This report is intended for Team White Marque Solutions (team.emkay@whitemarquesolutions

Pharmaceuticals

Pharma Weekly - ICYMI

This is the twentieth edition (week ending 9-Aug-26) of our Pharma Weekly – In Case You Missed It. The current edition includes a section dedicated to 2QCY26 earnings updates, with multiple global innovators/generic players reporting earnings over the last week. Key developments in the past week:

1) The USFDA approved Emerge Bioscience's Garzulys (insulin aspart), a biosimilar to NovoLog. Meitheal holds exclusive US commercialization rights under its agreement with Emerge Bioscience (relevant for Biocon).

2) Amgen's biosimilar portfolio grew 29% yoy to $855mn, led by Pavblu (Aflibercept) sales of $287mn, up 121% yoy (relevant for Biocon and Lupin). Prolia/Xgeva sales declined 33% yoy to $1.1bn amid biosimilar competition (relevant for Biocon, Dr Reddy's, and Aurobindo).

3) A US federal judge temporarily blocked the Pentagon from designating WuXi AppTec as a Chinese military-linked company, citing insufficient evidence. The ruling does not permanently remove WuXi from the Section 1260H list or prevent the department from designating the company again.

4) Merck's 2QCY26 Keytruda sales were up 4% yoy to $8.4bn, though US growth is expected to moderate as penetration peaks across key indications (read through for Zydus, Dr Reddy's, and Biocon). For Lipfendra, Merck is focused on expanding the oral PCSK9 market (regulatory reviews ongoing in Europe and China), while also developing combination therapies (relevant for Divi's).

5) Eli Lilly's Foundayo sales stood at $98mn in 2QCY26, with prescriptions showing an inflection following expanded access, DTC promotion, and the Medicare GLP-1 Bridge program; the drug is now under review in more than 40 markets, supporting its global rollout potential (read-through for Divi's).

6) BioCryst Pharma reported Orladeyo revenue of ~$158mn in 2QCY26, up 10% yoy. FY26 revenue guidance was maintained at $625-645mn, while pediatric Orladeyo pellets saw strong early traction (read-through for Sai Life).

7) Pfizer reported Nurtec revenue of ~$420mn in 2QCY26, up 18% yoy (relevant for Anthem and Piramal). Cibinqo revenue grew 38% yoy to $94mn; Mevrometostat is advancing through Phase 3 (both relevant for Laurus Labs).

8) Rhythm Pharma reported Imcivree revenue of ~$70mn in 2QCY26, up 19% qoq, driven by strong US demand. The product is expected to be launched in Japan in 4QCY26 and in Germany in 1HCY27. Supernus Pharma reported Qelbree sales of ~$89mn in 2QCY26, up 15% yoy (relevant for Neuland).

9) Vertex Pharma's Alyftrek revenue reached ~$575mn in 2QCY26, up 265% yoy, driven by continued Trikafta switching and strong US/Europe uptake (relevant for Laurus). Journavx revenue stood at $50mn, up 71% qoq (relevant for Laurus Labs and Anthem).

10) Acadia reported Daybue sales of $125mn in 2QCY26, up 30% yoy. The company raised CY26 Daybue guidance to $480-510mn and remains confident of reaching $700mn by CY28. ACP-211 is advancing in Phase 2 for a major depressive disorder (relevant for Sai Life).

11) Zoetis reported Simparica franchise sales of $442mn, flat yoy, with 19% international growth offset by a 6% decline in the US (relevant for Sai Life). Librela + Lenivia generated $105mn in sales in 2QCY26, down 8% yoy, although early response to the launch of Lenivia in Europe and Canada is encouraging, per the management (relevant for Syngene).

12) Insmed reported Brinsupri revenue of ~$310mn in 2QCY26; the company raised its CY26 revenue guidance to $1.25-1.4bn and peak sales expectations to >$7bn (read-through for Anthem).

Further coverage of Global innovators, CDMOs, and generic players on the next page

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News flow – Indian Pharma

1) Biocon launched Yesafili (Aflibercept), its interchangeable biosimilar to Eylea 2mg, in the US, enabling pharmacy-level substitution subject to state laws. The product had received USFDA approval and an interchangeable designation in May-24.

2) Sun Pharma initiated a precautionary withdrawal of several ophthalmic products in India, including Depopred, Brinolar, Brinzotim, Lotepred, Nepalact, and related eye drops; it instructed distributors to immediately stop billing and to return existing stocks.

3) Piramal Pharma Solutions launched a new spray drying suite at its Turbhe peptide facility. The closed-loop facility supports small-volume, high-potency batches and enables controlled processing to improve peptide stability, solubility, and bioavailability.

4) Gland Pharma and Neuland announced a long-term CDMO partnership, with Gland setting up a dedicated sterile API manufacturing suite at its Visakhapatnam facility for microparticle depot products, adding ~1,400kg annual capacity.

5) Dr Reddy's has terminated its Feb-22 agreement with Novartis India for distribution and promotion of select brands, with the company continuing to commercialize the products till 30-Sep-26. Following termination, Novartis India will re-acquire exclusivity and market access for the covered products.

6) Gland Pharma signed a strategic Manufacturing and Supply Agreement (MSA) with a global pharma company for manufacturing and supply of 55 sterile injectable SKUs across three sites, covering oncology and non-oncology products in the vial, lyophilized, ampoule, and PFS formats. Technology transfer is expected to be completed within two years, with revenue starting from CY29, with annualized revenue potential of $90-100mn once all products are commercialized.

7) AstraZeneca Pharma India received CDSCO approval for an additional indication of Enhertu (Trastuzumab Deruxtecan) for adjuvant treatment of HER2-positive breast cancer patients with residual invasive disease, following neoadjuvant therapy.

8) Dr Reddy's Laboratories registered a new Phase 1 trial for its proposed Abatacept biosimilar, evaluating auto-injector and prefilled syringe formulations for pharmacokinetic comparability, safety, and tolerability in 160 participants.

9) The Delhi High Court sought responses from Novartis, Astex Therapeutics, and the Controller of Patents on Natco Pharma's challenge to a patent granted for Ribociclib, with Natco alleging double patenting and unlawful extension of patent protection.

10) The Indian Pharmaceutical Alliance (IPA) has asked pharma companies to identify legacy drugs marketed in India without clear CDSCO approvals, seeking their regularization by the regulator. Examples include sodium valproate modified-release tablets, carbamazepine tablets, and lithium carbonate prolonged-release tablets, where certain strengths are not reflected in CDSCO's central approval records.

News flow – Global innovators, CDMOs, and generic players

1) Sandoz agreed to pay ~$450mn to settle remaining US state and territory claims related to alleged generic drug antitrust conduct, including $400mn payable over seven years from CY27 and ~$50mn to states that settled earlier. The settlement, along with a separate $28.5mn indirect reseller agreement, effectively resolves the company's remaining government and class-action claims.

2) Polpharma Biologics and Fresenius Kabi received FDA and EMA acceptance for review of PB016, a proposed Vedolizumab biosimilar to Takeda's Entyvio, for ulcerative colitis and Crohn's disease. Fresenius Kabi holds global commercialization rights, excluding the Middle East and North Africa.

3) USFDA approved Emerge Bioscience's Garzulys (insulin aspart), a biosimilar to NovoLog, for glycemic control in adults and pediatric patients with diabetes. Meitheal holds exclusive US commercialization rights under its agreement with Emerge Bioscience (relevant for Biocon).

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4) Eli Lilly plans to provide limited expanded access to Retatrutide before FDA approval for eligible patients with severe refractory obesity who cannot participate in clinical trials. Lilly plans to file for FDA approval in 1QCY27, following Phase 3 data showing 22.6% average weight loss at the highest dose over 80 weeks.

5) Amgen discontinued development of AMG 513, leaving MariTide as its sole near-term obesity drug candidate. AMG 513's Phase 1 trial will continue for existing participants, while Amgen's Phase 3 MariTide program remains on track for key weight-loss readouts in CY27.

6) Eli Lilly's Foundayo prescriptions rose 16% sequentially to 34,219, marking the fourth consecutive week of growth. Novo Nordisk's oral Wegovy was flat week-on-week, accounting for 35% of total Wegovy prescriptions, while Wegovy held ~40.6% of the US obesity market.

7) Amazon Pharmacy will offer eligible Medicare beneficiaries access to Novo Nordisk's Wegovy and Eli Lilly's Foundayo and Zepbound KwikPen for $50/month through the Medicare GLP-1 Bridge program.

8) Jiangsu Hengrui plans to file an NDA in China for Ribupatide after the GLP-1/GIP dual agonist achieved non-inferiority to Ozempic in a Phase 3 Type 2 Diabetes trial.

9) Adalvo and Gedeon Richter expanded their partnership to co-develop and supply Tirzepatide, targeting diabetes and obesity markets. The companies have secured FDA acceptance of two ANDAs for generic Tirzepatide injection.

10) Takeda received FDA approval for Oryeyful (Oveporexton), the first-in-class oral OX2R agonist for narcolepsy type 1 (NT1). The drug is the first US-approved therapy targeting the underlying orexin deficiency and treating the broad spectrum of NT1 symptoms, including excessive daytime sleepiness and cataplexy (relevant for gXywav filers and Suven Life).

11) Eli Lilly and the FDA are in dispute over whether Retatrutide should be classified as a biologic or a peptide/drug. Lilly wants biologic classification, while the FDA has classified it as a drug/peptide, with the distinction affecting exclusivity and potential compounding.

12) A US federal judge temporarily blocked the Pentagon from designating WuXi AppTec as a Chinese military-linked company, citing insufficient evidence to support the designation. The ruling provides temporary relief from the designation's adverse consequences, though it does not permanently remove WuXi from the Section 1260H list or prevent the department from designating the company again.

2QCY26 earnings updates – Global innovators and generic players

1) BioCryst Pharma reported Orladeyo revenue of ~$158mn in 2QCY26, up 10% yoy, with volume growth and pricing/reimbursement contributing almost equally. Pediatric Orladeyo pellets saw a strong start with 47 prescriptions through 31-Jul, while FY26 Orladeyo revenue guidance was maintained at $625–645mn (read-through for Sai Life).

2) Pfizer reported Nurtec revenue of $421mn in 2QCY26, up 18% yoy, with the product continuing to lead the oral CGRP class in total prescriptions. Pfizer is also advancing Phase 3 trials for menstrual migraine and acute-treatment redosing, while a pivotal trial in chronic migraine is expected to start this year (relevant for Anthem and Piramal). Cibinqo revenue grew 38% yoy to $94mn, driven by 39% yoy growth in the US while Mevrometostat is advancing through Phase 3, with Phase 1 data showing a 49% reduction in advanced prostate cancer disease progression or death when combined with Xtandi (relevant for Laurus Labs).

3) Rhythm Pharmaceuticals reported Imcivree revenue of ~$71mn in 2QCY26, up 19% qoq, driven by strong US demand following the launch for acquired hypothalamic obesity. CY26 launch momentum remains encouraging, with a launch in Japan expected in 4QCY26 and in Germany in 1HCY27 (relevant for Neuland).

4) Roivant Sciences expects topline Phase 2 data for Mosliciguat in pulmonary hypertension associated with interstitial lung disease (PH-ILD) in 2HCY26, with the management highlighting the potential for Mosliciguat's inhaled vasodilatory mechanism to improve outcomes in the severely ill PH-ILD population (relevant for Sai Life).

5) Vertex Pharma's Alyftrek revenue reached ~$575mn in 2QCY26, up 265% yoy, driven by continued switching from Trikafta and strong uptake in the US and Europe (relevant for Laurus). Journavx revenue stood at $50mn, up 71% qoq, in 2QCY26; the drug was added to formularies, protocols, and order sets across 1,400 hospitals and 130 Integrated Delivery Networks (relevant for Laurus Labs and Anthem).

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6) Jazz Pharma reported strong momentum for Xywav with revenue up 13% yoy to $471mn in 2QCY26. Uptake of high-sodium generics remains limited, supporting double-digit Xywav growth guidance for CY26 as its differentiated low-sodium profile and only approved indication for idiopathic hypersomnia continue to drive demand (relevant for gXywav filers).

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7) Merck reported Keytruda 2QCY26 sales rising 4% yoy to $8.4bn, driven by strong uptake in earlier-stage cancers and continued demand in metastatic indications; however, the company expects US Keytruda growth to moderate as the drug approaches peak penetration across key indications (read through for Zydus, Dr Reddy's, and Biocon). For Lipfendra, Merck is focused on expanding the oral PCSK9 market, with plans to broaden patient access through initiatives such as TrumpRx and ongoing regulatory reviews in Europe and China, while also developing combination therapies with Rosuvastatin and MK-7262 (relevant for Divi's).

8) Zoetis reported Simparica franchise sales of $442mn, flat yoy, with 19% international growth offset by a 6% decline in the US (relevant for Sai Life). Librela and Lenivia generated $105mn in sales in 2QCY26, down 8% yoy, although early response to the launch of Lenivia in Europe and Canada is encouraging, per the management (relevant for Syngene).

9) Acadia reported Daybue sales of $125mn in 2QCY26, up 30% yoy, driven by strong volume growth and rapid uptake of the new Daybue Stix formulation, with ~40% of US patients on Stix by quarter-end. The company raised CY26 Daybue guidance to $480-510mn and remains confident of reaching $700mn sales by CY28, supported by US growth and planned European expansion. The company is also advancing ACP-211 in a Phase 2 study in major depressive disorder (relevant for Sai Life).

10) Eli Lilly reported 2QCY26 revenue growth of 48% yoy, driven by strong Mounjaro and Zepbound performance; both brands generated $14.9bn of combined revenue. Foundayo sales stood at $98mn, with prescriptions showing an inflection following expanded access, DTC promotion, and the Medicare GLP-1 Bridge program; the drug is now under review in >40 markets, supporting its global rollout potential (read-through for Divi's).

11) Novo Nordisk raised its 2026 sales guidance to 0% to 6% decline at constant exchange rates, driven by stronger GLP-1 expectations. Obesity care sales grew 16% to ~$3.6bn, led by Wegovy injectable sales of ~$3bn (+1% cc) and Wegovy pill sales of ~$500mn. Wegovy pill uptake remains strong, with >5mn prescriptions in the US and ~90% share of the oral obesity market, while ~80% of users are GLP-1 treatment-naïve.

12) Eisai reported Dayvigo revenue of JPY18.9bn in 1QFY27, up 38% yoy, with strong growth across all regions. Dayvigo maintained the highest market share in Japan in the dual orexin receptor antagonist segment, while continuing to gain traction in the US, Canada, and China. Eisai expects JPY73.5bn revenue for FY27 and is expanding Dayvigo's global footprint, with regulatory applications for chronic insomnia submitted in the UK and Europe in July (relevant for Aarti Pharmalabs).

13) Bayer reported 42% and 33% yoy decline in Xarelto and Eylea sales in 2QCY26, respectively, driven by LOE and biosimilar pressure (read through for Cohance). Eylea 8mg continued to gain traction, reaching ~55% of franchise sales and remaining on track for ~70% share by year-end, partly offsetting the decline in Eylea 2mg (read-through for Biocon and Lupin). The Lynkuet launch remained in line with expectations, with further market launches planned through CY26 and beyond (read-through for Aarti Pharmalabs).

14) Amgen reported Otezla volumes were resilient, supported by its broad label, extensive clinical experience, and strong payer coverage, with the drug continuing to be used largely as a first-line systemic treatment. New entrants are primarily competing with Otezla, and pricing remains under pressure due to 340B exposure (relevant for Cohance and Sun Pharma). Amgen's biosimilar portfolio grew 29% yoy to $855mn, led by Pavblu (Aflibercept) sales of $287mn, up 121% yoy (relevant for Biocon and Lupin). Prolia/Xgeva sales declined 33% yoy to $1.1bn amid biosimilar competition (relevant for Biocon, Dr Reddy's, and Aurobindo).

15) Insmed reported Brinsupri revenue of ~$310mn in 2QCY26, adding ~7,000 new patients during the quarter. Strong launch momentum led the company to raise CY26 revenue guidance to $1.25-1.4bn and peak sales expectations to >$7bn. The company sees further upside from earlier diagnosis of bronchiectasis, including identifying patients with comorbid COPD and asthma (read through for Anthem).

16) Gilead reported Trodelvy sales of $457mn in 2QCY26, up 26% yoy, driven by strong demand across triple-negative and HR-positive/HER2-negative metastatic breast cancer. Recent FDA approvals in first-line metastatic triple-negative breast cancer across PD-L1 status significantly expand its addressable market, supporting further growth and taking Trodelvy toward a $2bn annualized sales run-rate (read-through for Cohance).

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17) Sandoz reported biosimilar sales growth of 20% in 1HCY26 and 22% in 2QCY26, with biosimilars reaching a record 33% of net sales. Wyost and Jubbonti, interchangeable Denosumab biosimilars, launches exceeded expectations, achieving 54% and 64% US biosimilar market share, respectively, while Pyzchiva (Ustekinumab) reached 35% share in major European markets. Sandoz also expanded its biosimilar pipeline to 36 assets, supporting multiple future growth opportunities.

18) Supernus Pharmaceuticals reported Qelbree sales of ~$89mn in 2QCY26, up 15% yoy, primarily driven by volume growth. Prescriptions increased 17% yoy to 265k, with prescription growth of 25% in adults and 14% in pediatric patients, maintaining Qelbree's strong growth trajectory in the ADHD market (relevant for Neuland).

19) Vanda Pharmaceuticals reported that Nereus was commercially launched in the US in May-26, initially through a direct-to-consumer offering, with personal promotion expected later in 2HCY26. Nereus generated $1mn in net product sales in 2QCY26, while wholesalers initially stocked $15mn of the product in 2QCY26 (the company recognized only $1mn due to revenue constraints related to patient demand and potential returns). Vanda expects CY26 Nereus sales of $10–30mn, with Phase 3 data in GLP-1-induced vomiting expected in CY26 (read-through for Sai Life).

Key regulatory developments

1) The USFDA outlined an expedited IND Pilot Program aimed at shortening the timeline to first-in-human trials by 6-12 months, with 8-10 drug development programs expected to be selected by end-CY26. The pilot will use rolling submissions and early, iterative FDA feedback through Qualified Research Institutions to streamline pre-IND development and reduce delays.

2) The CDSCO suspended registrations of eight clinical trial ethics committees across Delhi, Pune, Navi Mumbai, Ahmedabad, and Kolkata for violations of New Drugs and Clinical Trials Rules, Good Clinical Practice guidelines, and quality management requirements, reflecting stricter regulatory oversight of clinical trial compliance and participant safety.

3) The UK and Canada are exploring a pilot to mutually recognize pharmacovigilance inspections, aiming to reduce duplicate inspections of the same companies and facilities by relying on each other's inspection outcomes.

USFDA inspections/inspection outcomes

1) Alkem's Amaliya, Daman facility received an OAI classification from the USFDA following the Apr-May CY26 inspection, which resulted in seven Form 483 observations.

2) Emcure's Sanand, Gujarat formulations facility received an EIR from the USFDA with a VAI classification, closing the inspection conducted during 6-May-26 to 15-May-26.

3) Cipla's InvaGen Pharmaceuticals received an EIR from the USFDA, confirming closure of the PAI conducted in Feb-26 at its Hauppauge, New York facility.

4) Cohance Lifesciences's Pashamylaram, Hyderabad facility received 5 Form 483 observations following the USFDA inspection conducted from 27-Jul-26 to 5-Aug-26. None of the observations were related to data integrity issues.

Key USFDA Approvals (Final + Tentative): Indian Pharma/global generic players competing with Indian players in the specific product

Final Approval: gOfev (Macleods Pharma), gIC-Green (Zydus), gEntresto (Umedica), gCardene (Fresenius Kabi), gKeppra (Baxter Healthcare)

Tentative Approval: gRytary (Biocon, Hetero Labs)

Management changes/Corporate actions

1) Morepen Laboratories re-appointed Sushil Suri as Chairman and Managing Director for a further three-year term from 20-Oct-26 to 19-Oct-29.

2) Alkem Laboratories appointed Rajpal Singh Rana to a senior management position, effective 3-Aug-26.

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3) GSK India appointed Karine J F Natland as Non-Executive Director, replacing Subesh Williams, who stepped down from the Board effective 3-Aug-26. Bhushan Akshikar was re-appointed as Managing Director for a two-year term from 1-Dec-26.

4) Shilpa Medicare appointed Dr Uday N Harle as CEO of Shilpa Biologicals, its wholly-owned subsidiary, effective 3-Aug-26.

5) Sanofi India's CFO and Whole-Time Director Rachid Ayari stepped down from his positions, effective close of business on 30-Sep-26. It will reconstitute its Stakeholders Relationship and Risk Management Committees following changes to Board composition.

6) Emcure Pharmaceuticals appointed Raghu Kumar as an Additional Director (Non-Executive, Independent) for a three-year term. Berjis Desai will step down as Chairman and Director, following his appointment to the National Commission for Minorities, while Satish Mehta will become Chairman thereafter.

7) Biocon re-appointed Eric Vivek Mazumdar as Director, while Nicholas Robert Haggar retired as Independent Director upon completion of his term.

8) Poly Medicure's Deputy Company Secretary and Compliance Officer, Ravi Prakash, resigned to pursue an alternative career opportunity outside the organisation, effective close of business on 10-Aug-26.

9) Aarti Pharmalabs will appoint Rashesh Gogri as Managing Director, transitioning from Non-Executive Director, while Hetal Gogri Gala will move from Managing Director to Executive Director.

10) Aurobindo Pharma approved the merger of step-down subsidiaries Eugia Steriles and Eugia SEZ with wholly-owned subsidiary Eugia Pharma Specialities, with the Scheme of Amalgamation to be filed with NCLT, Hyderabad.

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ADD	5-15% upside
REDUCE	5% upside to 15% downside
SELL	>15% downside

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