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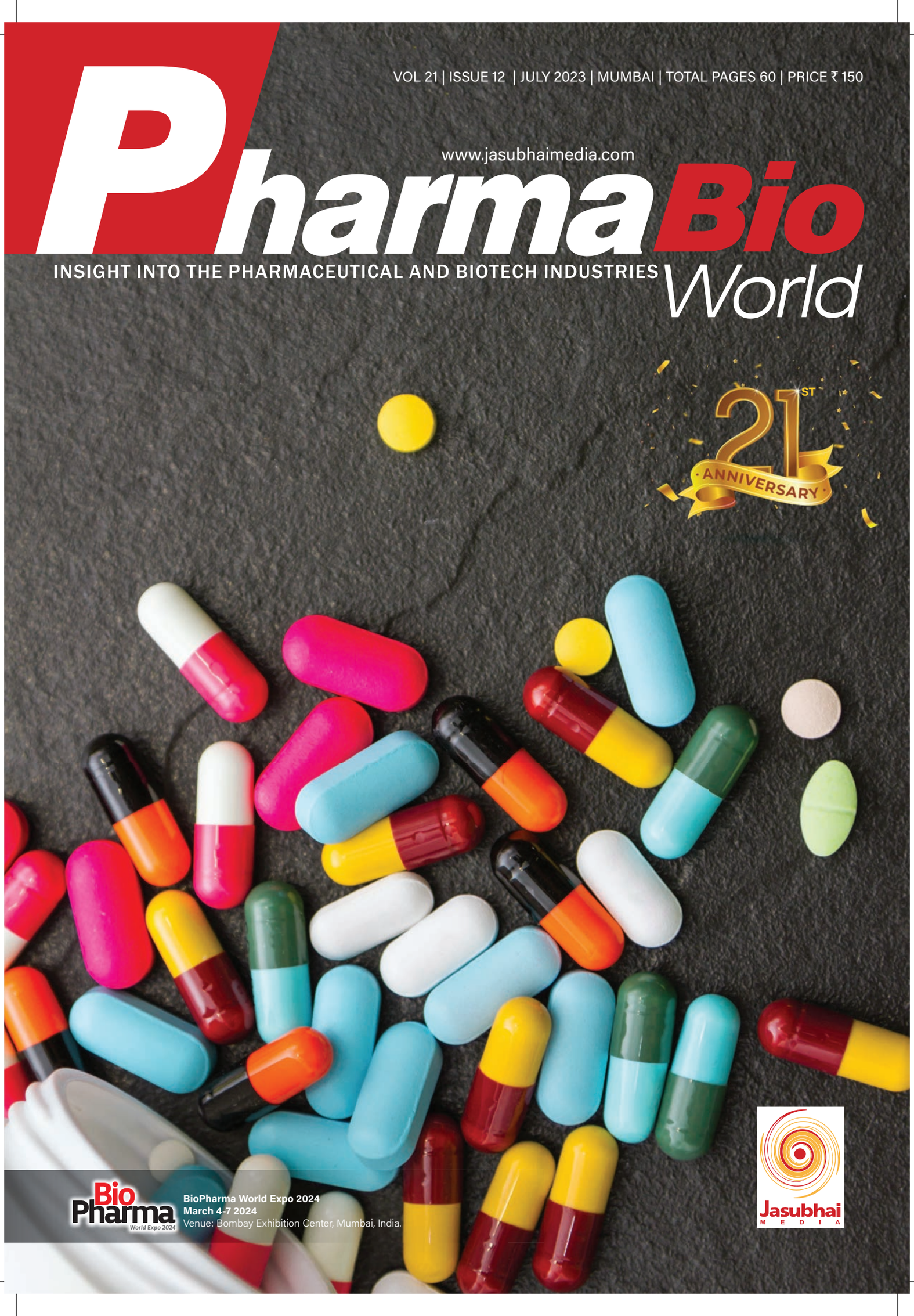

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Dr Mansukh Mandaviya stresses on need for self-regulation in MSME pharma sector

Dr. Mansukh Mandaviya, Union Minister of Chemicals & Fertilizers, and Health & Family Welfare

New Delhi, India: Dr. Mansukh Mandaviya, Union Minister of Chemicals & Fertilizers, and Health & Family Welfare met representatives from Pharma Companies from the MSME sector, stressing the need for self-regulation in the MSME pharma sector. "It is important for MSME Pharma Cos. to be alert to quality of drugs and expeditiously move towards Good Manufacturing Processes (GMP) through self-regulation," stated Dr. Mansukh Mandaviya.

"Our global position in the pharmaceutical sector is created through the quality of our products. We must undertake all possible steps to ensure that we strengthen this position in terms of value and quality. Hence, the role of self regulation becomes critical", he stated. Basis Industry's assurance, a major decision taken today, Schedule M shall be made compulsory for the MSME pharma sector in a phased manner. "This will help in quality assurance and also reduce compliance burden', the Union Minister said.

Dr. Mansukh Mandaviya has directed the Drugs Controller General of India (DCGI) to take stringent action against all pharmaceutical manufacturing companies that make spurious drugs. "There shall be no compromise with the quality of drugs manufactured in India", he emphasized. Highlighting that the Government has zero tolerance towards manufacturers not adhering to quality compliance and making spurious medicines, he stated that special squads have been formed to inspect drugs making companies and stringent actions has been taken.

The Union Minister further stated that in order to ensure the highest quality of pharma products, the regulatory authorities have started risk-based inspection and audit of plants. He stated that 137 firms were inspected, and action has been taken against 105 firms. Production has been stopped at 31 firms and Cancellation & Suspension of Product/Section Licenses have been issued against 50 firms. In addition, show cause notice has been issued to 73 firms, and warning letters have been issued against 21 firms. S. Aparna, Secretary (Pharma), Dr Rajeev Raghuvanshi, DCGI and senior officers from Department attended the meeting. Dr. Viranchi Shah, National President and other office bearers of IDMA were also present.

Serum Institute's multivalent meningococcal meningitis vaccine achieves WHO prequalification

Adar Poonawalla, CEO, Serum Institute of India

Pune, India: MenFive, the first conjugate vaccine to protect against the five predominant causes of meningococcal meningitis in Africa, has been prequalified by the World Health Organization (WHO). Developed through a 13-year collaboration between Serum Institute of India Pvt. Ltd. (SIIPL) and PATH, with crucial funding from the UK government's Foreign, Commonwealth and Development Office, MenFive® protects against meningococcal serogroups A, C, W, Y, and X and is designed to eliminate annual meningitis outbreaks and epidemics in the African meningitis belt—a string of 26 countries from Senegal and The Gambia in the west to Ethiopia in the east. It is also the only vaccine that prevents meningitis caused by meningococcal group X, a pathogen increasingly implicated in meningitis outbreaks in Africa.

WHO prequalification—which ensures a vaccine meets strict international quality, safety, and efficacy standards—was supported by extensive clinical studies in The Gambia, India, and Mali that demonstrated a high level of safety and immunogenicity. Importantly, prequalification allows MenFive to be procured by United Nations agencies and Gavi, The Vaccine Alliance.

Adar Poonawalla, CEO, Serum Institute of India, said, "MenFive is a game-changer vaccine developed

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through a powerful 13-year collaboration between SIIPL, PATH, and vital support from the UK government, in the fight against meningococcal meningitis in Africa. As the first conjugate vaccine to safeguard against the five predominant causes of this deadly disease, MenFive offers hope for a future free from annual outbreaks and epidemics in the African meningitis belt. It is a big moment as we, together, pave the way towards a healthier Africa, saving countless lives."

"MenFive is a much-required medical intervention that will be available at an extremely affordable price," says Dr. Rajeev Dhere, Executive Director of SIIPL. "Making sure vaccines are available to those who need them most is a philosophy SIIPL has followed with all our products and continues to follow with MenFive." "This landmark scientific achievement will have huge implications for improving public health," says the UK's International Development Minister Andrew Mitchell. "Having access to a new, affordable vaccine will save lives, prevent long-term illness, and move us closer to defeating meningitis by 2030. I am incredibly proud that the UK has supported PATH and the Serum Institute of India in this major achievement."

Meningococcal meningitis is a bacterial infection that sets in rapidly and can kill within hours. It can cause severe brain damage and sepsis leading to limb amputation and is fatal in 50 percent of cases if untreated. Anyone can contract meningococcal meningitis but children under age five—especially infants—are likely to suffer the most severe effects.

Indian pharmaceutical industry plays critical role in shaping the health outcomes of patients globally: Sudarshan Jain

Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance

Mumbai, India: The Indian pharmaceutical industry plays a critical role in shaping the health outcomes of patients globally, stated Sudarshan Jain, Secretary General, Indian Pharmaceutical Alliance, while delivering his address on Global Pharmaceutical Quality Summit.

Dr Mansukh Mandaviya also delivered his address during the closing ceremony. The theme for the Summit was, 'Patient Centricity: New Paradigm of Manufacturing and Quality.' The two-day Summit brought together industry leaders, global regulators, quality experts, and stakeholders to foster knowledge exchange and deliberate on areas of importance in shaping the pharmaceutical landscape in India. The conference highlighted the importance of the future of manufacturing and building quality as a culture in the pharmaceutical industry. Regulators from around the world - US FDA, MHRA, EDQM and CDSCO discussed the regulatory affairs highlighting recent inspection observations and trends. Leading CEOs of the pharma industry from Cipla, Dr Reddy's, Lupin, Sun Pharma and Zydus also provide their thoughts on the future of the Indian pharmaceutical industry.

Minister for Chemicals & Fertilizers and Health & Family Welfare, Government of India, Dr Mansukh Mandaviya said, "Quality, R&D and innovation are the need of the hour. India was in mission mode during COVID-19, and we played a sterling role as the pharmacy of the world, by ensuring an uninterrupted supply of quality medicines and vaccines to the world. In a global crisis, India displayed maturity, responsibility, and leadership. Quality is a top priority today and central and state regulators are working closely to ensure this. Let us collaborate and create new models to foster innovation and strengthen industry-academia linkages."

Jain added, "During the COVID-19 pandemic, the industry demonstrated resilience and is now known as the pharmacy of the world. Quality is the fundamental tenet of the pharmaceutical sector. Continuous investments in quality –systems, technology and talent – is fundamental as the overall healthcare landscape is evolving at an unprecedented pace. IPA is committed to making India a global benchmark in quality."

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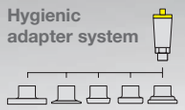

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Sun Pharma presents data from first-in-human phase 1 studies of GL0034


Dilip Shanghvi, MD, Sun Pharma

Mumbai, India: Sun Pharmaceutical Industries Ltd. announced results from two Phase 1 studies evaluating the tolerability, safety, pharmacokinetics and pharmacodynamics of GL0034, a novel long-acting GLP-1 receptor agonist, in non-obese and obese adults without diabetes. The data will be highlighted in poster presentations at the American Diabetes Association's (ADA) 83rd Scientific Sessions held from June 23-26, 2023, in San Diego, CA.

In one of the studies, GL0034 reduced triglyceride levels and body weight by Day 8 after a single dose in obese individuals without diabetes. In the other study, GL0034 administered at multiple- ascending doses once weekly for up to 8 weeks was well tolerated and resulted in meaningful pharmacodynamic effects in healthy individuals with normal body weight. In this study, marked dose dependent reductions in body weight of up to -10.7% were observed following GL0034 treatment of relatively low doses for 4 to 8 weeks. Across the two Phase 1 studies, the most common adverse events occurring (≥5 participants in any dose arm) included nausea, vomiting, decreased appetite, early satiety, and dyspepsia.

"The results of the Phase 1 trial of GL0034 are promising based on the safety and efficacy profile," said Richard E. Pratley, MD, Medical Director, AdventHealth Diabetes Institute and Senior Investigator, Diabetes Program Lead, Translational Research Institute. "GL0034 has a promising future in terms of weight loss and glycemic effects and based on these early results presented at ADA, GL0034 has a potential to be best in class. I look forward to learning more through further studies."

"The rising incidence of obesity and diabetes places significant burden on global healthcare systems, and GLP-1 agonists have emerged as a useful option for treating these conditions with a single agent. We believe the Phase 1 data of Sun's GL0034 potentially differentiates it from approved therapies in its class. We are excited to take the product through to the next stage of development," said Dilip Shanghvi, Managing Director, Sun Pharma.

GL0034 was discovered and is being developed by Sun Pharma. Further clinical studies are planned to confirm clinical safety and efficacy, including a 12-week proof of concept study in obese adults with type 2 diabetes, with non-alcoholic fatty liver (NAFL) and non-alcoholic steatohepatitis (NASH) biomarkers, which will begin enrollment during 2023."These Phase 1 studies suggest a potential role for GL0034 as a unique candidate to provide therapeutic benefits for obese adults," said Rajamannar Thennati, MD, Lead Investigator and Executive Vice President, Research & Development, Sun Pharma. "Initial results showed that GL0034 was generally well tolerated, and we are encouraged by the rate and durability of weight loss in these populations and look forward to proceeding to Phase 2 trials in obesity and type 2 diabetes."

Biocon Biologics expands footprint in emerging markets


Shreehas Tambe,
CEO & Managing Director,
Biocon Biologics

Bengaluru, Karnataka, India: Biocon Biologics Ltd (BBL), a subsidiary of Biocon Ltd announced that the company has completed the integration of the acquired biosimilars business in over 70 countries in Emerging Markets effective July 1, 2023, increasing the scale and scope of its business. Following the deal closure in November 2022, this marks the first wave of countries where Viatris' operations have fully transitioned to Biocon Biologics. The existing commercialized portfolio of biosimilars, including bTrastuzumab, bPegfilgrastim, bBevacizumab, bGlargine, bAspart, bAdalimumab, and bEtanercept, managed by Viatris in these markets, is now a part of Biocon Biologics' commercial organization. We will work with existing and new partners to expand our footprint and strengthen our business presence in these countries. Our best-in-class R&D capabilities, high-quality manufacturing, supply chain excellence, and commercial and regulatory expertise will enable us to expand access to a diverse portfolio of biosimilars, meet patients' needs and be a trusted partner to patients and the healthcare community in these markets.

Shreehas Tambe, CEO & Managing Director, Biocon Biologics said: "The successful integration of Viatris' biosimilars business to Biocon Biologics in over 70 countries is a significant milestone and marks the

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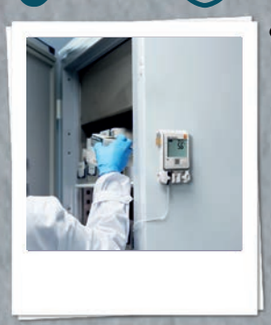

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beginning of the transition process. Working closely with our partners, Biocon Biologics will now lead commercial operations in these markets and broaden access to patients with our differentiated portfolio of high quality biosimilars. This first wave in the transition process comes ahead of plan, thanks to the tireless efforts of our colleagues at both companies, our advisors and partners who worked relentlessly to make this happen."

Susheel Umesh, Chief Commercial Officer - Emerging Markets, Biocon Biologics said: "The transitioning of these 70+ Emerging Markets to Biocon Biologics from Viatris marks the first phase of the business integration plan charted out for the acquired business. This will allow Biocon Biologics to meaningfully expand the geographic reach of the existing biosimilars portfolio and future pipeline into growth markets where Viatris has existing sales infrastructure and local market expertise. Working closely with key stakeholders in these markets will allow us to ensure reliable supplies of our biosimilars for those who need them the most, while enabling us to capitalize on the rapidly expanding global biosimilars opportunity."

Venus Remedies gets marketing approval for four key markets

Mumbai, India: Venus Remedies Ltd, a well-known provider of affordable cancer drugs worldwide, has further consolidated its position in the Gulf Cooperation Council (GCC), Association of South East Asian Nations (ASEAN), Balkan and Caribbean regions with marketing approvals from Oman, Malaysia, Bosnia and Trinidad & Tobago for key chemotherapy drugs. With this, the company has secured 503 marketing approvals for its oncology products across 75 countries.While Venus Remedies has secured marketing approval for pemetrexed from Malaysia, one of the largest markets in the ASEAN region, it has reached important regulatory milestones with product registration for docetaxel in Oman, gemcitabine in Bosnia and carboplatin, bortezomib and docetaxel in Trinidid & Tobago.

Saransh Chaudhary, President, Global Critical Care, Venus Remedies, said, "These marketing approvals will enable us to expand our operations to new geographies and open up new avenues for advanced cancer treatment with improved outcomes for patients battling various types of cancer. We remain steadfast in our commitment to provide access to life-saving treatment to more and more patients in keeping with our mission of meeting unmet medical needs in oncology and other critical care segments."

The $2.8-billion pharmaceutical market of Malaysia, a growing market for cancer drugs where Venus Remedies has so far secured marketing approval for 27 products across various segments, presents immense opportunities to the company to expand its operations in the Asia-Pacific region in general and Southeast Asia in particular through its elaborate range of drugs.

"While we have more than 140 marketing authorisations in the ASEAN region, including 147 for oncology drugs, we are banking on the product registration for pemetrexed from Malaysia to pave the way for faster approval of this drug in other ASEAN countries," said Chaudhary.Venus Remedies expects the marketing approval for docetaxel from the US $1.4-billion pharmaceutical market in Oman to facilitate the registration process in other Gulf countries as well, considering that many of them have similar regulatory requirements and processes. Since having a product registered in Oman, one of the largest markets in the GCC region, can provide a reference point for the registration of other products across this region, it can help streamline the registration process by providing a framework to different regulatory authorities to evaluate and compare the safety and efficacy data of new products.

Haling the achievement, Venus Remedies Executive Director Akshansh Chaudhary said, "These product registrations are an endorsement of the uncompromising quality of our products. Our team is working diligently to navigate the complex regulatory landscape and ensure that all our drugs meet the highest standards of safety and efficacy." Having secured its first marketing authorisation from Bosnia, Venus Remedies expects this approval for gemcitabine from the Euro 334-million pharma market to facilitate the registration process in the entire Balkan region, which has a market size of Euro 7 billion. The company's marketing approvals from Trinidad & Tobago for three oncology products, on the other hand, have further strengthened its commitment to provide affordable generic alternatives to cancer patients in need.

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Dr. Reddy's proposed rituximab biosimilar application accepted for review by USFDA, EMA and MHRA

Dr. Jayanth Sridhar, Global Head of Biologics, Dr. Reddy's

Hyderabad, India: Dr. Reddy's Laboratories Ltd announced that its Biologics License Application (BLA) for its proposed biosimilar rituximab candidate DRL_RI has been accepted for a substantive review by the U.S. Food and Drug Administration (USFDA). This follows acceptance of its rituximab biosimilar dossier for review by two other regulatory agencies – the European Medicines Agency (EMA) and the United Kingdom's Medicines and Healthcare products Regulatory Agency (MHRA). In January 2023, Dr. Reddy's had announced the successful completion of the full set of clinical studies of its proposed rituximab biosimilar candidate, DRL_RI, for filing in highly regulated markets such as the United States, European Union, and other regions. The submission of its dossier in April 2023 was based on a comprehensive data package including robust structural and functional analytical comparison data using multiple orthogonal techniques, pre-clinical, and head-to-head clinical studies that demonstrate similarity in pharmacokinetics, pharmacodynamics, safety, efficacy and immunogenicity with the EU* and US reference products.

Dr. Jayanth Sridhar, Global Head of Biologics at Dr. Reddy's, said: "This milestone underscores our capability for global clinical development of high-quality biosimilar products for highly regulated and global markets. It also reinforces the potential of DRL_RI as a safe and effective treatment option for patients across the globe. Development and commercialisation of biological drugs is an important growth lever for our business. We expect to bring many more biosimilar and other critical biological products to meet patient needs as we work towards our goal of serving over 1.5 billion patients by 2030."

Syngene to acquire multi-modal facility from Stelis Biopharma Ltd

Jonathan Hunt, Managing Director and CEO, Syngene

Mumbai, India: Syngene Ltd. announced the acquisition of Unit 3 biologics manufacturing facility in Bangalore, India, from Stelis Biopharma Limited (SBL). The companies have entered into a binding term sheet and, on completion of the transaction, the site will add 20,000 liters of installed biologics drug substance manufacturing capacity for Syngene. The site has the potential for future expansion up to a further 20,000 liters of biologics drug substance manufacturing capacity. It also includes a commercial scale, high speed, fill-finish unit – an essential capability for drug product manufacturing.

Syngene will acquire Unit 3 on a slump sale basis for a gross value of Rs 702 Crores (US$86Mn). Subject to closing adjustments, the consideration for the transaction will be settled in cash. The transaction has been approved independently by the respective Boards of Directors of both the companies. The transaction is expected to close within 90 days, subject to customary conditions, including receiving the required lender and regulatory approvals. The facility, which was initially built to manufacture Covid 19 vaccines, is now being repurposed to manufacture monoclonal antibodies and Syngene will further invest up to INR 100 Crores (US$12Mn) to repurpose and revalidate the facility.The facility covers both drug substance and drug product with installed capacity of 10 bioreactors of 2000L along with associated infrastructure and utilities. The facility also includes 10 additional uninstalled bioreactors - providing the potential for future expansion - and two high speed fill-finish lines.

Jonathan Hunt, Managing Director and CEO, Syngene said, "This acquisition strengthens our growing position as a leading biologics contract development and manufacturing service provider and adds drug substance capacity and a drug product capability years earlier than our internal capex program. We see healthy demand for high quality biologics manufacturing capacity from sectors ranging from large pharma to

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- Drug Delivery
- Contract Manufacturers

Equipment & Technology
- Pharma & Biopharma Processing
- Mixers & Blenders
- Agitators & Dryers
- Sterlizers & Autoclaves
- Homogenizers & Emulsifiers
- Instrumentation & Automation
- Lab & Analytical technologies
- Bioinformatics
- Packaging Machinery & Equipment
- Filtration & Separation

Pharma Chemicals
- APIs & HPAPIs
- Fine & Specialty Chemicals
- Formulations
- Excipients
- Pharma Ingredients

Research & Development
- Lifesciences
- Contract Research & Clinical Trials
- Contract Development & Manufacturing
- Research Institutes
- Academic Institutes
- Academic Institutions
- Government Institutions
- Testing & Inspection
- Intellectual Property Rights (IPR) & Legal Services

Infrastructure & Logistics
- Biotech Parks
- Warehousing
- Cold chain logistics
- Supply Chain Management
- Logistics services
- Online distributors

LAB ANALYTIX

Laboratory Technology
- Laboratory furniture, equipment, machines
- Chemicals, Consumable, reagents, glassware
- Laboratory data system and documentation
- Laboratory automation
- Laboratory diagnostics
- Instruments for environmental labs
- Forensic lab instruments

Analysis
- Chromatographes
- Spectroscopes
- Microscopes and imaging
- Analytica instrumentation and systems
- Instruments for physical and chemical analysis

Quality control / Measuring &Testing
- Characterization and properties of materials
- Quality control for pharmaceutical industry
- Material testing

Diagnostics
- Diagnostic Equipment and Reagents
- Diagnostic Technology & Devices
- IVD Medical Devices
- Clinical Diagnostic

Biotechnology
- Biochemicals
- Bioinformatics
- Medicine and diagnostics
- Life Sciences

Concurrent Events

EPC · Specialty ChemCAL · Chlor-Alkali World Expo & Conference 2024 · Refining & Petro Chemicals 2024 · WaterEX World Expo 2024 · Industry AUTOMATION & Control 2024

PVF World Expo 2024 · BOILER World Expo 2024 · Surface Engineering Coating & Corrosion World Expo 2024 · Student Outreach Program 2024 Develop Future Leaders

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emerging biotech companies. In each case, outsourcing to an experienced partner like Syngene is an attractive route to reliably deliver high quality products to market. We expect this facility to be operational in 2024, following completion of a programme of facility upgrades and re-validation."

Sibaji Biswas, Chief Financial Officer said, "This acquisition effectively replaces an internal capex investment program planned for the next three years and will be fully funded through internal accruals and cash. The Company will continue to maintain a strong balance sheet, a low debt profile and a good safety margin for debt covenants. As we ramp up utilization, we expect asset turnover to grow to 1x in less than 5 years, with EBITDA margins expected to be in line with the Company average from FY29. The acquisition will not materially impact the current financial guidance given for fiscal year 2023 - 2024. In the short term, we expect minor dilution of operating margins as a result of costs to be incurred in this facility and we expect this plant to positively contribute to the bottom line from FY27."

Sathgen Therapeutics announces the dosing of the first patient cohort with MSP008-22, a novel anti-cancer drug

Mumbai, India: Sathgen Therapeutics, a division of a leading chemical conglomerate in India - Godavari Biorefineries Limited (GBL), announced the completion of the first cohort in a Phase 1 clinical trial with their first-in-class New Chemical Entity (NCE), MSP008-22. Clinexel Life Sciences, a leading clinical research organisation, is supporting and managing the clinical development programme for global approvals.

Sathgen aims to develop MSP008-22 for difficult-to-treat cancers, starting with triple negative breast cancer (TNBC) and prostate cancer as proof-of-principle. The lead molecule targets both the bulk cancer cells as well as the treatment-resistant population, making it an exciting prospect against various types of aggressive cancers. Moreover, this NCE did not present any adverse events in the first cohort.

"TNBC accounts for 15% of all breast cancer and 30% of breast cancer-related mortality. They are characterised by the lack of expression of the estrogen and progesterone receptors and HER2, making it difficult to treat with conventional hormone therapy. MSP008-22 will address the significant therapeutic discrepancy and need that exists for TNBC", said Professor Sendurai Mani, Associate Director, Legorreta Cancer Center at Brown University and Scientific Co - Founder, Sathgen Therapeutics.

"The clinical trial of MSP008-22 marks our first programme to enter clinical development, which is a major milestone moment for us. This drug is our lead candidate for treating patients with TNBC and prostate cancer, and enhances the efficacy of standard-of-care chemotherapy", said Dr. Sangeeta Srivastava, Executive Director, Godavari Biorefineries Limited and CSO, Sathgen Therapeutics.

"At Godavari Biorefineries, we value research as the core of our work, creating ongoing benefits for society. We take pride in leading the way in research and innovation, seeking to generate value and sustainable advantages. We lay particular focus on cancer drug discovery, as cancer is a devastating disease with limited effective treatments. The MSP008-22 clinical trial marks a significant step forward in our mission to help patients with hard-to-treat cancers", said Mr. Samir Somaiya, Chairman and Managing Director, Godavari Biorefineries Limited and Executive Co - Founder, Sathgen Therapeutics.

Dr. Deepa Arora, CEO, Clinexel stated, "The successful completion of the first cohort of this study (NCT05478486) in patients with advanced solid tumours without any adverse events is very encouraging. We are designing the clinical development program to expedite the clinical development and marketing approvals for bringing a safe and effective oral therapy to address a major therapeutic gap in the management of TNBC and prostate cancer."

Lupin receives US FDA approval for Dolutegravir tablets for Oral Suspension

Mumbai, India: Global pharma major Lupin Limited announced that it has received tentative approval from the United States Food and Drug Administration (U.S. FDA) for its Abbreviated New Drug Application (ANDA), Dolutegravir Tablets for Oral Suspension, 5 mg, to market a generic equivalent of Tivicay PD Tablets for Oral Suspension, 5 mg of ViiV Healthcare Company. This product will be manufactured at Lupin's Nagpur facility in India. Dolutegravir Tablets for Oral Suspension (RLD Tivicay PD) had estimated annual sales of USD1 million in the U.S. (IQVIA MAT March 2023).

Lupin is an innovation-led transnational pharmaceutical company headquartered in Mumbai, India. The Company develops and commercializes a wide range

of branded and generic formulations, biotechnology products, and APIs in over 100 markets in the U.S., India, South Africa, and across the Asia Pacific (APAC), Latin America (LATAM), Europe, and Middle East regions.

Aurobindo Pharma arm enters into license agreement with USA based BioFactura

K Nithyananda Reddy, Vice-Chairman and Managing Director, Aurobindo Pharma

Hyderabad, India: Aurobindo Pharma Limited announced that CuraTeQ Biologics Private Limited, its wholly owned subsidiary, has entered into an exclusive license agreement with the USA based BioFactura to commercialize BFI-751, a proposed biosimilar to Stelara (Ustekinumab). Ustekinumab is a recombinant monoclonal antibody that works by blocking both interleukins IL-12 and IL-23 and is used for treating Crohn's disease, ulcerative colitis,plaque psoriasis and psoriatic arthritis. The global drug sales of Ustekinumab stood at close to 10 billion in 2022 presenting a significant opportunity with a good number of indications and a wider use.Under the terms of the agreement, CuraTeQ have been granted exclusive license rights to commercialize BFI-751 in all major regulated markets including US, EU, UK, Canada, ANZ and certain other semiregulated and emerging markets worldwide. Additionally, CuraTeQ will have the global manufacturing rights for this product, which will be produced at CuraTeQ facilities in Hyderabad, India. BioFactura plans to begin a global Phase 3 trial of the product as the next logical milestone in development. CuraTeQ intends to file this product in India and Emerging Markets as early as in 2024 and the regulated markets filing is expected to begin in 2026.

Commenting on the deal with BioFactura, Dr. Satakarni Makkapati, CEO – Biologics, Vaccines and Peptides, Aurobindo Pharma said, "BioFactura has demonstrated bio-equivalence of BFI-751 vs US and EU registered originator product Stelara in a three-arm Phase 1 study conducted in 200 plus healthy subjects. We are excited by the prospect of this Ustekinumab biosimilar advancing to Phase 3 clinical studies in the due course of time. Ustekinumab fits into our expanding immunology products portfolio very well and we will use our presence across key markets to commercialize this product."

Commenting on the deal with BioFactura, Nithyananda Reddy, MD and Vice Chairman, Aurobindo Pharma said, "This agreement underscores our investment intentions in biosimilars business. It is our commitment to improve lives of patients suffering from these debilitating immune and inflammatory diseases by delivering them access to cost-effective and high quality biosimilars such as Ustekinumab. "

Cadila Pharmaceuticals launches 10 Products in 2023

Ahmedabad, India: Cadila Pharmaceuticals, a leading pharmaceutical company committed to improving global healthcare, proudly announces the launch of 10 cutting-edge products from January 2023 to May 2023. These ground-breaking additions to our portfolio offer advanced solutions to address various medical conditions and further enhance patient care.

The 10 products includes Ferowall Tablet, Cadilyse T Chewable Tab, Yunara Tablet,Cadilyse Syrup, Tarzed 150,Esiloc D,Oxybro N, Haem Up XT+, Bactocad CA,Cadeltro 25 & 50. This formulation helps protect the skin from free radicals and damage caused by UV rays. These ground-breaking products demonstrate Cadila Pharmaceuticals' ongoing commitment to delivering innovative healthcare solutions and improving patient outcomes. Each product has been meticulously formulated and tested to meet the highest quality standards, ensuring safety and efficacy.

Zydus Lifesciences, through its subsidiary ZAHIL acquires 6.5% stake in Mylab Discovery Solutions

Pune, India: Zydus Lifesciences Limited, a discovery-driven, global life sciences company, through its wholly owned subsidiary Zydus Animal Health &Investments Limited (ZAHIL), has acquired 6.5% stake in Mylab Discovery Solutions from Rising Sun Holdings Pvt Ltd, an investment company owned by Adar Poonawalla. The acquisition represents collective vision to transform healthcare by combining therapeutic expertise in human formulations and diagnostic capabilities of the two companies. Hasmukh Rawal, Managing Director, Mylab, said, "The research and development capabilities of Zydus in therapeutics, combined with the R&D expertise of Mylab in diagnostics, along with Zydus' last-mile access, have the potential to bring decentralized healthcare solutions to the masses. By focusing on decentralized healthcare, the companies

can empower individuals, healthcare providers, and communities with timely and accurate diagnostics, effective treatments, and localized healthcare services."

Sujit Jain, Director of Strategy, Mylab Discovery Solutions said, "It is the first time in India, a pharmaceutical company, a diagnostic company, and a vaccine manufacturer join forces with each other. I am confident that this partnership will revolutionize the way diseases are diagnosed, treated, and prevented." The synergy through this collaboration will open up new possibilities for advancements in precision medicine, personalized treatments, and preventive care. It will foster innovation, promote cross-disciplinary collaboration, and pave the way for new discoveries and therapies.The transaction is subject to the fulfilment of customary closing conditions.

Enzene Biosciences launches Bevacizumab for treatment of metastatic colorectal cancer

Enzene Biosciences facility

Mumbai, India: Known for its disruptive innovation and extensive experience in developing high-quality biosimilars, Pune-based Enzene Biosciences has announced the India launch of Bevacizumab, a biosimilar of Avastin that is used for the treatment of metastatic colorectal cancer.

An alternative to the more expensive Avastin biologic, Bevacizumab is the 6th biosimilar from Enzene Biosciences' strong biosimilar pipeline that has been launched in the Indian market. Aimed at penetrating the Indian market for Bevacizumab that is valued at ~₹260 crores, Enzene's version is the first of its kind to be manufactured using the firm's patented continuous manufacturing process at its Pune facility.

"Enzene Biosciences is at the forefront of providing affordable healthcare solutions during this critical time," stated Dr. Himanshu Gadgil, CEO of Enzene Biosciences Ltd. "With our commitment to incorporating the latest technologies in drug manufacturing, we have successfully developed the Bevacizumab biosimilar our 6th Biosimilar product for Indian patients. Utilizing our fully integrated and automated continuous biologics manufacturing process, we uphold stringent quality standards while reducing overall manufacturing costs. We are confident that the significant price reductions passed on by our partners will greatly benefit thousands of metastatic colorectal cancer patients, supporting our mission to make cancer treatment more accessible and affordable in our country."

Also used in the treatment of non-squamous non-small cell lung cancer and glioblastoma, Enzene's Bevacizumab is a recombinant humanized monoclonal IgG1 antibody that is effective against vascular endothelial growth factor called VEGF. Bevacizumab acts by binding to VEGF and subsequently inhibiting its receptor binding process, thereby preventing the growth of the tumor and cancerous cells in affected patients. Considered the sixth most common form of cancer in India, colorectal cancer patients in the country will be the ultimate benefactors as Enzene's Bevacizumab will be supplied at a radically lower cost to the company's B2B partners such as Alkem Laboratories and other big pharma players. Moreover, with its significantly smaller production facility and lower carbon emissions, Enzene Biosciences is also addressing the current need for more ecologically sustainable manufacturing operations.

"Enzene Biosciences is poised to revolutionize the landscape of biosimilar manufacturing," stated Sandeep Singh, MD of Alkem Laboratories. "Our remarkable progress in developing a Bevacizumab biosimilar exemplifies our commitment to making a lasting impact on human lives through manufacturing innovation. By strategically investing in state-of-the-art technologies, we have successfully disrupted the cost of producing biosimilar monoclonal antibodies, propelling us closer to our ultimate vision of delivering affordable healthcare to individuals affected by debilitating illnesses. With an unwavering dedication, we are steadfast in our mission to emerge as the forefront biotech company in the nation, positively shaping the global healthcare ecosystem through trusted and accessible biosimilar solutions."

With the launch of Bevacizumab, Enzene Biosciences has now successfully introduced biosimilars for the treatment of critical illnesses such as squamous cell cancer of the head and neck, osteoporosis, postmenopausal

osteoporosis, immune thrombocytopenic purpura (ITP), rheumatoid arthritis and metastatic colorectal cancer. The company has multiple biosimilars and synthetic peptides that are in the development and clinical stage, for the delay of imminent pre-term birth and the treatment of Type II diabetes mellitus, chronic idiopathic constipation and osteoporosis. A subsidiary of Alkem Laboratories, the company is emerging as a key player in the domestic biosimilar market and the global CDMO space, and is securing India's position as an innovative manufacturing hub that is catering to the world's healthcare needs.

Gland Pharma's Hyderabad unit receives one observation from USFDA for Pashamylaram Facility

Mumbai, India: Gland Pharma Limited stated that the United States Food and Drug Administration (US FDA) has conducted Pre-Approval Inspection (PAI) for Seven (7) Products and Good Manufacturing Practice (GMP) Inspection at the Company's Pashamylaram Facility at Hyderabad between 15th June 2023 and 27th June 2023. The company said that the inspection was concluded with ONE (1) 483 Observation. This observation is procedural in nature and the corrective and preventive actions for this observation will be submitted to the US FDA within the stipulated period. The observation issued is neither a repeated observation nor related to data integrity.

Indoco's Goa facility (Plant III) receives EU GMP certification from German Health Authority

Aditi Panandikar, Managing Director – Indoco Remedies Ltd

Mumbai, India: Indoco Remedies has received EU GMP certification from the Competent Health Authority of Germany for its manufacturing site situated at L-32/33/34 Verna Industrial Estate, Goa. The European Agency conducted an inspection at Indoco's manufacturing facility for solid oral dosage form in Goa (Plant -III) from April 20-25, 2023. The EU GMP certification issued by the German Health Authority (LAGeSo) confirms that the site complies with the Good Manufacturing Practice requirements as referred to in the EC Directive. The EU certification will support supplies of drug products registered in Europe and other regions from this manufacturing site.

Aditi Panandikar, Managing Director – Indoco Remedies Ltd. said, "The EU GMP certification for our site in Goa (Plant - III) complements our unswerving efforts to supply quality and affordable medicines in Europe and other geographies. We remain fully committed to adhering to cGMP standards and ensuring the delivery of quality products to our valued customers and patients worldwide."

Granules India completes USFDA inspection for two facilities

Pune, India: Granules India Limited, a leading vertically integrated pharmaceutical company has completed the U.S. Food and Drug Administration's (US FDA) Pre-Approval Inspection (PAI) and GMP audit for their Unit IV facility located at Visakhapatnam, Andhra Pradesh, India with zero 483 observations. Recently, Granules India's Jeedimetla facility located at Telangana, Hyderabad, India also successfully completed the US FDA's surveillance inspection with zero 483 observations. The Vizag facility was inspected by the US FDA from 26th June to 30th June, 2023 and the Jeedimetla facility from 19thJune to 23rd June, 2023. The zero-observation outcome reflects the company's robust quality management systems and commitment to excellence in its operations.

"We are proud of the successful completion of the US FDA surveillance inspections at our Vizag and Jeedimetla facilities with zero observations. This achievement is a testament to our unwavering commitment to quality and compliance. It reinforces our position as a trusted and reliable global pharmaceutical manufacturer." said Dr. Krishna Prasad Chigurupati, Chairman and Managing Director, Granules India.

The Unit IV facility located at Visakhapatnam manufactures Active Pharmaceutical Ingredients (API) and the Jeedimetla facility manufactures Active Pharmaceutical Ingredients (API) and Pharmaceutical Formulation Intermediates (PFIs).

Alembic Pharmaceuticals received 5 USFDA approvals in Q1 FY24

Mumbai, India: Alembic Pharmaceuticals Limited has received US Food & Drug Administration (USFDA) approvals on 5 of its Abbreviated New Drug Application (ANDA) in Q1 of FY 23-24. The Company has received 4 final approvals that includes Bepotastine Besilate Ophthalmic Solution, 1.5%, Nadolol Tablets USP, 20 mg, 40 mg, and 80 mg, Carboprost Tromethamine Injection USP, 250 mcg/mL Single-Dose Vials, Doxercalciferol Injection, 4 mcg/2 mL (2 mcg/mL) Multiple-Dose Vials. Besides these, the Company has received one tentative USFDA approval for Doxycycline Capsules, 40 mg.

Anupam Rasayan signs MoU with 3xper Innoventure

Surat, India: Anupam Rasayan, one of India's leading custom synthesis & speciality chemicals manufacturer, has signed Memorandum of Understanding (MoU) with 3xper Innoventure Limited, a subsidiary of Tube Investments of India Limited a leading business conglomerates of India for supply of targeted and identified new age pharma molecules. The identified products for Active Pharmaceutical Ingredients (API) will be developed under the CRAMS and CDMO models.

Anand Desai, Managing Director of Anupam Rasayan, said, "We are elated to embark on this technical collaboration which will leverage Anupam's strong process optimisation capabilities and allowing us to build upon the existing robust pipeline of new age pharma molecules with focus on continuous processes. This is a natural extension of our company's capabilities built over a decade in flow chemistry to manufacture niche pharma intermediates for various key customers on custom manufacturing model. The MoU perfectly aligns with our strategic objective of increasing the target market for our chemistries and expanding our pharma portfolio in an accelerated manner by enhancing the product basket offerings. It serves as yet another testament to our long-term revenue visibility and sustainable business model."

N.Govindarajan, CEO of 3xper Innoventure Limited said, "3xper is delighted to forge this collaboration to leverage each other's capabilities and create value. We are a young and nimble organisation and forging this kind of collaboration will help 3xper to enhance its playing field and reach to global customers. This collaboration fits into our strategic imperatives to fulfil our aspirations to become the global CDMO with differentiated technology platforms to leverage and foster innovation for the customers."

DISSO India-Mumbai conference 2023 held in Mumbai

Mumbai, India: The 12th Annual International Symposium, DISSO India-Mumbai 2023 was held in Mumbai, on June 26 and June 27. The theme of this year's conference was Importance of dissolution science and technology in drug development and quality assurance. The inaugural function was graced by Dr. Jayant Gandhi, Consultant ENT surgeon, Vile Parle, Mumbai and Trustee of the Kelwali Mandal as the Guest of honour. Dr. Tina Morris, Executive Director, (AAPS), USA also addressed the gathering and stated that the SPDS and AAPS collaboration is growing in strength over the years.

The inauguration also addresses by Professor. Patric Sinko, Professor. Padma Devarajan- President SPDS and Dr.L. Ramaswamy- SPDS secretary. Professor. Arvind Bansal apprised the delegates about the crisp programme put together, covering a gamut of subjects to be deliberated by resource persons across the globe. The founder secretary Dr. L. Ramaswamy was honoured by SPDS with the Creative Legend award for having steered SPDS to such great success in just about a decade, his vision and passion for SPDS.

The programme was planned by the Scientific Co-chair with the able advice of the International Chair Dr. Vinod Shah (ex-USFDA), Vijay Kshirsagar, Former President SPDS and Professor. Padma Devarajan. It included important modules namely Concepts of Dissolution in Drug Development, Technological Advancements in Dissolution Testing including Automation and Artificial Intelligence, Dissolution in Formulation Development which included IVRT of complex products, Role of excipients and Bio predictive tools for injectable formulations. A panel discussion on Life cycle management was also moderated by Vijay Kshirsagar. A highlight of Disso India 2023 was the launch of the first India round of DRPI (Dissolution

Research Presentations International) at the hands of our Guest of honour, Dr Jayant Gandhi , Dr, Vinod Shah and Ajit Singh. The conference was attended by Pharma Industry Professionals from Analytical Research and Development, Quality Control, Quality Assurance, Formulation Development, Regulatory Affairs, CRO's and Contract Research Laboratories and Professors/ Faculty from Pharmaceutics and Pharmaceutical Analysis.

Sanofi receives marketing authorization for Dupixent

Mumbai, India: Sanofi Healthcare India Pvt. Ltd. announced that it has received marketing authorization for Dupixent (dupilumab), the first biologic medicine for the treatment of moderate-to-severe atopic dermatitis in adults whose disease is not adequately controlled with topical prescription therapies or when those therapies are not advisable. Dupixent® can be used along with or without topical therapy. Globally, Dupixent has transformed the treatment landscape for patients around the world by targeting the type 2 inflammation that underlies the disease, rather than broadly suppressing the immune system.

Anil Raina, General Manager, Sanofi Specialty Care (India), "Dupixent receiving marketing authorization in India is a significant milestone, as we now have the opportunity to offer our first-in-class and best-in-class therapy to treat people living with atopic dermatitis, in India. Approved in the U.S., the European Union, Japan and more than 60 countries for one or more indications other than atopic dermatitis, Dupixent® is the first and only biologic medicine in India that has shown significantly improved disease signs, symptoms, and quality of life measures, for this particularly difficult-to-treat skin condition."

Atopic dermatitis, a form of eczema, is a chronic type 2 inflammatory disease with symptoms often appearing as a rash on the skin. Moderate-to-severe atopic dermatitis is characterized by rashes often covering much of the body, and can include intense, persistent itching and skin dryness, cracking, redness, crusting, and oozing.

Dr. Shalini Menon, Country Medical Lead, Sanofi (India) stated, "The prevalence of atopic dermatitis in adults in India ranges from 2 % to 8 %* and there has been a trend* of increasing prevalence observed in India. Many often struggle to control their disease with the treatment options currently available. Itching is one of the most burdensome symptoms for patients and can be debilitating. People living with moderate-to-severe atopic dermatitis can experience unbearable symptoms and have significantly impaired quality of life, including disrupted sleep, and increased anxiety and depression symptoms. The chronicity and often visible lesions lead to considerable social stigma. Through studies Dupixent® has shown that it helps clear the skin, manage the persistent debilitating itch, and improve overall quality of life along with proven long-term safety."

With more than 600,000 patients being treated with Dupixent globally, Dupixent® will soon be available as an option for controlling moderate to severe atopic dermatitis for adults in India. Dupilumab is being jointly developed by Sanofi and Regeneron under a global collaboration agreement.

BDR Pharma launches Nilotinib for PH+ Leukemia

Mumbai, India: BDR Pharmaceuticals, a leading pharmaceutical company announces the launch of Nilotinib, a rare subtype of the most common childhood cancer, acute lymphoblastic leukemia. PH+ Leukemia, encompassing Acute Lymphoblastic Leukemia (ALL) and Chronic Myeloid Leukemia (CML) are infrequent and complex types of cancer that affect both children and adults. While this Philadelphia chromosome is rare in pediatric ALL, it is much more common in adult ALL. While commenting on the new launch, Raheel Shah, Director of BDR Pharmaceuticals said, "We are thrilled to introduce Nilotinib as a groundbreaking treatment option for patients with Philadelphia chromosome-positive leukemia. The results from our clinical trials have demonstrated the exceptional efficacy of Nilotinib in achieving major molecular responses and significantly improving overall survival rates. We firmly believe that this drug will revolutionize the management of Ph+ leukemia, providing new hope to patients and their families."

BDR Pharma remains committed to advancing innovative therapies and enhancing the lives of patients. With the introduction of Nilotinib, the company strives to provide a game-changing solution for individuals battling Ph+ leukemia. India's ongoing efforts in oncology healthcare demonstrate a comprehensive approach to address the needs of patients. By investing in cutting-edge research, fostering collaborations, and continually improving medical infrastructure, India is ensuring that patients receive the best care possible.

Marksans Pharma receives USFDA approval for Acetaminophen and Ibuprofen tablets

Mumbai, India: Marksans Pharma Ltd. announced that it has received final approval from the US Food and Drug Administration ("FDA") for its Abbreviated New Drug Application ("ANDA") for Acetaminophen and Ibuprofen tablets, 250 mg/125 mg, over the counter ("OTC) bioequivalent of Advil Dual Action Tablets 250 mg/125 mg.The Acetaminophen and Ibuprofen Tablets, 250 mg/125 mg (OTC)are bioequivalent to the reference listed drug (RLD),Advil Dual Action of GlaxoSmithKline Consumer Healthcare Holdings (US) LLC.Advil Dual Action was first available as an over-the-counter drug in 2020.

The pivotal approval, Acetaminophen and Ibuprofen Tablets, 250 mg/125 mg provides relief for multiple pain-related symptoms by combining two powerful ingredients indicated for OTC pain relief, ibuprofen and acetaminophen. Ibuprofen works through the body targeting pain at the source while Acetaminophen blocks pain signal to the brain. The innovation takes these two powerful pain fighting ingredients and combines them into one tablet to offer fast, strong pain relief. The company plans to launch the product immediately.

Commenting on the approval, Mark Saldanha, Managing Director of the Company said "We are committed to expanding our portfolio in aTe Pain Management, this approval further demonstrates our regulatory and manufacturing capabilities and our strength to follow a focused growth approach. We will continue to work diligently towards sustaining this momentum in the coming quarters." ■

Credit profile to Indian pharmaceutical industry to remain healthy

India is the world's largest provider of generic medicines by volume, with a 20% share of total global pharmaceutical exports.

The Indian pharmaceutical industry has been able to withstand various challenges over the past two years, such as the Covid-19 pandemic, resulting in supply chain disruption including raw material unavailability and severe commodity price inflation. Besides, there were instances of regulatory non-compliances, especially with the United States Food & Drug Administration (USFDA) along with geo-political issues. Most industry players have reported resilient performance, supported by their diversified revenue base, introduction of new products on a regular basis, cost control initiatives, continued optimisation of R&D spends, and ability to deal with challenging circumstances. Moreover, the credit profile of the Indian pharmaceutical industry has remained healthy, as reflected by comfortable leverage and strong liquidity position. Apart from the domestic market, all major pharma companies have also established their presence in other geographies to fuel growth. Thus, the industry fortunes are determined by developments in these key markets.

Domestic market: In the domestic market, structural factors such as an ageing population and a continued rise in lifestyle/chronic diseases are expected to fuel the growth of pharmaceutical companies. Growth will also be supported by WPI-linked price hikes for products under the National List of Essential Medicines (NLEM), new product introductions, and price hikes for non-NLEM products. While performance of some companies has been impacted post moderation in demand of Covid-related drugs, the domestic pharmaceutical industry has witnessed a revival in growth, supported by both chronic and acute segments. Revenues are expected to be driven by sustained price growth and improved volume growth. The global supply chain was severely impacted during the pandemic and then due to the ongoing Russia-Ukraine conflict. As a result, pharmaceutical companies, globally, are taking steps to diversify their vendor network to become more resilient to such global challenges. Many Indian pharmaceutical companies (including both formulations and API/bulk drugs manufacturers) are starting to benefit from the contract manufacturing opportunities emerging due to the 'China + 1' strategy, as India has emerged to be one of the preferred alternative manufacturing hubs. The industry is also focused on adopting higher level of digitisation to support its growth and increased penetration levels.

To reduce healthcare costs for patients, there is increasing focus on driving generic prescriptions by doctors. Any significant regulatory mandate in this regard will force the branded generic formulations manufacturers to re-evaluate their business models in the country as the same will result in significant price erosion, impacting sales as well as profitability.

US market: Revenue growth in the US market has moderated over the past few years due to continued pricing pressure and delays in product approvals due to increased scrutiny by the USFDA. The US market has continued to witness pricing pressure in the generics portfolio, especially in the oral solids segment, which has impacted Indian pharmaceutical companies with relatively smaller product baskets or higher proportion of oral solids in their portfolio. ICRA expects upto high single digit pricing pressure to continue in the near term. Indian pharmaceutical companies are thus focusing on new launches (including first-to-file opportunities) of complex generics and specialty drugs to combat the pricing pressure. The key therapies driving growth include biosimilars, inhalation, ophthalmology, dermatology, CNS, oncology, anti-

diabetes, osteoarthritis and pulmonary. Further, Indian companies have also adopted cost optimisation measures to improve profitability and mitigate the pricing pressure. These also include increased efforts towards optimisation of their product portfolios by discontinuing low-margin products amid increased competition and a shift of focus towards optimising the R&D spend to more complex molecules and specialty products. Companies are also leveraging product pipelines built for the US market to expand to other regulated/semi-regulated markets.

While there was a temporary disruption in USFDA inspections due to the pandemic-induced restrictions, the pace of inspections has picked up since then and there have been instances of import alerts, warning letters and Form 483 being issued to various Indian pharmaceutical companies. Timely resolution of these issues and successful receipt of Establishment Inspection Reports (EIRs) during future inspections remain key factors for the Indian companies' performances in the US market. The pandemic had also resulted in slower approvals of Abbreviated New Drug Applications (ANDAs), and consequently, Indian companies have a strong pipeline of ANDAs pending for approval, which indicates a healthy growth possibility for them in the US. Moreover, several of the major blockbuster drugs have either gone off-patent recently or are expected to go off-patent over the next few years, which creates a considerable opportunity for Indian pharmaceutical companies.

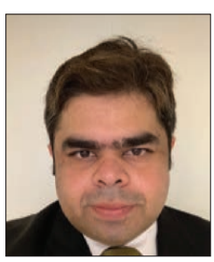
Regulatory restrictions continue to be major challenges for the Indian pharmaceutical companies. Any adverse outcome of regulatory issues like patent claims and anti-trust litigations can impact the earnings of Indian companies. In the past, there have been some instances of sizeable provisioning and/or payouts by the Indian companies towards such issues. Moreover, the US introduced the Inflation Reduction Act in August 2022. While the implementation is still pending, certain provisions of the act aim at reducing the cost of healthcare by introducing price caps, which can impact the revenues and earnings of pharmaceutical companies. As a result, Indian pharmaceutical companies might have to reassess their portfolio strategies and R&D investment plans.

European market: Market conditions in Europe are expected to remain challenging, given the ongoing macroeconomic situation, even as the same is expected to be mitigated to a certain extent by expansion in product offerings. Volatility in foreign exchange rates had also impacted the profit margins of Indian pharmaceutical companies with sizeable exports to Europe. Some demand contraction has been witnessed in the key markets of Germany, the UK, and Eastern Europe, which, coupled with increased competition, has impacted the growth of some pharma companies in these markets. Moreover, for companies which have a manufacturing footprint in Europe, the cost of production has been impacted by elevated energy costs and higher costs of imports of key starting materials (KSMs) and active pharmaceutical ingredients (APIs). While there has been some moderation in the cost of KSMs and APIs over the past few quarters, the same remains a key monitorable for the industry. The biosimilars market in Europe is expected to grow significantly, with a strong pipeline of biologic drugs expected to lose exclusivity over the next five years.

Emerging markets: Key emerging markets across the globe include Mexico, Brazil, Russia, South Africa, China, Australia, etc. Similar to India, these markets have an ageing population and growing prevalence of chronic diseases and are focussing on lowering treatment costs and ensuring better insurance penetration, which are expected to support growth of the pharmaceutical industry in these markets. Given the challenges being faced in the US and European markets, most Indian players have increased their focus on emerging markets to fuel revenue growth. In emerging markets, new product launches, strong demand, and depreciation of the INR against certain currencies have supported revenue growth and the trend is expected to continue, going forward.

Notwithstanding a steady outflow towards capital expenditure and R&D spends, the overall credit profile of Indian pharmaceutical companies is expected to remain healthy, supported by their stable earnings profile, comfortable leverage and coverage metrics, and strong liquidity position. ■

Author



Deepak Jotwani
Assistant Vice President & Sector Head – Corporate Ratings, ICRA Limited

Reimagining Business Models: Future of Pharma and Biopharma Sectors

Prof. Reddanna Pallu
Emeritus Professor, School of Life Sciences, University of Hyderabad & Principal Research Scientist, Brane Enterprises

Healthcare Industry - Evolutionary Trends

The healthcare industry is evolving continuously, based on the understanding of the disease processes, to come up with safe and effective treatments, starting from Traditional to Modern Systems of Medicine. While the traditional systems of medicine are being practiced and revalidated through modern scientific approaches, the business models of the modern systems of medicine are being reimagined continuously keeping in pace with the technological advances. The developments in the modern systems of medicine could be categorized into three main periods:

The first can be traced to the nineteenth century where the basis of drug discovery relied on the serendipity of the medicinal chemists.

The second period from the early to the end of the twentieth century was revolutionized by rapid advances in drug discovery, with the development of powerful new techniques such as molecular modelling, combinatorial chemistry, high-throughput screening, and the emergence of recombinant DNA technology.

The third period in the twenty-first century, with all the expansion of new technologies such as the "Omics" revolution, gene editing tools and emergence of cell-based technologies, has kick-started with an increase in biopharmaceutical drugs, involving Monoclonal Antibodies, Recombinant Growth Factors, Purified Proteins, Recombinant Proteins, Recombinant Hormones, Vaccines, Recombinant Enzymes, Cell, Gene Therapies, Synthetic Immunomodulators, and Other Product Types, orienting towards precision and personalised medicine.

The healthcare industry is thus continuously evolving, quite rapidly in the recent times, with a shift from small molecule (Pharma) to large molecule and cell-based (Biopharma) therapies. Added to these the emergence of gene editing tools, Artificial Intelligence (AI), Machine Learning (ML) and Block chain technologies are making a lasting impact on the way the Pharma and Biopharma industries must operate. Keeping pace with the technological advances, the Regulatory agencies have come up with the stringent guidelines to be followed by the industry in order to get the approvals. It is thus becoming a challenging task for the industry to adapt to these rapidly evolving technological advances and comply with the regulatory guidelines, not to just survive, but thrive, and succeed into a business-propelling differentiation. Companies failing to adapt to these will face out from the competitive environment.

Pharmaceutical Industry Global Scenario

The Pharma and Biopharma industries are poised for significant transformation in recent years, driven by advancements in technology, evolving patient needs and market dynamics. Master Control (https://www.mastercontrol.com/industries/pharma/), a global company offering solutions for highly regulated companies to ensure quality and compliance in their life sciences operations, has come up with Pharmaceutical Industry E Book to list out the lingering obstructions that consistently plague companies. It is quite evident that no matter how innovative a company is, they never seem to be able to fully escape the increasing relentlessness and numbers of competitors, the incessant obstacles posed by heightened regulation enforcement, globalization issues, exorbitant drug development costs, and time-to-market delays. As per the report the recurrent challenges, and the pressure on pharma, and biopharma companies have been escalating in recent years, primarily due to the impact of three booming industry trends:

- Declining return on Capital (ROC)
- Ever Expanding outsourcing/contract ecosystems
- New hubs of innovation.

Declining Return on Capital (ROC)

Profits, margins, and revenue are traditional measurements for assessing the health and success of any business. For a pharma or biotech company, however, it is more important evaluator of success in order to allocate capital to drive innovations and profitability. In recent years the ROC is not that encouraging as it declined from 16.6% across the industry in 2011 to just 11.9% in 2017 ("Return on capital performance in life sciences and health care," Deloitte Insights, 30 Apr. 2019). The raising input costs and ever-increasing regulatory guidelines have resulted in a decline in the development of new drugs in the past 10 to 20 years. To cope up with these, companies are bucking the general ROC decline that has touched every corner of the industry by pivoting to different, more specialized areas of therapeutic focus. In fact, companies with specialty focus areas have recently had well-above-average ROC performance — as high as 10% to 30%, depending on the area of focus. As a result, an increasing number of companies are pivoting away from pursuing traditional therapies and clamouring to uncover new specialized opportunities in order to be more competitive and avoid the declining ROC.

The Ever-Expanding Ecosystem of Contractors

As competition increases, timelines tighten and pharmaceutical products get more complex, companies throughout the industry are staying competitive by outsourcing more operational components. Over the next three years, in fact, 91% of life sciences companies plan to expand their use of contract manufacturing organizations (CMOs), contract packaging organizations (CPOs) and contract development manufacturing organizations (CDMOs). In addition, the companies are also relying more and more on Contract Research organisations (CROs) for their innovations. This puts the companies to not only focus on quality management and compliance efforts in house but also on the entire list of suppliers -CROs, CMOs, CPOs, CDMOs etc. It requires altogether a different exercise for the companies to have a full control and complete oversight of quality to maintain continual visibility throughout the entire ecosystem. The companies require not only a platform that enables them to digitize, automate and connect quality processes internally, but one that leverages modern integration management capabilities.

"We've developed an end-to-end portfolio of software and automation solutions in the form of the Digital Enterprise to help us digitalize the entire value chain" says Rebecca Vangenechten, head of Global Pharma Business at Siemens.

Realising the opportunity companies like Master Control and others have stepped in to offer services through a

robust Quality Management System (QMS) platform that synchronizes between systems and provides the visibility and control needed to maintain compliance and uphold quality consistency across the entire ecosystem.

New Hubs for Innovation:

Traditionally the Pharma companies used to rely mostly on academic institutions or the startups promoted by the faculty members for their innovations. The in-house R&D units also contribute to a little extent. Many of the innovative products we see today have their origins from academic institutions, including the recent mRNA vaccine and gene editing technologies. Today we see that an increasing number of pharma companies are engaging in partnerships with technology giants like Microsoft and Google, which have revolutionised the innovation ecosystem with the use of AI, ML, and other technologies. This is evidenced by the fact that nearly 270 companies are working in the AI-driven drug discovery industry, with more than 50 percent of the companies based in the United States, though key hubs are emerging in Western Europe and Southeast Asia, according to Mckinsey report on AI in BioPharma research.

Companies have a choice to prioritise Ai and adopt it or perish - "AI in India – A strategic Necessity" – A pragmatic playbook for Indian organizations to leapfrog on AI maturity - A report by Indian Institute of management, Ahmedabad – Brij Disa Center for Data Science and Artificial Intelligence (IIMA -BCG), July 2023.

Google's new Quantum Computer, which is 241 million times faster than the one it released in 2019, can finish 47 years of computing tasks in just 6 seconds (Science Alert, PHYSICS,05 July 2023).

Google AI offshoot "DeepMind" has made a gargantuan leap in solving one of biology's grandest challenges — determining a protein's 3D shape from its amino-acid sequence (Nature News, 30th November, 2020).

These technological breakthroughs enabled Google to discover drugs and vaccines through molecular simulations, which otherwise is impossible with the current computing capabilities. Similarly revolutionary robotic technologies have come up in the synthesis of novel proteins, and their sequencing, which form the key components in the biologics and biosimilar industry. With these capabilities the big tech companies are even making their own forays into the lucrative pharma space.

Thus, it is becoming a challenging task for the Pharma and Biotech companies to embrace these emerging technologies and compete with the technology giants. To navigate the complex landscape of emerging technologies and therapies, pharma and biopharma companies need to engage in more collaborative partnerships with technology companies, academic institutions, contract research organizations (CROs), and startups to access expertise, leverage resources, and drive innovation.

The Pharma and Biopharma Industries – Indian Scenario

Indian Pharma and Biopharma industries have made tremendous progress, though not in coming up with innovative products, in offering generics and biosimilars at affordable prices not only in India but also around the world. The average Indian life expectancy has increased from 32 years in 1947 to 70.19 years in 2022. Significant control of communicable diseases, control of infant, child, and maternal mortalities due to better availability of treatments, affordable medicines, and evolving technology. The credit for these achievements goes to the Indian Pharma and Biopharma industries for coming with the life-saving drugs and making them available at affordable prices not just in India but also globally.

Pharma Industry

Today, India is the largest manufacturer of generic drugs in the world supplying more than 50% of the global demand for various vaccines, 40% of the generic demand in the USA, and 25% of all medicines in the UK. India has nearly 3,000 drug companies and 10,500 manufacturing units. About 80% of the antiretroviral drugs used globally against AIDS are supplied from India, and hence it is rightly described as the 'pharmacy of the world (https://www.ibef.org/industry/pharmaceutical-india).

The Indian pharmaceutical industry, valued at US $ 42 billion in 2021, is estimated to reach ~US $ 65 billion by 2024, and US $ 120-130 billion by 2030. This has become a flourishing industry growing at a compound annual growth rate (CAGR) of 9.43% over the past 9 years.

India is currently ranked 3rd in pharmaceutical production by volume. However, in the international pharmaceutical trade (expected to reach US $ 1-1.3 trillion by 2030), India's current share is just 2.5%!

Indian Pharma sector can reach a share of 6-7% by 2030 by focusing on innovative product development and expanding the existing export corridors and

developing new ones. (https://www.thehindu.com/brandhub/the-giant-leap-of-indias-pharmaceutical-industry/article65670866.ece). It is high time to identify new avenues/possibilities to support Indian pharma's positioning as a global leader thereby boosting the Indian economy.

Biopharma Industry

With a solid foundation in the pharma sector based on India's expertise in academic chemistry, the big Pharma companies entered biopharma sector with the production of biosimilars (vaccines, therapeutic molecules) and emerged as a global player in the biopharma industry also. Around 300+ companies produce hormones, insulin, blood products, and vaccines, the sales of which registered INR 33.067 billion in 2020-21. During the current COVID-19 pandemic, it registered a superior growth rate of 13% (https://www.biospectrumindia.com/features/18/21144/indian-biopharma-industry-hits-rs-33k-crore-with-13-growth-in-2020-21.html). India administered nearly 4 million doses of COVID-19 vaccines per day and a total of 1.45 billion doses in 2021. India will soon enter the big league of the world biotech ecosystem. The Indian COVID economy had a share of 18.17% (2nd largest contributor to the total bio-economy of US $ 80.12 billion) in 2021. The bioeconomy is projected to reach US $ 271 billion by the year 2030 with government support as seen during the COVID-19 crisis, according to BIRAC India_Bioeconomy Report. To date, the Indian biotech industry's focus has been on vaccines and therapeutic molecules and there is greater scope to enter specialized areas, like cell-based and gene therapies, a fast-growing segment of the biopharma industry.

Role of Start-ups

With the changed vision of the Union govt, efforts are now being made to promote innovation and entrepreneurship through the establishment of incubation centres and promoting the start-up ecosystem in the country. As of 30th November 2022, there were 84,012 start-ups (58% of them being in five states), 700+ incubators, 108 unicorns, and more (https://smefutures.com/govt-recognises-over-84012-startups-58-are-in-5-states/). Around 10,000+ start-ups are established in various Universities, National Laboratories, and most of these have been started by students/faculty members. Start-ups play a crucial role in bridging the gap between academia and industry. By working closely with universities and research institutions, they help to commercialize new technologies and ideas that have been developed in academia. Industry needs to leverage with these developments in the startup ecosystem to channelise the discoveries into innovative product development.

Conclusions and the way Forward:

In general, the focus of pharma, and biopharma has so far been on generics, biosimilars, and me-too products with little or no emphasis on innovations. There is need for the Pharma and biopharma industries to graduate into innovative product development, by harnessing the innovations from the academy and the startups, in order to play a significant role in the global healthcare system (Reddanna, p., The Indian Pharma & Biotech Industry - Will they graduate? Pharma Bio World, July 2020). To achieve this industry needs to adopt new models of innovative product development by involving academia in the forefront of discovery and focus on later stages of drug development (Reddanna, p., Pharmaceutical Research in India – New Models of Drug Discovery, Pharma BioWorld, September, 2020).

In the light of rapidly evolving technological advances, the industry also needs to embrace and implement them in their day-to-day operations in order to be in the race, even for generics and biosimilars. The choice is to adopt these emerging technologies in the entire value chain or perish in the global competition. ■

Ensuring Pharma compliance with testo data measurement technology

Be sure. testo

Due to the crucial necessity and its direct impact on human health and welfare, Pharma is probably the most important and critical sector among others. As a consequence of which, it becomes essential to store pharmaceuticals, vaccines, laboratory samples or units of blood at the right temperatures to ensure that they remain effective and that quality is maintained. Another reason for the Pharma division to ensure safety measures & controlled environment is stringent regulations and inspection of the facilities. This elementary need for climate control can only be ensured with right data monitoring systems. Testo being a market leader in testing & measurement sector provides the best in class data loggers and data monitoring systems for the Pharma division.

Ensuring end to end climate monitoring – Testo Data Loggers

Pharma goods must be stored well in every situation as any deviation in the ambient temperature or humidity values may lead to deteriorated quality of the product. Testo data loggers can be used to test the optimum conditions for specific products or surroundings. Temperature & humidity data loggers are often used in Pharma industries to monitor the conditions in which drugs, medicines, vaccines are kept. Not only storage, but during the transit of goods, testo transport data loggers are useful to measure the transport conditions. The range of data loggers is very extensive. A temperature & humidity logger such as 174 T guarantees continuous monitoring in a storage or warehouse. Also, data loggers with multi channels for connecting external sensors & thermocouples, like testo 176 are available for ensuring secured work process in labs.

These data loggers are also critical for production quality assurance where the temperature has to be frequently checked at various points in production processes. Using thermocouple probes, data loggers can also record data in the kinds of extreme temperature ranges. The probe's fast response also contributes in the validation processes and quality standard optimization in QA units & clean room applications. These instruments are the most convenient and pocket friendly solution for all Pharma application areas.

The testo Saveris 2 WiFi data logger system is the simple, flexible and reliable solution to humidity and temperature monitoring in cold storage area like blood banks. This innovative monitoring system is ideal for high product quality & eliminates manual work of reading out or documenting measurement data. With a secure online storage of all readings in Testo Cloud the data can be managed and analyzed online by the user via smart phone, tablet or PC anywhere and anytime. In case of crises and deviations, it is provided with an alarm by e-mail, or optionally by SMS.

Another important and crucial application of a Pharma industry involves validation of sterilization and freeze-drying processes. Not only that, validating cleaning and disinfecting equipment is equally necessary. In order to allow a seamless operating procedure, the validation process and the documentation work must be as efficient and smooth as possible which could be easily achieved with testo 190 data logger solution that has innovative data loggers for temperature & humidity, smart software and accessories.

Data compliance for audits and inspections

Testo offerings are majorly related to the data security along with comprehensive analysis & evaluation of all the recorded measurement data. Testo data loggers ensure continuous monitoring of temperature and relative humidity of pharmaceutical products during production, storage or transit of goods. Real time data monitoring is important for the quality of Pharma goods and also enables the supplier to improve the life of the goods. Transportation trucks, warehouses, cold rooms etc. can now be remotely monitored via Testo data loggers & data monitoring systems. Our data loggers are EN 12830 and 21 CFR Part 11 compliant which ensure complete documentation of parameters, be it humidity, temperature or absolute pressure. They come with professional software where the data recorded cannot be modified and the audits can be easily complied with.

Service & Calibration made easy

Testo also has an established state-of-the-art NABL accredited service & calibration LAB in accordance with the standard ISO/IEC 17025:2017, that takes care of the after sales support locally from Pune. Testo service & calibration facility is highly cost effective as it delivers international standards very conveniently within a week's time. Instruments of any brand/make can be calibrated and serviced locally maintaining necessary standards.

The accredited parameters include Humidity, Pressure, Absolute Pressure, Contact Type Temperature, Non-Contact Type Temperature (Infra Red Thermometer, Thermal Imager). In fact, ours is the First and Only Lab in India to get NABL Accreditation for Dew Point Temperature as well. ■

For more details, login to our website www.testo.com or write back to us on info@testo.in

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"We are investing through innovation and partnerships."

Rajesh Khosla
President & CEO
AGI Glaspac

__Rajesh Khosla__ talks about trends and future for Pharma packaging. He also spoke about latest advancements in pharmaceutical packaging technology and the company's expansion plans.

What are the trends and future for Pharma packaging?

The pharma packaging industry is currently undergoing dynamic changes to meet the evolving needs of pharmaceutical companies. Several trends are shaping the landscape, and here are some key focuses:

- Improving Patient Accessibility: The industry is placing a strong emphasis on making medications more accessible and user-friendly for patients.
- Sustainability: There is a growing demand for eco-friendly and sustainable packaging solutions in the pharma industries to minimise waste, reduce carbon footprint, and are recyclable or made from renewable sources. This trend aligns with the industry's commitment to environmental stewardship.
- Streamlined Production Processes: Streamlining production ensures efficiency and cost-effectiveness while maintaining high quality and safety standards.
- Safety and Child-Resistance: Child-resistant packaging features are being implemented to protect young children from accidentally accessing medications. These features add an extra layer of security, ensuring that medications are kept out of reach of children.
- User-Friendliness and Intuitive Design: User-friendly packaging enhances medication management and administration, improving overall safety and patient satisfaction. Labels, instructions, and dosage information are made easily understandable for patients and healthcare professionals

The future of pharmaceutical packaging is driven by advancements in technology and evolving industry needs. Key trends include personalised medicine and patient-centric packaging, digitalisation, and connectivity, intelligent packaging with real-time monitoring, sustainability and environmental considerations, and anti-counterfeiting technologies. These developments aim to improve patient safety,

enhance medication adherence, increase supply chain transparency, and reduce environmental impact.

What role does smart packaging play in the pharmaceutical industry?

Smart packaging has emerged as a significant innovation in the pharmaceutical industry, offering advanced technologies that enhance various aspects of medication packaging. Smart packaging is also leveraging technologies like NFC tags or QR codes. One crucial aspect of smart packaging is tamper-evident seals, which ensure the integrity of the product. Temperature monitoring systems are another valuable inclusion in smart packaging. They help maintain optimal storage conditions for sensitive medications, such as vaccines or biologics. These features allow patients and healthcare providers to track and authenticate medications, ensuring their authenticity and preventing the entry of counterfeit drugs into the supply chain. Overall, smart packaging in the pharmaceutical industry enhances patient safety, improves medication adherence, and facilitates supply chain integrity.

What are the latest advancements in pharmaceutical packaging technology?

The pharmaceutical packaging industry has witnessed significant advancements in recent years. Smart packaging, incorporating technologies such as temperature monitoring, humidity control, tamper-evident seals, and RFID tracking systems, has emerged as notable innovation, enhancing product safety. There is a growing focus on sustainable packaging solutions, including the use of recyclable materials and biodegradable packaging, in response to environmental concerns. Anti-counterfeiting measures, such as tamper-evident packaging and serialisation, are being employed to combat counterfeit drugs. Patient-friendly packaging solutions, incorporating user-friendly features such as easy-open containers and dose reminders, aim to improve medication adherence and enhance the overall patient experience. Furthermore, the integration of digital technologies, such as QR codes and near field communication (NFC) tags, is enabling access to digital content and patient support resources. These advancements collectively contribute to improved safety, sustainability, patient experience, and supply chain efficiency in pharmaceutical packaging.

Brief us about the overview of AGI Glaspac expansion plans?

AGI Glaspac recently started commercial production from its state-of-the-art speciality glass manufacturing plant in Telangana with an installed capacity of 154 tonnes per day. This allows the company to meet the growing demand for glass packaging solutions from high-end pharmaceuticals including vials, perfumery, cosmetics and other segments. The company is also focused on expanding market reach both domestically and internationally. Recognising the strong demand for our products and the potential for supply in various regions, we have made the strategic decision to expand into export markets. This expansion allows us to tap into new opportunities and cater to a broader customer base. Currently, we are exporting high-end products such as perfumery and cosmetics catering to the specific needs of customers across EU, Canada, and South Africa. By understanding customer requirements and delivering high-quality glass packaging solutions, we have built strong relationships with our clients in India and other markets. Our customer-centric approach ensures customer satisfaction and loyalty, contributing to our continued growth.

Are there any upcoming investments in the pipeline to expand manufacturing capabilities?

Currently, one of our furnaces is temporarily shut down as we are undergoing the process of relining it. During this shutdown, we are also taking the opportunity to increase its capacity by 100 tonnes, bringing the total capacity to 425 tonnes. The capital expenditure (capex) required for this relining and expansion project amounts to approximately Rs 200 crore.

How did AGI Glaspac enhance the company's manufacturing capabilities and contributed to its overall business performance?

In January 2023, we successfully commenced commercial production at our state-of-the-art specialty glass plant located in Bhongir which has an installed capacity of 154 tonnes per day, enabling us to meet the growing demand in the high-margin cosmetic, perfumery, and F&B segments. This expansion has allowed us to enter new markets and diversify our product offerings. To further enhance our capabilities, we have also established a state-of-the-art technology integrated decoration facility within the plant. This facility enables us to provide hot foil stamping, coating, lacquering, and coloring services, ensuring high-quality decoration of our specialty glass products.

This facility will enable us to customise solutions to meet the requirements of our customers. One of our key strengths lies in the flexibility of our production lines. We can quickly adapt and customise our manufacturing processes to align with specific customer needs, ensuring timely delivery within stipulated timeframes. This agility allows us to cater to varying demand patterns and offer tailored solutions to our valued customers. The strategic location of our warehouses near our key markets helps us minimise delivery lead times and ensure prompt and efficient order fulfilment.

What challenges does the industry face in terms of reaching its sustainability targets?

Sustainability is a challenge in the packaging industry as it is in all industries across the globe. Here are some important aspects to consider:

- **Eco-friendly Materials:** Finding alternatives to traditional packaging materials, utilising biodegradable, compostable, or recyclable materials, such as paper, cardboard, plant-based plastics, and bio-based polymers is a must for the industry. It is important to assess the entire life cycle of materials, including sourcing, production, use, and end-of-life disposal.

- **Packaging Design Optimisation:** Optimising packaging designs for efficiency and resource conservation can significantly reduce environmental impact. This includes minimising material usage, right-sizing packaging, and using innovative design techniques to reduce waste. The design should also consider functionality, protection, and convenience for the consumer.

- **Recycling and Waste Management:** Exploring the use of recycled materials in packaging can contribute to a circular economy. Additionally, encouraging consumers to participate in recycling initiatives, collaborating with recycling facilities, and supporting infrastructure for collection and sorting can help increase recycling rates and reduce packaging waste.

- **Carbon Footprint Reduction:** Optimisation of manufacturing processes, transportation, and energy usage helps in reduction of carbon footprint/ Implementing energy-efficient technologies, utilising renewable energy sources, and improving logistics and supply chain practices can all contribute to lower carbon emissions.

- **Circular Economy Principles:** Embracing circular economy principles involves designing packaging to be easily recyclable or compostable, promoting the use of recycled materials, and establishing closed-loop systems. It also includes exploring innovative business models, such as refillable or reusable packaging, to minimise waste generation and extend the life cycle of packaging materials.

By focusing on these aspects, the packaging industry can make significant strides towards achieving sustainability goals.

How does AGI Glaspac differentiate itself from competitors in the pharmaceutical packaging market?

The company's focus on quality, innovation, sustainability, and customer satisfaction helps the company differentiate from the competition present in the market. Our state-of-the-art manufacturing plants, equipped with advanced technologies and production capabilities, allow us to deliver high-quality glass packaging solutions that meet stringent pharmaceutical industry standards. We offer a wide range of glass packaging solutions specifically designed for the pharmaceutical industry. This includes vials, bottles, ampoules, and containers of various sizes and shapes. Our emphasis on innovation in the packaging designs, combining functionality, aesthetics, and user-friendliness helps us in creating packaging solutions that enhance the safety, usability, and visual appeal of pharmaceutical products. We adhere to stringent quality control measures, including rigorous testing and inspection processes, to ensure that its packaging meets the highest standards, helping us to be a reliable and trusted partner for our pharmaceutical clients. We collaborate closely with pharmaceutical clients to provide tailored packaging solutions, offer technical support, and ensure prompt delivery. ■

"Pharmacists are an important driving force in pharmaceutical production and quality assurance."

Ajit Singh
Chairman,
ACG Worldwide

When re-imagining the future of pharma manufacturing, the role of pharmacists is important to consider but which is usually neglected. Pharmacists are an important driving force in pharmaceutical production and quality assurance. The pharma industry often complains that the freshers they employ from pharmacy colleges are not production ready. This is an area which affects production and needs a solution.Pharma production has become increasingly complex in recent times and now incorporates not only pharma science but also electronics, mechatronics, software and automation. Production equipments are moving towards in-line continuous production.

Therefore, the stoppage of a line due even to a minor breakdown in any one machine leads to a reduction in output of the whole line. With the focus on cost reduction and improvement in productivity, this is unlikely to be acceptable in future.

Often the breakdown can be corrected by a simple adjustment to the equipment. However, presently, pharmacists wait for the engineering department to arrive to get the line started. This takes its own time. Pharmacists need to be competent to fix the problem themselves.

Unfortunately, hardly any basic engineering training is provided to them during their pharmacy education. A course in pharmaceutical engineering and maintenance, even though brief, would be desirable.Otherwise re-imagining the future would need to envisage the replacing of pharmacists with chemical engineers and the like in pharmaceutical production. ■

Unlocking the power of science to transform healthcare AstraZeneca India

Dr Anil Kukreja
Vice President – Medical Affairs and Regulatory
AstraZeneca India

AstraZeneca is committed to transform healthcare for billions of people by unlocking the power of what science can do for the people, society and the planet. By leveraging our science, we accelerate our understanding of diseases, leading to improved predictions of clinical success and the development and delivery of life-changing medicines. Our focus lies in creating innovative solutions that make healthcare more affordable, accessible, and equitable for the Indian population, thereby driving success in our markets and therapy areas.

There is immense potential in science, technology, and public-private collaborations to foster innovation. Understanding this, AstraZeneca is committed to tackling future challenges through a comprehensive approach. Given the high prevalence of conditions such as cancer, diabetes, respiratory disorders, cardiovascular ailments, and rare diseases, we have collaborated with various stakeholders to ensure the effective delivery of medicines to the patients in need. By forging strategic alliances with government bodies, local healthcare institutions, startups and diagnostic organizations, we actively co-create healthcare solutions, enhancing overall access to care. Additionally, we are also harnessing the power of data and technology to expedite the discovery and delivery of potential new medicines. In addition to strengthening our internal capabilities, we partner with leading global technology companies to leverage AI and effectively serve patients worldwide. ■

"Bio pharma companies are likely to focus more on developing therapies for orphan diseases."

Dharmesh Kharwar
Managing Committee, FPME and Director,
NGB Laboratories Pvt. Ltd.

Emerging challenges & factors impacting your business

In the battle between small and large molecules , there is a significant and paradigm shift in the challenges that impact the overall healthcare and FPME members as well. Technology and Intellectual property protection are the main factors that have led to very small number companies offering the products and at a higher cost . This has reduced the access of lifesaving and life improving bio pharma in many countries . Most of these bio pharma products are not reimbursed as there are small molecules being prescribed , even though they are not the standard of care in the high income markets. New players are few and far between due to high capital investment & regulatory time scale as much as 3 x to 4 x in terms of time and cost . Patent expirations are just coming to fore but not all are able to unlock their value. And even if this risk is taken to develop , do complete clinical studies, launch , the pricing expected is such the breakeven is just impossible in standard financial durations. Complete new bio pharma is a long time away for Indian industry .

Key focus areas & growth drivers for future

There is some focus on this sector and it can be accelerated to develop the entire bio pharma system using biotechnology advancements including gene editing, cell and gene therapies, and personalized medicine, hold immense promise for treating previously incurable diseases. Continued investments in research and development in these areas are expected to lead to ground breaking treatments and substantial revenue potential. Rare Diseases and Orphan Drugs are gaining increasing recognition and support for rare diseases, bio pharma companies are likely to focus more on developing therapies for orphan diseases. These drugs often command premium pricing and have reduced competition, offering a viable market opportunity and recovery of investment . Indian Industry can focus on these which may not be priority for the big bio-pharma. Immunotherapy and Oncology are the leading large molecules to focus with PPP model , lower cost bio-similar needs to be developed. Drug Repurposing and AI/ML in Drug Discovery is a massive leaf forward to significantly reduce the time and cost of drug development. The application of artificial intelligence (AI) and machine learning (ML) in drug discovery and clinical trial design will accelerate the identification of potential drug candidates at a lower cost and higher speed for Indian bio pharma companies .

Innovations & New products in the pipeline

Gene therapies have been making significant strides that can target a broader range of diseases, such as muscular dystrophy, hemophilia, and inherited

retinal disorders. Cell Therapies including CAR-T cell therapies have in treating certain types of blood cancers, solid tumors and other non-cancerous conditions. Neurological Disorders like Alzheimer's, Parkinson's, and amyotrophic lateral sclerosis (ALS) also have promise with bio pharma therpaies since small molecules have had limited success.

Rare Diseases and Orphan Drugs means the development of drugs for rare diseases and orphan indications continues to be a priority. Many bio pharma companies have been focusing on these areas, driven by incentives provided by regulatory agencies to encourage the development of treatments for unmet medical needs. Immunotherapies: beyond oncology, immunotherapies are being explored for autoimmune diseases and inflammatory disorders, with the aim of modulating the immune system to restore balance. Personalized Medicine and Biomarkers play a critical role in identifying patient subpopulations that respond well to specific treatments. As more is learned about disease genetics and individual variability, personalized medicine is becoming increasingly important. Regenerative Medicine is the development of tissue engineering products and cell-based therapies for repairing damaged tissues and organs.

Investments, Expansions & Future plans

Govt. of India has initiated number of facilitations for start-up and established companies under BIRAC, PLI and others . India's BioEconomy in 2021 registered 14.1% growth over 2020. India's The Indian BioEconomy for the period January-December 2021 is valued at $80.12 billion. The BioEconomy in 2020 was valued at $70.2 billion. IBER report has set out to reach ambitious target of $150 billion BioEconomy by 2025. BioPharma still accounts for the largest share of the BioEconomy. BioPharma accounted for 49 percent share of the BioEconomy. The total economic contribution of this segment was estimated at $39.4 billion. Diagnostics accounted for 52.8% share of the total BioPharma Market, while Therapeutics segment stood at 26%, according to India Bioeconomy Report 2022 by BIRAC.■

"Filing of new dossiers in key markets for new products will be among our key focus areas."

Saransh Chaudhary
President, Global Critical Care, Venus Remedies Ltd,
and CEO, Venus Medicine Research Centre

Emerging challenges and factors impacting your business

The volatility in the API segment and pricing pressures owing to the hike in fuel and other input costs are the major factors impacting our business. Much like any other pharmaceutical company eyeing higher growth, we have encountered challenges associated with profitability and monetisation of our efforts, but we have overcome them with a focused and actionable approach.

Taking on these challenges, backed by precise projections and a proper risk mitigation and management framework, whets out appetite for growth. While there are risks associated with every business, a strong risk management structure, like the one we have at Venus Remedies, is critical to an enterprise's overall profitability, competitive market positioning and long-term financial viability. Integral to our core philosophy and working, risk management enables us to meticulously examine business activities.

We have overcome the challenge of sustaining our growth by focusing on internal efficiencies to considerably improve product and process quality and optimise cost structures. We have also improved organisational liquidity through stringent monitoring of working capital. Our increased business volumes have helped us in absorbing fixed costs, leading to improved cash flow. We have also succeeded in surmounting the challenge of profitability by diversifying our operations and building a robust pipeline consisting of a balanced mix of generic and R&D-based products.

Key focus areas and growth drivers for the future

Our topmost priorities include forging synergic partnerships for our leading generic and research products, optimising organizational leverage to maximize our gains and astute capital investment. Building on our robust pipeline of patented and generic products, we are constantly extending our footprint to new geographies worldwide through marketing tie-ups with leading pharmaceutical companies in countries where we want to mark our presence. Equipped with CTD dossiers for major regulated international markets, including the European Union, we market our wide range of injectables for critical segments like antimicrobial resistance, oncology, and now anticoagulants through retail sales, institutional sales and marketing collaborations. Hence, filing of new dossiers in key markets for new products will be among our key focus areas.

Coming to optimization of our organizational leverage, we believe that human capital holds the key to wealth creation through constant value addition and improvisation. Over the next five years, attracting the

best talent to the company remains a key priority. Astute capital investment is also one of our top strategic priorities, under which we have defined four areas for capital investment, namely infrastructure upgradation, productivity enhancement, regulatory compliance, and technology and data.

While our key growth drivers in the international market are entry into new geographies, high-standard services through digitalisation and focus on key therapeutic segments like oncology and novel antibiotics, the factors that have enabled us to excel in the domestic market are timely execution of products, bolstering partnerships with public and private hospitals and our foray into the rapidly growing consumer healthcare market.

Innovations and new products in the pipeline

Intensely involved in the development of novel, innovative research products and solutions for therapeutics, which focus on drug development based on targeted drug deliveries, molecular biology research, integrated herbal medicine and nano-formulation research, the Venus Medicine Research Centre (VMRC) has come up with several novel breakthroughs catering to critical care segments like antibiotic resistance, pain management and haemostasis.

With an aim to preserve the life of existing antibiotics and to guide better clinical decisions, VMRC is targeting its efforts towards novel drug delivery mechanisms and toxicity reduction of antibiotics. The Venus Remedies research wing is, at present, working on the Renal Guard technology that focuses on reducing the nephrotoxicity associated with antibiotic compounds like polymyxin B, colistin and amikacin. Based on this platform technology developed in our organ-on-chip lab, we will be looking to commercialise our anti-infective R&D pipeline. As a result of our concerted R&D efforts, we now have a functional pipeline of drugs which is specifically looking at Renal Guard. The Organ-on-a-chip model is enabling us to understand the mechanisms leading to organ damage in humans and enhance our ability to find better solutions for patients and caregivers. We plan to use this technology to create more relevant in vivo systems by making a tandem connection to other human organs using flow dynamics. But as of now, our major efforts around organ-on-a-chip are targeted towards kidney-in-a-chip models, under which we are specifically looking at screening antibiotics for toxicity.

VMRC also has five preclinical antibiotic candidates in the development pipeline out of the 13 preclinical candidates from India listed in the WHO's Antibacterial Pipeline Review 2020. It is also working on new research products in the haemostatic and natural products segments.

Investments, expansions, and future plans

Since exports account for about 70 per cent of our revenue, we have elaborate plans to expand our global footprint in new regulated and unregulated markets by focusing on antibiotic, anti-coagulant and oncology segments. For instance, we have a carefully devised strategy in place to promote our oncology products in all existing as well as new markets that we aim to penetrate. This will allow us to increase the proportion of our high-margin business in our overall revenue pool.

To sustain our growth momentum to move into the big league, we will expand our product basket selectively, customised to the opportunities in each country. This will allow us to offer the right product basket in the right market. We will also rebalance our revenue between acute and chronic therapies to improve overall business profitability.

We intend to enhance our global stature by signing business deals with pharma majors, securing more and more marketing authorisations and aggressively bidding for institutional tenders. Setting our course for the future, we plan to commercialise all our dormant marketing approvals in our existing markets. We have also planned extensive market potential analyses to achieve our targets in the institutional business domain. In the domestic market, our focus will be on launching new products in the institutional division, enhancing the reach of our OTC products, expanding our institutional business operations to new geographies and entering into partnerships with big hospitals, government medical colleges and public sector organisations.

Last but not the least, we will continue to work on high-volume products to optimise the overall cost of production, and hence improve returns. We will also implement new IT solutions to maintain product quality and improve plant efficiency. ■

"Avesthagen will be able to expand into molecular diagnostics using its proprietary Avgen Diagnostics platforms."

Dr Amjad Hussain
Senior Vice President, Pharma R & D and Business Development Avesthagen Ltd.

Emerging Challenges & factors impacting your Business

Countless businesses have already risked everything on the frontier of Life Science, spanning from corporate giants to pioneering start-ups born in the crucibles of the world's most visionary laboratories. More than two decades ago, Avesthagen Limited embarked on a groundbreaking journey to unravel the secrets of the Zoroastrian-Parsi genome, blazing a trail as true pioneers in the field.

In this dynamic landscape of innovation, even visionary companies like Avesthagen encounter formidable challenges in securing the necessary funds to fuel their pursuit of cutting-edge science. Avesthagen embarks on a remarkable journey of renewal, revitalizing its commercial, financial, and M&A plans through intricate alliances and strategic partnerships.

Together, through collaborative efforts and a shared commitment to pushing boundaries, we will shape a future where groundbreaking discoveries and life-altering solutions redefine the landscape of science, benefiting countless lives across the globe.

Key focus areas & growth drivers for future

Almost 40 years ago, researchers had a challenging time mapping the codes of even a few genes during the 1980s. But the rate of discovery and technology advancements in fields as diverse as computing, genomics and AI-ML have offered researchers a potent new set of tools for locating, mapping, and changing genetic information at speed.

The commercial opportunities have increased as our understanding of the science of life has advanced, drawing a sizable and diverse array of businesses. It

helps to compare life science to information technology to better grasp how extensive the potential business influence of life science will be. Being into an era of genomics, genetic code has become a language. Similar to how changes to computer code modify the information flow, changes to DNA alter the form of life.

Additionally, bioinformatics and other information technology firms are becoming essential players in the life sciences sector. If we simply consider what has happened to the agricultural seed industry over the past twenty years, we would realize how genetic discoveries are erasing the distinctions across industries. As agricultural, chemical, and pharmaceutical businesses competed for their acquisition, seeds went from being a little-noticed commodity to a popular product, increasing the valuation of the companies in seed - Agri businesses. Avesthagen stands as an unparalleled industrial ecosystem, forged through strategic alliances with marquee businesses, academic institutions, start-ups, and top-tier global talent. Guided by our vision for the future, we are driven to harness the full potential of technological advancements in understanding the intricate human genome—the very blueprint that governs our biological processes.

We are at the forefront of pioneering new frontiers in disease diagnosis and treatment, leveraging early adoption of revolutionary technologies like Genome driven Precision and Personalized Medicine. Our focus on agri-biotech, precision and preventive diagnosis, health and wellness, cell therapies, and genome editing serves as the cornerstone of our growth strategy for the next decade, propelling our business to unparalleled heights.

Innovations & New products in the pipeline

Avesthagen Limited, a scientist-led, research and innovation-driven company, is dedicated to transforming the lives of patients by providing precision and preventive diagnosis, and giving affordable access to high-quality plant derived bioactive containing super foods. Avesthagen also has a pipeline of biosimilar drugs in various stages of preclinical development, and would be able to launch these products in India and globally directly or through the partnerships and alliances.

With a strong focus on diabetes care, oncology, and nutrition, the business has a comprehensive pipeline of 20+ products including 8 biosimilar compounds in oncology, rheumatoid arthritis, renal diseases, and 7 bioactive compounds formulated into variety of super foods, gummies, cereals for the treatment of diabetes, cardiovascular diseases and bone malformations.

Avesthagen will be able to expand into molecular diagnostics using its proprietary Avgen Diagnostics platforms, which provides it access to a range of gene panels, exome and whole genome sequencing that are designed to predict a number of chronic diseases in advance including cancer, cardiovascular and neurodegenerative disorders. A multi-site manufacturer with end-to-end capabilities for generating diagnostic solutions, drug products, and precision super foods.

Investments, Expansions & future plans

With specific annual goals for important criteria like increasing access to biosimilars in low- and middle-income countries and bringing naturally processed branded bioactive food with scientific validation for human wellness, Avesthagen is dedicated in developing products with extensive research and quality and bringing these products into the market for betterment of society.

According to a recent survey, approximately 40-50% people from the developed world are interested in genetic profiling to determine their illness propensity, and a significant percentage are willing to pay more for medications that are specifically tailored to their genetic makeup. However, in India that time has not yet arrived, but it is catching up.

The next decade promises to be a turning point for India in the development and expansion of the life science sector. Avesthagen's capabilities in personalized genomic analysis and nutraceuticals with natural bioactives will pave the way for significant business coming to the company. Through its subsidiaries and partnerships in the United States and Europe, Avesthagen is getting ready to launch its product globally. With expansion through mergers and strategic partnerships, structure will continue to be dynamic, putting millions or possibly billions of dollars in research. ■

Digital Therapeutics: Reimagining Business Models in the Pharma Business Industry

Digital therapeutics are essential to healthcare delivery systems. Digital Therapeutics are patient-facing software applications that help patients treat, prevent, or manage a disease and that have a proven clinical benefit.

The convergence of healthcare and technology has given rise to a groundbreaking field known as Digital Therapeutics (DTx). These innovative solutions combine evidence-based medicine with software applications to improve clinical outcomes. Depending on the stage, DTx can help in prevention, management, or treatment of various medical conditions. Digital therapeutics is reshaping the traditional business models of the pharmaceutical industry, compelling companies to adapt and innovate. There will be a profound impact of digital therapeutics on the pharma sector, let us look at the key factors driving the need for a reimagination of business models.

The rise of digital therapeutics

Digital therapeutics encompass a wide range of software programmes and applications that leverage algorithms, artificial intelligence, and patient-generated data to deliver personalized and effective interventions. While in some cases DTx can be a standalone First Line of Therapy, the majority of DTx solutions often serve as a complement to or enhancement of traditional pharmaceutical interventions, providing accessible and cost-effective options for patients.

One of the primary reasons for the rise of digital therapeutics is the increasing prevalence of chronic diseases and the need for scalable and sustainable healthcare solutions. These software-based interventions can empower patients to take an active role in their healthcare journey, offering personalized feedback, reminders, and support.

Impact on pharma business models

Shifting Focus to Outcomes: Traditionally, the pharmaceutical industry's revenue model revolved around selling drugs. However, digital therapeutics are transforming this approach by placing a greater emphasis on patient outcomes. Pharma companies are realizing that delivering measurable and data-driven results is more valuable than simply selling medications. This shift incentivizes a new approach to research and development, encouraging the integration of technology and data analytics to improve treatment effectiveness. By focusing on outcomes, pharmaceutical companies can align their goals with the aim of improving patient health and well-being.

Collaboration and Partnerships: The emergence of digital therapeutics has fostered collaboration between pharmaceutical companies and technology firms. Pharma companies are recognizing the need to tap into the technological expertise of these firms to develop and market digital therapeutics effectively. Strategic partnerships are being formed to leverage the respective strengths of both sectors, leading to innovation in areas such as drug development, clinical trials, regulatory compliance, and commercialization. This collaboration allows pharma companies to leverage cutting-edge technologies, enhance their product portfolios, and reach a wider patient population.

Value-Based Pricing: Digital therapeutics offer an opportunity for pharma companies to differentiate their products by providing measurable value to patients, healthcare providers, and payers. As these solutions demonstrate improved patient outcomes, they provide a basis for value-based pricing models, where payment is tied to the achieved results. This approach encourages pharmaceutical manufacturers to invest in the development of effective digital therapeutics and enhances the overall affordability and accessibility of healthcare. Value-based pricing incentivizes the

creation of solutions that deliver tangible benefits to patients, ensuring that healthcare resources are allocated more efficiently.

Data Integration and Analytics: Digital therapeutics generate a vast amount of real-time patient data, offering valuable insights into treatment efficacy and patient behaviour. The pharmaceutical industry can leverage this data to gain a deeper understanding of diseases, patient populations, and treatment responses. Advanced analytics and machine learning algorithms can help identify trends, optimize treatment protocols, and tailor therapies to individual patients, leading to more targeted and efficient drug development. For example at Fitterfly, we can even show the impact of a diabetes drug on blood sugar levels which can be important for real world study for new pharma molecules. The integration of data and analytics allows pharma companies to make informed decisions, streamline research processes, and develop drugs that are better aligned with patient needs.

Enhanced Patient Engagement: Digital therapeutics have the potential to significantly improve patient engagement and adherence to treatment plans. By leveraging mobile apps, wearables, and other digital tools, patients can actively participate in their own healthcare journey, receiving personalized feedback, reminders, and support. Increased patient engagement not only improves treatment outcomes but also provides valuable data for pharma companies to refine their products and services further. Engaging patients in their own healthcare promotes a more patient-centric approach and can lead to better treatment adherence and overall health outcomes.

How can Pharma companies work with DTx companies

Two common approaches are:

- **Companion DTx :** where pharma companies provide DTx along with a pill to improve adherence and outcomes. Here the pharma companies can either pay for the DTx or can just improve access of DTx to relevant patient groups.

- **Co-development deals:** This is a more exciting way of having a deeper business tie-up. The co-development deal involves pharma company and a DTx company coming together to develop, test, get regulatory approvals and finally commercialise a new DTx product. While a DTx company brings technology, know-how, DTx systems, research, operations into the relationship, pharma companies can bring their distribution muscle and market knowhow to the equation.

Conclusion

The emergence of digital therapeutics has compelled the pharmaceutical industry to rethink its traditional business models. Digital therapeutics offer new opportunities for pharma companies to improve patient outcomes, enhance collaboration and partnerships, implement value-based pricing models, leverage data integration and analytics, and enhance patient engagement.By embracing digital therapeutics, pharma companies can improve treatment effectiveness, patient satisfaction, and long-term profitability. However, challenges such as regulatory frameworks, data privacy, and reimbursement models need to be addressed to fully realize the potential of digital therapeutics.

The shift toward patient-centric outcomes and the integration of technology in healthcare are transforming the pharmaceutical industry. Companies that adapt and innovate in response to these changes will position themselves at the forefront of the digital health revolution. ■

Author

Dr Arbinder Singal
CEO & Co-Founder
Fitterfly

INTERVIEW

"We are planning to launch 20-25 products in FY24 in the US market"

Mitanshu Shah
Senior Vice President, Finance
Alembic Pharmaceuticals Ltd

__Mitanshu Shah__ talks about the overview of the Pharma industry and major challenges in US market. He also spoke about the product launches and revenue guidance going ahead.

Brief us about the overview of the Pharma industry?

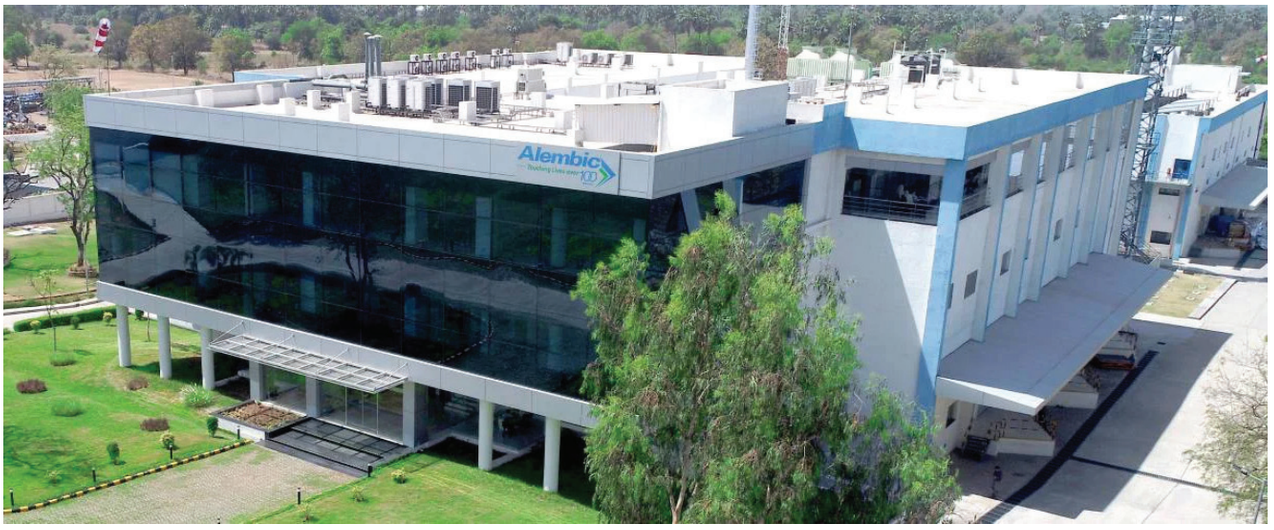
The sequential moderation in price erosion in USA will help the pharmaceutical industry and new product launches will drive growth domestic as well as internationally. The margins in pharma space are back on track.

What are the major challenges that you see in the US market?

The US business continues to remain challenging on account of competitive intensity. Despite difficult US market scenario and some delay in commercialisation of new plants, we still did managed to grow our volume by 18% in last financial year in US. Generating healthy earnings is becoming difficult in US market, if you consider that large portion of R&D is attributable to US business. We are focusing on complex / speciality products to protect from price pressure.

What are your expansion plans?

India Branded Business continues to outperform the market especially on focused products / therapeutic segments. Clubbed with growth in Rest of the World (RoW) and API business, we are looking for good numbers going ahead. We have started commercialization of products from our injectable and oncology facilities. We believe we have created niche capabilities to capture future opportunities in International markets. We already have strong balance sheet and if needed can be leveraged for growth.



Tell us about the US FDA inspection at F3 and F2 facility.

We commercialized F2 and F3 plants during the quarter. United States Food and Drug Administration (USFDA) conducted an inspection at the company's Injectable and Ophthalmic Facility (F-3) located at Karkhadi from 16th March, 2023 to 24th March, 2023. The USFDA issued a Form 483 with 2 minor procedural observations. The Company is committed to maintain the highest quality standards and compliance at all times. All our plants are FDA approved and there is no regulatory overhangs.

How many more products are you planning to add?

The company has received 7 ANDA approvals and we filed 4 ANDAs during the quarter. We are planning to launch 20-25 products in FY24 in the US market and are confident of growth going ahead. We have cumulative 245 + ANDA filing in USA now.

Brief us about the business highlights for the quarter?

It was a muted quarter. The sales were flat at Rs. 1406 crore and large portion of this was attributable to US de-growth. For the quarter ended 31st March, 2023, the company's net sales for the quarter was at Rs.1406 crores, while net profit for the quarter was at Rs.153 crores. The company met its entire capex, as well as the dividend payment out of its internal accruals. The cash flow for the company continues to remain robust. The launches in US from new and existing facilities will drive growth in upcoming quarters in US.

Going ahead, we are eyeing growth in Rest of the World (RoW) markets of 10-12% and branded business to grow 12-13%. API business also expect to grow at 12% in FY24.

What was the growth in India branded and speciality segment?

India Branded Business recorded 9% growth with top-line of Rs 490 crores for Q4 FY23, while Specialty segment grew 13%. The growth in specialty segment was driven by gynaecology, cardiology, anti-Diabetic, ophthalmology. The new product launches as well as dossier extensions are on track to accelerate growth. Our veterinary business also saw growth of 21% in quarter. This business is becoming valuable growth driver for us.

What is your revenue guidance for API business?

The strong momentum delivering growth of 24% on annualized basis, largely led by high off-take and better product mix for FY23. Our API business grew 41% at Rs. 313 crores in this quarter, backed by strong order book. We are eyeing 12-15% growth in API business in FY24. ■

Emerging Trends in Novel Drugs and Biologics Delivery

Digital therapeutics are essential to healthcare delivery systems. Digital Therapeutics are patient-facing software applications that help patients treat, prevent, or manage a disease and that have a proven clinical benefit.

Today, the pharmaceutical industry is being revolutionized by the advent of targeted drug and biologics delivery systems utilizing biocompatible lipids. This cutting-edge technology, known as lipid nanoparticle (LNP) technology, represents a rapidly advancing frontier in biopharmaceutical science, offering a versatile and expansive platform for medicinal applications.

With its potential to effectively transport a diverse array of therapeutic agents, including genes, RNAs, peptides, and diagnostic imaging agents, LNP technology holds immense promise.

Extensive research is currently focused on lipid-based drug delivery systems, exploring their remarkable potential to facilitate the administration of drugs and nutrients through diverse routes. These systems are highly regarded for their exceptional biocompatibility, gradual or controlled release kinetics, remarkable stability, and minimal toxicity. Among the most extensively studied variants are Nanostructured Lipid Carriers (NLC), founded on phospholipids.

Nevertheless, using phospholipids derived from natural sources presents certain challenges. These phospholipids contain several species of unsaturated fatty acids, which carry the risk of oxidative stability and contribute to the production of diverse components in varying ratios that can differ from one batch to another. Consequently, the resulting variations can pose obstacles in developing robust and consistent controlled-release drug delivery systems.

Fortunately, advancements in lipid science have paved the way for the emergence of synthetic phospholipids, offering a solution to this challenge. These modern, fully saturated synthetic phospholipids present several advantages. They are easier to standardize, enabling consistent production. Moreover, since they have sharp Phase Transition Temperatures (PTT), their properties can be precisely adjusted under appropriate conditions. This is particularly beneficial when developing liposomal systems that require enhanced physical stability, such as improved stability in blood plasma or phospholipids with powder-like characteristics. Importantly, these synthetic phospholipids lack antigenic properties, ensuring easy metabolism within the body. They also exhibit reduced toxicity and enhanced solubility, making them excellent candidates for liposomal-based drug delivery systems, especially when considering parenteral administration and inhalation dosage.

Empowering drug delivery with Lipid-Based Systems

The advancements in LNP (Lipid Nanoparticle) delivery systems have revolutionized the development of robust drug delivery platforms. Notably, the utilization of synthetic lipid nanoparticles has been demonstrated in the technology behind the Covid-19 vaccine delivery, showcasing their ability to ensure stability throughout

the delivery process and facilitate a potent immunogenic response. Encapsulating the fragile mRNA strand encoding the key protein within synthetic lipid nanoparticles significantly improves delivery efficiency while protecting the mRNA from both, storage and in-vivo degradation.

Extensive research is also underway to explore the potential of nucleic acid drugs encapsulated in synthetic LNPs for various applications. These include replicon-related therapeutics in oncology, protein replacement therapy, and aiding gene-editing procedures. Incorporating ionizable lipids, a critical component of LNPs, plays a crucial role in determining their potency in targeting specific sites and enhancing penetration into tissues such as the liver and solid tumours. This allows for more effective delivery of therapeutic payloads and facilitates the desired therapeutic outcomes.

Lipid-based drug delivery systems have transformed various therapeutic fields, offering significant advancements in biomedical and therapeutic approaches. These systems have found applications in several areas.

One such area is drug-based therapy. Lipid nanoparticles filled with antibiotics have proven effective in treating drug-resistant bacterial infections, particularly in ocular, pulmonary, and topical applications. These drug-loaded liposomes offer advantages such as improved protection of antibiotics from degradation and enhanced biodistribution within the system. Overcoming membrane repulsive forces, liposomes can selectively target and penetrate bacterial colonies. This technique is valuable for eliminating intracellular bacterial growth within infected tissues, as it enhances antibiotic retention and enables controlled drug release with fewer side effects.

Overall, lipid-based drug delivery systems have emerged as versatile tools in various therapeutic fields, contributing to more effective and targeted treatment strategies while minimizing adverse effects.

Liposomes have also shown the potential to enhance the therapeutic effects of certain cardiovascular drugs. Long-circulating liposomes (passive targeting) are gaining importance in treating cardiovascular diseases such as myocardial infarction and atherosclerosis. In platelet accumulation conditions, targeted liposomal drug delivery to platelets offers promising therapeutic applications. Coating liposomes with biocompatible molecules helps pinpoint targeting and prevent their destruction, prolonging their presence in the system and increasing efficacy.

Another area that lipid-based drug delivery systems have revolutionized is cancer treatment. These systems efficiently deliver active molecules to target cancer cells. Encapsulating these molecules in liposomes enables

their precise delivery to the tumour site. Liposomes, with a size of up to 100 nanometers, can easily penetrate tumours and remain stable for extended periods.

By attaching antibodies to liposomes, tumour-specific antigens can be targeted, allowing for localized drug delivery while minimizing side effects on surrounding cells and tissues. These nanoparticles are particularly valuable in addressing brain tumours by overcoming the blood-brain barrier. An example of their clinical use is PEGylated nanoliposomes encapsulating doxorubicin, approved for cancer treatment.

Innovations with siRNA delivery agents

Promising advancements in the field involve the utilization of cationic lipids as emerging technologies for siRNA delivery. Synthetic cationic lipids, such as oxime ether lipids with hydroxylated head groups, have demonstrated superior capabilities as siRNA delivery agents. These lipid-based agents offer huge potential in breast cancer treatment through Small Interfering RNA (siRNA)-based gene silencing therapy.

By virtue of their small size, they can readily penetrate tumour cells and release the therapeutic payload within the intracellular space. This targeted delivery mechanism using lipid nanoparticles (LNPs) helps minimize side effects on surrounding healthy tissues. With their tiny size, these nanoparticles can successfully navigate various barriers encountered during treatment, enhancing bioavailability and efficacy.

Value of utilizing synthetic phospholipids

Synthetic phospholipids with diverse polar head groups and fatty acid compositions can be produced through various synthesis methods. By incorporating different fatty acids into these phospholipids, it becomes possible to investigate variations in the physical properties of liposomes. However, this process involves intricate chemistry and complex characterization procedures and can be costly.

Nevertheless, employing synthetic phospholipids offers notable advantages, particularly in terms of their relatively high purity. Such purity ensures a more stable delivery system with a predictable release pattern, allowing precise control over drug delivery. Additionally, synthetic phospholipids enhance the targeting capabilities of the delivery system, facilitating efficient delivery to the intended site of action. These benefits highlight the value of utilizing synthetic phospholipids in the development of drug delivery systems.

Public-private collaboration towards lipid-based drug delivery systems

Extensive research is continuously conducted to modify lipid-based drug delivery systems to minimize toxicity, enhance efficacy, and prolonged circulation time in the bloodstream. Experimental studies focus on developing complex multi-functional liposomal formulations to create more efficient drug delivery systems. Several challenges still hinder the clinical translation of lipid-based drug delivery systems. These challenges include state regulations, pharmaceutical manufacturing, and intellectual property (IP) concerns. Ensuring quality assurance and cost-effectiveness remains a significant obstacle. The manufacturing process's scalability, reliability, reproducibility of the final product, and product stability pose challenges. Moreover, the lack of in-house expertise further complicates matters. Securing IP rights for liposomal-based drug delivery systems is complex and expensive. Additionally, conducting clinical trials for liposomal formulations tends to be more intricate and time-consuming than traditional chemical formulations. ■

Author

Arun Kedia
Managing Director
VAV Lipids

"Pharmaceutical industry is moving towards a more personalized approach to drug development and patient care".

Daara B Patel
Secretary – General, IDMA

__Daara B Patel__ talks about the market dynamics of global pharma industry and opportunities for Indian pharma in India & globally. He also spoke about the initiatives of IDMA to support the growth of Indian Pharma.

Brief us about the market dynamics of global pharma industry and impact of geopolitical shifts.

The market dynamics of the global pharma industry are influenced by various factors, including geopolitical shifts. Here are some key points to consider:

- **Market size and growth:** The global pharmaceutical market has been over the years, driven by factors such as population growth, aging demographics, increasing prevalence of chronic diseases, and technological advancements.
- **R&D and market competition:** The pharma industry invests heavily in research and development (R&D) to discover and develop new drugs. The pharmaceutical industry is highly competitive, with both established multinational corporations and smaller innovative companies vying for market share.
- **Regulatory Environment:** The pharma industry operates within a stringent regulatory framework to ensure safety, efficacy, and quality of drugs. Regulatory bodies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) set guidelines and conduct rigorous evaluations before approving new drugs for market entry.
- **Intellectual Property Rights:** Intellectual property protection, including patents, plays a crucial role in the pharma industry. Patents enable drug manufacturers to recoup R&D costs and maintain a competitive advantage.

- **Pricing and Market access:** Drug pricing is a significant aspect of the pharmaceutical market, and it can be influenced by geopolitical factors and vary across countries due to variations in healthcare systems, government regulations, and reimbursement policies.

- **Geopolitical Shifts:** Political events and geopolitical shifts have far-reaching implications for the global pharmaceutical industry. The changes in government policies, trade agreements, intellectual property laws, and regulatory frameworks can impact market conditions, supply chains, market access, and investment opportunities.

What are the driving forces that will reshape the future of pharma industry & what kind of paradigm shifts do you anticipate?

Several driving forces are likely to reshape the future of the pharmaceutical industry in the coming years. With advancements in technologies like genomics, proteomics, and data analytics, the pharmaceutical industry is moving towards a more personalized approach to drug development and patient care. This can be seen in approaches such as targeted therapies and use of companion diagnostics, which are tests that identify patients who are most likely to benefit from a particular treatment, will become more prevalent ensuring that drugs are prescribed to patients who are most likely to respond positively, improving treatment outcomes and reducing healthcare costs.

Also, a paradign shift can be seen in integration of digital technologies and data analytics into healthcare systems is rapidly transforming the pharmaceutical industry. The adoption of telemedicine, electronic health records (EHRs), wearables, artificial intelligence (AI), and block chain is revolutionizing how healthcare is delivered and managed.

Over the horizon of next 5 years please share your views on opportunities for Indian pharma in India & globally.

The domestic opportunities consist of rising healthcare spending which is a result of growing middle-class population, and government initiatives to improve healthcare access. Also, India is a major player in the global generic drug market. Indian pharma companies can leverage their expertise in generic drug manufacturing and distribution to capture a larger market share. Indian pharmaceutical companies have transitioned from producing basic, no-frills generic drugs to manufacturing more innovative generic medications. These value-added generics offer additional features, such as improved formulations, enhanced efficacy, extended-release mechanisms, novel drug delivery systems, or combinations of active ingredients.

India has a strong contract manufacturing and research segment, which offers opportunities for collaboration with global pharmaceutical companies. Indian pharma companies can provide contract manufacturing services, including active pharmaceutical ingredient (API) production, formulation development, and packaging, to international clients.

Speaking about these global opportunities, these can be seen Generic and Biosimilar market as Indian pharma companies have a competitive advantage in producing and exporting generic drugs and biosimilars. The global market for generic and biosimilar products is projected to grow, driven by patent expirations and increasing healthcare costs.

India, having a large patient population and a diverse gene pool, making it an attractive destination for conducting clinical trials. Indian pharma companies can collaborate with global pharmaceutical companies to conduct trials, which can accelerate the drug development process and expand their global footprint.

We are a major producer of APIs, and the COVID-19 pandemic highlighted the importance of a robust and diversified API supply chain. The global demand for APIs is expected to increase, presenting opportunities for Indian pharma companies to expand their API manufacturing capabilities and establish secure and reliable supply chains.

Tell us about the recent initiatives of IDMA to support the growth of Indian Pharma.

The Indian Drug Manufacturers' Association (IDMA) plays a significant role in supporting the growth and development of the Indian pharma sector. Here are some general initiatives and activities undertaken by IDMA to support the growth of the Indian pharmaceutical industry:

- **Representation and Support:** IDMA represents the interests of the Indian pharmaceutical industry at various forums, both nationally and internationally. It supports its members by addressing industry-related challenges, advocating for favourable policies, and providing a platform for collective action.

- **International Collaborations:** IDMA collaborates with international organizations and industry associations to foster collaborations, exchange best practices, and explore opportunities for the Indian pharma industry in global markets. Such collaborations can promote innovation, technology transfer, and market expansion.

- **Policy Advocacy:** IDMA actively engages with the government and regulatory authorities to provide inputs and recommendations on policy matters related to the pharmaceutical industry. It represents the interests of its members and strives to create a conducive business environment for the growth of the sector. For example, IDMA has published a voluntary Code of Marketing Practices quite some time ago for our Member-companies and is committed to the code of ethical marketing practices broadly in line with the UCPMP. IDMA is seized of this important matter and is in dialogue with the Government and other authorities so that the industry as a whole adheres to a workable practical Code. Though the Code is voluntary, Members are requested to adhere to the same to ensure ethical and transparent marketing practices.

- **Regulatory Compliance:** IDMA provides guidance and assistance to its members regarding regulatory compliance, quality standards, and good manufacturing practices. It promotes adherence to regulatory requirements to ensure the production of safe, efficacious, and quality pharmaceutical products. IDMA has always supported initiatives for improvement of quality, availability and affordability of drugs.

- **Skill Development and Training:** IDMA conducts training programs and workshops to enhance the knowledge and skills of professionals working in the pharmaceutical industry. It focuses on areas such as quality control, manufacturing practices, regulatory affairs, and research and development. IDMA has always been in the forefront in promoting Quality Excellence in the pharma industry by organizing various technical seminars and workshops – The Pharmaceutical Analyst Convention (PAC) also IDMA has organized two (2) Series of "Advanced Program in Pharmaceutical Quality Management" (APPQM) in collaboration with NSF Health Sciences, UK

- IDMA and Department of Pharmaceuticals have been jointly organizing Seminars and Workshops for the past 3 years to train SMEs on upgradation to WHO-GMP and beyond. IDMA had organized a 'Workshop on E-Governance Initiatives of CDSCO' in February 2020 at Mumbai jointly with CDSCO and CDAC.

- **Knowledge Sharing and Networking:** IDMA organizes seminars, conferences, and symposiums to facilitate knowledge sharing and networking among industry professionals, researchers, and experts. These events provide a platform for discussing emerging trends, technologies, regulatory updates, and best practices in the pharmaceutical sector.

- **"Vriddhi" :** IDMA has envisaged plans to support its members & bring them on the rapid growth path by knowledge sharing and hand holding. The Series is named VRIDDHI meaning Knowledge Sharing, Hand Holding & Growth. The first series was organized on 16th September 2022 and covered the different aspects & importance of "Founder's Mentality"."Vriddhi" is an insights-exchange series envisaged with the objective of supporting Indian pharmaceutical companies to expand their vision by embracing founder's mentality and making PE work to their advantage. ■

Read entire interview on https://chemtech-online.com/

INTERVIEW

"We see healthy demand for high-quality biologics manufacturing capacity from sectors ranging from large pharma to emerging biotech companies."

Dr Mahesh Bhalgat
COO, Syngene International

Dr Mahesh Bhalgat *talks about the emerging trends and opportunities for the Contract Research, Development and Manufacturing Organization (CRDMO) market. He also spoke about plans for manufacturing services, development services, and discovery services segments and capacity expansion for Hyderabad facility.*

What are emerging trends and opportunities do you see for the Contract Research, Development and Manufacturing Organization (CRDMO) market?

Historically, biotech and pharma companies worked with Contract Research Organizations (CROs) or Contract Development and Manufacturing Organizations (CDMOs) to execute relatively simple (distinct) pieces of work as part of their total value chain. However, there has been a distinct shift in the characteristics of those relationships in recent times. Biopharma companies in the West increasingly seek partners who can provide comprehensive solutions, innovation, and a deep understanding of the pharmaceutical landscape. While remaining cost competitive is still important, it's clear that pharma and biotech companies are placing more emphasis on the intellectual capital that comes with partnering with CRDMOs like Syngene.

With the learnings from the pandemic, many pharma and biotech companies have recognized the need to strengthen their supply chain resilience. Companies are now more inclined to partner with CRDMOs balancing geopolitical risk, enhancing flexibility, and optimizing costs while ensuring reliable supplies.

The emergence of newer modalities, such as mRNA and DNA vaccines and the growing focus on personalized medicine, including gene and cell therapies, have created new opportunities for CRDMOs. The increasing complexity of regulatory requirements poses challenges for pharmaceutical and biotechnology companies.

There is also an increasing trend of CRDMOs fostering strategic collaborations with academic institutions that enable knowledge sharing, access to specialized capabilities, and the development of innovative solutions. Pharma-biotech companies also seek to partner with CRDMOs that can integrate advanced technologies, such as artificial intelligence (AI), machine learning, automation, and data analytics.

Brief us about the capacity expansion for the Hyderabad facility?

The ongoing expansion at the Hyderabad facility is part of Syngene's broader growth and expansion strategy. Hyderabad allows Syngene to leverage the city's favorable ecosystem, attract top talent, and enhance its research capabilities to meet the increasing demand for research services. The facility, inaugurated in 2020, is now spread across 200,000 sq. ft and accommodates ~900 scientists.

As part of the expansion, we have established a specialized capability for proteolysis-targeting chimeras (PROTACs), a class of therapeutics growing in prominence for conducting research in cancer treatments and other therapeutic areas. PROTACs is a targeted protein degradation technology that enables unique therapeutic interventions for challenging targets.

The company also commissioned a new automated compound management facility in Hyderabad.

The facility serves as critical infrastructure in the drug discovery program in Hyderabad and provides efficient compound sourcing, storage, handling, distribution and data management services. It enables our scientists to access diverse compounds, maintain their quality and integrity, and streamline the entire drug discovery process. Gradually, we also plan to extend scientific capabilities across multiple disciplines to Hyderabad. Our vision is to offer twin-site capabilities and strengthen Syngene's position as a leading service provider for fully integrated therapeutic discovery.

What are your plans for manufacturing services, development services, and discovery services segments?

Integrated drug research: As the demand for new and novel drugs continues to rise, Syngene sees significant growth potential in the manufacturing, development, and discovery services segments. Syngene's proprietary platform, SynVent, is designed to offer integrated services that streamline the R&D process for clients working on target validation, translational interrogation, therapeutic discovery, and preclinical development of both large and small molecules. We expect SynVent to become the R&D engine for emerging biopharma companies and significantly contribute to the process of bringing new compounds to the clinic.

Discovery Services: The global drug discovery market valued at US$ 55.46 billion in 2022 is expected to be worth around US$ 133.11 billion by 2032, growing at a CAGR of 9.2% from 2023 to 2032, according to Precedence Research. The company continue to see good demand for chemistry and biology as many of our Western clients work to recover from lost time during the pandemic. Syngene is well-positioned to capitalize on this growth opportunity by driving integrated drug discovery solutions, commitment to continued investment in differentiating capabilities, technologies and platforms and expanding laboratory space.

Syngene is committed to integrating advanced technologies, such as artificial intelligence (AI), machine learning, automation, and data analytics, to enhance operational efficiency, accelerate drug discovery processes, and improve quality control. Syngene's proprietary AI platform Syn.AI significantly contributes to various drug discovery programs. The platform integrates and learns from diverse chemical, biological and clinical data to provide better and faster outcomes and helps identify effective targets for a disease area and reduces the risk of later-stage failure for efficacy or safety reasons.

Development Services: The core strength of the company's development services capabilities is our ability to provide integrated chemistry manufacturing control (CMC) services. By vertically integrating CMC activities, we are hopeful of achieving greater control, efficiency, and coordination throughout the drug development process. We continue to focus on providing our clients with a comprehensive range of services, including clinical manufacturing and conducting clinical trials all the way to late-stage clinical development. Syngene continues to build capabilities critical for product and process development. For example, we recently commissioned a state-of-the-art sterile fill-finish facility to meet market demand for clinical supplies of sterile drug products with short development timelines. We also signed a commercial agreement to acquire additional reactors to expand our nGMP capabilities.

Manufacturing Services: Manufacturing Services saw remarkable growth last year, primarily driven by our commercial-scale biologics manufacturing business. Our long-term partnership with Zoetis and the successful USFDA, MHRA and EMA regulatory inspections of our biologics facilities have laid a robust foundation for future success. We see healthy demand for high-quality biologics manufacturing capacity from sectors ranging from large pharma to emerging biotech companies. Operationally the focus remains on optimizing capacity and building new capacity for future client demand. Recently, we signed a binding agreement with Stelis Biopharma for Rs. 700 Cr to acquire a multi-modal facility that adds 20,000 liters of installed biologics drug substance manufacturing capacity, with scope for further expansion, and a high speed, commercial scale, fill-finish unit, to our existing capacity. We expect this facility to be operational in 2024 after completing a program of facility upgrades, re-validation, and adding to our growing biologics manufacturing business. This acquisition strengthens our growing position as a leading biologics contract development and manufacturing service provider and adds drug substance capacity and a drug product capability.

What were the major drivers for the growth in the last financial year – FY23?

Our revenue performance has been positive, and we are setting a new trajectory that bodes well for the Company. Notably, all our business divisions witnessed evolution and growth, contributing to our overall success.

Discovery Services has had a particularly strong year, with sustained growth in chemistry playing a pivotal role. We have made significant progress in Development Services, improving our operating performance and translating into repeat orders from our existing clients. Manufacturing Services has seen good growth, primarily driven by our commercial-scale biologics manufacturing business. Our long-term partnership with Zoetis and the successful regulatory inspections of our biologics facilities have laid a robust foundation for future success. Looking ahead, we maintain an optimistic outlook despite the challenges posed by inflation, geopolitical uncertainties, and recessionary pressures in certain regions. Our performance over the past year and the strategic development of the Company position us favorably for the year ahead.

During the year, we continued to invest in building capacity. For eg. Syngene commissioned a PROTACs facility at Hyderabad, which is part of Syngene's novel drug discovery strategy for clients involved in cancer research. We also added a kilo lab for enhancing the delivery of materials during preclinical development. In Bangalore, a new R&D facility for peptide-oligonucleotides and a yeast display facility help expand our technology offerings. The state-of-the-art sterile clinical scale fill-finish facility commissioned has added to the end-to-end capability we offer in development services.

How do you see the demand in US and Europe from clients?

We continue to see good demand in the client markets of US and Europe, which combined with strong execution and forward planning. Baxter, BMS, and Amgen are exemplary collaborations, with dedicated facilities on our premises managed and operated by Syngene. As a strategic partner, we work seamlessly with their internal scientific teams, delivering innovative, flexible, and efficient solutions at scale. For instance, BMS' largest R&D facility outside the USA is in Bangalore, employing over 700 Syngene scientists as part of their global R&D network. Our ability to provide equal scientific expertise and innovative solutions often leads to longer contract durations. We also extend our partnerships to small and medium-sized biotechs, supporting them through various regulatory milestones.

Brief us about your investments in biologics manufacturing?

Over the past three years, we have made sustained investments in our state-of-the-art microbial and mammalian biologics facilities, advanced technologies and highly skilled professionals. The 10-year deal, worth up to $500 million, which we signed with Zoetis, a leading animal health company, is a significant milestone in our biologics journey. We see healthy demand for high-quality biologics manufacturing capacity from sectors ranging from large pharma to emerging biotech companies and veterinary organizations.

The successful inspection of our biologics facilities by thein FY23 is a testament to our robust systems and processes that ensure compliance with global regulatory standards and our commitment to consistently delivering safe and effective biologics. We have also completed the adoption of eBMR (electronic batch manufacturing records) as part of the Industry 4.0 initiative to track and monitor production throughout manufacturing. As the demand for biologics continues to grow, we remain committed to further expanding our capabilities and staying at the forefront of innovation in this field. ■

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