecitabine, Gemcitabine Hydrochloride, Axitinib, Erlotinib Hydrochloride and Irinotecan Hydrochloride for various regulated markets including USA, Europe, Japan, South Korea, Russia, Mexico, Brazil, and other emerging markets. While SML's underlying expertise is in the field of oncology, it also derives its revenue from sale of non-oncology APIs. With key products being Ambroxol (Mucolytic agent) in Europe and Tranexmic Acid and Ursodeoxycholic acid in India.



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 Formulations



Robust research orientation resulting in innovative products



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



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

CHAIRMAN'S MESSAGE



Dear Shareholders

Welcome to our FY22 Annual Report.

2022 is our country's 75th year of independence. Our liberation and growth achieved so far have been through the hard work of our countrymen and women, political leaders, farmers, social reformers, and last but not least business leaders of the country. We are also indebted to our brave soldiers for protecting the country.

I am delighted that in the 75th year of independence the pharma sector has put the country on the global map. The transformation of the pharma sector in India in fact started after three decades of our independence. Today India is one of the largest sources of pharmaceuticals for countries across the globe and our influence is increasing year on year.

FY22 has been an eventful year for our company. We progress on all important expansion strategies and product development initiatives. We further strengthened our API and formulations business. Biologicals have emerged as one of our niche segments opening up global opportunities for new product launches as well as for co-creating value with peer pharma companies.

Key Developments

To further strengthen our strategic initiatives towards strong verticalization of our business units the Board of Directors has approved the transfer of API Unit 1 & Unit 2 to the wholly owned subsidiary Shilpa Pharma Lifesciences Limited through a slump sale. This exercise is to build an independent business of API and rationalize the corporate entities of the group For the which the approval of members was

received in the month of March 2022.

The Board on 08 February 2022 approved the fundraising plans in the transferred entity either from strategic investors through private placement or from investors at large through public issue.

Stepping into FY23, our API facility (Unit I) at Raichur, Karnataka has received GMP (good manufacturing practice) certificate from MOH-Russia.

Fundraising

In October, 21 The Board of Directors of the company approved the preferential allotment of 52.75 lacs equity shares aggregating to Rs. 297.51 crores to various marquee investors at a price of Rs. 564 per share. The marquee investors who participated in the fundraising include Malabar India Fund Limited, Malabar Select Fund, Malabar Midcap Fund, Think India Opportunities Master Fund LP, Blue Diamond Properties Private Limited, Ohm Core Investment Corp, Hypnos Fund Limited and Mr. Madhusudan Kela.

Pharma Sector

During the pandemic, the global pharma and healthcare sector exhibited its capabilities to fast forward innovation and product development. The sector continues to grow for providing better health of all whole humanity. immunology, oncology and neurology are some of the fastest-growing therapy areas and are expected to be the main sources of growth through 2026. The biologics market is growing at a significant rate and is expected to continue outstripping that of small molecules in the coming decade. The three largest biological therapy areas include oncology, autoimmune

and diabetes. We at Shilpa with our diversified product capabilities in APIs, Formulations and Biologicals are totally in alignment with the global pharma industry's demand drivers.

India ranks third worldwide for production in terms of volume and 14th by value. With the sector's innovation and product development capabilities increasing year on year, I am confident that India's pharma sector will further consolidate its position in terms of value.

The Indian pharmaceutical industry is known for its generic medicines and low-cost vaccines globally. India's pharma exports touched Rs 1.8 trillion in fiscal 2022, said the commerce ministry, marking flat growth compared to last fiscal. In the pandemic year of 2020-21, pharma exports had grown by 18 percent to \$24.4 bn (roughly Rs 1.8 lakh crore at current exchange rates). Compared to 2013-14, pharma exports from the country have doubled. India had exported Rs 90,415 crore worth of pharma products in FY14.

Our company is a fast emerging global brand in manufacturing and supplying affordable API and formulation globally in different regulated markets. I am delighted that our progress is in alignment with the development in the global pharma sector and also in alignment with our core purpose i.e innovating for affordable medicare.

Environment Social and Governance

We continue to follow all regulatory and corporate governance guidelines meticulously. Social and environmental protection initiatives are driven and monitored by the board. During the year we allotted Rs.3.7 crores towards the development of education, medical infrastructure and drinking water in

our areas of operations. Apart from the environment, energy and water conservation initiatives across our units during the year under our CSR initiatives we also contributed to social plantation initiatives in Raichur.

Leadership

During the year Mr. Naresh Patwari - Non-executive Director and Mr. Piyush Goenka - Independent Director of the Company tender their resignation on personal reasons. Mr. Rajender Sunki Reddy & Mr. Pramod Kasat, ceased to be the Independent Directors of the Company with effect from the day of the conclusion of 34th Annual General Meeting held on 28 September 2021 on account of completion of their tenure. On behalf of the board of directors, I would like to thank them for their contributions while on the board of the company.

I take this opportunity to thank our shareholders, senior management, banks, regulatory bodies, government agencies and the public for their support and guidance.

Jai Hind

Omprakash Inani
Chairman

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REVIEW BY MANAGING DIRECTOR



Dear Shareholders

FY22 has been a significant year for us as we emerged from the challenges posed by the pandemic. During the year we progressed on our revenue as well as operational strategies. On Consolidated basis our revenue during the year is Rs.1160 crores which is a year on year growth of 24.5%. Margins were impacted due to the ongoing remedial measures and raising inflationary pressures.

We continue to pursue our niche growth strategies in biologicals and transdermal oral dissolving film formulas. Our strategic intents are supported by robust research and development initiatives for developing innovative products across therapeutic areas. We continue to strengthen our competitive advantages for achieving our core purpose i.e which is making healthcare affordable.

Active Pharma Ingredients (API)

For a renewed focus on API business, are in the process of transferring the business along with intermediates, polymers, peptides & CDMO related to API business to the wholly owned subsidiary, Shilpa Pharma Lifesciences Ltd (SPL). The Board has agreed to initiate fund raising process of SPL to unlock the value of the API business and provide the requisite impetus for its growth. I am pleased with how our consistent focus on delivering a superior value proposition to clients is ensuring year-on-year growth.

How We Performed in API

In API business, oncology registered a growth of 30% year on year and non-oncology and significant 71%. Despite a 28% negative growth in CRAMS the overall API business improved 26% year on year.

Formulations

In FY22 we further strengthened our formulations business. Shilpa's Pemetrexed Injection ready to use formulation is approved by European Authorities, through its agreed partners in Europe. According to IQVIA MAT Q2'2021 (June 2021) data, the EU market for Pemetrexed Injection is approximately EURO 519 Million. During the year we Shilpa Medicare launched PRUCALSHIL (Prucalopride) Orally Disintegrating Strips 1 mg and 2 mg in India, a unique formulation developed for the first time in the World. Prucalopride is used for the symptomatic treatment of chronic constipation in adults in whom laxatives fail to provide adequate relief.

How we performed in formulations

Formulations business improved 42 per cent year on year in the FY22 as we registered a revenue of Rs.353 crores as against Rs.248 crore in FY22. We could also grow across geography. Revenue contribution from Europe improved by 45% year on year and revenue contribution from USA improved by 33%.

Biologicals

SML views Biologicals as a strategic growth area and has made significant investments in setting up a High end, Flexible Biologicals facility in SBPL, Dharwad to cater to the requirements of the fast-growing biologicals field, which include the DNA vaccine, adenoviral, subunit vaccines, Monoclonal antibodies & fusion proteins.

Stepping into FY22 – in April 2022, we received an NoC from RCGM, Dept of Biotechnology to approach the Drugs Controller General of India (DCGI) to conduct clinical studies for

its Biosimilar Aflibercept. Aflibercept is a vascular endothelial growth factor (VEGF) inhibitor. It is indicated for the treatment of neovascular (wet) age-related macular degeneration, macular oedema following retinal vein occlusion, diabetic macular oedema and diabetic retinopathy in patients with diabetic macular oedema. India has amongst the highest incidences of the above indications and the market is under-catered to by current therapies. The Drug had global sales of appx \$9.38 billion in 2021 and is amongst the top ten drugs today, growing at 19% pa. The biosimilar product at SBPL is partly funded through the BIRAC grants and developed at its integrated Dharwad facility. The Company intends to ensure global accessibility to the product via differentiated pricing and formulations/delivery mechanisms. Biosimilar Aflibercept is the second biosimilar product from SML that has entered the clinical trial phase after Biosimilar Adalimumab.

Cocreating Value

We also entered into a definitive agreement with Cadila Healthcare Ltd (CHL) for the production-supply of the ZyCoV-D vaccine drug substance. The targeted production of the ZyCoV-D vaccine from this facility will be mutually agreed upon by both parties.

We also signed a MOU with Mylab Discovery Solutions, through our subsidiary Shilpa Biologicals Pvt Ltd for foraying into the vaccine and therapeutics segments - starting with Covid-19 vaccine manufacturing. The parties plan to strengthen the relationship by expanding the product portfolio in various other areas including various biosimilars, other vaccines & diagnostics.

We are moving ahead with plans for biologicals with 3 products at the clinical phase and tapping a very attractive segment in the market, with limited competition and good potential to grow. The Company is prioritizing the development of world-class, new products in multiple segments, which upon launch is likely to result in a superior business and earnings profile

IPM

In FY 21-22, our group companies filed 27 patents applications taking the cumulative total to 491 patent applications in India and other countries. We received grants for 26 patents during FY 21-22.

Going forward

The healthy momentum of sales continues to build on the back of growth in commercially launched products in key markets. The Formulations segment is recording traction in ex-US markets including across the EU, India and RoW. We have an attractive portfolio of products lined up for launch that will support this growth. The process of remediation is progressing as required. We are continually gearing towards increasing our footprint in the business through new launches and enhancements to existing products.

I thank all our customers, regulatory agencies, government agencies, shareholders and employees for their continued support

Regards

Vishnukant C Bhutada
Managing Director

+45%

Increase in formulations revenue from Europe

27

Patents filed by group companies in FY22

491

Cumulative patents filed as on March 2022

KEY DIFFERENTIATORS

Global Standards

The facilities are cGMP Complaint & approved by many national & international regulatory bodies like USFDA, EU, Cofepris-Mexican, PMDA-Japan, Korean FDA, TPD Canada & TGA-Australia.

19 API & Intermediate manufacturing blocks

The company is having about 19 API & intermediate manufacturing blocks with segregation of Oncology and Non-Oncology manufacturing facilities. Blocks are designed to handle small scale, medium scale & high-volume scale to handle different levels of Batch size like 500 gm to 350 kg.

First company to invest in India in containment technologies

Shilpa is the first company to invest in India in containment technologies for the manufacturing of oncology drug substances in a contained environment & also the latest technologies like the Bipolar system from Japan to ensure the manufacturing process is sustainable with less consumption of natural resources & safe operations