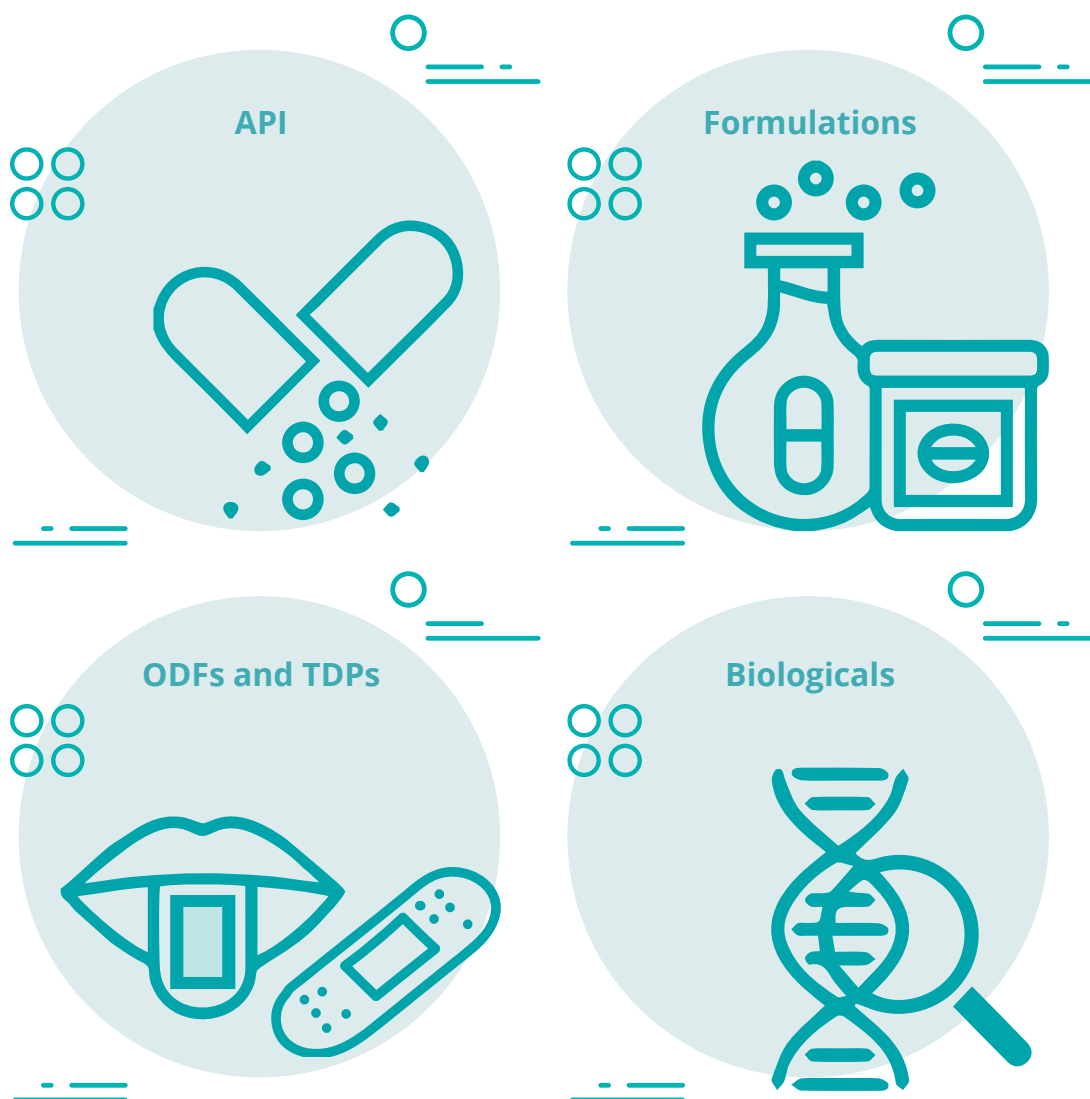




Innovating for
affordable healthcare

Shilpa Medicare Limited



Integrating | Innovating | Expanding

36th Annual Report 2022-23

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Integrating Innovating Expanding
Shilpa Medicare's transformative journey embodies its dedication to Integration, Innovation, and Expansion. The company has propelled pharmaceutical innovation by seamlessly integrating research and advanced technologies. Driven by unwavering excellence, global expansion has become attainable, touching countless lives. Centered on these core pillars, Shilpa Medicare advocates elevated healthcare standards, fuelling growth and enriching global well-being.

About Shilpa Medicare Limited

Shilpa was incorporated in 1987 at Raichur, Karnataka, India. Shilpa is one of the leading API and formulations manufacturers with strong capabilities in the therapeutic area of oncology. Shilpa supplies more than 30 oncology APIs including key products such as Capecitabine, Gemcitabine Hydrochloride, Pemetrexed, Axitinib, Erlotinib Hydrochloride and Irinotecan Hydrochloride for various international markets including USA, Europe, Japan, South Korea, Russia, Mexico, Brazil, and other emerging markets. On the non-Oncology API front, Shilpa derives revenues from select key molecules which amongst others include Ambroxol (Mucolytic agent), Tranexmic Acid and Ursodeoxycholic Acid.

While Shilpa's underlying expertise is in the field of APIs, it is also strengthening its position in formulation business with revenue generation from products such as Azacitidine, Pemetrexed, Capacitabine, Imatinib, Erlotinib etc. in domestic as well as various international markets. Shilpa's manufacturing capabilities encompass various dosage forms ranging from oral solids & injectable, orally dispersible films & transdermal patches.



Company Overview



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



Pursuing niche growth businesses like Biologics, Transdermal Patches & 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

Message from the Chairman



Dear Esteemed Shareholder,

I hope this message finds you well.

The fiscal Year 2023 has been a period of contrasts for us. Our performance has been somewhat subdued due to pricing pressure, the aftershocks of the pandemic and challenges triggered by the Russia-Ukraine conflict. Nevertheless, we remain steadfastly focused on our strategic intent of pursuing leadership in complex Oncology Active Pharmaceutical Ingredients (APIs), while consistently optimising our manufacturing processes to deliver a better portfolio of products. We are also developing proficiencies in high-end Non-Oncology APIs in key global markets. The other research-backed segments where we are displaying emphasis are peptides, polymers and Contract Development

and Manufacturing Organization (CDMO) businesses. These are critical building blocks in our endeavour to create a balanced, innovative, and sustainable portfolio.

Our company is progressing up the value chain through the Formulation business, specialising in complex Oncology and Non-Oncology treatments on a global scale. In light of the United States Food and Drug Administration (USFDA) observations, key products are being commercialised through a site transfer. At the same time, we are redesigning our sales portfolio mix by expansions in international markets other than the US.

We are contemporaneously venturing into the development of value-added offerings via transdermal (TD) and oral

dissolving film platforms (ODF). There are also robust plans in place for the Biologicals division, with the intention to create an cohesive line-up that will contribute significantly to our future growth.

Our subsidiary, Shilpa Biologicals Private Limited (SBPL), has received a No Objection Certificate from the Review Committee on Genetic Manipulation, allowing us to conduct clinical studies for our Biosimilar Aflibercept with the Drug Controller General of India. This biosimilar, the first in India, fills a significant market gap. Our strategy involves conducting local and global clinical studies in therapeutic areas such as Wet Age-Related Macular Degeneration, Diabetic Retinopathy, and Diabetic Macular Edema, where India has high incidences.

Despite these exciting advancements, it's important to acknowledge the challenges that the Indian pharmaceutical sector faces. Even though the Indian government is making efforts to boost domestic pharmaceutical manufacturing through a production-linked incentive (PLI) scheme, the nation's pharmaceutical industry is still grappling with increased imports of raw materials, drugs, and medical devices, and a lower than anticipated uptake of the PLI scheme.

Our industry's hallmark is the mass production of high-grade generic drugs and vital medical supplies, priming us for forthcoming challenges. Nevertheless, to entrench our global pre-eminence, we must address existing gaps. This involves fostering research and innovation, optimising manufacturing costs, and facilitating partnerships among pharmaceutical entities to capitalise on mutual core competencies.

As we navigate through this phase of our journey, we are mindful of the significant challenges we face, such as the volatility in our financial performance owing to the extended resolution of the import alert at Jadcherla, the in our primary API business, and the envisaged contribution from new business lines currently in the investment phase. Nonetheless, rest assured, we are actively engaged in addressing these issues. While the fruits of our mitigation strategies may take time to discern, we remain confident in their long term efficacy and their role in fortifying our financial resilience. Our new business lines, still in their infancy and in the investment phase, are a testament to our commitment to future growth and diversification. We harbour optimism about their potential contribution to our revenue streams in the forthcoming years.

Our Board of Directors steadfastly monitor and ensures that the company adheres to Environmental, Social, and Governance (ESG) principles, a commitment that threads through our continuous innovation and efficiency enhancement journey. Including the statutory Business Responsibility and Sustainability Report (BRSR) in this annual report is a strategic move towards measuring our preparedness to integrate ESG principles into our operational matrix seamlessly. Beyond a mere assessment tool, the BRSR fortifies our commitment to transparency, providing our stakeholders with an all-encompassing insight into our sustainability endeavours. We perceive this initiative as an optimum platform to underscore our relentless dedication to responsible and sustainable practices, affirming our conviction that

progress must be charted with ethical integrity, social accountability, and environmental stewardship.

As we continue this exciting journey, your unwavering support and belief in our vision are appreciated. We remain committed to keeping you informed of our progress and look forward to sharing more exciting news in the near future.

Thank you for your continued trust and partnership.

Yours sincerely,

Omprakash Inani
Chairman

Our company is progressing up the value chain through the Formulation business, specialising in complex Oncology and Non-Oncology treatments on a global scale. In light of the United States Food and Drug Administration (USFDA) observations, key products are being commercialised through site transfers.

Review by the Managing Director



Dear Shareholders

I am delighted to take this opportunity to express my sincere gratitude for your ongoing trust and support for Shilpa Medicare. Your steadfast commitment and belief in our potential enable us to innovate and positively impact the pharmaceutical industry.

Navigating the aftermath of two intense years triggered by the pandemic and the geopolitical crisis, Shilpa Medicare is recalibrating its operational strategy to remain agile. While we continue to focus on improving our capabilities our renewed strategies are aimed at tackling external challenges like inflation and increased complexity. This transition is seen as an opportunity to deliver greater value, stay ahead of industry challenges, maintain our commitment to innovation and deliver

affordable healthcare. The emerging opportunities include accelerating our product innovations, ESG commitments, digitalisation and better resource allocations across our value chain.

On Performance:

In the fiscal year 2023, our revenue decreased to Rs 1,050 crore from Rs 1,145 crore during the corresponding period last year. EBITDA also fell to Rs 119.68 crore from Rs 218.10 crore. Furthermore, the full-year margin decreased to 11% from 19% in FY 2022, and a loss of Rs 32.47 crore was registered compared to a net profit of Rs 60 crore last year. Despite these challenges, we managed to generate positive operational cash flows. While the past year presented substantial challenges, we are committed to

improving our financial performance. With well-thought-out strategies to enhance operational efficiencies and implement robust financial strategies, we are optimistic about overcoming these difficulties and returning to a growth trajectory in the next fiscal year.

Despite ongoing global challenges, this year's operational performance showcases our continuous and persistent efforts to consolidate our position in Active Pharmaceutical Ingredients (APIs) and Formulations, in domestic and international markets. We have successfully maintained our established presence and continue to take steady steps in strengthening our market position.

I am delighted to share that our API business has made significant strides. We've broadened our market presence, filing over 200 Drug Master Files across various geographies and leveraged our expertise in diverse areas such as polymer, peptide, CDMO, import-substitute APIs, and capacity expansion.

In Formulations, our strategic remediation measures and compliance initiatives have elicited positive feedback from the US FDA, and thus we await a favourable resolution to the import alert on our Jadcherla facility. This facility has been cleared by Canadian authorities. Our other facility at Nacharam has been cleared by the US FDA already and we are consequently moving some product analysis work to this site. We continue focusing on complex formulation development for products in global markets. In addition to enabling site transfers for formulation sales into the US, we have explored the EU and ROW regions for our portfolio. Moreover, we have worked towards creating out-

licensing opportunities in order to tap our developmental capabilities.

UK MHRA's approval has enabled our film formulation and transdermal products to enter the UK market, bolstering revenue growth for us. Progress in developing biologicals and cost rationalisation efforts promise potential revenue generation in a profitable manner. With a robust portfolio, we're poised for a performance transformation in the coming years, focusing on managing cash flows, maximising revenue and the bottom line. Your continued support propels us to innovate and create value.

Our Strategies

Shilpa Medicare is committed to forging a leadership position in the manufacture of complex Oncology APIs, persistently optimising our processes to deliver an improved product portfolio. We are also developing proficiency in high-end Non-Oncology APIs for key global markets, alongside a growing emphasis on peptides and CDMO services, reflecting our dedication to research-backed segments.

Moreover, we are steadily ascending the value chain through our Formulations business globally, encompassing both complex Oncology and Non-Oncology areas. We are commercialising key products via a strategic site transfer, while our sales to international markets outside the US remain active and robust.

We invest in developing transdermal (TD) and oral dissolving film platforms (ODF) to enhance our offerings. Additionally, we are executing robust plans for Biologicals and aim to introduce an attractive product

line-up. Our progress and initiatives exemplify our dedication to innovation, operational excellence, and delivering value to our shareholders. Your continued trust fuels our mission to enhance healthcare accessibility worldwide.

Concluding Remarks

While navigating a complex and volatile landscape across its business segments, Shilpa Medicare has stood steadfast in its growth strategy and regulatory compliance. Our strong adherence to mandated processes and unwavering commitment to quality underlies our solid foundation for achieving strategic business expansion.

Our API business, known for its stronghold position, is again thriving in a dynamic market environment, enabling our growth agenda. Furthermore, our team's agility in defining comprehensive responses to business challenges in our other segments is ensuring sustainable business momentum overall. We are positioning the company to move up the value chain by pursuing complex and niche opportunities in a profitable manner. Towards this end, our R&D investments have been most instrumental.

We are cognizant of the necessity for predictability and visibility in our performance. To this end, we are committed to improving our operational and financial metrics through rigorous performance management, cost optimisation, strategic planning and transparent communication. Shilpa Medicare remains committed to upholding high standards of ethics and corporate governance and consistently striving for excellence in our operations.

Our future endeavours will remain aligned with the principle of **वसुधैव कुटुम्बकम्** "vasudhaiva kutumbakam." i.e The World Is One Family. As a global community, we should strive to ensure affordable healthcare for every individual, transcending borders and disparities to foster a healthier and more equitable world. Our strategic and operational decisions will always echo our commitment to the health, well-being, and unity of the global community we serve.

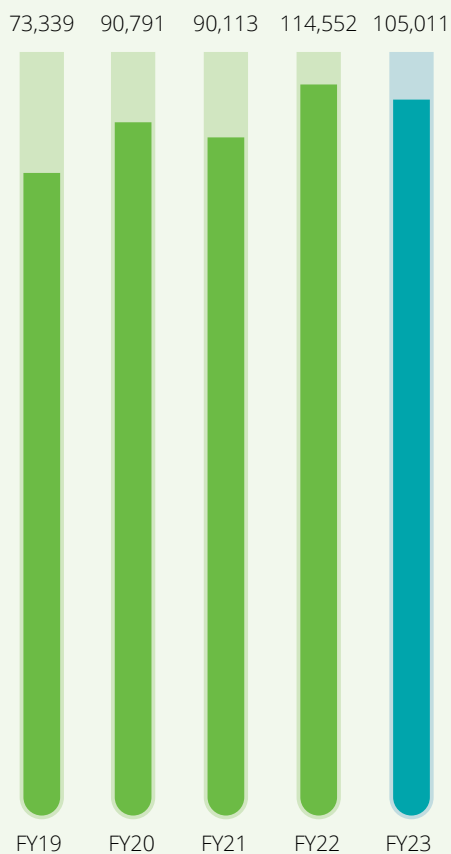
I sincerely thank our esteemed shareholders for their unwavering faith and support in our endeavours. We also thank the regulatory bodies for their guidance, ensuring we consistently uphold the highest compliance and quality standards. Our heartfelt thanks go to our dedicated employees, whose hard work, resilience, and ingenuity continue to drive Shilpa Medicare's growth and success. We express our appreciation to the Central and State Governments for their consistent support and enabling policies. Lastly, we acknowledge the pivotal role of our banking partners in aiding our financial stability and growth. Thank you all for being an integral part of our journey, as we continue to strive towards excellence in the pharmaceutical industry.

Yours Sincerely

Vishnukant Chaturbhuj Bhutada
Managing Director

Consolidated Financial Highlights

Operating Revenue (In ₹ Lakhs)



EBITDA (In ₹ Lakhs)

