VOL 21 | ISSUE 11 | MAY 2023 | MUMBAI | TOTAL PAGES 36 | PRICE ₹ 150

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R.N.I. No.: MAHENG/2002/08502

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Indian Pharma Market reports 11 percent growth in April: IQVIA

Mumbai, India: The Indian Pharmaceutical Market (IPM) has reported 11 percent growth for the month of April 2023, according to IQVIA report. The report stated that among top 25 companies, Sun Pharma has maintained its top position in IPM with a market share of 8%. While Intas, Torrent Pharma and Eris Lifesciences improved by 1 rank each and Sanofi improved by 2 ranks to reach 18th position, the report said. Among the top 25 products, Mixtard gained 1 rank and is at no 1 position at month with -1% growth. Among the top 10 brands, Monocef has posted highest growth followed by Foracort, the report said. The report said that Indian companies gained 12% growth, While MNCs posted 8% growth for the month of April.

Formulation exports to rise 7-9% this fiscal for Pharma cos: Crisil

Mumbai, India: Crisil rating stated that export of formulations by domestic pharmaceutical companies is likely to grow 7-9% in fiscal 2024, supported by lower price erosion of existing products and higher number of new product launches in the US, and steady demand from the rest of the world (RoW, includes semi-regulated and regulated countries excluding US).Formulation exports typically contribute about half of the total revenue of domestic pharmaceutical players, with sales to the US and RoW contributing almost equally. In fiscal 2023, formulation exports grew 10-12%, aided by depreciation in the Indian rupee and a lower base. Growth was reported in mid-single digits during fiscals 2021 and 2022 due to stiff pricing pressure

Crisil further added that domestic companies' manufacturing facilities catering to the US market need to be US Food and Drug Administration (USFDA) compliant and periodic inspections undertaken by the USFDA not only serve the purpose of certifying new facilities but also clear any previously issued official action initiated (OAI1) status for plants, thereby paving the way for new launches.

"Increased inspections by USFDA after the pandemic and higher withdrawals of abbreviated new drug applications due to intense competition are leading to moderation in overall supply of existing drugs," stated Anuj Sethi, Senior Director, CRISIL Ratings.

Lupin Q4 sales stood at ₹ 43,303 million

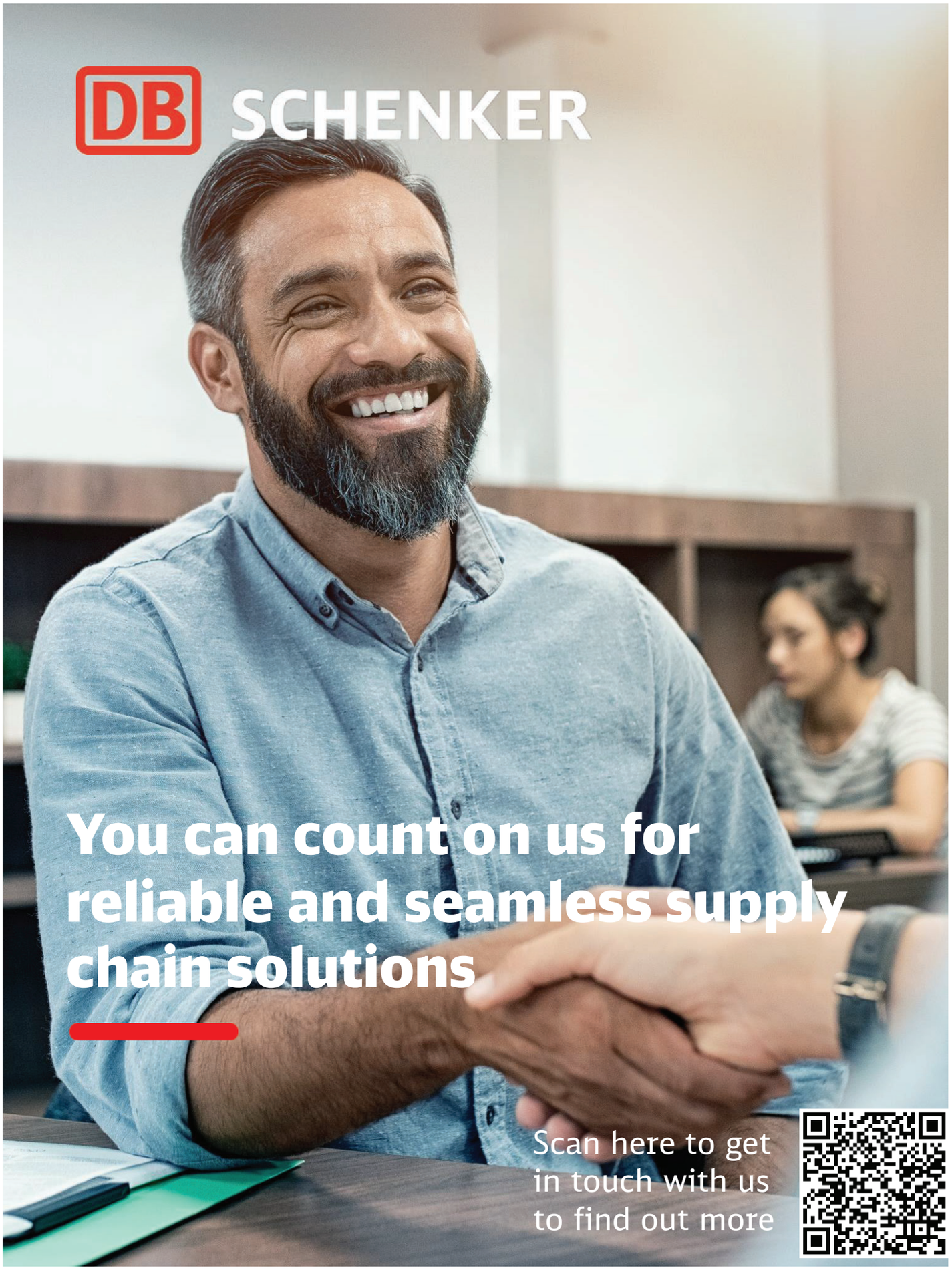
Nilesh Gupta, MD, Lupin Limited

Mumbai, India: Pharma major Lupin Limited reported its financial performance for the fourth quarter ended March 31, 2023. The company's Gross Profit stood at ₹ 25,802 million as against ₹ 25,375 mn in Q3 FY2023, with gross margin at 59.6%. The company's sales stood at ₹ 43,303 million, while Investment in R&D for the quarter was at ₹ 3,050 million.

Commenting on the results, Nilesh Gupta, Managing Director, Lupin Limited said, "We were able to drive continued improvement in operating margins on account of improved growth in India, improvement of margins in the U.S. as well as growth in other areas like our API business, EMEA and APAC regions. Our India business recorded 15%+ growth per IQVIA, ex-diabetes. In the U.S. we improved our margins for the third quarter in a row through maximizing our portfolio, optimizing expenses and more focused R&D investment into complex products. We are committed to sustaining this positive momentum into the new year and drive strong growth across our regions, in particular India and the U.S. aided by our recent sales force expansion and material new product launches respectively."

Need to harness India's vast potential in the pharmaceutical & medical devices sectors: Dr Mansukh Mandaviya

New Delhi, India: The Union Minister of Health & Family Welfare and Chemicals & Fertilizers, Dr Mansukh Mandaviya said, "There is a need to harness India's vast potential in the pharmaceutical and medical devices sectors." Addressing the inauguration of the 8th edition of the International Conference on 'India Pharma & India Medical Device 2023, the Minister highlighted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Dr Mansukh Mandaviya, Union Minister of Health & Family Welfare and Chemicals & Fertilizers

the government's collaborative approach, and said that transformative outcomes have been achieved in these sectors through discussions between the government and industry.

Dr Mandaviya also recalled Prime Minister Narendra Modi's visionary words and highlighted the significance of the pharma and medical device sectors in India. "The India Pharma Conference paved the way for game-changing initiatives like the PLI scheme, Bulk Drug Park, and Medical Device Park," said the Minister, underscoring the fruitful collaboration between the government and industry.Referring to Prime Minister's call to unleash India's true potential, the Minister expressed confidence in the country's abundant resources. "We possess unmatched Brain Power, Manpower, Management Power, and Innovation Power," he stated emphasizing the need to tap this potential for exponential growth of the sectors.

Satish Reddy, Chairman, Dr Reddy's Laboratories, said, "Today we are a 42-billion-USD industry; we say we want to reach 65 billion US dollars by 2024, and by 2030, we would like to be a 130-billion US dollar industry. However, moving forward requires innovation, and to achieve this goal, I think we should discover drugs and market them ourselves. That will add value as we all know that with volume, we stand 3rd in the world, but with value, we stand 14th, and to bridge this gap, we need a compelling mission to get there."

Aravind Viswanathan, CEO, Transasia Bio-Medicals Ltd, said, "To achieve an aspiration goal of 50 billion US dollars over the next five years, we have targeted multifront growth by 2047 when we celebrate our 100th year of Independence. The theme resonates well with our PM Narendra Modi's vision of Innovate in India. The National policy shall have a great boost to the ecosystem, which has created a foundation to drive the growth of the MedTech sector."

Gujarat FDCA issued fresh licenses to 2267 cos from April 1, 2020 to March 31, 2023

Ahmedabad, India: The Gujarat Food and Drug Control Administration (FDCA) has issued a total of 2,267 fresh manufacturing licenses from April 1, 2020 till March 31, 2023. This includes 1682 allopathic licenses, 172 ayurvedic licenses, 409 cosmetics licenses and 4 homoeopathic licenses. Gujarat FDCA also granted fresh plan approved for 1130 companies. As per data, the fresh licenses issued to 494 allopathic companies, 222 ayurvedic companies, 410 cosmetics companies and 4 homoeopathic companies.

"Gujarat is the land of opportunities, we try to fulfill the vision of our honourable prime minister 'make in India' through 'make in Gujarat', stated Gujarat FDCA Commissioner, Dr H G Koshia. Gujarat FDCA makes optimum use of information technology for achieving excellence in performance. FDCA, Gujarat is the first state to initiate online software for sales and manufacturing licenses.

Dr. Reddy's Laboratories receives US FDA approval for Regadenoson Injection

Hyderabad India: Dr. Reddy's Laboratories Ltd has received U. S. Food and Drug Administration (US FDA) approval for Regadenoson Injection in the U.S. market, a generic therapeutic equivalent of Lexiscan (Regadenoson) injection. Dr. Reddy's Regadenoson Injection is supplied as single-dose pre-filled syringes, 0.4 mg/5 mL (0.08 mg/mL). Lexiscan is a registered trademark of Astellas US LLC.

Venus Remedies secures Kenyan GMP Certification for manufacturing facilities in Baddi

Mumbai, India: Venus Remedies Limited, a leading research-based pharmaceutical company, has secured a Good Manufacturing Practices (GMP) certification from Kenya for all its production facilities in Baddi. This recognition, encompasses a wide range of parenteral formulations, including pre-filled syringes, ampoules, vial liquids and lyophilised and dry powder injections. The GMP certification extends to the manufacturing facilities for cephalosporins and carbapenems as dry powder injections, oral granules and liquid and lyophilised oncology products. The Pharmacy and Poisons Board (PPB) of the Kenyan Health Ministry granted the certification following a rigorous audit of the company's production facilities in Baddi. Panchkula-based Venus Remedies Ltd is among the 10 leading fixed-dosage injectable manufacturers in the world.

Saransh Chaudhary, President, Global Critical Care, Venus Remedies Ltd, said, "This GMP certification validates our relentless pursuit of excellence and further strengthens our position as a leading manufacturer of fixed-dosage injectables.

Akshansh Chaudhary, Executive Director, Venus Remedies, said the company will leverage this certification to bring it diverse range of high-quality products to the Kenyan and other African markets, thus making a positive impact on healthcare in the region. "This achievement is aligned with our vision of improving global health and reinforces our commitment to delivering excellence in pharmaceutical manufacturing," he said.

Dr M.S. Reddy discovers a revolutionary method to control the Covid pandemic by inactivating RNA and DNA

Hyderabad, India: Dr. M.S. Reddy, an Indian American Scientist, gets a patent for his research to curb the spread of COVID. Dr Reddy, a global figure, who holds 150 American patents to his credit, discovered a method to control the COVID pandemic and disclosed this in a press note issued in Hyderabad. Dr Malireddy Srinivasulu Reddy (Dr M.S. Reddy) says by inactivating viral RNA we can control the spread of the COVID virus. He opines that in future we can control life-threatening viruses like COVID before they spread. Dr Reddy has registered for a patent on this method with the U.S. Patent Department.

Dr. M.S. Reddy, Indian American Scientist

Experts say this is a revolutionary step in the field of science. It is learnt that we can curb the spread of viruses by inactivating RNA and DNA. So far experts have never thought that naked genetic material is more dangerous than the virus. Applauds are pouring in from different quarters for Dr Reddy for thinking in this direction and also for finding a solution.

Dr Reddy is a world-renowned scientist in the field of Microbiology. He has been conferred with 160 national and international awards. He got the prestigious American Dairy Science Association Richard M. Hoyt memorial award. It is worth mentioning that he is the only foreign-born U.S. Citizen to receive this prestigious national award. He has got many patents for his research work in America. His research on Cheese made him very popular and he is referred to as 'Cheese Reddy.'

Sun Pharma reports net profit of ₹.19,845 million in Q4

Mumbai, India: Sun Pharmaceutical Industries Limited reported financials for the fourth quarter and full year ending March 31, 2023. The company reported net profit for Q4FY23 at ₹ 19,845 million as compared to net loss of ₹ 22,773 mn for Q4 last year. The company's gross sales stood at ₹ 107,256 million, growth of 14.3%, while EBITDA was at ₹ 28,021 million, up 19.7%. The company's India formulation sales stood at ₹ 33,641 million, up 8.7%.

Dilip Shanghvi, Managing Director, Sun Pharmaceutical Industries said, "I am pleased with well-rounded growth demonstrated in FY23 by the company. Several of our

businesses including Specialty, India and Emerging markets have continued to progress well. Our Specialty business remains on growth path and we are committed to continue scaling it up."

Sun Pharma holds 8.3% market share and is ranked No. 1 in the Rs. 1,850 Billion plus Indian pharmaceutical market as per AIOCD AWACS MAT March-2023 report. For Q4FY23, the company launched 24 new products in the Indian market.

IOL Chemicals and Pharmaceuticals receives CEP for Paracetamol to export in European Market

Ludhiana, India: IOL Chemicals and Pharmaceuticals Limited (IOL), a leading manufacturer of pharmaceutical (APIs) and specialty chemicals, has received the European Directorate for the Quality of Medicines & HealthCare's (EDQM) Certificate of Suitability (CEP) to export Paracetamol to the European Market. Paracetamol is utilised commonly in medication prescribed for pain relief and to treat fever.

The certification issued by the EDQM verifies the compliance of pharmaceutical substances and with this backing, IOL will now be able to export Paracetamol to the European continent. IOL is the world's largest producer of Ibuprofen API with 33% market share globally. Additionally, it has over 13 APIs in its portfolio, including Metformin, Fenofibrate, Lamotrigine, Clopidogrel Bisulphate, and Pantoprazole.

Glenmark Pharma reports revenue of ₹ 33,737 million in Q4

Glenn Saldanha, CMD, Glenmark Pharmaceuticals Ltd.

Mumbai, India: Glenmark Pharmaceuticals Limited, an innovation-driven global pharmaceutical company, announced its financial results for the fourth quarter ended March 31, 2023. For the fourth quarter of FY 2022-23, Glenmark's consolidated revenue was at ₹ 33,737 million as against ₹ 30,191 million, recording an increase of 11.7% YoY. The company's EBITDA was at ₹ 6,050 mn in the quarter ended March 31, 2023, as compared to ₹ 4,634 million in the previous corresponding quarter, registering growth of 30.5%. EBITDA margin for Q4 FY 2022-23 was 17.9 %.

"We delivered yet another year of robust performance, despite the challenging global macro-economic environment. Our India business recorded double-digit growth in secondary sales. The North America business showed strong recovery, and the EU and RoW markets did phenomenally well. We continued to make headway in launching Ryaltris, our first global branded specialty product," said Glenn Saldanha, Chairman and Managing Director, Glenmark Pharmaceuticals Ltd.

Biocon reports revenue of ₹ 3,929 crore in Q4

Kiran Mazumdar-Shaw, Executive Chairperson, Biocon and Biocon Biologics.

Bengaluru,, India: Biocon Ltd , an innovation-led global biopharmaceuticals company, announced its consolidated financial results for the fourth quarter ended March 31, 2023.The company's revenue stood at ₹ 3,929 crore, up 59%; while Net Profit (before exceptional Items) was at ₹ 335 crore, up 28%. The company's EBITDA stood at ₹ 1,152 crore, up 75% in Q4.

"FY23 has been a transformational year led by the acquisition of our partnered biosimilars business from Viatris, which has significantly contributed to Biocon's robust consolidated financials. Revenues grew 38% to ₹ 11,550 crore, EBITDA was at ₹ 2,888 Crore, reporting a 32% growth, stated Kiran Mazumdar-Shaw, Executive Chairperson, Biocon and Biocon Biologics. Kiran Mazumdar-Shaw added, "We ended FY23 with a strong Q4 performance where Revenues grew by 59% to ₹ 3,929 crore and EBITDA by 75% to ₹ 1,152 crore. Biosimilars continue to be the largest business segment for Biocon, with revenues of ₹ 2,102 crore, a growth of 114%, exiting the year on a USD 1 billion revenue trajectory."

"The Generics business performance in FY23 was in line with our expectations, delivering healthy year-on-year revenue growth that was driven by immunosuppressants, specialty APIs, and a ramp up of some of our recently launched generic formulation products. Profitability for the year was muted, mainly on account of pricing pressure in our key markets, as well as increased input costs, that was partially mitigated by cost improvement initiatives," stated Siddharth Mittal, CEO & Managing Director, Biocon Limited.

Lord's Mark Industries partners with IIT Bombay Partner to transform sickle cell testing

Sachidanand Upadhyay, Founder, Lord's Mark Industries

Mumbai, India: Lord's Mark Industries, a prominent diversified business group, has partnered with the Indian Institute of Technology Bombay (IIT-B) to revolutionize sickle cell testing in India. The company will invest Rs 25 crores to develop and distribute the technology-enabled POS equipment, targeting revenue of Rs 100 crores by year 2026-27. The first-ever AI-enabled POS equipment in the country, patented by IIT Bombay, will address challenges associated with sickle cell testing, making it more accessible with 100% accuracy.

Sachidanand Upadhyay, Founder, Lord's Mark Industries said, "We are also investing in the establishment of 1000 pathology labs across the country, with an initial investment of Rs. 50 crores, to provide easy access to sickle cell testing and other healthcare services. We aim to make equipment and testing available across government healthcare centers and hospitals."

Cipla Q4 Income from Operations stood at ₹ 5739 crore

Mumbai, India: Cipla Limited announced its audited consolidated financial results for the fourth quarter ended March 31st, 2023.The company's Income from Operations stood at ₹ 5739 crore, while adjusted PAT stood at ₹ 708 Crore.

"I am pleased to share that we continue to make significant progress across our focused markets.In FY23, we recorded highest ever revenue with EBITDA crossing INR 5,000 Cr for the first time. Our One-India business continued the double-digit trajectory growing at 13% ex-Covid during the yearled by branded prescription and sustained growth across our acute and chronic therapies. Our continued focus on differentiated portfolio has strengthened our US business which posted highest ever quarterly revenue at $ 204 Mn and $ 733 Mn for FY23. Adjusting for covid, our core operating profitability continues to be strong at ~23% expanding by 100 bps over last year. We are excited for the upcoming year, where we look forward to deepening our leadership in branded markets and expanding our differentiated pipeline in the US," stated Umang Vohra MD and Global CEO, Cipla Ltd.

Piramal Pharma Ltd reports net profit of ₹ 50 crore in Q4

Nandini Piramal, Chairperson, Piramal Pharma Limited

Mumbai, India: Piramal Pharma Limited announced its consolidated results for the fourth quarter (Q4) ended 31st March 2023. The company's revenue from Operation grew by 2% YoY in Q4FY23, while net profit stood at ₹ 50 crore in Q4. The company continue to see good demand for our CDMO services in the niche areas of high potent API,

peptide and anti-body drug conjugate. New capabilities / capacity expansion gone live at Riverview (US), peptide facility (Turbhe, India) and Ahmedabad PDS, witnessing healthy customer demand. The company expect to go live with expansion at our Grangemouth facility in H2FY24 which should help strengthen our position in the anti-body drug conjugate segment.

Nandini Piramal, Chairperson, Piramal Pharma Limited said, "Our CDMO business, which had a challenging year, witnessed significant pickup in order bookings in Q4.Our Inhalation Anesthesia portfolio continues to see a healthy demand and hence we are expanding our capacities. Our India Consumer Healthcare business is delivering good growth driven by our power brands. We continue to maintain our quality track record with successful US FDA inspections – zero observations at Riverview and Digwal facilities, and EIR received for Lexington and Sellersville facilities."

JB Pharma Q4 revenue rises 22%

Mumbai, India: JB Pharma, one of the fastest growing pharmaceutical companies in India, announced its financial results for the fourth quarter ended 31st March, 2022.

The company recorded revenue of ₹ 762 crores in the fourth quarter ended 31st March 2023 as against ₹ 625 crores in Q4 FY22, registering growth of 22%, while Operating EBITDA increased by 21% to ₹ 181 crores as compared to ₹ 149 crores. The company's net profit stood at ₹ 88 crores as compared to Rs. 85 crores, registering growth of 4%.

Nikhil Chopra, CEO and Wholetime Director, JB Pharma mentioned, "JB continued its growth journey in the fourth quarter, thereby ending FY23 with strong performance across business segments. Our performance in the International business has seen commendable gains amidst a challenging business environment. International formulations clocked mid-teens growth for the quarter. We continue to witness increased interest from existing and new clients in the CMO business especially in the lozenges segment. We expect to build on this growth in the long term by expanding our pipeline for international business."

Mankind Pharma Q4 revenue from Operations up 19%

Rajeev Juneja – VC & MD, Mankind Pharma

New Delhi, India: Mankind Pharma, India's fourth largest pharmaceutical Company announced its financial results for the fourth quarter ended March 31, 2023. The company's revenue from Operations at ₹ 2,053 crore, up by 19% YoY, while PAT was at ₹ 294 crore, up by 52% YoY. The company' EBITDA stood at ₹ 419 crore, up by 45% YoY with margin of 20.4%. The company said that New integrated API/formulation manufacturing plant expected to be commercialized in H1FY24.

Rajeev Juneja – Vice Chairman & Managing Director said, "The company maintained its strong growth trajectory during the year. Our domestic business continued to outperform the IPM in FY23, led by growth in chronic segments whose share has increased to 34% from 33% in FY22. Our consumer healthcare business has maintained its double-digit growth with dominant brand leadership in its categories. Our focus is on increasing value of prescription within existing class II-IV and rural markets and increasing penetration in Metros through higher chronic presence. We also plan to leverage our brand dominance to grow our consumer healthcare business, going ahead".

Hester Biosciences reports consolidated revenue from operations of ₹ 67.30 crore in Q4

Rajiv Gandhi, CEO & MD, Hester Biosciences

Ahmedabad, India: Hester Biosciences Limited, one of India's leading animal health company, manufacturing vaccines and health products has reported consolidated revenue from operations of Rs. 67.30 crore for the Q4FY23, growth of 19% Y-o-Y from revenue of ₹ 56.47 crore in Q4FY22. Operating profit during the quarter ended March 2023 was reported at ₹ 11.67 crore, 13% growth Y-o-Y from ₹ 10.33 crore in Q4FY22.

The company said that Q4 sales of Animal Healthcare division got a big boost due to the demand for Goat Pox Vaccine consequent to the outbreak of Lumpy Skin Disease (LSD) in cattle. The commissioning of the Fill-finish facility (Drug Product) will be completed in Q1 FY24. This expansion, along with the already completed expansion of Bulk Antigen (Drug Substance) production capacity, will double the production capacity in vaccines. Petcare Division, launched during the year is gaining traction. Until date, since inception of this division 9 months ago, 10 products have been launched in 15 sales territories. The market response has been very encouraging and this division is set to grow in geometric progression.

West Pharma inaugurates newly advanced manufacturing facility in Singapore

Singapore: West Pharmaceutical Services, Inc. (West), a global leader in innovative solutions for injectable drug administration, inaugurates its newly advanced manufacturing facility in Jurong, Singapore. This is part of West's commitment to invest more than US$350 million globally in 2023, with the majority used to expand capacity and deliver on demand of drug customers for the West's products and services, and to meet the growing needs of customers to support sensitive and complex molecules and the changing regulatory environment.

The Jurong facility investment comes at a critical time as the advancement of biologics is reshaping the way many diseases are prevented, diagnosed, and treated. This facility investment enables West to serve its customers' requirements by providing high-quality containment products for injectable drugs at one location, from start to finish, in the Asia Pacific region, helping to reduce overall lead times for customers.

Eric Green, President, CEO, and Chair of the Board of Directors, West, said, "This year, West celebrates a major milestone - its 100th anniversary. As we embark on the next century of scientific innovation, we look forward to strengthening our global networks to meet the needs of the growing critical changes in healthcare and drug delivery. This investment in our Jurong facility will continue to play a critical role in fulfilling our purpose of providing customers and their patients access to medicines globally."

IIT Kanpur researchers visualize communication of G-protein coupled receptors

Kanpur, India: A group of researchers led by Professor. Arun K Shukla in the Department of Biological Sciences and Bioengineering at the Indian Institute of Technology Kanpur (IIT-K) has unraveled a previously unknown mechanism that regulates an important class of drug targets known as G protein-coupled receptors.

The discovery has important implications for not only understanding the fundamental mechanism of cellular signaling in our body but it also has potential to facilitate novel drug discovery for several human disease conditions.

Says Professor Shukla, "This study has opened up novel directions for improving the currently existing medicines by lowering their side-effects, and also provides an opportunity for discovering new medicine for several human disease conditions."

Alembic Pharma reports net profit of ₹ 153 crore in Q4

Mumbai, India: Alembic Pharmaceuticals Limited reported its consolidated financial results for the fourth quarter ended 31st March, 2023.The company's net sales for the quarter at ₹ 1406 crores, while Net Profit for the quarter was at ₹ 153 crores. The company's India Branded Business grew 9% to ₹ 490 crores in the quarter, while API business grew 41% at Rs. 313 crores in the quarter. The company has received 7 ANDA approvals received during the quarter and 4 ANDA filings during the quarter.

Pranav Amin, Managing Director, Alembic Pharmaceuticals Limited said "The USA business continues to remain challenging, however, the Company witnessed topline growth across all other verticals. In particular, the API business outperformed with a 41% growth and Ex-US generics with 33% growth during the quarter. We have started commercialization of products from our injectable and oncology facilities. India Branded Business continues to outperform the market especially on focused products / therapeutic segments.

Eris Lifesciences reports net profit of ₹ 615 million in Q4

Mumbai, India: Eris Lifesciences Limited, a leading Indian branded formulations manufacturing company, announced its earnings for the fourth quarter ended FY23.The company's PAT for Q4 FY 23 is ₹ 615 million. The company's Revenue of Q4 FY 23 grew by 32% YoY to ₹ 4,028 million, while EBITDA for Q4 FY 23 is ₹ 1,189 million, with ~ 30% margin.

Commenting on the results, Amit Bakshi, Chairman & Managing Director of Eris Lifesciences Ltd., said, "FY23 has been a year of massive investment for us starting with the Oaknet deal in May '22 right through to the DRL brands deal in March '23. We are happy to note that things are coming together well and we will start seeing tangible results from FY24 onwards. We will continue to focus on delivering high-quality growth while preserving our industry-leading margins and cash generation ratios."

Lincoln Pharma Q4 net profit rises 14%

Mahendra Patel, MD, Lincoln Pharmaceuticals Limited

Ahmedabad, India: For Q4 ended FY23, Lincoln Pharmaceuticals Limited, one of India's leading healthcare companies reported net profit of Rs. 12.56 crore as against net profit of ₹ 11.02 crore in the corresponding period last year, growth of 14.00%. The company's total Income for the Q4FY23 was reported at ₹ 116.41 crore, higher by 11.47% over previous fiscal's same period income of Rs. 104.4 crore. The Company reported EBITDA of ₹ 20.54 crore in Q4 FY23, rise of 6.26% as compared to ₹ 19.33 crore in the corresponding period last year.

Commenting on the results and performance, Mr. Mahendra Patel, Managing Director, Lincoln Pharmaceuticals Limited, said, "Company has achieved the milestone of Rs. 500 crore revenue and Rs. 100 Crore in Profit in FY23 with a robust operational and financial performance along with healthy growth in revenue, margins and profitability. We expect the growth momentum to continue and expect to get further boost in coming years. Company has set a target of achieving Rs. 750 crore revenue by FY26 while maintaining or improving its margins. "

Aurobindo Pharma Q4 revenue rises 11%

Hyderabad, India: Aurobindo Pharma Limited announced its consolidated financial results for the quarter ended March 31, 2023. Revenue from Operations stood at ₹ 6,473 Cr increased by 11.4% YoY, while US formulations revenue increased by 11.6% YoY to ₹ 3,045 Crore. The company's Net Profit stood at ₹ 506 Crore as against ₹ 491 crore in the previous quarter. The company

Filed 12 ANDAs including 3 Injectables with USFDA in Q4 FY23. The company also received final approval for 26 ANDAs including 4 injectable products in Q4 FY23

Commenting on the Company's performance, K. Nithyananda Reddy, Vice-Chairman and Managing Director of the Company said: "We saw decent performance in the current quarter, on the back of stable demand and pricing environment across our portfolio and geographies. We remain committed to executing our growth strategies, continuing new launches, and focusing on operational efficiencies."

Jubilant Ingrevia Q4 net profit stood at ₹ 69 crore

Noida, India: Jubilant Ingrevia Limited posted financial results for the quarter ended March 31st, 2023. The company's net profit stood at ₹ 69 crore in Q4, while total revenue stood at ₹ 1296 crore.

Commenting on the Company's performance, Shyam S Bhartia, Chairman and Hari S Bhartia, Co-Chairman, Jubilant Ingrevia Limited said: "We are happy to announce that during the year FY23 our Specialty chemicals business grew 29%, Chemical Intermediate business placed highest ever volume of Acetic Anhydride and gained higher market share globally, however Nutrition business have faced headwinds for Niacinamide leading to lower volume as well as lower price realization. EBIDTA in FY'23 was lower mainly on account of higher energy prices and challenging market situation of Niacinamide business."

Gland Pharma Q4 net profit stood at ₹ 787 million

Hyderabad, India: Gland Pharma Limited, a generic injectable focused pharmaceutical company, announced its financial results for the fourth quarter ended March 31, 2023. The company's net profit stood at ₹ 787 million. The company's revenue from operations during the quarter has declined by 16%, while Gross Margin of the Company remained stable during the quarter as compared to same quarter previous year.

Commenting on the results, Srinivas Sadu, MD & CEO of Gland Pharma said "We have formally closed the acquisition of Cenexi and welcome it to be a part of the Gland-Fosun family. This is our first overseas acquisition and our move into the next phase of growth and expansion. We made progress on our path to building a Bio-CDMO and signed our first contract for Plasma Protein at our Shamirpet facility. Our full year FY23 revenue stood at ₹ 36,246 million, and our full year FY23 PAT stood at ₹ 7,810 million in the midst of challenging business environment."

Emcure Pharmaceuticals launches 750 mg injectable variant of Ferric Carboxymaltose

Pune, India: Emcure Pharmaceuticals Limited (EPL) has announced the launch of Orofer FCM 750, a new extension of its parenteral iron brand containing Ferric carboxymaltose (FCM).The new dosage variant is designed to provide a more effective and convenient option for patients with iron deficiency and iron deficiency anaemia (IDA). DCGI-approved FCM is indicated for treatment of iron deficiency when oral iron preparations are ineffective or cannot be used.It is already available in dosage forms 1000mg/ 20ml and 500mg/ 10ml single-use vials.

Anil Kothiyal, President India Business at Emcure Pharmaceuticals said "At Emcure Pharmaceuticals, we recognize IDA as a major public health concern in India, particularly among women.We believe Orofer FCM 750, with its convenient dosage strength, will provide an important treatment option for patients with IDA who may not have responded to oral iron preparations or who cannot tolerate them. Orofer FCM will be available in leading pharmacies and hospitals shortly".

Wockhardt Q4 revenue up 7%

Mumbai, India: Wockhardt Limited, the Pharmaceutical and Biotechnology major, reported its 4th Quarter Results for Financial Year 2022-23. The Company recorded a Revenue of Rs.710 crore in Q4FY23 compared to Rs.666 crore in Q4FY22 registering a growth of 7%.

The company's India Business stood at ₹125 crore in Q4FY23. India Business contributed 19% of the Global Revenue. EBITDA for the quarter is ₹ 47 crore as compared to ₹ (22) crore in Q4FY22 registering a substantial growth of 314%.Research and Development expenditure during the quarter was at Rs.25 crore (3.5% to sales) and including capital expenditure was at 7.1% to sales. Emerging Markets Business of the Company stood at Rs.173 crore in Q4FY23 compared to Rs.148 crore in Q3FY23 registering a growth of 16%.

Rakuten Medical to start a global Phase 3 trial of Alluminox treatment for Recurrent Head and Neck Cancer in India

Mumbai, India: Rakuten Medical, Inc, a global biotechnology company developing and commercializing precision, cell-targeting therapies based on its proprietary Alluminox platform, announced that the Company has been granted permission from the Indian Central Drugs Standard Control Organization (CDSCO) to conduct its global, pivotal Phase 3 clinical trial evaluating Alluminox treatment (photoimmunotherapy) using ASP-1929 in patients with locoregional, recurrent head and neck squamous cell carcinomas (HNSCC) in India, and the registration of clinical trial information with the Clinical Trial Registry of India (CTRI) has been completed.

"We are very pleased to be conducting the pivotal Phase 3 study of Alluminox treatment using ASP-1929 in India, where there is a high unmet need for head and neck cancer treatment," said Mickey Mikitani, Co-CEO of Rakuten Medical.

ASP-1929 is a conjugation of an antibody cetuximab and IRDye® 700DX, a light activatable dye, and is Rakuten Medical's first pipeline drug developed on its Alluminox™ platform. It binds to epidermal growth factor receptor (EGFR), which is highly expressed in head and neck cancers.

Zydus receives final approval from USFDA for Ephedrine Sulfate Injection

Ahmedabad, India: Zydus Lifesciences Limited has received final approval from the United States Food and Drug Administration (USFDA) to manufacture and market Ephedrine Sulfate Injection USP, 50 mg/mL single-dose vials. Ephedrine Sulfate Injection is indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia. The drug will be manufactured at the group's injectable manufacturing facility at Jarod, near Vadodara (India). The group now has 368 approvals and has so far filed over 440* ANDAs since the commencement of the filing process in FY 2003-04.

Cadila Pharma's Rabies Vaccine 'ThRabis' wins top honour at the Golden Globe Tigers awards

Ahmedabad, India: Cadila Pharmaceuticals' breakthrough three-dose rabies vaccine, Thrabis, has won the top honour at the The Golden Globe Tigers Awards.Cadila Pharmaceuticals achieved the "Innovative Product of the Year Award" for ThRabis at a grand function in Malaysia on Tuesday. Pankaj Sharma, Vertical Head of Cadila Pharmaceuticals' Magfam Division, virtually accepted the award on behalf of the company.

"It is an honour to receive this Innovative Product of the Year award. We are thankful to The Golden Globe Tigers Awards for this opportunity to share and showcase ThRabis, which is truly a breakthrough vaccine with the potential to save thousands of lives in India and globally. This award is a huge recognition of Thrabis' potential and reflection of Cadila Pharmaceuticals' commitment to innovation," Sharma said.

FPME highlights industry growth and innovation opportunities

Sandeep Modi, Joint Secretary, FPME

Mumbai, India: Federation of Pharmaceutical and Allied Products Merchant Exporters (FPME) highlighted industry growth and innovation opportunities, at the recently held meeting at Indian Merchant Chamber in Mumbai. The event was attended by a diverse group of participants, including pharmaceutical exporters, government officials, and industry experts. The attendees had the opportunity to listen to the insights and experiences of distinguished speakers such as Dr. Bhagwat Kishanrao Karad, Union Minister of State and Finance, Government of India, and Member of Parliament, Rajya Sabha, Maharashtra, Dr. PV Appaji, founder and former director general of Pharmexcil, and Dr. Radhakrishnan Pillai, Author of Bestseller Corporate Chankaya, Sumanta Chaudhari, Advisor, Pharmexcil and Namit Joshi, Director of Centrient Pharmaceuticals and Vice Chairman of Pharmexcil.

Dr. Bhagwat Kishanrao Karad, Union Minister of State and Finance, Government of India, and Member of Parliament, Rajya Sabha, Maharashtra and Dr. PV Appaji, founder and former director general of Pharmexcil virtually attended the annual event. Speaking at the Annual Event, Dr. Bhagwat Kishanrao Karad, Union Minister of State and Finance, Government of India, and Member of Parliament, Rajya Sabha, Maharashtra, stated that the Under Leadership of Honorable Prime Minister Narendra Modi ji's government commitment to supporting small and medium-sized enterprises (MSMEs), promoting the Indian pharmacopeia, and supporting innovation and research and development (R&D). All of these initiatives are aimed at promoting economic growth and development in India.

He also stressed that one of the benefits of allowing rupee trade is that it can help to reduce currency volatility and make it easier for Indian businesses to engage in international trade. When businesses are able to trade in their local currency, they do not have to worry about fluctuations in exchange rates, which can be a significant risk factor in international trade. This can help to encourage more businesses to engage in cross-border trade, which can in turn promote economic growth and development.

Sandeep Modi, Joint Secretary, FPME, emphasised the role of merchant exporters in ensuring last-mile delivery of medicines to any part of the world. The Production Linked Incentive (PLI) scheme is another important initiative aimed at supporting the Indian pharmaceutical industry. The scheme provides financial incentives to pharmaceutical companies that invest in R&D and manufacturing within India. By providing these incentives, the government is encouraging the development of a robust and competitive pharmaceutical industry within the country, which can help to drive innovation, create jobs, and improve access to affordable healthcare.

Dr. Karad has also highlighted some issues that have been raised by the Federation of Pharma Entrepreneurs (FPME) regarding his ministry, including issues related to customs, bank charges, and the Export Credit Guarantee Corporation (ECGC).

Torrent Pharma Q4 revenue rises 17%

Ahmedabad, India: Torrent Pharma posted results for the fourth quarter ended 31st March, 2023. The company's Revenue stood at Rs. 2,491 crores up by 17%, while Profit after tax was at Rs. 287 crores. The company said that robust growth aided by strong performance of new launches in chronic therapies and integration of Curatio. India revenue at Rs 1,257 crores grew by 22% in Q4.

As per AIOCD secondary data, Torrent's growth for the quarter was 12% vs IPM growth of 11%. Torrent is now the 6th largest company in the IPM as per MAT March 2023 data. Torrent Pharma, with annual revenue of more than Rs 9,600 crores, is the flagship Company of the Torrent Group, with group revenue of ~Rs. 37,000 crores. As on March 31, 2023, 46 ANDAs were pending approval with USFDA and 3 tentative approvals were received. During the quarter, 3 ANDAs were filed & 2 ANDAs were approved.

Marksans Pharma Q4 Operating revenue up 16%

Mumbai, India: Marksans Pharma Ltd reported the financial results for the fourth quarter ending March 31, 2023.The company's Operating revenue stood at Rs. 486.0 crore., up by 16.3% YoY driven by market share gains in the existing products and markets. Gross profit stood at Rs. 242.1 crore, up by 17.3% YoY. The company's revenue stood at Rs. 206.3 cr. from the UK and Europe Formulation business in Q4FY23 as compared to Rs. 155.0 cr. during last year, registering a growth of 33.1%

The company completed Teva Pharma Manufacturing unit acquisition in May 2023, doubling the Indian manufacturing capacity for the company. The company raised a total amount of Rs. 372.40 crore in equity in January 2023 through warrant conversion by OrbiMed and the Promoter.

Mark Saldanha, Managing Director of the Company said "Our consistent growth trend continues in the quarter, driven by gains in existing store brands, products, and markets, as well as normalization of freight expenses. We have completed the acquisition of Teva Pharma manufacturing unit in Goa which will enable us to accelerate the growth of our business and strengthen our position as a leading low-cost manufacturer.We have exceeded our FY23 guidance of INR 1,800 crore. This milestone is our testament to our commitment to delivering value creation for our stakeholders. We aim to continue our success in the coming year, with a focus on extending our footprint in the multi-billion-dollar OTC opportunities, focusing on margin improvement, and strengthening our balance sheet."

Strides Pharma Science receives EIR from US FDA for Puducherry facility

Bangalore, India: Strides Pharma Science Limited stated that it has received an Establishment Inspection Report (EIR) from the U.S. Food and Drug Administration (USFDA) for its Puducherry manufacturing facility (Facility), stating the inspection conducted between February 20-24, 2023 has been closed. The USFDA has classified the facility from Official Action Indicated (OAI) to Voluntary Action Indicated (VAI).

The USFDA had classified Strides Puducherry facility as OAI in May 2019 followed by issuing a warning letter to this site in July 2019. The company remains committed to the highest standards of compliance and will continue to focus on manufacturing high-quality pharmaceutical products for the Global markets.

Laurus Labs invests ₹ 80 crore in Cell and Gene therapy company ImmunoACT

Hyderabad, India: Laurus Labs Ltd announced that it has signed definitive agreements to acquire additional stake of 7.24% in Immunoadoptive Cell Therapy Private Limited (ImmunoACT), an advanced cell and gene therapy company for a cash consideration of Rs.80 Crore. Post the completion of the deal, Laurus Labs' stake in ImmunoACT will increase to 33.86% (on fully diluted basis).

This fresh infusion of capital will enable ImmunoACT to fast track the additional supply of the lead candidate HCAR-19along with the further expansion of the multi-

location GMP facilities for manufacturing Chimeric Antigen Receptor T cells (CAR-T cells) treatment to support the growing need for scalable manufacturing. Additionally, some promoters and senior management of Laurus Labs would also acquire in

ImmunoACT for a 0.54% stake (before this investment) for approximately Rs. 4 crore at the same price and terms through secondary purchases.

Laurus Labs' earlier investment in ImmunoACT in November 2021 has supported ImmunoACT in successfully creating GMP manufacturing facility along with state of the art R& D facility at Navi Mumbai and currently conducting Phase II study at various hospitals including Tata Memorial Hospital. Phase I data was presented at the American Society of Hematology (ASH) during Nov-2022 that showed a favorable balance of efficacy and toxicity with lowgrade cytokine release syndrome.

Commenting on the development, Founder and Chief Executive Officer Dr. Satyanarayana Chava stated "This Investment further strengthens Laurus Labs' commitment to access novel Cell and Gene Therapy technology and enhance its affordability for patients. This investment will further help ImmunoACT to gear up for the manufacture of more treatments. This acquisition is also a step towards our commitment to promote and access novel technologies and making it commercially viable in unmet medical needs of auto immune diseases and oncology. We are looking to invest further in disruptive innovation with a disciplined approach, to enable our strategic partners and customers to bring these promising therapies to patients."

Natco Pharma Q4 net profit stood at ₹ 276 crore

Hyderabad, India: Natco Pharma Limited has recorded consolidated total revenue of ₹ 2811.7 Crore for the year ended on 31st March, 2023, as against Rs. 2043.8 Crore for the last year, reflecting 37.6% growth. The net profit for the period, on a consolidated basis, was ₹ 715.3 Crore, as against ₹ 170.0 Crore last year.

The increase in revenue and profits for the year was driven by business growth in the US market and growth in our subsidiaries in Canada & Brazil. Our Crop Health Division started off well with strong growth potential in ensuing years.

For the fourth quarter (Q4) ended March 31st, 2023, the company recorded a net revenue of ₹ 926.9 Crore, on a consolidated basis, as against ₹ 610.6 Crore during Q4, FY 2022. The profit for the fourth quarter, on a consolidated basis was ₹ 275.8 Crore, as against a loss of ₹ 50.5 Crore last year fourth quarter.

Solara Active Pharma Sciences Q4 revenue stood at ₹ 3,853 million

Jitesh Devendra, MD, Solara Active Pharma Sciences Ltd

Bengaluru, India: Solara Active Pharma Sciences Ltd (Solara) , a leading Active Pharmaceutical Ingredient / CRAMS company, today announced the financial results for the fourth quarter (Q4'23).

The company's Revenues stood at ₹ 3,853 million, while EBITDA margins was at 13.4%.

Commenting on the financial performance, Jitesh Devendra, MD of the Company, remarked, "We are delighted to conclude fiscal year 23 on a positive note, having accomplished many of the goals we set

for ourselves at the beginning of the year. The prior fiscal year (FY22) was a difficult one for the company, prompting the board to make several important decisions to ensure Solara returns to positive growth territory with sustained profitability. We had set forth key strategic priorities, which included resetting and concentrating the base business, restoring R&D velocity, addressing under-recoveries at our newly commissioned Vizag site, and expanding into new products and geographies. I am pleased to report that we are trending positively toward a broad range of outcomes, and our performance in FY23, particularly the second half, is indicative of the company's efforts to rebound. Additionally, to the FY23 results, we have made major strides toward founding a strong base, yielding even greater future performance as we keep expanding. As we enter FY24, we are extremely optimistic about the business's prospects. We are confident that Solara will have another successful year. We remain committed to delivering value and thank our investors for their continued support."

Caplin Steriles gets US FDA approval for Ketorolac Tromethamine Injection

C. C. Paarthipan, Chairman, Caplin Point Laboratories Limited

Chennai, India: Caplin Steriles Limited (Caplin), a Subsidiary Company of Caplin Point Laboratories Limited, has been granted final approval from the United States Food and Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) Ketorolac Tromethamine Injection USP, 15 mg/mL and 30 mg/mL Single-dose Vial, a generic therapeutic equivalent version of (RLD), TORADOL injection of Roche. Ketorolac Tromethamine Injection USP is a nonsteroidal anti-inflammatory drug (NSAID),indicated for the short-term (≤5 days) management of moderately severe acute pain. According to IQVIA (IMS Health), Ketorolac Tromethamine Injection USP had US sales of approximately $53 million for the 12-month period ending December 2022.

C. C. Paarthipan, Chairman of Caplin Point Laboratories Limited commented "Our regulated markets business continues to grow at a robust pace, and this new approval will help augment the growth. We have also received a few approvals from other markets such as Canada and Australia and we look forward to launches there within this year too."

Caplin Steriles Limited, a Subsidiary of Caplin Point Laboratories Limited, is a niche sterile product manufacturing company that is approved by several regulatory agencies such as US FDA, EU-GMP and ANVISA. Caplin Steriles Limited, has developed and filed 30 ANDAs in USA on its own and with partners, with 21 approvals so far. The Company is also working on a portfolio of 40+ simple and complex Injectable and Ophthalmic products, that it intends to file over the next 4 years. ■

"We have plans to leverage on the robust growth of the domestic generic formulations CDMO business"

Hitesh Windlass
Managing Director
Windlas Biotech Limited

Please share insights into the emerging market trends, challenges & opportunities for CDMO business?

As per the findings of Skyquestt, the Global Contract Development and Manufacturing Organisation (CDMO) Outsourcing Market has been appraised at USD 217.6 billion in the current year. The market is anticipated to expand from USD 237.62 billion in 2022 to USD 524.67 billion by 2030, with a Compound Annual Growth Rate (CAGR) of 9.2% during the period of 2023-2030. Anticipated growth in the CDMO sector is expected to be highest in India, owing to the cost-effective R&D and manufacturing, as well as the presence of a highly skilled workforce. The primary advantage of outsourcing to India lies in the cost benefit it provides. Based on estimates, outsourcing to India is 37.5% less expensive than outsourcing to the United States and Europe.

The contract development and manufacturing organisation outsourcing market incudes several distinct verticals related to contract research generic produce, clinical research including BA/BE studies, bulk drugs custom development and manufacturing for innovators and finished formulation development and manufacturing for innovator brands, branded generics and other generic marketers. This large and diversified industry will continue to grow as the pharmaceutical industry expands.

The CDMO space is experiencing accelerated expansion due to a number of factors. Branded generic pharmaceutical companies are increasingly realizing the need to focus on the core aspects of brand building and partnering with a well-developed and mature ecosystem of contract manufacturers who can deliver to the rising quality standards, provide the benefit of economies of scale and develop new product as per current guidelines.

Furthermore, CDMOs have established themselves as viable alternatives to the R&D and manufacturing divisions of the major pharmaceutical companies. They have become an integral component of the major pharmaceutical corporations. Companies in the

formulations sector outsource one-third of their research and development to CDMOs worldwide and India is growing as a prominent player in the CDMO space.

There are multiple tailwinds for the CDMO sector. Customers are demanding enhanced quality systems and enhanced safety in both research and development and manufacturing; marketers are held to the same standard of responsibility for the quality of the drug product in the eye of regulators and after implementation of new schedule M, if the manufacturers don't practice the schedule, many small pharma manufacturing units may become unviable. Windlas, with its focus on quality and long-standing relationships with the top pharmaceutical companies in the country, is well positioned to capitalize on all these opportunities.

Consistent efforts in CDMO sector, such as new patent expiry launches, wallet share gains from existing customers, acquisition of new clients and introduction of distinctive products supported by superior R&D, are all initiatives and focus areas that we are working on to reenergize growth in this vertical.

Our growth strategy primarily involves the early detection of products that are encountering an upsurge in demand and concurrent broadening of markets, procurement of novel customers and augmentation of revenue from the company's current customer base. The government's emphasis on quality also bodes well for future of the larger and organized players like Windlas Biotech in CDMO market space.

What was the growth for Indian formulations CDMO market?

In comparison to the growth of formulations, the robust demand for outsourcing by large pharmaceutical and Indian pharmaceutical companies has outpaced the growth of contract manufacturing of formulations. Domestic formulations by CDMOs are projected to grow at a CAGR of 14% by FY25—driven by strong outsourcing demand from big pharma companies (Indian and global) and rising demand for generic products in the chronic therapeutic category.

Innovation and rapidity to market are the focal points of the pharmaceutical industry. One of the primary development drivers for CDMOs is their ability to provide integrated services throughout the entire drug lifecycle including formulations. Diverse pharmaceutical companies are eager to form partnerships with CDMOs that offer integrated supply chain opportunities. To maximise development time and cost, pharmaceutical companies are eager to advance their products with minimal supply chain complexities. This has enabled Indian formulations CDMO market to broaden their capabilities and become the partner of choice.

What is your focus area going ahead?

We are focusing our efforts on areas that are experiencing strong growth already, such as domestic trade generics and institutional brands SBV, as well as markets that are seeing high growth internationally, and make the most of opportunities in the sector.

We have plans to leverage on the robust growth of the domestic generic formulations CDMO business as well as the growing outsourcing trend of the Indian generic formulations CDMO sector. We further plan to capitalize on our expertise in the production of complex products.

The company also plan to expand customer base by capitalising on the fact that there are few providers with a diverse offering of Generic Formulations CDMO products and having extensive experience in providing customer-centric additive manufacturing solutions. We maintain our focus on improving product development and manufacturing capabilities for complex generic products and make use of the upcoming patent expiration dates for key molecules.

We are also constantly strengthening our manufacturing capabilities to meet our clients' growing demand as chronic illness rates rise and a new drug delivery system emerges.

We are also entering the injectables market, for which an additional manufacturing facility is under construction and will commence operations in H2FY24, where we will manufacture ampoules, vials, and lyophilized vials. The

global injectables market is expected to expand at 8% CAGR from USD 502 billion, to USD 700-800 billion, while the domestic injectable CDMO sector is expected to increase at a 12% CAGR from USD 32 billion in 2020-21, to USD 51 billion in 2024-25.

CDMO vertical contributed approximately 78% for both FY23 and Q4FY23 respectively to the consolidated revenue. Because we are working to expand each of the other two segments i.e. trade generic and exports which have the potential to expand at a more rapid rate, the composition of the company's revenue may change in the years ahead.

Brief us about your new product launches.

In terms of new products associated growth, in CDMO vertical we are launching several new products. A number of DCGI permissions that we are getting has increased significantly from, what it used to be last year or even before that. So, these are the methods for driving faster implementation, greater customer connect and improving product match with customers.

We are present in orals, solid and liquids and shall foray in injectables segment in FY24 with vials, lyophilized vials and ampoules. Injectables business will complement our existing CDMO offerings and will enable to improve our margins profile.

Comment on your Capex plans.

As of March 2023, all of the funds that were raised for the injectable facility have been utilized and the construction of the plant has begun in earnest. We anticipate reaching mechanical completion by the end of the second quarter of current fiscal year.

The company is also actively looking at prospective inorganic growth opportunities to obtain synergies, diversify its product line and achieve scale.

Brief us about your financials.

For FY23, consolidated revenue, EBITDA and PAT grew by 10%, 15%, and 12% to Rs. 513.1 crores, Rs. 60.2 crores, and Rs. 42.6 crores, respectively. Gross margins for FY23 were 160 bps higher YoY at 36.6% and EBITDA margins were at 11.7%

Revenue for CDMO vertical stood at Rs. 398.3 crores in FY23 up 5% YoY. CDMO vertical contributed approximately 78% to the FY23 consolidated revenue.

Revenue for trade generics & institutional vertical stood at Rs. 90.5 crores, up 49% YoY. Trade generics and institutional vertical contributed approximately 18% to the FY23 consolidated revenue.

Revenue for exports vertical stood at Rs. 19.8 crores. This vertical contributed approximately 4% to the FY23 consolidated revenue. ' ■

GUEST COLUMN

Regulations for Contract Manufacturing

R. S. Raveendhren
Advocate
High Court of Madras

Contract manufacturing has become a prominent practice in the pharmaceutical industry, where a principal manufacturer outsources the production of finished or semi-finished products to a third-party manufacturer. This business model offers significant cost-saving advantages for the principal manufacturer, as it eliminates the need for creating manufacturing and delivery infrastructure. In India, contract manufacturing has shown a whopping 20% growth rate and the stakeholders firmly believe, the country is slated for further growth and is even expected to exceed China, Vietnam and Ireland. However, the absence of a comprehensive legal framework poses challenges and limitations for contract manufacturing arrangements in India. The author explores the evolution of contract manufacturing, the existing legal provisions, and the government's measures to address the regulatory gaps while discussing the need for a holistic policy approach to ensure the industry's sustainable growth.

We all hear of contract manufacturing in the pharmaceutical industry; field experts and medico-legal gurus are at loggerheads discussing how and why the legal system in our country hasn't warmed up to modern-day challenges. Contract manufacturing, in the simplest of terms means manufacturing that is undertaken by a third party. It is a form of outsourcing where a principal manufacturer utilises the services and infrastructure of a secondary manufacturer to produce a finished or a semi-finished product. Therefore, whenever we talk of contract manufacturing in the pharmaceutical industry, we are talking of a vertically-integrated business model where one big company outsources its product manufacturing to one or many smaller companies.

The biggest advantage of having their production outsourced is that the principal manufacturer can save big bucks that they would otherwise have to invest in creating manufacturing and delivery infrastructure. The principal manufacturer avails benefit from the contract manufacturer's existing equipment, their supply chain, labour and other resources including direct delivery to clients.

A lot of MNCs regularly outsource products to Indian manufacturers. It allows them a leverage on their brands while steeply reducing their cost of operation. From manufacturing active ingredients to formulations and from stability testing to manufacturing chemical intermediaries, primary & secondary packaging, labelling and clinical trial supplies, it is no surprise that India has highest number of US Food and Drug Administration-approved manufacturing plants outside of the US.

How and when of Contract Manufacturing in India

Contract manufacturing became a hit model in India way back in 2014 when the union government's "Make in India" initiative opened a plethora of opportunities. A policy decision allowing 100% Foreign Direct Investment (FDI) in contract manufacturing through the automatic route provided the necessary impetus to transform India into an attractive manufacturing hub.

According to Indian Drug Manufacturers, contract manufacturing has shown a whopping 20% growth rate, believed to be one of the highest in the world. Stakeholders firmly believe that given India's reasonable cost of manpower, its knowledgeable work force and its compliance to WHO guidelines, the country is slated for further growth and is even expected to exceed China, Vietnam and Ireland.

Let us see how contract manufacturing evolved

Worldwide, the evolution of Contract Manufacturing Organizations can be classified into

- **Early Years (1975 -1980):** The earliest years relate to a period when more and more drugs were being discovered and it began posing a challenge to in-house capacity of small and medium-sized companies.
- **Growth Years (1980-1996):** The growth years reflected an increase in Research & Development, emergence of newer technologies and significance of Biotechnology. What it did was that it stretched the capacity of the plant prompting a need for a model that would help supplement the growing requirement. It is quite interesting to note that first Contract Manufacturing Organisations came up in the United States and Western Europe.
- **Competitive Years (1997-2010):** The competitive years started with countries from the Asian world joining the competition. The expanding economies of India and China, the cost benefits, cheap labour etc posed a stiff competition to the Western world.
- **Resurgent years (2010- present):** The resurgent period signaled an increased spending in healthcare and emergence of newer business entities. There began a reported shift in manufacturing processes back to countries in US and Europe. The industry's re-focus from "lesser costing" to "the right manufacturing assets, facilities and experience" and repeated warning letters from the FDA to CMOs in Asia pointing to their lack of quality compliance resulted in serious erosion of trust in them. In this

context, it is important to note that countries in this part of the world need to take a cue and work more on quality compliance in order to attract business.

But does India have a legal framework for governing pharmaceutical contract manufacturing?

The laws relating to drugs in India date back to the colonial era's Drugs and Cosmetics Act of 1940 and the rules made under it in 1945. It is clear that there is no express provision for contract manufacturing nor is there a regulatory framework for third party manufacturing agreement.

The Drugs and Cosmetics Rules state that drugs be manufactured in three ways:

- Own manufacturing license
- Repacking license &
- Loan license (Rule 75A)

While first and second are self-explanatory; manufacturing by loan license is when the applicant does not possess an arrangement for manufacturing but intends to avail the facilities owned by another licensee.

Challenges posed by insufficient legal provisions

- In a contract manufacturing arrangement, a company selling/distributing a product under wholesale license cannot be held responsible for quality compliance except for the pricing of the drug under the Drug Price Control Order (DPCO)
- There is absolutely no liability under any substantive law other than under the 'product liability' under section 2(34) of the Consumer Protection Act of 2019
- On the contrary, in the US, actions pertaining to 'product liability' are mainly brought under Law of Torts under State law which ensures strict accountability. The European Union also strictly addresses 'product liability' on the basis of the Council Directive 85/374.

Measures by the government

In order to wriggle out of legal obligations and liabilities with respect to the third party contract manufacturing in the industry, the government introduced an amendment (with effect from March 1, 2021) amending Rule 2 of the Drugs and Cosmetics Rules of 1945 by including the term 'marketer' under clause (eb). Apart from this, Rules 84D and 84E have been inserted after Rule 83C to define an agreement for marketing and spelling out the responsibilities of the marketer of drugs. The newly inserted Rule 84D contains agreement for marketing and states that "no marketer shall adopt any drug manufactured by another manufacturer for marketing of such drug by labelling or affixing his name on the label of the drug with a view for its sale and distribution without an agreement as referred to in clause (ea) of Rule 2".

Rule 84E that talks of responsibilities of marketer of drugs states that any marketer who sells or distributes any drug shall be responsible for quality of that drug as well as other regulatory compliances along with the manufacturer under the present rules.

Conclusion

It can be clearly seen that a lack of exclusive regulatory framework is driving the authorities to making rules in bits and pieces rather than approaching the subject holistically by framing a comprehensive policy. And no policy framework is possible in the absence of a parliamentary legislation addressing it. The recent pandemic made the pharmaceutical sector to seek contract manufacturing in a big way. Its growth from US$934.8 billion in 2017 to $1.17 trillion in 2021 gives an insight of the exponential boom the industry is experiencing. Even though there is light at the end of the tunnel in the form of a new draft Bill called the Drugs, Medical Devices and Cosmetics Bill 2022 whose primary object is to ensure a comprehensive legislation regulating medical products, there remain pressing doubts and concerns if it will address all the challenges posed by contract manufacturing arrangements. Time will have to tell. ■

Navigating challenges : CRAMS Industry holds long-term growth potential

The Contract Research & Manufacturing Services (CRAMS) contribute approximately 15% to 20% of the Indian Pharmaceutical Industry, which has a total value of around USD 48 billion in FY23. Over the period of FY18 to FY22, the CRAMS segment experienced a robust growth rate of about 17%. However, due to geopolitical developments and recessionary trends in regulated markets, the growth rate of the segment decelerated to approximately 4% in FY23. This slowdown in growth has also impacted the operating profitability margins, causing a decline of about 350 basis points during the same fiscal year, based on industry aggregates representing over 70% of the CRAMS segment.

CareEdge Ratings anticipates that this contraction in the CRAMS segment is temporary and expects a recovery starting from Q3FY24. The palpable reason for this recovery lies in the resumption of research activities by innovator and biotech companies, gradually returning to normalcy. The following section highlights the factors that contributed to the slowdown and contraction in the CRAMS segment and outlines the expected evolution of the segment going forward.

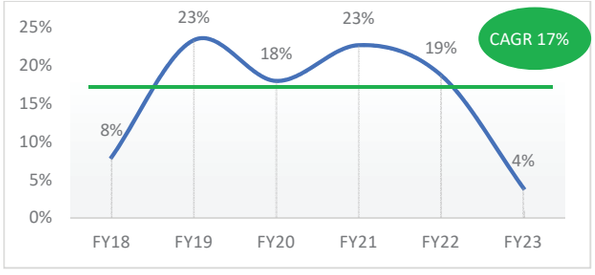
Factors for Higher Growth Rate during FY18 to FY22:

Discovery and development of a new drug is a quite lengthy and complex process, generally involving 10-15 years of time with investments running in billions (more than USD 5 billion). More than ever, the innovator companies are looking for partners across the pharmaceutical value chain to encourage innovation, optimise costs, enhance efficiency, flexibility and productivity through the various stages of drug discovery to development.

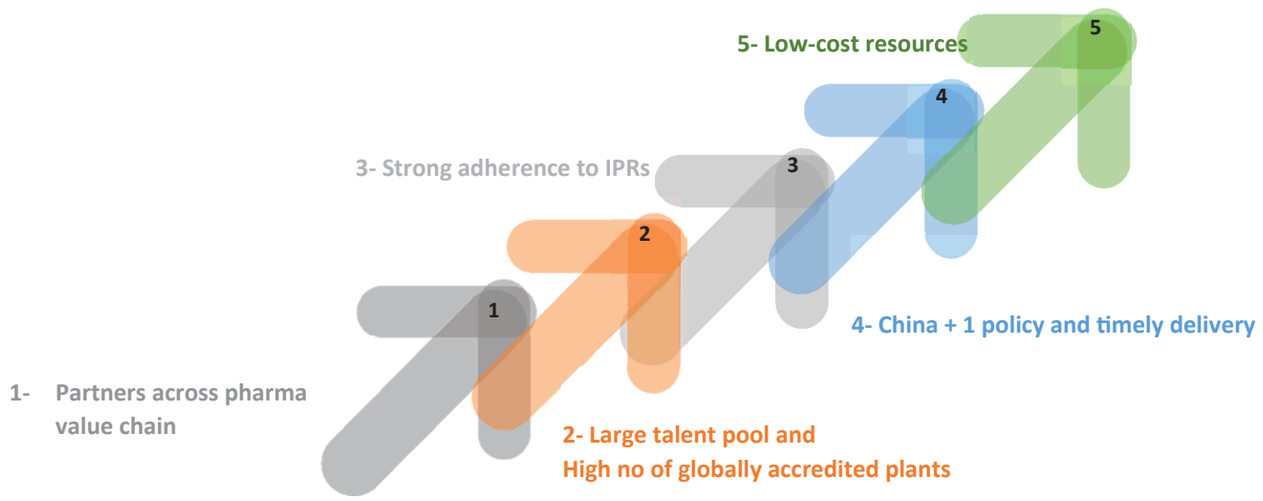
Indian CRAMS players offer a complete end to end solution viz. right from the drug discovery and preclinical studies to drug development and manufacturing. The segment has grown over time from simple molecule research and manufacturing to manufacturing of complex molecules requiring high end research. The presence of large talent pool, large globally accredited plants, strong adherence to Intellectual Property rights (IPR), efficient and reliable delivery timelines, China plus one policy, low cost and deep research acumen has made India as the preferred destination for global pharma innovators. The analysis of data of industry aggregates that represent over 70% of the CRAMS segment shows over a period of 7 years viz. FY18-FY28, the industry has registered a CAGR growth. of about 17%.

Factors Denting Growth Rate and Profitability Margins in CRAMS Segment during FY23:

Revenue growth rate of CRAMS **industry during FY18 to FY23**

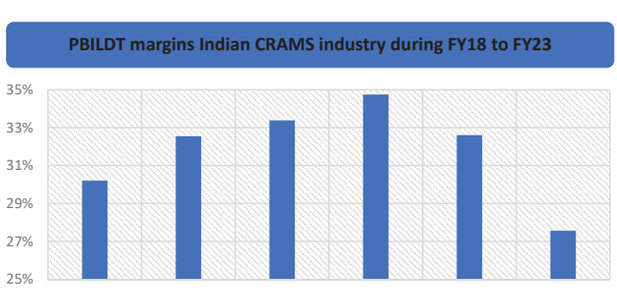


Despite the promising long-term growth potential of the Indian CRAMS market, the industry is currently grappling with several challenges that have affected the performance of key players in FY23. The slowdown can be attributed to the impact of rising inflation and recessionary pressures in the US and European markets. Leading innovator and biotechnology companies have reduced their investment in research and development for drug discovery and development, which has directly



impacted the Indian CRAMS segment, predominantly reliant on exports.

Specifically in the European market, energy prices have surged by over 30%, logistics costs have increased by over 100%, and there has been a more than 50% rise in the input cost of raw materials due to geopolitical tensions. These factors have resulted in significant cost inflation. Notably, CRAMS players with manufacturing



units overseas have been more severely affected, experiencing deeper margin reductions compared to those with manufacturing units in India. Furthermore, leading CRAMS players in India have witnessed an overall increase in raw material and freight costs, amounting to approximately 20%, thereby denting their margins by around 350 basis points during FY23.

Way Forward

The credit quality of Indian CRAMS players has demonstrated stability and is expected to continue in the future. This is primarily due to their low-leveraged balance sheets and moderate capital expenditure plans. According to CareEdge Ratings, the CRAMS segment is projected to experience robust growth of around 10% in the medium to long term. This growth will be driven by the increasing trend of outsourcing by innovator.

CareEdge Ratings anticipates that innovator and biotechnology companies will regain momentum in their research and development spending during the current fiscal year, gradually returning to normal levels by Q3FY24. This is crucial for them as each stage of the drug discovery process is time-bound and critical. Looking ahead, CareEdge Ratings expects the PBILDT (Profit Before Interest, Taxes, Depreciation, and Amortization) margin of CRAMS players to improve and remain within the range of 29-30%, aligning with the normalization of revenue growth..' ■

Authors

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"Akums plans to enter into niche dosage forms as well as newer therapeutic areas."

Sanjeev Jain
Co-founder & Director
Akums Drugs & Pharmaceuticals Limited

What outlook do you see for CDMO business?

The growing prevalence in chronic diseases and the expanding geriatric population has sparked an urgent need for medical products that can reach the market swiftly and gain regulatory approval promptly. As a result, the demand for pharmaceuticals and CDMO services in India is experiencing a remarkable surge. The CDMO outsourcing market is expanding in tandem with the robust growth of the pharmaceutical sector. Notably, the API manufacturing segment is likely to exhibit the fastest growth rate during the forecast period in India.

Pharmaceutical companies are increasingly opting for full-service CDMO outsourcing to simplify their supply chains and accelerate time to market for their products. With its impressive growth rate, cost-effective R&D and manufacturing, and a skilled workforce, India is poised to become a key player in the global pharmaceutical CDMO industry. By leveraging its strengths, pharmaceutical companies can optimise their operations, streamline their supply chains, and bring innovative products to market more efficiently.

What is the market opportunity for CDMO business?

The market opportunity for CDMO business is significant. The global CDMO market size is expected to reach USD 278.98 billion by 2026. CDMOs offer a number of advantages to pharmaceutical companies, including: access to specialised expertise and resources, reduced risk and cost, and increased speed to market. As the pharmaceutical industry continues to evolve, the demand for CDMOs is expected to grow. CDMOs are well-positioned to capitalise on this growth by providing innovative and cost-effective solutions to pharmaceutical companies.

This requires a high level of manufacturing expertise, which CDMOs can provide.The rising regulatory requirements are also driving the growth of the CDMO market. The pharmaceutical industry is subject to a number of regulations, which can be complex and time-consuming to comply with. CDMOs can help pharmaceutical companies to comply with these regulations, which can free up resources to focus on other areas of the business.The consolidation of the pharmaceutical

industry is another key trend that will driving the growth of the CDMO market. As the pharmaceutical industry consolidates, larger pharmaceutical companies are increasingly outsourcing their manufacturing to CDMOs. This is because CDMOs can offer a more cost-effective and efficient manufacturing solution.

Brief us about your expansion plans for CDMO space?

Akums is planning to expand its capacity for injectable even further this year which will drive significant business volume for the company in the future.

The company is setting up another nutraceutical facility to tap the growing market of sports nutrition, medical nutrition, and daily well-being. Globally, the nutraceuticals market is over USD 350 Bn and India is witnessing a steep growth. We have several domestic as well as global nutraceutical and wellness brands associated with Akums. Thus, the growth looks equally promising.

The company plans to aggressively foray into the global markets across APIs, finished pharmaceuticals dosages, as well as nutraceuticals. Akums facilities are approved by global regulatory authorities for supply in 75+ countries, across Europe, CIS, South East Asia and Africa. In the next 5 years, exports will be a major focus for the company and it will contribute to the growth of Akums in a considerable way.

Active Pharmaceutical Ingredients is a growth vertical for Akums. Started as a new business unit in FY2022-23, the unit clocked USD 25 Mn in sales in the initial year. With growing importance of global API supply chain robustness and focus on Indian API industry by the government and the companies across the world,Akums is geared to grow well in the space.

The company plans to enter into niche dosage forms (e.g., lyophilized injectables, nasal sprays, gummies etc.) as well as newer therapeutic areas (e.g., oncology, niche anti-infectives, peptides etc.). These differentiated dosage forms will position Akums as one the key CDMOs in Asian and global markets.

Your plans for global market? What percentage of revenue comes from CDMO business?

We are in talks with our partners abroad. In 2022, we got the European Union's (EU) stringent Good Manufacturing Practice (GMP) stamp of approval for two of our units in Haridwar. Our plan to focus on Europe is based on the strength of our products internationally. Moreover, most of our existing clients in India have their presence abroad. We have several plans in the pipeline and are working on strategic partnerships to venture into the global market. Akums generates 3/4th of its revenue from formulation CDMO business.

What are you plans in terms of expanding capacity at its existing facility?

We are constantly working on expanding at our current sites to install new capacities, upgrade new machinery as well as bottleneck capacity. At present, we are working to enhance our capacities of tablets, ampoules, vials, oral liquids, eye drops, and nutraceuticals.

Brief us about your tie-up with industry-academia partnership with SGT University?

We have signed an MOU with SGT University, Gurugram, to provide a platform for students wherein they can engage in experiential learning, get hands-on training, and experience live research projects of the pharmaceutical industry, and most importantly, have access to placement opportunities at Akums. With the collaboration, we aim to foster a bridge between academia and industry by providing them access to the necessary resources and guidance. Through such initiatives, we want to make the next-generation of pharmacy students future-ready so that they areable to contribute to the growth of our country.

Brief us about your IPO and acquisition plans? Your revenue target for next year?

We are currently evaluating when to go public. We are still firming up our plans and timelines.

Akums has always been open for meaningful acquisition opportunities. We ventured into API with the acquisition of Parabolic Drugs.

We recently acquired the infrastructure of Ankur Drugs. We are also currently open for expansion in injectables, oncology, and niche drug delivery technologies.

Our current turnover is of over Rs 4,000 crore. With the rising demand in the Indian pharma sector, we are aiming to grow our business at a CAGR of 12-15% over the coming five years. ■

Pallets keep the pharma supply chain moving

Nitin Kalla
Founder
EXZOD India

Pallets give pharmaceutical firms the power they need to handle their products, increase storage efficiency, and protect products in the warehouse. They are used to stack, store, protect, and transport a variety of pharmaceutical materials. According to a McKinsey analysis, the pharmaceutical business has a rare opportunity thanks to a number of local producers of branded generics. The industry has had amazing expansion, going from being non-existent to having a global pharmacy.

The pandemic's ensuing supply chain problems had an influence on pallet availability. The new normal has shown, however, that pharma supply networks need to be resilient and agile, driving manufacturers and suppliers to improve their pharmaceutical product storage, shipping, and supply chain management capabilities in order to add value for consumers.

The events of the pandemic have really opened people's eyes to the relevance of the pallet industry and the role it plays in the supply chain.

Digitalisation: The supply chain can be streamlined and its agility and flexibility increased by implementing technologies like automation, blockchain, and artificial intelligence.

Fragmented logistics network: The supply chain management can become complex due to the fragmented logistics network, leading to inefficiencies.

Regulatory compliance: The sector is governed by regulations, and it can take up a lot of time to make sure that all the rules are being followed. Adhering to regulations like Good Manufacturing Practice, Good Distribution Practice, and Good Clinical Practice can have an effect on the supply chain.

Cold chain management: Pharmaceutical products demand storage and transportation at controlled temperatures, which can pose a challenge. In India, the cold chain infrastructure does not meet the desired standards and necessitates significant investment in constructing temperature-controlled areas. The extreme temperatures in several parts of India add to the complexity of maintaining cold chains.

Transportation challenges: Pharmaceutical products require special storage and transportation conditions, particularly temperature control, which must be strictly adhered to. Any deviation from these requirements can have adverse effects on the quality and effectiveness of the products. Transportation issues like delays, damage, or loss pose a significant threat to the supply chain, causing disruptions.

Creating infra for better pharma handling: In recent years, India has made significant advancements in the handling and logistics infrastructure of the pharmaceutical industry. These improvements have contributed to India's rise as a top supplier of generic pharma products worldwide. The development of new technology and facilities, including the use of cold chain logistics, has enhanced the storage and transportation of pharma products. Although there is still scope for further improvements, these advancements have solidified India's position as a leading global manufacturer and supplier of pharmaceuticals. The National Logistics Policy has set out a clear roadmap for India to establish itself as a dominant player in the global logistics industry.

Quality control: Quality control is an essential aspect of the pharmaceutical supply chain. India, however, has encountered issues with counterfeit and substandard medications, as well as regulatory non-compliance. It is crucial to tackle these problems to uphold the supply chain's credibility.

Crucial role of technology: The transportation and storage of pharmaceutical products heavily rely on the advancements in technology and innovation. The safety of pharma shipments is at risk due to various factors, such as temperature, humidity, and light, making it necessary for shipment and storage facilities to have automated tracking systems, proper temperature-controlled storage, advanced handling equipment, and procedures. The utilisation of Artificial Intelligence, Internet of Things, and Blockchain enables real-time tracking of temperature and humidity levels, which brings transparency and enhances the entire process of pharma cargo handling and transportation.

Technology and automation: Technology and automation, like GPS tracking and real-time temperature monitoring, are effective tools for preserving the quality of time-sensitive pharmaceutical shipments. By using these tools, temperature fluctuations can be prevented, resulting in less wastage and on-time delivery of the shipments.

Minimize carbon footprint: The importance of supply chain sustainability is increasing day by day, leading to a rise in demand for reusable and recyclable pallet materials in the pharmaceutical industry. Although wood is an inherently sustainable material, the newer plastics and composites offer even higher levels of sustainability. This trend is driven by the collective desire of companies and consumers to reduce their carbon footprint.

Adoption of agile supply chain strategies: Supply chain agility is essential to ensuring that pharmaceuticals are delivered to clients quickly. To respond to shifting consumer expectations, supply chain disruptions, and regulatory changes, we created flexible supply chain methods.

Pharmaceutical companies should prioritize enhancing their supply chain efficiency to stay ahead in the industry since every life is valuable. We have taken steps to improve our supply chain and respond to evolving customer demands by developing flexible solutions that meet their requirements. Managing pharmaceutical supply chains demands expertise, and we have a team of professionals who are knowledgeable in handling shipments that require special handling conditions. Our size and variety of pallets allow us to cater to this industry effectively.' ■

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