VOL 22 | ISSUE 4 | NOVEMBER 2023 | MUMBAI | TOTAL PAGES 40 | PRICE ₹ 150

www.jasubhaimedia.com

# PharmaBio World

INSIGHT INTO THE PHARMACEUTICAL AND BIOTECH INDUSTRIES

## BIOPHARMA PROCESSING: INNOVATIVE SOLUTIONS



Jasubhai MEDIA

**PTFE LINED SYSTEMS**
VALVES | PIPES | FITTINGS | COATINGS

| PTFE | PFA | FEP | ETFE
| PVDF | ECTFE | PP | HDPE

www.ptfeindia.com

HI-TECH®
APPLICATOR
a Global Trusted Brand

# YOUR SUSTAINABLE BUSINESS PARTNER
IN FLUOROPOLYMER LINED PRODUCTS SINCE 1994

## LINED VALVES

## LINED PIPES

## LINED FITTINGS

## FLUORO-POLYMER HEAT EXCHANGER

Material options available on customer request from world renowned fluoropolymer suppliers

Chemours™ | dyneon 3M | AGC Fluon | SOLVAY asking more from chemistry® | DAIKIN | GFL™


**HI-TECH APPLICATOR**
1102-B, Phase-3, G.I.D.C. Ind. Estate, Vatva, Ahmedabad - 382 445, Gujarat - India.
+91 79 4030 7621 / 2583 3040 / 2589 1740 | +91 97370 46491 | hitech@ptfeindia.com


ISOQAR REGISTERED | UKAS MANAGEMENT SYSTEMS | CE | ASTM F-1545 | D&B

HORIZON POLYMER

www.horizonpolymer.com

# India's Largest Processor of **FLUOROPOLYMERS**



**Valves qualified ISO 15848-Part 1.**

**Pipework qualified ASTM F 1545**

**Chemours Co FC LLC - Delaware appoints Horizon Polymer as TEFLON® Licensing Partner for India Under Trademark license agreement to promote and sell PTFE/PFA/FEP Lined Piping products using TEFLON® PTFE/PFA/FEP Fluoropolymer.**

TEFLON and Teflon diamond brand logo are registered trademarks of The Chemours Company FC, LLC used under license by Horizon Polymer Engineering Pvt. Ltd.

**Horizon Polymer Eng Pvt. Ltd.:**
204, Sumer Kendra, Pandurang Bhudhkar Marg, Worli, Mumbai - 400018. India
**Contact:** +91 22 24965031-36 I **Fax:** +91 22 24961073
Email: **vp@horizonpolymers.com**

**PHARMA BIO WORLD**
**R.N.I. No.: MAHENG/2002/08502**

**CHAIRMAN**
Maulik Jasubhai Shah

**PUBLISHER & CEO**
Hemant K. Shetty

**EDITOR**
Mittravinda Ranjan

**SUB EDITOR**
Yash Ved

**CREATIVES**
Arun Parab

**GENERAL MANAGER SALES**
Amit Bhalerao
Prashant Koshti

**BRAND MANAGER**
Sudhanshu Nagar

**SALES**
Godfrey Lobo
Chandrahas M Amin
Yonack Pradeep



Single Copy Price: ₹ 150/-
Annual Subscription: ₹ 1620/-, Foreign: USD 180

**PLACE OF PUBLICATION**
**JASUBHAI MEDIA PVT. LTD.**

210, Taj Building, 3rd Floor, Dr. D. N. Road, Fort, Mumbai 400 001, Tel: +91-22-4037 3636

**Registered Office:** 26, Maker Chambers VI, 2nd Floor, Nariman Point, Mumbai 400 021, INDIA.
Tel.: 022-4037 3737 Fax: 022-2287 0502
E-mail: sales@jasubhai.com

Printed and published by Mr Hemant K. Shetty on behalf of Jasubhai Media Pvt. Ltd., 26, Maker Chamber VI, Nariman Point, Mumbai 400 021.

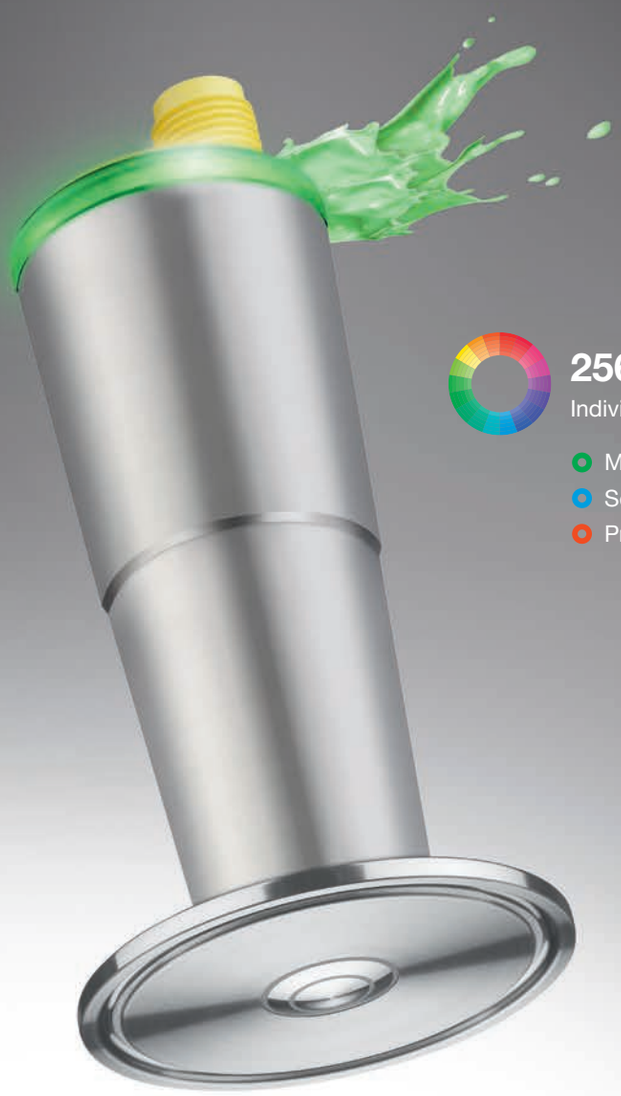
Printed at The Great Art Printers, 2 5, S A Brelvi Road, Fort, Mumbai 400 001.

Published from 3rd Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001.

Editor: Ms. Mittravinda Ranjan, 3rd Floor, Taj Building, 210, Dr. D N Road, Fort, Mumbai 400 001.

# We bring colour into view!

**Compact capacitive level switches with 360° custom-colour status display**



**256 colours**
Individually selectable:

- Measurement in progress
- Sensor switching
- Process malfunction

Hygienic adapter system

IO-Link

Adjustment via smartphone

Completely flush sensing element
Works on pastes and viscous media
No spray cleaning shadows
Very small installation dimensions

VEGA India Level and Pressure Measurement Pvt. Ltd.

Phone: +91 20 6731 4000
Email: sales.in@vega.com

**www.vega.com/vegapoint**

VEGA HOME OF VALUES

# CONTENTS

## INTERVIEW



## FEATURES



## AD INDEX

seal.tech

# sealmatic®

# MECHANICAL SEALS

Oil & Gas
Refinery
Petrochemical
Chemical
Power
Fertiliser
Pharmaceutical
Paper
Aerospace
Marine


**Sealmatic India Ltd.**
Bldg A, Indiplex IV, Survey No-12, Hissa No-9A,
Village Ghodbunder, Shanti Vidya Nagri Road,
Mira Road (E). Thane - 401104. India.

T : +91 22 50502700
E : info@sealmaticindia.com


TÜVRheinland®
European Directive 97/23/EC
QS-System (Module H)

TÜV INDIA
CE Ex II 3 G/D c T2
ATEX - 2014/34/EU

UKAS MANAGEMENT SYSTEMS
ISO 9001:2008
ISO 14001:2004
BS-OHSAS 18001:2007

Q1 API Spec Q1 Registered

sealmaticindia.com

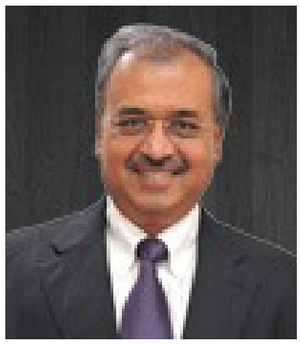
## Dr. Raghuvanshi emphasizes critical aspects of pharmacopoeia standards and quality considerations


**New Delhi, India:** Dr. Rajeev Singh Raghuvanshi, Secretary cum Scientific Director at the Indian Pharmacopoeia Commission (IPC) highlighted the importance of updating the industry in collaboration with global regulator and emphasises the critical aspects of pharmacopoeia standards and quality considerations, stressing that it is the industry's responsibility to execute the provisions of IPC 2022 and timely implementation of the revised Schedule M notification.

The Association of Devbhumi Pharma Industries, Uttarakhand, hosted an interactive meet held at Haridwar, which brought together pharma professionals managing quality, regulatory and manufacturing functions to discuss vital topics related to pharmacopoeia standards, quality considerations, and the revision of Schedule M. The event was graced by Dr. Rajeev Singh Raghuvanshi and Drug Controller General of India (DCGI), Central Drugs Standard Control Organization (CDSCO) as the Chief Guest and Tajber Singh, Drug Controlling and Licensing Authority, Uttarakhand as the Guest of Honor. Sandeep Jain, Chairman of ADPI and Joint Director of Akums Drugs & Pharmaceuticals Limited, facilitated the event and welcomed the dignitaries and delegates for their gracious presence.

Delhi Pharmaceutical Sciences and Research University (DPSRU), Govt. of N.C.T of Delhi, and Akums Drugs & Pharmaceuticals Limited also embarked on a collaborative journey to research on specific therapy-gaps and introduce novel products for Indian patients. This Industry-Academia partnership will also enhance pharmaceutical education and research opportunities for DPSRU students. The Memorandum of Understanding (MoU) sealing this partnership was signed by Dr Harvinder Popli (Registrar & Dean - DPSRU) and Arushi Jain ([Director – Akums).

## Sun Pharma Q1 net profit stood at ₹ 23,755 million



Dilip Shanghvi, MD, Sun Pharma

**Mumbai, India:** Sun Pharmaceutical Industries Limited reported financials for the second quarter ending September 30th, 2023. The company's gross sales stood at ₹ 120,031 million, growth of 11.0% as against Q2 last year. The company's India formulation sales stood at ₹ 38,425 million, up 11.1% as against Q2 last year, while US formulation sales stood at USD 430 million, up 4.2% as against Q2 last year. The company's net profit for the quarter was at ₹. 23,755 million, up 5% YoY . The company's R&D investments stood at ₹. 7,734 million (6.4% of sales) as compared to ₹. 5,710 million.

Dilip Shanghvi, Managing Director, Sun Pharma said, "US FDA's acceptance of deuruxolitinib NDA for treatment of moderate to severe alopecia areata marks an important milestone. There are limited treatment options for alopecia areata and deuruxolitinib should make a meaningful difference in patient lives, once approved. Similarly, another late stage candidate Nidlegy will potentially complement our Odomzo franchise. Nidlegy's recent positive phase-3 data in patients with locally advanced fully resectable melanoma positions us to provide patient solutions across a broad spectrum of skin cancer. "

## Lupin Q2 gross profit stood at ₹.32,365 mn

Nilesh Gupta, MD, Lupin

**Mumbai, India:** Pharma major Lupin Limited reported its financial performance for the quarter ending September 30, 2023. The company's Gross Profit was ₹. 32,365 mn compared to ₹. 31,013 mn in Q1 FY2024, while manufacturing and other expenses were 31.4% of sales at ₹. 15,520 mn compared to ₹. 14,724 mn in Q1 FY2024.The company's India sales

# LINED PIPES & FITTINGS SOLUTIONS
## FOR CORROSIVE APPLICATIONS

**UNPPolyvalves**

Manufacturer of PFA/FEP/PTFE Lined & Plastic Valves,
Pipes & Pipe Fittings


**SIZE RANGE**
½" to 24"

**PIPES**
ASTM A 106 Gr. B SCH 40
SA 312 TP 304
SA 312 TP 316

**LINING OPTIONS**
PTFE
ANTISTATIC PTFE #
PFA
FEP
ANTISTATIC PFA #
PVDF

**FLANGES**
ASTM A 105
IS 2062
SA 182 F 304
SA 182 F 316

**FITTINGS**
ASTM A 234 WPB
SA 403 WP 304
SA 403 WP 316

**CASTINGS**
ASTM A 216 GR.WCB
ASTM A 351 GR.CF8/CF8M

# CONDUCTIVE

inhouse

**VADODARA - OFFICE & FACTORY**

5 to 12 PR Industrial Estate, Por GIDC - Kashipura Road,
Moje : Kashipura - 391 243, Dist. Vadodara. INDIA
Phone: +91 70434 30467/77, 70430 20707
Email : sales.baroda@polyvalve.com

**MUMBAI - THANE**

207, Orion Business Park, Next to Cine Max, Kapurbawdi,
Ghodbunder Road, Thane (W) - 400 607. INDIA.
Phone: +91 22 2589 6422, 2589 6524 /25
Email : sales.thane@polyvalve.com

www.polyvalve.in
www.polyvalve.com

for Q2 FY2024 were ₹. 16,915 mn, up 3.2% as compared to ₹. 16,384 mn in Q1 FY2024; up 6.8% as compared to ₹. 15,841 mn in Q2 FY2023; and accounted for 34% of Lupin's global sales.

Nilesh Gupta, Managing Director, Lupin Limited said, "We delivered growth across all our target geographies, while managing costs and achieving operating leverage, thereby driving strong topline and bottomline growth. The U.S. launch of Tiotropium DPI was the highlight of the quarter, making inhalation a substantial portion of our U.S. sales. Our India business continues to do well, with growth in our target therapies ahead of market. We are also making progress on our goal of becoming best in class in quality and compliance with both our Nagpur-1 and Mandideep-2 facilities received satisfactory inspection closures".

## Strides announces sale of manufacturing facility in Singapore

Arun Kumar, Executive Chairperson & MD, Strides Pharma

**Bangalore, India:** Strides Pharma Science Limited announced that its step- down wholly owned subsidiary, Strides Pharma Global Pte. Limited, Singapore, has entered into a binding agreement with Rxilient Biohub Pte. Ltd. (Rxilient Biohub) for the sale of its manufacturing facility including licenses, equipment, vendor contracts, etc. for a total cash consideration of USD 15mn. As part of the transaction, Rxilient Biohub will also take over the long term lease obligation of the manufacturing site from Strides.

This transaction is the culmination of the manufacturing network optimization efforts as we continue to focus on driving profitability and operational efficiency. This sale will help further reduce annual costs by USD 9m (~ ₹750 mn), of which USD 2mn (~₹180 mn) reduction in operating expenses ( EBITDA accretive) and USD 7mn (~₹570 mn) in Depreciation and operating lease expenses, thereby being immediately accretive to EPS ( annualized ~ ₹ 7/share). The transaction is expected to close in Q3FY24 on receipt of necessary approvals and completion of customary & other closing conditions. Proceeds from the transaction will be utilized for debt reduction.

## Biocon Biologics announces divestment of two non-core branded formulations business units in India

Shreehas Tambe, CEO & MD, Biocon Biologics

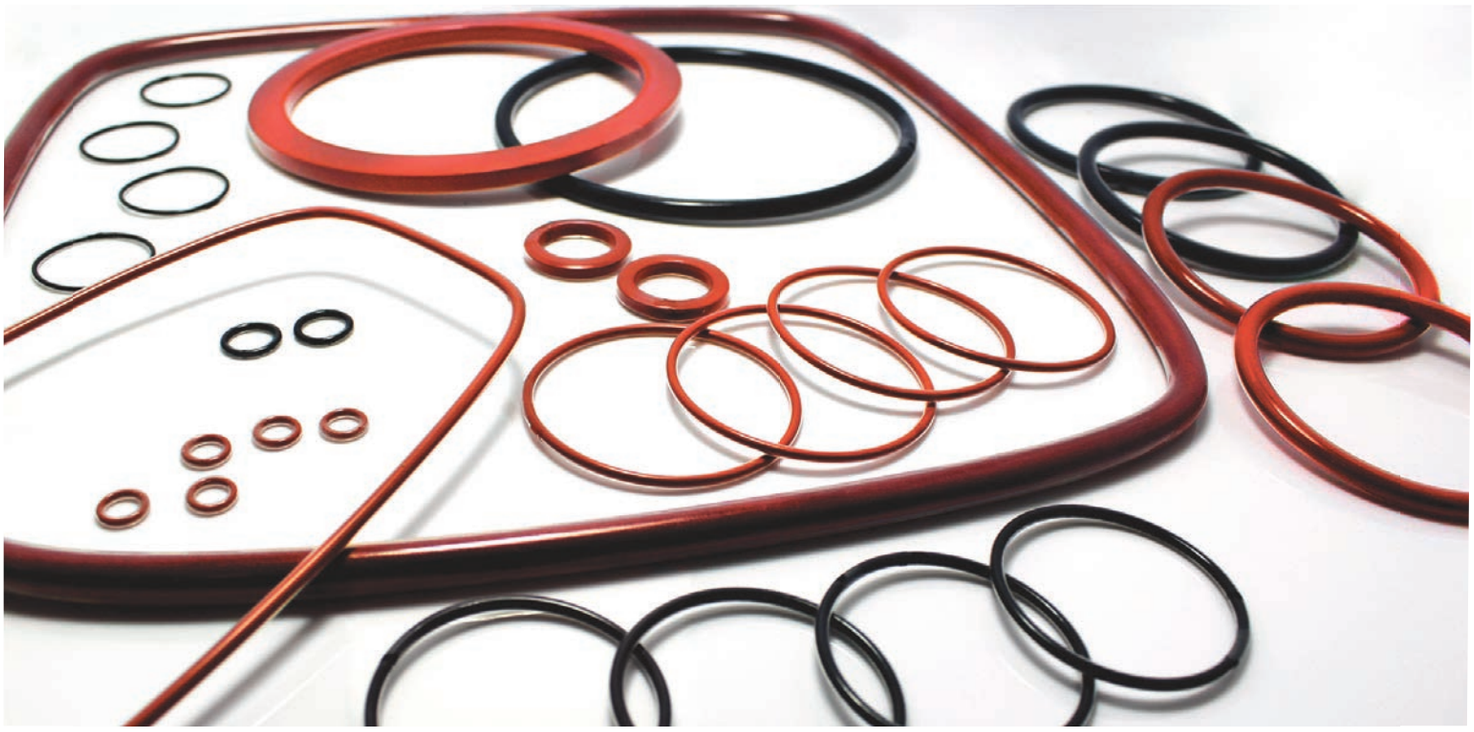
**Bengaluru, Karnataka, India:** Biocon Biologics has entered into a definitive agreement with Eris Lifesciences (Eris) for the divesture of its Dermatology and Nephrology branded formulations business units in India that mostly comprised of its legacy small molecules' brands. The transaction is a 'Slump Sale' that will enable a seamless transfer of the product brands and employees associated with these businesses. The total transaction value of the divestment is ₹ 3,660 million, inclusive of working capital conveyed as part of the deal, and represents an accretive multiple of 4x on Revenues and 22x on EBITDA. Post deal close, over 120 employees of the two business units are expected to transition to Eris, ensuring continuity for both employees and patients

The divestiture is expected to close by the end of Nov 2023, subject to customary closing conditions. The divestment of the non-core branded formulations business units in India is in line with BBL's strategy. This is to sharpen focus on core therapy areas as a fully integrated biosimilars company. Shreehas Tambe, CEO & Managing Director, Biocon Biologics, said: "This divesture of non-core assets allows Biocon Biologics to unlock value within our Branded Formulations portfolio in India and sharpen focus on our core therapy areas like Diabetes, Oncology and Immunology. We believe that Eris Lifesciences is well positioned to build further on the Dermatology and Nephrology franchise in India. Biocon Biologics remains committed to a successful transition of employees of these business units, our product brands, and customers to ensure continuity for patients."

Commenting on the acquisition, Amit Bakshi, Chairman & Managing Director of Eris Lifesciences Ltd., said: "We have successfully demonstrated our ability to turn around and create value in acquired businesses. The acquisition of Biocon Biologics' Nephrology and Dermatology Branded Formulations businesses in India is in-line with our strategic goals as well as our capital

KAF SEAL INC.

Website : +91 9323684474, 7400050022
Email : kasfseals@live.in
www.kal.vulcanindia.com



## Rotary Equipment Pumps, Valves, Pipes & Fittings

### What is Encapsulated O-rings ?

An Encapsulated 'O'-Ring combine the energizing properties of an elastomeric 'O'-Ring with the resilience to extreme temperatures and hostile chemicals of FEP/PFA.

### Encapsulated O-rings

- Universal seal for any application
- Low coefficient of friction allowing reduced wear of equipment & seal itself
- Aggressive media / temperatures doesn't influence O-ring performance
- High Thermal stability & resistance to corrosion
- Chemical and temperature resistance of PTFE
- Non contaminating
- Temp: -60 to 260 Deg Cel.
- 3-A Sanitary, USP Class VI , FDA Regulation 21.CFR.177.1550, BSE/TSE , EU VO 1935/2004
- Cost efficient alternative to Kalrez® and similar perfluoroelastomer 'O'-Rings
- Applications

▪ Pumps and valves ▪ Chemical reactor vessel
▪ Pressure vessels ▪ Gas compressors ▪ Gas service
▪ Butterfly valves ▪ Air operated vents ▪ Flowmeter
▪ Vacuum service

### Conventional O-rings

- Maintain huge inventory for multiple MOC
- High friction leads to damage O-rings resulting into product contamination /recall.
- Aggressive media / temperatures influence poor performance
- Poor thermal stability & susceptible to corrosion
- PTFE O-ring wouldn't have the flexibility you need for compressive fluid sealing
- Contaminating
- Temp: -20 to 150 Deg Cel.
- Only FDA
- . Industry

▪ Chemical Process ▪ Oil refinerie ▪ Photochemical
▪ Polymer Production ▪Dye and Paint manufacture

**• Embrace Excellence - Service, Quality and Value •**

allocation framework. We are very happy to welcome domain experts in Nephrology and Dermatology from Biocon. I look forward to all of us working together to build a large franchise that will deliver immense value to patients. I am confident that this acquisition will deliver value to shareholders in line with the deals we have done in FY23 and prior."

## Dr. Reddy's Laboratories Q2 revenue stood at ₹ 68,802 mn

G V Prasad, Co-Chairman & MD, Dr. Reddy's Laboratories

**Hyderabad, India:** Dr. Reddy's Laboratories Ltd. announced its consolidated financial results for the quarter ended September 30, 2023. The company's revenues stood at ₹. 68,802 mn, while Profit after Tax was at ₹.14,800 mn. The company's Global Generics (GG) Q2 FY24 revenue stood at ₹. 61.1 billion, YoY growth of 9% and QoQ growth of 2%. This growth was primarily driven by North America and Europe, while the company's North America Q2 FY24 revenue was at ₹. 31.7 billion, YoY growth of 13% and QoQ decline of 1 %. The company's Q2 FY24 revenue from Emerging Markets at ₹. 12.2 billion, YoY decline of 1 % and QoQ growth of 5%. The company's Pharmaceutical Services and Active Ingredients (PSAI) for Q2 FY24 revenue stood at ₹. 7.0 billion, with a growth of 9% YoY and 5% QoQ. YoY growth was mainly driven by new product launches, favorable move from foreign exchange partly offset with price erosion.

Commenting on the results, Co-Chairman & MD, G V Prasad said: "We delivered another quarter of strong results with highest ever sales and profits, driven by market share gains & momentum in our US generics business and robust growth in Europe. We are continuing to strengthen our pipeline both organically and through business development to drive growth and create differentiation." The company's Capital expenditure for Q2 FY24 was at ₹. 3.2 billion.

## Cipla Q2 net profit up 43%

Umang Vohra, MD & Global CEO, Cipla Ltd

**Mumbai, India:** Cipla Limited announced its consolidated financial results for the second quarter ended September 30th, 2023. The company's income from operations for Q2 stood at ₹.6678 crore, up 14.6% YoY, while net profit after tax stood at ₹ 1131 crore, up 43.4% YoY. The company's R&D investments stands at ₹.379 crore or 5.7 % of sales, higher by 13% YoY driven by continued progress of clinical trials on key pipeline assets. The company's North America Quarterly revenue scales to USD 229 mn driven by 28% YoY growth and QoQ growth of 3%; strong momentum continues with key milestones achieved across multiple pipeline assets, While strong balance sheet health continues with a robust net cash position of ₹. 5,850 crore.

"Pleased to share an exceptional set of results reflecting the strength of our core business across key markets of India, North America and South Africa. We reported our highest ever quarterly revenue with EBITDA margins scaling up to 26%. One-India business grew at a healthy 10% YoY with continued market beating performance in the branded prescription and trade Generics business. In South Africa, the private market business grew in double digits driven by strong execution across prescription and OTC. The North America business scaled up to USD 229 mn, growing 28% YoY, driven by strong traction across core products with share expansion in differentiated assets. Our pipeline is progressing really well with key milestones achieved in respiratory and Peptide assets. We will continue our focus on driving profitable growth across businesses, stated Umang Vohra, MD and Global CEO, Cipla Ltd.

## Torrent Pharma Q2 net profit rises 24%

**Mumbai, India:** Torrent Pharma has posted results for the second quarter ended 30th September 2023.The company's revenue stood at ₹ 2,660 crores up by 16%, while Net profit after tax was at ₹. 386 crores up by 24%. The company's India revenue stood at ₹ 1,444 crores grew by 18%, while Brazil revenue at ₹ 252 crores, was up by 36%. The company's Germany revenue stood at ₹ 266 crores was up by 21%, while US revenue at ₹ 248

HRS
process systems

# MOST EFFICIENT HEAT TRANSFER EQUIPMENT FOR PHARMA INDUSTRY.

Our association with the pharmaceutical industry is built on the solid premise of technological competence. Our heat transfer innovations like **ECOFLUX*** corrugated tube heat exchangers, **HRS FUNKE** Plate Heat Exchangers & compact skid based HE systems continue to be the trusted choice of major leading pharma companies in key applications.

**ECOFLUX***
Corrugated Tube Heat Exchanger

**HRS** Heat Exchanger
Based Systems

**HRS FUNKE**
Plate Heat Exchanger

**HRS Process Systems Ltd.**
201/202 Karan Selene, 851, Bhandarkar Institute Road,
Pune 411 004, Maharashtra - India
Ph. : +91-20-2566 3581/6604 7894 & 95 | Fax :+91-20-2566 3583
info@hrsasia.co.in | www.hrsasia.co.in

TÜV NORD ISO 9001

ASME 'U' Stamp Certified Company

crores, was down by 15%. The company's Dahej facility has received EIR which paves way for the new product approvals. As on September 30, 2023, 41 ANDAs were pending approval with USFDA and 3 tentative approvals were received. During the quarter, 1 ANDA was approved. Torrent Pharma, with annual revenue of more than ₹ 9,600 crores, is the flagship Company of the Torrent Group, with group revenue of more than ₹ 37,000 crores. It is ranked 6th in the Indian Pharmaceuticals Market and is amongst the Top 5 in the therapeutics segments of Cardiovascular (CV), Gastro Intestinal (GI), Central Nervous System (CNS), and Vitamins Minerals Nutritionals (VMN) and Cosmo-Dermatology.

## Glenmark Pharma Q2 consolidated revenue up 6.3%

Glenn Saldanha, CMD, Glenmark Pharmaceuticals

**Mumbai, India:** Glenmark Pharmaceuticals Ltd, a research led, global pharmaceutical company, announced its financial results for the second quarter ended Sept 30, 2023. For the second quarter of FY 2023-24, Glenmark's consolidated revenue was at ₹. 35,879 Mn as against ₹. 33,752 Mn recording an increase of 6.3% YoY. The Adjusted EBITDA was at ₹. 6,732 Mn in the quarter ended Sept 30, 2023 as against ₹. 6,216 mn in the previous corresponding quarter, registering an increase of 8.3% YoY, and margins of 18.8%.

Glenn Saldanha, Chairman & Managing Director, Glenmark Pharmaceuticals Ltd., "We maintained strong growth momentum during the quarter that was led by Europe and the RoW markets. We continue to take strides and move up the value-chain with the in-licensing of Winlevi for Europe and South Africa. The recently announced proposed divestment of 75% stake in Glenmark Life Sciences is another step in this direction. Our first global brand, Ryaltris, has demonstrated robust growth across the 29 markets in which it is already present. Our partner in China successfully completed the Phase 3 clinical trial on Ryaltris; with the product meeting the primary endpoint. We are expecting to launch it in newer markets over the course of the year.

The company's sales from the formulation business in India in Q2 FY 2023-24 was at ₹. 11,217 mn as against ₹. 10,916 mn in the previous corresponding quarter, recording growth of 2.8% YoY, while North America registered revenue from the sales of finished dosage formulations of ₹. 7,392 mn for the quarter ended Sept 30, 2023, as against revenue of ₹. 7,533 mn for the previous corresponding quarter, recording decline of 1.9% YoY.

## Piramal Pharma Q2 revenue from operation up 11%

Nandini Piramal, Chairperson, Piramal Pharma Limited

**Mumbai, India:** Piramal Pharma Limited, a leading global pharmaceuticals company, announced its consolidated results for the second quarter ended 30th September 2023. In Contract Development and Manufacturing Organization (CDMO) business, the company's Good revenue growth visibility for FY24 was driven by better execution and healthy demand for our differentiated offering. Recent order inflows have had higher quotient of innovation related work with good proportion of commercial manufacturing order for on-patent molecules. The company witnesses steady growth on our CHG business primarily on account of healthy volume led growth in Inhalation Anesthesia (IA) products. The company's revenue from Operation grew by 11% YoY and 14% YoY in Q2FY24 and H1FY24 respectively, driven by broad base performance across all the three businesses.

Nandini Piramal, Chairperson, Piramal Pharma Limited said, "We have delivered a healthy performance in the first half of the financial year with 14% revenue growth accompanied by over 300 bps improvement in EBITDA margin. Our CDMO business returned to mid-teen growth with continued order inflows, especially for differentiated offerings and innovation related work. Our capacity expansion for inhalation Anesthesia products is progressing well as we look to capitalize on the healthy demand in the global market. Our India Consumer Healthcare business is delivering steady growth driven by our power brands. Historically, our H2 has been better than H1, both in terms of revenue and profitability. We expect similar trend to play out this financial year as well, more specifically in Q4.

## Supriya Lifescience signs agreement with Kalinga Institute of Industrial Technology


Dr. Satish Wagh, Founder and Chairman, Supriya Lifescience Ltd

**Mumbai, India:** Supriya Lifescience, one of India's leading speciality active pharmaceutical ingredients (API) manufacturing company and CDMO signed an agreement with Kalinga Institute of Industrial Technology for further development of GelHeal, a protein-based crosslinked Hydrogel. The gel-based cream is mapped out and designed taking into account the In-Situ scaffolding for mechanical support into the deep wounds and scar-free skin regeneration. The gel-based cream may prove to be prolific in easing and healing not only third-degree wounds, cuts, bite/ballistic wounds but also diabetic foot ulcer, pressure ulcer, venous leg ulcer and surgery wounds.

Dr. Satish Wagh, Founder and Chairman, Supriya Lifescience Ltd says, "As we have already demarcated positive change by recently signing an agreement to develop Quickblue which is the oral cancer detection kit in collaboration with Kalinga Institute of Industrial Technology, we are looking forward in aiding more innovative products like GelHeal, the simplest and cheapest wound healing gel". Dr. Satish Wagh further said, "Supriya Lifescience has established itself as a CDMO player over decades, Supriya Lifescience is putting a step forward into diversification of our business by banking on our world-class CDMO capabilities and offering niche products for healthcare needs. We believe more and more of such products will establish Supriya Lifescience Ltd as an integrated healthcare provider."

## RPG Life Sciences Q2 revenue from operations up 14%


Yugal Sikri, MD, RPG Life Sciences Ltd

**Mumbai, India:** RPG Life Sciences, engaged in the manufacturing and marketing of pharmaceutical products, posted a jump in PBT by 29% Y-o-Y and by 17% Q-o-Q for Q2 FY24, maintaining the upward trajectory in EBITDA margins, which improved from 23.0% to 25.5% Y-o-Y and Q-o-Q. The company's revenue from operations at ₹ 153.58 crore registered a growth of 14% Y-o-Y and a growth of 4% Q-o-Q for Q2 FY24. For H1 FY24 too, the company posted a jump in PBT by 29% Y-o-Y and recorded EBITDA margin expansion from 22.8% to 24.3% Y-o-Y. The company's revenue from operations stood at ₹ 301.36 crores registered a growth of 14% Y-o-Y for H1 FY24. Yugal Sikri, Managing Director, RPG Life Sciences Ltd. said, "In Q2 FY24, the overall performance of the Company continued to be strong. Revenue and PBT grew by 14% and 29% respectively Y-o-Y. EBITDA margin retained its 5-year long upward trajectory growing from 23.0% to 25.5% Y-o-Y.

The company continues to remain debt-free. Domestic Formulations business, the biggest contributor to the Company's business, recorded robust growth both in value and volume - significantly and consistently ahead of the market. While our comprehensive life cycle management program for legacy brands is helping them register healthy growth and become bigger brands, our new product portfolio comprising of newer and progressive segments is also shaping new therapies and product portfolio. Our foray into Rheumatology has strengthened our Specialty segment.

## Ajanta Pharma Q2 net profit up 25%

**Mumbai, India:** Ajanta Pharma Ltd. a specialty pharmaceutical formulation company reported its performance for second quarter ended 30th September 2023. The company's Revenue from operations at ₹ 1,028 crore as against ₹. 938 crore.; up 10%, while Profit after tax at ₹. 195 crore as. against ₹. 157 crore.; up 25%; PAT at 19%. Ajanta Pharma is a speciality pharmaceutical formulation company having major focus on branded generic business across India, Asia & Africa. Company has ground presence in each of these 30+ countries.


Mannalal Agrawal, Chairman, Ajanta Pharma

Many of company's products are 1st to market and are leading in their sub-therapeutic segments. This business contributes 73% in total revenue. The Company's state of the art R&D centre is located in Mumbai. Company has 7 world class manufacturing facilities located in India. For last 5 financial year, company has posted healthy performance with its Revenue from Operations growing at 16% CAGR and net profit at 11% CAGR.

## Zydus Lifesciences to acquire LiqMeds Group


Dr. Sharvil Patel, MD, Zydus Lifesciences

**Mumbai, India:** Zydus Lifesciences Limited, a discovery-driven, global lifesciences company, through its wholly owned subsidiary Zydus Pharmaceuticals UK Limited, announced the acquisition of the UK headquartered LiqMeds Group of companies which has capabilities and specialisation in development, manufacturing and supply of oral liquid products for global markets, which it currently commercializes through partner. The group's subsidiary LM Manufacturing Limited (LMML), has an oral liquids manufacturing site at Weedon, Northampton, UK, which supplies products to the US and UK markets. Zydus will pay an upfront consideration of GBP 68 million and yearly earn-outs until 2026 depending on achievement of certain agreed milestones towards acquisition of the LiqMeds Group of companies. The transaction will be EPS accretive for Zydus from the first year of acquisition.

Speaking on the development, Managing Director of Zydus Lifesciences Limited, Dr. Sharvil Patel said, "We believe that liquid orals is a large, growing market and serves unmet needs with significant new market expansion opportunities. In line with our patient-centric approach, we believe that oral liquid formulations would help geriatric and paediatric patients, bringing in greater ease of convenience and therapy compliance." Zydus Lifesciences Ltd. with an overarching purpose of empowering people with freedom to live healthier and more fulfilled lives, is an innovative, global lifesciences company that discover, develops, manufactures, and markets a broad range of healthcare therapies.

## Accent Microcell Limited files DRHP with NSE Emerge

**Ahmedabad, India:** Accent Microcell Limited, one of the leading manufacturer of cellulose-based excipients, announced the filing of its Draft Red Herring Prospectus (DRHP) with NSE Emerge. The offering consists of a fresh issuance of 56,00,000 equity shares with a face value of ₹ 10 for each share. Corporate Capital Ventures has been designated as the Book Running Lead Manager to the issue while KFIN Technologies Limited is the Registrar. The Ahmedabad based headquartered company intends to deploy the net proceeds from the offering to establish a new plant at Navagam Kheda for manufacturing Croscarmellose Sodium (CCS), Sodium Starch Glycolate (SSG) and Carboxymethylcellulose (CMC) as well as for general corporate purposes. Out of the total proceeds from the fresh issue, the company proposes to invest ₹. 48.39 crore in the current financial year and ₹. 6 crore in FY2025 towards the establishment of Unit-III.

The company predominantly manufactures Microcrystalline Cellulose ("MCC"), which is widely used as a texturizer, anticaking agent, binder, lubricant, bulking agent, and diluent with an extensive range of applications in pharmaceutical, nutraceutical, food, cosmetic and other industries. In addition to MCC, it produces other excipients such as Croscarmellose Sodium (CCS) and Magnesium Stearate (MS).

Vasant V Patel Promoter and Chairman of Accent Microcell Limited, said, "Our advanced production capabilities, strategically located manufacturing facilities and strong supplier base for sourcing raw materials place us in an authoritative position in the industry. The demand for our products is propelled by the utilization of microcrystalline cellulose in the pharmaceutical, personal care, cosmetic, food, and beverage industries. To enhance our capabilities further, we are planning to set up a new plant at Navagam Kheda in Gujarat for producing Croscarmellose Sodium (CCS), Sodium Starch Glycolate and Carboxymethylcellulose (CMC) with the help of funds raised from this IPO. The new facility is expected to be commercialised by April 2025."

## Lincoln Pharmaceuticals Q2 net Profit stood at ₹. 27.65 crore


Mahendra Patel, MD, Lincoln Pharmaceuticals Limited

**Ahmedabad, India :** Linco ln Pharmaceuticals Limited, one of India's leading healthcare companies has reported standalone net profit of ₹. 27.65 crore for the quarter ended 30th September 2023, growth of 16.62% Y-O-Y as compare to the net profit of ₹. 23.71 crore in Q2 FY23. The company's total Income from operation for the Q2FY24 was reported at ₹. 164.68 crore, higher by 12.56% over Q2 FY23 total income from operation of ₹. 146.30 crore. EBITDA for the Q2 FY24 ended September 2023 was reported at ₹ 39.84 crore as compared to ₹. 34.59 crore in Q2 FY23 registering growth of 15.18%. EPS for Q2FY24 was reported at ₹. 13.81 per share. Shareholder at the 29th Annual General Meeting (AGM) approved a dividend of ₹. 1.50 per share for the FY 2022-23.

Mahendra Patel, Managing Director, Lincoln Pharmaceuticals Limited, said, "We are delighted to share that company has continued to experience robust growth across all business verticals in Q2 and H1FY24, all while maintaining net debt-free status. We expect better growth in Q3 and Q4 of the financial year, driven by new product launches in both the domestic and export markets, as well as improvements in operational efficiency and higher-margin products. With the robust growth initiatives, product and geographical expansion, and operational efficiency, we expect to achieve revenue of ₹. 750 crore in FY26."

In FY24, company will continue to build a strong portfolio in lifestyle and chronic segment especially women healthcare, dermatology to complement its strong presence in the acute segment. During FY23, company launched 18 products in the domestic market and filled 130 plus dossier in the export market. Company has over 1,700 registered products and another 700 in pipeline. The Company has completed expansion of the Cephalosporin plant at Mehsana, Gujarat. Commercial production from this plant has started and the company has initiated sales in the domestic markets. Furthermore, the company is in the process of registering the product for export to many countries. The plant is expected to contribute sales of around ₹. 150 crore in next 3 year.

## Shilpa Medicare to acquire US-based Pilnova Pharma

**Mumbai, India:** Shilpa Medicare stated that it has acquired Pilnova Pharma Inc in the United States. The acquisition of the shares will be done at par value of $1.00/share. and the transaction will be completed by November 15. Pilnova Pharma, Inc was incorporated under the provisions of US laws having its registered office at 27 Jamieson Way, Hillsborough, NJ USA - a Delaware corporation. Shilpa Medicare Limited (SML) started its operations as API manufacturer way back in 1987 at Raichur, Karnataka- India. The commercial production in the SML was started in November 1989. Shilpa Medicare Limited is a global brand in manufacturing and supplying of affordable API and Formulation globally in different regulated markets.

## Natco Pharma announces completion of USFDA inspection

**Mumbai, India:** Natco Pharma Limited announce the successful completion of United States Food and Drug Administration's (USFDA) inspection of the firm's compliance to Pharmacovigilance requirements with zero observations. Natco's Pharmacovigilance Department, at its Corporate Office in Hyderabad, was inspected from October 30, 2023 to November 1, 2023. The Pharmacovigilance procedures of Natco for its products marketed globally and particularly, in USA, were inspected and found to comply with USFDA's requirements.

Natco Pharma Limited was incorporated in Hyderabad in the year 1981 with an initial investment of ₹ 3.3 million. With a modest beginning of operations as a single unit with 20 employees, Natco has eight manufacturing facilities spread across India with dedicated modern research laboratories, capabilities in New Drug Development, etc.

## Hikal Q2 PAT rises 82%


Jai Hiremath, Executive Chairman, Hikal Ltd

**Mumbai, India:** Hikal Ltd., a preferred long-term partner for leading global life sciences companies, announced its financial results for the quarter ended 30th September 2023. The company's revenue stood at ₹ 435 crore, up 12% on QoQ basis, while EBITDA stood at ₹. 57 crore, up 14% on QoQ basis. The company's PAT stood at ₹. 13 crores, up 82% on QoQ basis. The company's Pharmaceutical sales stood at ₹. 270 crore in Q2 FY24. The company stated that it has started receiving regulatory approval across geographies for newer API product portfolio. The company's New multipurpose plant for Animal Health is completed at Panoli, Gujarat and commissioning is underway.

Jai Hiremath, Executive Chairman, Hikal Ltd. said, "The global chemical industry continues to experience a challenging period with prices declining across product segments coupled with the high channel inventory levels and intense price competition. Custome₹ are focusing on lower prices to bring down their average inventory cost while selectively making new purchases. We expect prices to bottom out, elevated inventory levels to subside and demand is likely to pick up from the end of this financial year resulting in an improvement in operating profitability quarter on quarter going forward. For Q2FY24, we reported revenues of ₹. 435 crore. and EBITDA of ₹. 57 crore. "

## Gland Pharma Q2 net profit down 20% to ₹ 194 crore

**Hyderabad, India:** Gland Pharma Limited, a generic injectable-focused pharmaceutical company, announced its financial results for the second quarter and six months that ended September 30, 2023. The company's revenue stood at ₹ 13,734 million, a y-o-y growth of 32% with a PAT of ₹ 1,941 mn.

Commenting on the results, Srinivas Sadu, MD & CEO of Gland Pharma, said, "We ended the first half of FY24 with revenue of ₹ 25,821 million, a 36% year-over-year increase, and a net profit of ₹. 3,882 million. Pricing and market share trends have shown encouraging indicator of normalization in our key products, contributing to our revenue growth. The overall business stability is


Srinivas Sadu, MD & CEO, Gland Pharma

restoring confidence, and we stay optimistic about future growth with the forthcoming launches, portfolio expansion, and entry into new markets via a partner-led strategy. Considering the annual summer shutdown in France & Belgium, revenues at Cenexi are in line with our estimates; However, the gross contribution margins saw a sequential improvement. Cenexi remains a strategic asset with a distinctive acquisition thesis, and we are committed to instituting effective measures and new investments to optimize operations and deliver long-term value to our shareholder." The company said that US market accounted for 54% of Q2FY24 revenue as against 65% in Q2FY23, while growth in the Europe and ROW market due to the acquisition of Cenexi.

## Venus Remedies secures Government of India's coveted 'Three Star Export House' Certificate


Peeyush Jain, Deputy MD, Venus Remedies

**Mumbai, India:** Venus Remedies Limited, a noted name in the pharmaceutical industry, has received the "Three Star Export House" certificate from the Government of India. This certificate, given to companies which have demonstrated consistency in their export growth and have contributed significantly to the country's foreign trade, is a recognition of Venus Remedies' stature as a leader in international trade and a valuable contributor to India's economy. It is a validation of the company's commitment to providing high-quality pharmaceutical formulations globally.

To attain this coveted Three Star status, a company must demonstrate a significant export performance by reaching a milestone of US $100 million in a span of three years. Venus Remedies has excelled in achieving this benchmark through its substantial contributions to India's foreign trade landscape. Venus Remedies' rapid growth and commitment to transnational trade have led to this remarkable progression. The company previously

held the Two Star Export House status, which required export performance criteria of USD25 million.

Peeyush Jain, Deputy Managing Director, Venus Remedies, said, "Receiving the 'Three Star Export House' certificate from the Government of India is an honour for Venus Remedies. This recognition would further enhance our export capabilities and expand our presence in key markets around the world, thus aligning with our vision of leaving a positive footprint on human health and meeting unmet medical needs across the globe in areas far and wide. "

## Hester Biosciences Q2 revenue from operations stood at ₹.70.46 crore

Rajiv Gandhi, Founder, CEO & MD, Hester Biosciences

**Ahmedabad, India:** Hester Biosciences Limited, one of India's leading animal health company, manufacturing vaccines and health products has reported consolidated net profit of ₹. 10.75 crore in H1FY24 ended September 2023 as against net profit of ₹. 10.16 crore in H1FY23, growth of 6%. The Company reported revenue from operations of ₹. 158.31 crore for the H1FY24, growth of 28% Y-o-Y as compared to revenue of ₹. 123.85 crore in H1FY23. EBITDA during H1FY24 ended September was reported at ₹. 27.58 crore, 37% growth Y-o-Y from ₹. 20.18 crore in H1FY23. EPS for H1FY24 was reported at ₹. 12.64 per share.

The company's revenue from operations stood at ₹ 70.46 crore, while EBITDA was at ₹ 13.21 crore. The company's consolidated results include operations of subsidiaries from Nepal and Tanzania. Hester Nepal had a turnover of ₹. 0.73 crore in Q2 FY24, primarily from domestic sales of vaccines with overall Net Loss of ₹. 0.71 Crore. The overall impact of exports and international tender has also been felt at Nepal but we are neutralizing that impact by focusing on domestic business which is showing a lot of potential.

The company's Hester Africa business has continued with export sales aggregating to ₹. 1.96 Crore in Q2 FY24 with overall loss of ₹.4.92 Crore, arising primarily on account of foreign exchange fluctuation on borrowings. The plant is ready with 6 vaccines registered and another 5 on way to be registered by the end of this financial year. The much awaited harmonization of registration process is under implementation, which will then enable us to start marketing our vaccines immediately to other East African countries, a process which was supposed to have been implemented over a year ago within the East African community.

## Alembic Pharmaceuticals Q2 net profit stood at ₹ 137 crore

Pranav Amin, MD, Alembic Pharmaceuticals Limited

**Mumbai, India:** Alembic Pharmaceuticals Limited reported its consolidated financial results for the second quarter ended 30th September, 2023. The company's net Profit for the quarter stood at ₹ 137 crores, while company's Net Sales grew 8% to ₹.1595 crores for the quarter.

Shaunak Amin, Managing Director, Alembic Pharmaceuticals Limited said, "Despite the challenges of a muted demand in the Antibiotic and respiratory market, it was a satisfactory quarter, backed with a strong performance by our specialty and animal healthcare portfolio. We are confident of returning to an industry beating growth moving forward". Pranav Amin, Managing Director, Alembic Pharmaceuticals Limited said "It was a satisfactory quarter led by growth in all the verticals of the company, in particular Ex-US which grew by 17% and the API business outperformed with a 10% growth during the quarter".

The company's India Branded Business was at ₹ 577 crores witnessed growth of 5% in Q2FY24 against IPM growth of 7%, while Specialty therapies recorded growth of 10%* as against industry growth of 9%. The company's API business grew 10% at ₹ 322 crores in the quarter, while US Generics at ₹. 444 crores up by 6% on YoY basis and by 14% on QoQ basis.

## Eris Lifesciences Q2 revenue up 10%

**Mumbai, India:** Eris Lifesciences Limited, a leading Indian branded formulations manufacturing company, announced its earnings for the second quarter and half year ended of FY24. The company's PAT for Q2 FY 23 is ₹. 1,223 mn with 24% PAT margin and H1 FY 24 is ₹. 2,160 mn with 22% PAT margin, while Revenue of Q2 FY 24 grew by 10% YoY to ₹. 5,053 mn and H1 FY 24 grew by 13% YoY to ₹ 9,719 mn. The company's EBITDA for Q2 FY 24 is ₹. 1,811 mn, with 36% EBITDA margin and H1 FY 24 is ₹. 3,509 mn with 36% EBITDA margin.

Commenting on the results, Amit Bakshi, CMD, Eris Lifesciences, said, "We continue to witness strong momentum, significant margin expansion and robust cash generation in our business as the investments made in FY23 have started delivering results this year. We are well on track to achieve our strategic and financial objectives for FY24 as outlined at the start of the year. We are looking at Revenues of ₹. 2000+ crore this year with an EBIDTA of ₹. 700+ crore and PAT of ₹. 410+ crore". The company has signed a definitive agreement with Biocon Biologics Ltd. to acquire its Branded Formulations' India (BFI) business units of Nephrology and Dermatology. The acquisition of Biocon's BFI business units also enables Eris to consolidate its position in Dermatology. Post deal, Eris would become the 2nd largest player in Psoriasis with a 11% market share. Dermatology is all set to become Eris' third largest therapy soon, after Diabetes and Cardiovascular. With dominant market positions in 3 of the Top-5 chronic therapies, Eris is well-positioned to deliver market leading growth in the years to come.

## West Pharmaceutical Services appoints Nilesh Shah as VP and GM of Emerging Markets

Nilesh Shah, VP and GM, Emerging Markets

**Singapore:** West Pharmaceutical Services, Inc. (West), a global leader in innovative solutions for injectable drug administration, has appointed Nilesh Shah as Vice President and General Manager of Emerging Markets, based in Singapore. Overseeing the Asia Pacific and South America regions, Nilesh will be responsible for growing West's presence and leadership in these markets. Shah joins West with a 25-year tenure in the medical devices industry, holding leadership roles at large corporations such as Johnson & Johnson, GE Healthcare, Fortive and Draeger.

On the appointment, Cindy Reiss-Clark, Chief Commercial Officer at West, said, "Asia Pacific is an integral region to West, and we have exciting milestones ahead across the markets in this region. Nilesh's multifaceted expertise, dynamic leadership, and unwavering dedication uniquely position him as a transformative force, poised to drive innovation and shape success in the ever-evolving landscape in emerging markets." Nilesh Shah shared, "I am excited to join West, an organization with a long legacy, an impressive global footprint, and a strong reputation as one of the world's leading manufacturers and providers of injectable drug packaging and delivery solutions to top pharmaceutical companies. The Asia Pacific region is ripe with opportunities, boasting one of the fastest rates of innovation in drug discovery in the world. I look forward to further fueling our growth and business performance in the region through collaboration, innovation, and talent."

## Aurobindo Pharma Q2 revenue from operations up 26%

K. Nithyananda Reddy, Vice-Chairman and MD, Aurobindo Pharma

**Hyderabad, India:** Aurobindo Pharma Limited announced its consolidated financial results for the quarter ended September 30, 2023.The company's revenue from Operations increased by 25.8% YoY to ₹. 7,219 Crore with growth seen across key segments, while Net Profit after Share of Profit/Loss of JV and minority interest stood at ₹. 752 Crore, as against ₹. 409 crore in Q2FY23. The company's US formulations (excluding Puerto Rico) revenue increased by 35.7% YoY to ₹. 3,385 crore, while Europe formulation revenue increased by 16.7% YoY to ₹. 1,769 Crore.

Commenting on the Company's performance, K. Nithyananda Reddy, Vice-Chairman and Managing Director of the Company said: "This is yet another quarter with highest ever sales, driven by robust performance across the markets, and continued margin expansion, aided by operational leverage and efficiencies. With our strong product pipeline, focus on compliance and key projects in advanced stages, we will continue our growth journey, while generating value for our stakeholde₹." The company's US revenue increased by 35.7% YoY to ₹. 3,385 Crore, while API business revenue increased by 20.3% to ₹. 1,166 Crore. As on 30th September 2023, on a cumulative basis, the company has filed 817 ANDAs with USFDA and received 628 final approval and 32 tentative approval.

The company has also received final approval from the US Food & Drug Administration (USFDA) to manufacture and market Testosterone Cypionate

Injection USP 1,000 mg/10 mL (100 mg/mL) and 2,000 mg/10 mL (200 mg/mL) in Multi-Dose Vial and 200 mg/mL in Single-Dose Vial, which is bioequivalent and therapeutically equivalent to the reference listed drug (RLD), Depo-Testosterone Injection, 100 mg/mL and 200 mg/mL of Pfizer Inc. The product is expected to be launched in November 2023.

## Metropolis Healthcare launches Next Best Action (NBA) initiative to combat Chronic diseases

Dr. Kirti Chadha, Chief Scientific Officer, Metropolis Healthcare Limited

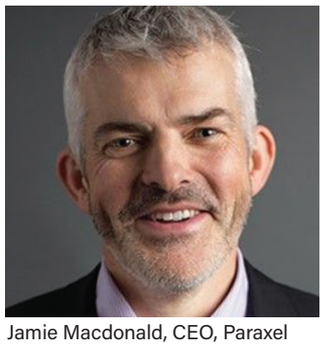
**New Delhi, India:** Metropolis Healthcare Limited, India's leading diagnostic service provider, has launched the Next Best Action (NBA) initiative, a comprehensive patient education program designed to address the alarming rise in chronic diseases. This ground-breaking initiative is fuelled by an in-depth data study involving 1,50,261 adults who underwent general body check-ups under the TruHealth package by Metropolis, from 2019 to 2022. Chronic diseases, such as diabetes, are on the rise, posing a significant threat to public health. According to the International Diabetes Federation (IDF) and the World Health Organization (WHO), by 2030, 1 in 9 people, or 640 million individuals, will be affected by diabetes. Notably, nearly half of these cases remain undiagnosed, leading to severe complications and life-threatening consequences.

Dr. Kirti Chadha, Chief Scientific Officer, Metropolis Healthcare Limited said, "Many patients are unaware of their diabetes status, which silently affects vital organs such as the heart, kidneys, liver, & pancreas. As per IDF, 7 in 10 diabetics are diagnosed as a result of complications & our Metropolis study also shows similar trends. Through its Next Best Action (NBA) initiative, Metropolis leverages its scientific expertise to provide data science backed diagnostic algorithm & actionable medical remarks to mitigate the risks associated with diabetes and its complications."

## Wockhardt Q2 revenue jumps by 11%

**Mumbai, India:** Wockhardt Limited announced its financial results for the quarter ended 30th September, 2023. The company's revenue for the quarter stood at ₹. 762 crore, a growth of 11% on a YoY basis, while EBITDA for Q2FY24 stood at ₹. 81 crore as compared to ₹. 50 Crore in Q2FY23, a growth of 62% on a YoY basis. The company's UK Business stood at ₹.254 crore in Q2FY24 compared to ₹..226 crore in Q2FY23 registering a growth of 12% and contributed about 33% of Global Revenue in the current quarter, while India Business stood at ₹.140 crore in Q2FY24 contributing to 18% of the Global Revenue in Q2FY24. The company's US Business stood at ₹.47 crore in Q2FY24 contributing 6% of the Global Revenue. The company's Research and Development expenditure during the quarter was at ₹.34 crore (4.4% to sales) and including capital expenditure was at 8.8% to sales.

## Parexel Named "Best Contract Research Organization" at 19th Annual Scrip awards



Jamie Macdonald, CEO, Paraxel

**Mumbai, India:** Parexel, one of the world's largest clinical research organizations (CROs) providing the full range of Phase I to IV clinical development services, announced it has been named "Best Contract Research Organization" in the Full-Service Provider category at the 19th Annual Scrip Awards. The Best CRO ranking from Scrip follows the company's recognition earlier in the year as Top CRO to Work With in the 2023 WCG CenterWatch Global Site Relationship Benchmark Survey and winner of the 2023 Society for Clinical Research Sites (SCRS) Eagle Award recognizing the CRO committed to advancing the clinical research profession through strong site partnerships.

"Parexel colleagues are passionate about developing life-changing new therapies to advance world health," said Chief Executive Officer Jamie Macdonald. "This exciting recognition is a true testament to their efforts and collaboration with our customers, sites and partners across the clinical research enterprise to make a difference for patients. We remain committed to innovating across Phase I to IV clinical development to drive research forward and make clinical trial participation more accessible and inclusive for all." ■

INTERVIEW

# "We will continue to invest in R&D to discover and develop innovative drugs and therapies."

**Ramesh Juneja**
Chairman & Whole -Time Director
Mankind Pharma Ltd

**Ramesh Juneja** emphasizes about challenges and opportunities for the Pharma industry. He also elaborates about the investment in research and development, global expansion, and new product launches in the cardiovascular and anti-diabetes segments.

**Brief us about the overview of the Pharma industry.**

The pharmaceutical sector is a multifaceted industry that encompasses a spectrum of activities, including research, development, manufacturing, and distribution of pharmaceutical products. It stands as a pivotal pillar within global healthcare systems, bearing the responsibility for discovering and producing medications and therapies that not only enhance but also safeguard human lives.

This industry is marked by its relentless pursuit of innovation, placing a significant emphasis on the research and development endeavors aimed at pioneering novel drugs and treatments. Pharmaceuticals hold a pivotal position in the management and eradication of diseases, addressing pressing public health challenges, and elevating the overall quality of life for individuals on a worldwide scale.

**What are the challenges and opportunities do you see for the Pharma industry?**

The pharmaceutical industry operates in a complex and ever-evolving landscape. It faces several challenges, such as stringent regulatory requirements, escalating research and development costs, and increasing competition. Regulatory hurdles can delay product approvals and add significant costs to drug development.

However, the industry also presents numerous opportunities in expanding into emerging markets,

where there is a growing demand for healthcare products and services. Additionally, advancements in biotechnology and genomics have opened up new avenues for drug discovery and personalized medicine. The ongoing global need for innovative healthcare solutions and therapies also offers opportunities for pharmaceutical companies like Mankind Pharma to develop and market novel drugs. For example, IPM chronic contribution stands at 38% in FY23 while Mankind's stands at 34%. We have further potential to increase our contribution from chronic diseases which will help drive growth.

**What will be the strategic focus areas over the next two to three years?**

Historically, the company has been growing 1.5 X faster than the IPM, going forward, keeping in line with this trend, they are looking at a growth of 1.3X-1.4X times that of the IPM. Over the next two to three years, our strategic focus areas will revolve around several key priorities including:

- **Cost Reduction**: We are actively working on reducing the costs associated with our existing filed API's and formulations to improve efficiency and affordability pertaining to drugs in India.
- **Research and Development**: We will continue to invest in research and development to discover and develop innovative drugs and therapies. This includes seeking DCGI registration for new and innovative developments catering specifically to the Indian market.
- **Global Expansion:** We aim to expand our presence in international markets, forging partnerships and collaborations to access new patient populations and markets.
- **Digital Transformation**: Leveraging digital technologies to improve healthcare delivery and patient outcomes is a top priority. We will invest in Artificial intelligence, digital platforms, telemedicine, health informatics, and digital therapeutics to enhance patient care and bridging gaps to make healthcare more accessible.

**Brief us about your new product launches in cardiovascular and anti-diabetes segments in India?**

While we are actively working to expand our product portfolio in the cardiovascular and anti-diabetes segments in India, the exact number of products may vary based on market needs, regulatory approvals, and ongoing research and development efforts. We have entered into in-licensing agreements with other pharmaceutical companies to launch differentiated molecules with growth potential in the domestic market, including in the anti-diabetic and cardiovascular therapeutic areas from Glenmark Pharmaceuticals Limited and Novartis Healthcare Private Limited.

**What are your plans for chronic segments? What growth do you see for the next year?**

In addressing the chronic segment at Mankind Pharmaceuticals, we adopt a forward-thinking approach to foster sustainable growth. Despite our focus on the acute portfolio, we consistently outperform IPM's growth in the chronic segment. For the upcoming year, our strategic initiatives include:

- **Diversification**: We've launched eight new divisions in therapy areas such as cardiovascular, diabetes-metabolic, neurology, ophthalmology, respiratory, gynecology, and critical care, targeting the chronic and semi-chronic segments. We also plan to foray into urology and nephrology in the coming years.
- **Strategic Acquisitions**: Notably, we recently executed the acquisition of Panacea, a move that has not only expanded our market footprint but has also provided us entry into high-barrier therapy domains, including Transplant and Oncology.
- **Geographical Focus**: To reinforce our presence in the chronic segment, we are placing a significant emphasis on metropolitan and tier 1 cities. To facilitate this, we have established a dedicated team of regional medical advisors whose primary role is to engage with prominent Key Opinion Leaders (KOLs) and Key Business Leaders (KBLs) in these pivotal urban centers.
- **Exploration of Alternative Distribution Channels**: We are acutely aware of the evolving dynamics within the pharmaceutical industry and are actively exploring alternative distribution

channels such as Modern Trade (MT) and E-commerce.

**Brief us about the launch of DMF Quality Drugs for Indian Patients.**

India has long been recognized as a global leader in the production of generic medicines that adhere to stringent DMF quality standards for Active Pharmaceutical Ingredients (APIs). Mankind Pharma is pioneering the introduction of DMF quality medicines in the Indian market. DMF Quality APIs represent the pinnacle of excellence, surpassing conventional standards. These medicines adhere to the stringent norms for quality, safety, and effectiveness set by the USFDA, as defined by the Drug Master File (DMF). The DMF contains comprehensive information about an API, including details on its manufacturing, stability, quality, packaging, purity, and impurity profile. This information is crucial for regulatory authorities to ensure that medicines meet the highest standards of quality and efficacy.

Furthermore, DMF quality APIs are exceptionally pure, as they adhere to the US pharmacopeia and are manufactured in USFDA-approved facilities. This commitment to excellence ensures that the medicines we offer are of the highest quality and efficacy, furthering our mission to provide affordable, world-class healthcare solutions to the Indian population.

**What are the therapeutic segments you are planning to expand? What percentage of revenue comes from domestic sales?**

Mankind Pharma is strategically expanding its therapeutic segments with a specialized division focusing on chronic areas like anti-diabetic, cardio, neuro/CNS, and respiratory therapies. The recent acquisition of Panacea Biotec Pharma Limited's domestic formulations brand portfolio has propelled us into high-barrier therapies like Transplant and Oncology. Looking forward, we plan to foray into urology and nephrology, demonstrating our commitment to comprehensive healthcare solutions. We are actively seeking in-licensed or co-marketing products that fit our strategic goal. Furthermore, we have a robust pipeline for the next 3-5 years, in alignment with our strategic vision. A significant portion of our revenue is derived from domestic sales, reflecting our strong market presence and leadership in the Indian pharmaceutical industry. Specifically, 97% of our revenue comes from domestic sales, underscoring our strong market presence and leadership.

**Are you looking at any inorganic growth?**

The company has displayed robust organic growth, reaching a significant milestone with Rs. 8,749.43 Crore revenue in FY23. Impressively, the company outpaced the IPM with a growth rate of 10.6%, demonstrating its market strength across various segments. This growth is underscored by its expanded brand portfolio, introduction of new products, and a strong foothold among healthcare practitioners with the highest prescription share in the industry at 15.54%. The company has historically prioritized organic expansion, its strategic acquisitions, including the noteworthy acquisition of Panacea in 2022 and brand acquisitions from Dr. Reddy's, highlight its potential for inorganic growth.

Mankind Pharma's comprehensive distribution network, which includes 15,000+ field force members, extensive doctor coverage, and a vast network of stockists and C&F agents, positions the company

for continued success. Furthermore, its commitment to affordability, quality medicines, and world-class R&D capabilities are key strengths driving its growth. With a strong presence in both acute and chronic segments and a focus on market expansion, especially in metro and Tier 1 cities, Mankind Pharma is well-equipped to explore further opportunities for growth, be it organically through new product launches or strategically through potential inorganic ventures.

**Comment on your CAPEX plans.**

In FY23, the company has incurred a capex of Rs. 832 crores which has been fully funded through internal accruals. Broadly, the capex has been incurred for capacity enhancement of our manufacturing plants, infrastructure upgradation and to support digitalization and automation initiatives. Capex for FY24 is expected to be close to ₹ 600 crores, which includes growth as well as maintenance capex. Our Capex strategy underscores our commitment to strategic investments in both tangible and intangible assets to support our business operations, expand our product offerings, and drive sustainable growth in the pharmaceutical industry.

**What is your current market share. How do you plan to increase market share in the foreseeable future.**

Our market share in the Consumer Healthcare business for FY23 is strong, with notable percentages for key products, including PregaNews at 82%, Manforce at 30%, and Unwanted 72 at 62%. We have maintained #1 rank in prescriptions with 15.4% share in Q1FY24 versus 15.1% in Q1FY23. Historically we have outperformed the IPM and our endeavour is to continue to outperform the IPM by 1.3 to 1.5X.

To further bolster our market share, we have adopted a comprehensive growth strategy. This strategy encompasses engaging with prominent figures in the healthcare industry, such as Key Opinion Leaders (KOLs) and Key Business Leaders (KBLs), primarily in metro and Class I cities, through a dedicated team of regional medical advisors.

We have been expanding our advisor network, especially in cities such as Delhi NCR, Bengaluru, Mumbai, Hyderabad, Cochin, Chennai, and Kolkata. These efforts aim to improve our relationships with healthcare institutions and cater to the critical care segment. We are also actively pursuing strategic acquisitions and collaborations to diversify our product portfolio. Furthermore, our commitment to digital platform expansion and investment in telemedicine and technology infrastructure will enhance our engagement with healthcare providers

**Brief us about your financials. Your outlook on the margins.**

For the second quarter ended September 30, 2023, the company's revenue from Operations stood at ₹. 2,708 crore, up by 12% YoY, while PAT stood at ₹ 511 crore, up by 21% YoY with margin of 19%. The company's EBITDA stood at ₹ 686 crore, up by 15% YoY with margin of 25%. The company's domestic Business achieved a steady YoY growth of 7%* during Q2FY24, while company's Exports business witnessed a growth of 159% YoY in Q2FY24 aided by certain one-off opportunities in the US. The company's Consumer Healthcare segment witnessed a muted growth during the quarter due to initiatives taken towards optimization of channel inventory.

In our Pharma business, secondary sales growth in FY23 significantly outpaced the IPM, achieving 10.6% growth rate compared to the IPM's 7.9% growth. Additionally, our volume growth in FY23 was 2.6%, considerably higher than the IPM's volume growth of 0.1%. These figures place us as the 3rd ranked company by sales volume in the IPM. Regarding our outlook on margins, our strong growth trajectory and expanding brand portfolio indicate a positive outlook for margins.

We are confident that we will achieve an operating margin band of 24% to 26% in the medium term. By consistently outperforming the IPM and achieving substantial volume and revenue growth, we are well-positioned to continue our growth trajectory. As we further strengthen our presence in the pharmaceutical market and expand our product offerings, we anticipate continued healthy financial performance and sustained margins. ■

INTERVIEW

# "Merck's investment in the Jigani plant intended to benefit India's industrial economy."

**Eileen McCracken**
Head of Diagnostics & Regulated Materials
Science & Lab Solutions, Merck Life Science

**Eileen McCracken** emphasizes about the overall perspective of the diagnostics industry, company's future and investment plans. She also spoke about the expansion of its worldwide footprint and enhancing its presence in high-growth potential markets.

**Brief us about the overview of the diagnostics industry?**

Stable isotopes, such as D2O, have been advancing groundbreaking applications, such as medicines pharmacokinetics, semiconductors, OLEDs and electronics. The Diagnostic industry too has been leveraging these components for a number of applications.

For instance, for medical imaging procedures, identifying indicators of our metabolism and even point of care tests, such as urea breath tests to detect certain stomach cancers in non-invasive ways.

We collaborate with customers to provide them with customized raw materials, such as APIs, for their diagnostic manufacturing needs of high purity components for increased accuracy. On a broader outlook for the diagnostics industrial environment, breakthroughs in technology, genetics, and data analytics have fueled extraordinary transformations in recent years.

The diagnostic space is critical in healthcare because it enables early illness identification, tailored medicine, and better patient outcomes. The potential for transforming healthcare delivery is enormous with the emergence of breakthrough diagnostic techniques such as next-generation sequencing, liquid biopsies,

Merck lifescience facility

and point-of-care diagnostics. These developments not only improve diagnosis accuracy and speed, but also lead to cost reductions and more tailored treatment techniques. Furthermore, the incorporation of artificial intelligence and machine learning into diagnostics promises to improve data interpretation and decision-making even further, ushering in an era of precision medicine.

Digital software technology has the potential to enable a more innovative approach to diagnosis. The decentralization of lab facilities, as well as the implementation of various digital technologies, has become vital and common in diagnostic laboratories. Personalized and precision medicines are gaining popularity, and these considerations suggest that next-generation diagnostics will impact the future. The capacity of big data to provide access to comprehensive patient data allows healthcare practitioners to improve diagnosis accuracy and personalize treatment plans for specific patients, which has the potential to transform medical diagnostics.

As the diagnostic industry continues to evolve, it holds the promise of not only improving patient care but also shaping the future of healthcare by enabling proactive and preventive approaches to managing health.

**What are the future growth plans to process heavy water and make deuterated compounds in the country and making them available across markets to domestic manufacturers?**

Merck India is embarking on an endeavor to expand and improve its D-labelled compounds processing capabilities, as well as to enter the deuterated product production space. Merck Life Science has signed five-year agreement with the Heavy Water Board (HWB), part of the Department of Atomic Energy, to achieve this goal. This collaboration aims to ensure a steady supply of heavy water for the manufacture of deuterated products in India. This strategic alliance is an important component of Merck India's expansion plan and supports the Indian government's "Make in India" vision.

Merck India hopes to open up a new world of opportunity for enterprises involved in medicines, semiconductors, and electronics manufacture by building domestic manufacturing capabilities for deuterated products. Merck India's collaboration with HWB will have a significant impact on the expansion of India's chemical, pharmaceutical, and technological industries, hence strengthening the country's innovation landscape. This partnership aligns with our aim of providing critical components to diagnostic and pharmaceutical producers. In addition to the agreement, Merck will be assisting local Indian firms with strong regulatory assistance and expertise, helping them to impact life and health with science.

**Please tell us more about your investments and future plans?**

Merck has made significant investments in infrastructure development at the Jigani site in Bengaluru. In 2023, we expanded our research and development capability and began d-labeled capabilities in Jigani. Additional investments in the facility are already in the works and will be completed within the next 1-3 years.

India is becoming increasingly important for Merck and its Life Science division. India presently occupies a critical role in the global pharmaceutical business, and we believe that this impact will expand into new areas during the next decade.

We are enthusiastic to play a part in advancing India's development, as demonstrated by our partnerships with government entities, educational institutions, pharmaceutical companies, and various local stakeholders, as mentioned earlier. Furthermore, we are planning to expand our presence and activities in the region.

**Brief us about your five-year agreement between Merck and Heavy Water Board entail? How would this partnership bolster Merck in the Make in India?**

Merck's long-term arrangement with the Heavy Water Board (HWB) seeks to ensure a steady supply of heavy water. Merck India intends to expand its manufacturing facility for D-labeleld compounds using Heavy Water. With this continuous and dependable supply of heavy water, we hope to open doors for companies that make pharmaceutical medications, semiconductors, and electronics, so contributing to the expansion of India's chemical, pharmaceutical, and technological sectors. Merck is a leading global producer of deuterated products by serving specialist markets worldwide, especially those in Japan, China, and South Korea.

Merck's recent engagement with the Heavy Water Board (HWB) is a significant step toward reinforcing Merck's commitment to the Make in India initiative. Merck India would be able to create important deuterated compounds in the nation as a result of this collaboration. Furthermore, the increased capacity will address the growing demand for specialist products and establish Merck India as a leading worldwide manufacturer of deuterated products, allowing the company to satisfy the needs of markets around the world.

This collaboration opens up opportunities for India to take a significant role in the global supply chain for deuterated products, hence encouraging the development of the domestic chemical, pharmaceutical, and technical sectors. It will benefit the country by increasing the availability of key commodities and strengthening India's innovation ecosystem. Merck's endeavors to create local manufacturing capabilities for deuterated compounds in India reflect the company's commitment to the country's industrial growth by producing these goods and satisfying the growing need for unique and effective solutions. This agreement with HWB will boost Merck's position as a major player in the global pharmaceutical market while simultaneously contributing to India's industrial sector and bolstering the Make in India effort.

**Can you give some details about your plans to explore to new countries you have received interest from such as Germany, the US, South Korea, and China ?**

We have garnered interest from prospective partners regarding the export of our deuterated products. The specifics of our export activities, such as when and how much we export, are determined by a variety of factors that include legal requirements, regulations, and particular commercial agreements. As a result, Merck, as a responsible organization, would follow the guidelines and processes established by authorities in relevant regions when making choices concerning its export activities.

At the same time, the company remains committed to expanding its worldwide footprint and enhancing its presence in high-growth potential markets. The company intends to target worldwide markets with specialty goods and develop itself as a top deuterated product manufacturing facility. These items are in high demand in the electronics market, particularly in Japan, China, and South Korea.

**What prompted Merck to choose its Jigani site in India for the production of deuterated compounds? How will this site contribute to enhancing India's global market presence in deuterated products and increasing its market share?**

Merck has built cutting-edge infrastructure at its Jigani location in Bangalore, India, which has been in operation since 2003. This facility, which spans an amazing 40,388 square meters, features best-in-class proprietary synthesis and catalogue production yields. The site also includes a 6800-square-meter distribution center and warehousing facilities. It is responsible for producing and filling approximately 5% of Merck's global catalogue items while maintaining ISO9001, ISO14001, and OHSAS 18001.

Merck's Jigani facility in India is strategically positioned to serve as a vital export hub to markets such as the United States and Europe. This role will bolster India's presence on the global stage for deuterated products and enhance its market presence.

Merck's commitment to increasing its deuterated compound manufacturing capabilities is shown in investments in the state-of-the-art facilities at its Jigani plant in Bengaluru, India. Additional improvements in the Jigani site are being planned and will be carried out during the following 1-3 years. Merck's investment in the Jigani plant is intended to benefit India's industrial economy while also reinforcing Merck's position as a major worldwide player in the pharmaceutical business. These investments demonstrate the company's dedication to building a strong local presence, catering to niche customers, and bringing value to India's manufacturing sector. ■

# Amid Healthcare Evolution: Indian Diagnostic Sector to See Stable Double-digit Growth in Medium Term

Healthcare is one of the key sectors in India in terms of both revenue and domestic product (GDP) in FY23 and FY22, against 1.6% in FY21, as per the Economic Survey 2022-23. The share of expenditure on health with respect to the total expenditure on social services, has increased from 21% in FY19 to 26% in FY23 (BE).

Diagnostic forms a very essential part of the healthcare industry and is usually the first step towards treating diseases, starting from the detection of the disease to prognosis and determination of treatment regime to posttreatment monitoring of the patient. The Indian diagnostic services market was valued at USD 14.57 billion in 2022 and USD 16.23 billion in 2023 and is forecasted to reach USD 43.57 billion by FY32 (as per a report published by Polaris Market Research in March 2023). SPER market research predicts the Indian diagnostic lab market to reach USD 44.92 billion by 2032.

The growth in the diagnostic sector is supported by an increase in healthcare spending by an ageing population, rising income levels, rising awareness for preventive testing, advanced healthcare diagnostic tests offerings, market penetration of healthcare insurance and healthcare measures by the central government.

## Key Characteristics and Trends

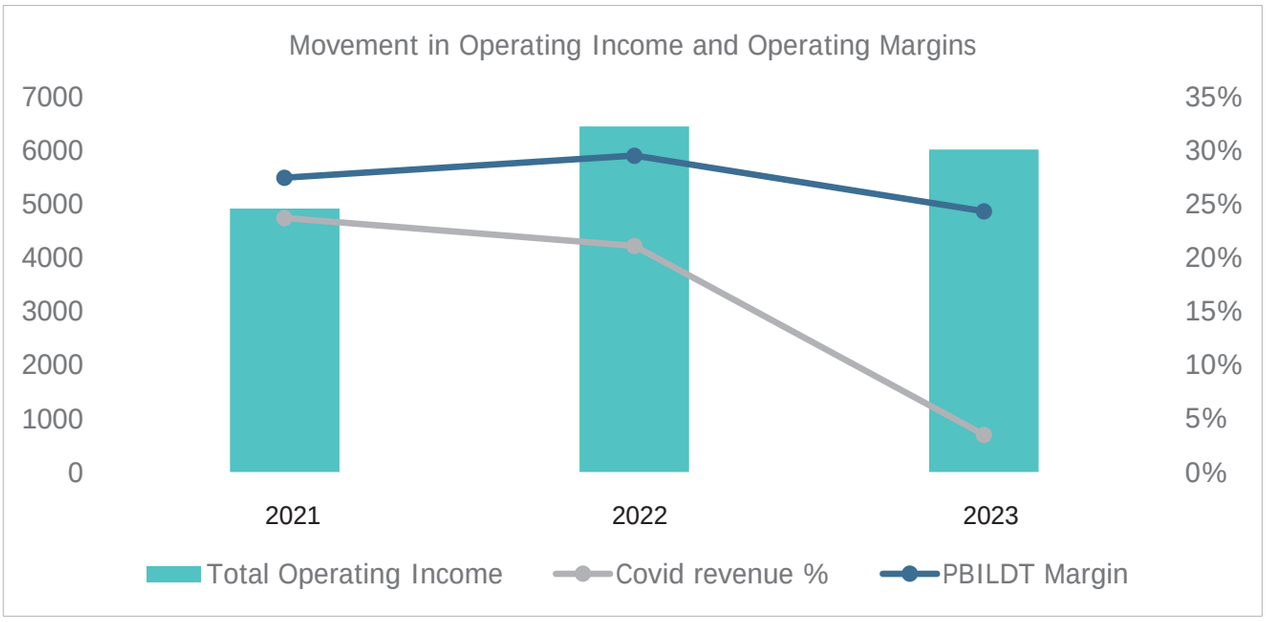
**Increasing income levels backed by improved awareness about preventive healthcare**

India's approach towards preventive healthcare has undergone a change post the Covid-19 pandemic. Individuals are now more inclined towards preventive healthcare than curative healthcare. The increasing income levels of people, as reflected in the increase in GDP per capita to over US $2,388 in 2022 from US $1,958 in 2017 (as per the World Bank data) have also backed the paradigm shift in this inclination. The diagnostics companies would benefit from this shift, and growth of around 12%-14% in the revenue of the diagnostic companies is expected in the medium to long term.

## Organic and inorganic growth strategies

Owing to the highly fragmented nature of the industry, the companies in the sector are employing inorganic growth strategies as a move towards consolidation apart from the organic growth measures being used for expansion. The companies are setting up new centres in untapped geographies majorly based on the franchisee model for organic growth. For example, Dr Lal Path Labs, which is a leading player in the northern and eastern parts of India, is expanding its presence in the west as well as central India by the acquisition of Suburban Diagnostics India Private Limited. Metropolis, a leading brand in the Mumbai Metropolitan Region is considering creating a presence in north and south India. Thyrocare, having a strong presence in the south, has set up a central laboratory in Delhi-NCR.

The large players are using inorganic strategies acquiring small players to expand their presence in the new territories. Furthermore, owing to the strong balance sheet of major listed players, supported by a high level of cash profits along with a strong liquidity position and low reliance on debt, CareEdge Ratings expects the momentum of inorganic growth by major players to continue in the medium term.




*The data have been taken for the top six listed companies in the diagnostic industry

### Companies' focus on digital initiatives and home-visit segment

The major players in the diagnostic industry have focused on reinventing by integrating technology and digitisation. Increasing demand for testing post-pandemic along with the need for faster results and accurate diagnosis, has compelled the diagnostic companies to focus on a customer-centric approach. The companies are largely focusing on the home visit segment and are looking to provide service at par with the lab visit walk-ins. The strategy is to digitise the end-to-end home visit segment by employing various artificial intelligence/ machine learning techniques since the customers now look for omni channel presence for better service. The digitisation has also led to the entry of new startups in the diagnostic ecosystem which is primarily focused on home visit diagnostic services like Tata 1mg, PharmEasy, Healthians, Orange Health, etc. Apart from this, the companies are also focusing on geographical network expansion by considering penetrating Tier-2 and Tier-3 cities.

### Conclusion

CareEdge Ratings expects the diagnostic industry to witness stable double-digit revenue growth, ranging from 12%-14%, driven by both organic and inorganic expansion of the players and a paradigm shift in the consumers towards preventive healthcare. However, the operating profitability margins are likely to be at pre-COVID levels and remain in the range of 23%-25%, on account of the entry of health tech diagnostic startups like Tata 1mg, Healthians, Neuberg, Redcliffe etc., price capping by the government and increase in the price of the input reagents stressing the gross margins of the companies. ■

## Authors

**Priti Agarwal**
Senior Director
CareEdge Ratings

**Sajan Goyal**
Director
CareEdge Ratings

# Ionizable Lipids are Critical for mRNA Vaccine Development

The pharmaceutical industry has witnessed a significant transformation in vaccine development, shifting from the 1950s, with the concept of one egg yielding one vaccine dose, to adopting a streamlined and efficient manufacturing protocol. **Arun Kedia** writes about how mRNA-based vaccines with lipid nanoparticles has ushered in a highly effective and innovative vaccine platform.

Single strand messenger RNA (mRNA), a nucleic acid, triggers synthesis of specific protein chains in the living cell's cytoplasm. However, they are extremely vulnerable in the human body. In recent times, lipid nanoparticles have emerged as a cutting-edge technology, proving highly effective for the in-vivo delivery of mRNA with a protective nanocapsule of phospholipids. This is particularly relevant in the COVID-19 vaccine administration, where achieving successful and protective vaccines hinged on utilizing highly efficient mRNA delivery systems.

However, despite existing vaccines, developing more effective and easily adaptable ones that offer enhanced safety against various SARS-CoV-2 variants remains a significant challenge.

## mRNA Vaccine Development: An Overview

Today, lipid nanoparticles or LNPs represent the most advanced non-viral gene delivery system in clinical practice. They are a safe and efficient means of delivering nucleic acids, effectively overcoming a critical hurdle in developing and applying genetic medicines and vaccines.

At present, LNPs are widely used in mRNA delivery vehicles. LNPs consist of four distinct lipid categories, including ionizable lipids, neutral or helper lipids, cholesterol, and sometimes lipids with polyethylene glycol (PEG) attachments. Specifically, considering ionizable lipids play a pivotal role in mRNA complexation and in vivo delivery, they assume a bigger spotlight in the discussion.

Progress in mRNA-based delivery methods has demonstrated their therapeutic potential in various biomedical uses like protein replacement treatments, vaccines, cell reprogramming, and cancer immunotherapies. To reap the best therapeutic results of mRNA delivery systems, it is essential to shield mRNA from in-vivo degradation and deliver it to specific cells for triggering protein production.

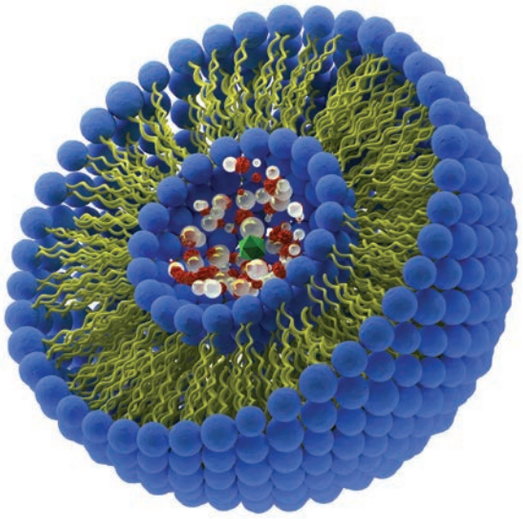
However, targetability, stability and endosomal escape remain significant challenges and hurdles in mRNA delivery systems, underlining the significance of safe and efficient mRNA delivery.

Recently, the utilization of LNPs in COVID-19 mRNA vaccines has gained popularity because of their crucial role in protecting and delivering the mRNA payload to particular cells. Currently, in clinical application, these mRNA-LNP vaccines for COVID-19 show an inventive strategy within mRNA-based treatments. The promising developments indicate a potential transformation in how we combat infectious diseases.

## Ionizable Lipids and their Importance in mRNA Delivery

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.



In actuality, each part of the four lipid types mentioned earlier is needed to ensure the mRNA can be delivered well and the particles stay stable. However, ionizable lipids are the most essential components of LNPs. They decide how well the mRNA is delivered, how cells accept the mRNA, how it escapes from endosomes, and how safe it is. So, a well-designed LNP delivery vehicle with ionizable lipids makes it easier for cells to take in mRNA. This way, the delivery process of mRNA can be enhanced significantly.

Ionizable lipids are unique because they react to the acidity level (pH) around them, changing their charge depending on it. When the pH is low, they become positively charged. However, when the pH is normal, the ionizable lipids become neutral. This means that in a normal pH environment, they do not interact much with the cell membrane, which makes the LNPs work well with the body.

But when they get inside an endosome (a small part inside a more acidic cell), the positively charged ionizable lipids join with negatively charged lipids in the endosome, creating a unique structure that helps the LNPs work more effectively.

### New Research on Applications of Ionizable Lipids in mRNA Vaccines

While research on ionizable lipids for mRNA vaccines is an ongoing endeavour, a recent effort towards designing more powerful RNA vaccines is worth mentioning. Even though the COVID-19 RNA vaccines have shown their effectiveness in lessening the disease's severity, a group of scientists at MIT is dedicated to enhancing their performance further.

Their work is a testament to the ever-evolving landscape of mRNA vaccine development and the relentless pursuit of medical innovation that showcases the potential to enhance the global response to infectious diseases.

Through alterations in the vaccine's design, the scientists aim to showcase their ability to develop mRNA vaccines in mice that stimulate a more robust immune response, all while necessitating a smaller dosage. These efforts hold promise for more efficient and accessible vaccine strategies.

As a phase in their research plan, the scientists altered the LNPs responsible for transporting the RNA vaccine. They created a library of 480 ionizable lipids with different chemistries that become positively charged when they enter acidic environments. These modified lipids assist in RNA delivery and naturally boost the immune response, making it stronger.

When tested on mice, the research team noted that the mice receiving this vaccine generated ten times more antibodies than those given the earlier COVID RNA vaccines. Also, the new vaccine induced a more vigorous response from cells crucial in combating the SARS-CoV-2 virus, highlighting its potential as a highly effective solution.

### Conclusion

In recent years, there has been remarkable progress in mRNA therapeutics, largely influenced by the extensive research conducted over decades on LNPs, particularly focusing on a crucial component, ionizable lipids.

In addition to ensuring safety and effectiveness for mRNA delivery, the next-generation ionizable lipids can also incorporate extra features like specific targeting. These are extensive prospects for further enhancing and innovating ionizable lipids to facilitate the widespread adoption of mRNA therapeutics and vaccines. ■

## Author

**Arun Kedia**
Managing Director
VAV Lipids

# Scope of Drug Discovery Research Using Marine Biological Resources

The pharmaceutical industries are creating new generation antibiotics to handle antimicrobial resistance (AMR), primarily through the chemical modification of older drugs and/or repurposing of drug formulations using combinatorial approaches. However, less than 5% of these derivatized /repurposed drugs could cross clinical trials in last 20 years. **Hari S Misra and Kiranmai Reddy** talks about the directed research on drug discovery, design and development.

The World Health Organization (WHO) has declared antimicrobial resistance (AMR) as the global pandemic and a serious threat to public health. Nearly 500,000 annual deaths have been recorded worldwide due to multi-drug resistant (MDR) pathogens, which is predicted to grow more than 10 million annually by 2050. Infectious diseases are a major health care burden around the globe, and the treatments of antimicrobial resistance (AMR) in multidrug-resistant (MDR) pathogens have become a challenging health problem (Armitage, 2021). The development of AMRs is multifaceted that include the indiscriminate use of antibiotics by health agencies, and the molecular adaptation of infectious agents to selection pressures. The pharmaceutical industries are working on this problem largely through derivatization of existing drugs but the success rate of post clinical trials is worrisome and less than 5%. Therefore, the newer ways to control AMR would be through the discovery of new bioactive compounds, and/or using genetic methods like CRISPR tools etc, for targeted killing of MDR pathogens.

The bacteria belonging to actinomycetes family have been the source of new drugs in the past, and several existing drugs have been isolated from these microorganisms. Actinobacteria are very important to agriculture, food production and human health by being the potential source of new drugs, and are the part of nearly one-third of the gut microbiota, mostly Bifidobacterium sps. Streptomyces are the best studied actinobacteria and have also been isolated from a vast source like milky exudate (moonmilk), caves, glacial clay in Canada, the alkaline soil lying on the top of carboniferous limestone, Beewolf solitary digger wasps, attine (fungus-growing) ants, guts of termites, beetles, millipedes, wood lice and earthworms and in marine zooplankton (Chevrette et al., 2019).

Dr Selman Waksman and colleague discovered streptomycin from Streptomyces griseus. Streptomyces are known for the production of secondary metabolites that are used as anti-tumour and immunosuppressant drugs, herbicidal and antimicrobial substances for the treatment of bacterial infection, and MDR pathogens (Chevrette et al, 2019, Singh 2019, Alam et al 2022). Majority of these drugs are the secondary metabolites which is growing continuously in Streptomyces (Xia et al 2020). A variety of natural products such as glycopeptides, terpenes and antibiotics like tetracyclines, macrolides, aminoglycosides are being produced in Streptomyces (Tyurin et al. 2018).

Cytogenetic features of Streptomyces are unique and genetic studies on secondary metabolite production showed that the genomes of these bacteria contain a sets of the biosynthetic gene clusters (BGCs). Many of these BGCs encode non-ribosomal peptide synthetase (NRPS), polyketide synthase (PKS), terpenes, lantipeptides, and other ketide synthases, and some distinct differences have been recorded when compared with other well studied bacteria. Streptomyces synthesize antibiotics using these large multi-enzyme complexes. Based on these genetic features and diversity in the BGCs, the capability of Streptomyces producing ~100,000 antibiotic

compounds, around 70 to 80% of naturally occurring bioactive compounds has been suggested (Bubici et al.2018, Harier et al 2018, Abdel- Razaek et al. 2020, Alam et al 2022). It has been shown that these multiprotein complexes can derivatize the known bioactive compounds to the one that is most compatible with the nature. Evolutionarily, the bacteria belonging to actinomycetes genera have evolved the natural DNA uptake mechanism(s) that help them to acquire environmental DNA (eDNA) (Fabbretti et al., 2019). The sources of eDNA are chromosomal and organelle DNA (mitochondria and chloroplasts) that are released from the organisms living into the environment, secreted feces, mucous, gametes, skin hair and carcasses etc. These bacteria have mechanisms to assimilate eDNA into their genome (the blue print of life) and make them as a part of their genetic materials. Since genome composition determine the physiology, fitness and cellular repertoires of any organism, the change in genome composition by acquiring eDNA in actinomycetes, is likely to affect the diversity of secondary metabolites and the source of new drugs in these bacteria.

Marine ecosystem is the richest source of microbial diversity that includes actinomycetes. Streptomyces have also been isolated from a vast sources including marine zooplankton (Chevrette et al., 2019). Majority of these isolates have been shown to be an effective control of fungal and both Gram positive and Gram negative bacteria. Recently, the symbiotic association of Streptomyces with marine invertebrates like sponges and cone snails has been reported and a large number of marine Streptomyces with novel antimicrobial compounds effective against bacteria including MDRs and MRSA have been characterized (Kemung et al. 2018).

The metabolic and molecular basis of metabolite diversity that leads to the production of novel bioactive compounds are not well understood. Several labs including a few in India are involved in discovery of new drugs from Streptomyces. For example, the actinomycetes isolated from the marine waters showed antimicrobial activity against Staphylococcus aureus, Salmonella typhi, Pseudomonas aeruginosa, and Vibrio cholera (Devi et al. 2006). The Streptomyces isolated from marine environments showed better prospects with novel bioactive compounds as compared to the terrestrial parts. They found abundance of Streptomyces from the coastal areas of Gokhaarna and Muradeshwara of Karnataka state, exhibiting higher antibacterial activity on Gram-positive and Gram-negative bacteria (Vijayakumar et al. 2010). Nandhini and coworkers (2013) have assessed the antibacterial properties of Streptomyces isolated from marine waters of the coastal region of Tamil Nadu. Surprisingly, only a few studies particularly on drug discovery, have been carried on marine Streptomyces from the coastline of Bay of Bengal in Vishakhapatnam. The Gandhi Institute of Technology and Management (GITAM) a Deemed to be University, has its campuses in Vishakhapatnam, Hyderabad and Bangalore, India. This university provide a research ecosystem and a common platform for medical, paramedical, pharmaceutical, and science researchers to deliberate the research problems on bio-medical sciences. One of the research mandates of GITAM is Drug Design, Development and Discovery of new bioactive molecules from the marine biological resources in the coast of Visakhapatnam. Here, we aim for directed basic research on the characterization the marine Streptomyces diversity for bioactive secondary metabolites with antimicrobial, anti-cancer and anti-inflammatory properties. Further, we aim to understand the molecular basis of secondary metabolites diversity in the bacteria belonging to the genus of actinomycetes. ■

## Authors

**Hari S Misra**
Prof.
GITAM University

**M Kiranmai Reddy**
Assistant Professor
GITAM University

# Quality Assurance in Indian Pharmaceuticals

Often hailed as the "Pharmacy of the World," the Indian pharmaceutical sector is in the midst of an active phase, introducing novel drugs and distributing them worldwide. Nevertheless, amid this surge of new drug launches, some companies are falling short in upholding the required standards for product quality. **Nikkhil K Masurkar, CEO, Entod Pharmaceuticals** elaborates upon how pharmaceutical sector in India is dealing with a regulatory challenges and counterfeit drugs.


The United States Food and Drug Administration (US FDA) is vigilantly scrutinizing the manufacturing of these drugs. This has resulted in the Indian pharmaceutical industry becoming entangled in debates concerning quality assurance. Whether a company is large-scale or smaller in size, ensuring product quality remains a paramount concern for all.

To circumvent these discrepancies and potential violations, the implementation of a robust and comprehensive Quality Assurance Program across all facets of pharmaceutical operations emerges as a clear-cut solution. Since the pharmaceutical industry plays a crucial role in saving lives, it's extremely important to uphold high quality standards. This ensures that the medicines produced are trustworthy and work effectively. It should be implicit that pharmaceuticals originating from India not only meet but exceed global quality standards. This necessitates adopting a resolute zero-tolerance approach and enforcing stringent measures against counterfeit and substandard drugs. Prioritizing quality assurance and control should stand as the foremost objective for every pharmaceutical entity.

### Regulatory Challenges

The pharmaceutical sector in India is grappling with a deficient regulatory framework, leading to detrimental consequences. Instances of illicit practices like bribery and clandestine dealings have cast a shadow on the reputation of the country's pharmaceutical industry.

Additionally, it is imperative for the leadership of Indian pharmaceutical companies to recognize the adverse repercussions of substandard drug production. There have been numerous instances where top management exerts pressure to expedite production, resulting in the clearance of batches with questionable quality. Moreover, the irregularity of regulatory audits is attributed to a shortage of qualified auditors and a dearth of expertise in this domain. Urgent steps need to be taken to recruit and train auditors. They should be granted the authority to enforce stringent measures against manufacturers compromising the quality and integrity of drug products.

Another pressing issue is the pricing dynamics within the industry. Often, traditional generics are sold at minimal profit margins, or even at a loss. Consequently, major companies exhibit reluctance in their production, shifting their focus towards higher-priced generics or tailoring product quality for specific markets. This vacuum is being filled by smaller companies, which, unfortunately, may lack the financial resources, expertise, and infrastructure required to guarantee product quality.

Furthermore, a significant challenge lies in ensuring data integrity. Many facilities fail to uphold a culture of stringent data integrity, adopting practices that give rise to serious apprehensions regarding the reliability and authenticity of the generated data.

### Mitigating the Counterfeit Drug Menace

India, with the highest number of USFDA-approved pharma plants outside of the US and a significant count of EU/Japan/Australia FDA-approved facilities ensuring top-notch products, grapples with the persistent challenge of counterfeit drugs. Shockingly, about 10% of medicines in India are estimated to be counterfeit. Harnessing technology to thwart this threat is crucial.

The government's directive to incorporate a Quick Response (QR) code on the packaging label of the top 300 drug formulations emerges as a potent tool in combating counterfeit drugs. This QR code serves as a tracking mechanism, following the journey of the drug from production to the end-user. It encodes vital information including unique product identification, generic and brand names, manufacturer particulars, batch numbers, manufacturing and expiration dates, and licensing details. This single tool harbors the potential to markedly bolster the assurance of drug and vaccine quality.

Manufacturers are now obligated to validate their adherence to pertinent regulations. A resilient, rigorously documented quality assurance system aids drug makers in validating their compliance with regulatory standards. This system addresses not only deliberate malpractice but also concerns arising from procedural lapses, human error, or deficient collaboration.

### Additional Measures to Enhance the Quality of Pharmaceutical Products in India

Fostering a culture of quality throughout the supply chain, from leadership to field staff, is paramount. Regulatory standards must evolve alongside advancing processes and technology, with a focus on implementing the Revised Schedule M. India should seek membership in key organizations like the Pharmaceutical Inspection Co-operation Scheme (PICs) and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH). Building expertise in life sciences and technology is crucial, necessitating strong industry-academia collaboration.

Manufacturers must uphold unwavering commitment to the quality of their products. Rigorous quality assurance measures should extend from raw material procurement to final product stages. Collaboration between Indian Pharmacopoeia/Regulators and their global counterparts is vital in setting robust guidelines and specifications.

Currently, a three-tiered testing process involving manufacturer's Certificate of Analysis (COA),

Central Drug Laboratories (CDL) testing, and country-specific testing is in place. Regulators must ensure adherence to testing guidelines and product specifications at every stage. While the incidence of compromised quality is presently low in comparison to the volume of drugs exported by Indian companies, emerging trends necessitate immediate action to safeguard the industry.

To mitigate potential risks, both regulators and manufacturers should heighten their quality consciousness. Ongoing training for floor-level scientists should encompass not only scientific techniques but also a strong focus on drug quality and data integrity. Regulators must establish robust testing guidelines with clear specifications, increase auditing frequency, and enforce strict measures in response to any identified deviations. These proactive steps are essential to uphold the integrity of the pharmaceutical industry.

### Conclusion

Emphasizing quality will be the cornerstone of India's pharmaceutical exports, aligning with the vision of an "Atmanirbhar Bharat." A collective spirit of determination and collaboration among all stakeholders is the key to ensuring the exceptional quality of India's pharmaceutical products. ■

## Author

**Nikkhil K Masurkar**
CEO,
Entod Pharmaceuticals

CHEMTECH FOUNDATION 1974-2024 Inspiring Intelligence... ..Igniting Innovation

*Join us for 50th Year Celebration*

# ChemTECH WORLD EXPO 2024

Supported by

सत्यमेव जयते

Ministry of Chemicals & Fertilizers
Department of Chemicals and Petrochemicals, Government of India

Chemtech FOUNDATION Inspiring Intelligence > Igniting Innovation

DECHEMA Society for Chemical Engineering and Biotechnology e. V.

VDMA Process Plant and Equipment

## Most Defining & Powerful International Event for the Bio-Pharma Industry and Laboratory Technology, Analytix and Diagnostics

# Bio Pharma World Expo 2024

# LAB & ANALYTIX World Expo 2024

## 31st International Exhibition & Conferences

**4-7 March 2024**

**Venue:** Bombay Exhibition Center, Goregaon (East), Mumbai, India

Chairman
CAB BioPharma World Expo 2024

**Dr Rajesh Gokhale**
Secretary, DBT, Ministry of Science & Technology, Govt. of India

## BIO-PHARMA

### Manufacturing
- Vaccines
- Serums
- Biologics & Biosimilars
- Generics
- Bulk Drugs
- Drug Discovery & Development
- 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

**More than 500 Exhibitors already confirmed**

## 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 Expo | Specialty ChemiCAL | 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

Co Operation Partners

Gold Partners

LARSEN & TOUBRO | BURNS McDONNELL | EVONIK Leading Beyond Chemistry

Bronze Partners

POONAM PIPES & TUBES PVT. LTD. | aarvi | CHEMIPLANT ENGINEERING ENCOMPASSING TECHNOLOGY

Organised by:

Jasubhai MEDIA

## Jasubhai Media Pvt Ltd

Taj Building, 3rd Floor, 210, Dr. D N Road, Fort, Mumbai – 400 001, INDIA.
**Tel:** +91-22-4037 3636, **Email:** sales@jasubhai.com

Ahmedabad - 09833104834 | Bangalore - 09892644177 | Chennai - 09176963737
Delhi - 09891469629 | Hyderabad / Pune - 09822209183 | Vadodara - 09820544904

**sales@jasubhai.com** **www.chemtech-online.com**

R.N.I. No.: MAHENG/2002/08502. Date of Publication: 26th of every month. Poster Registration No: MCS/207/2023-25 Posted at Patrika Channel Sorting Office, Mumbai 400001. On 27th every month. Total Pages 40