

PHARMA MONTHLY MUSINGS

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Lupin

- **USFDA approval:** Eribulin Mesylate Injection (generic of Halaven), with alliance partner Natco Pharma, for metastatic breast cancer and liposarcoma.
- **USFDA approval:** Ranluspec (ranibizumab-hkdz), an interchangeable biosimilar of Lucentis, for multiple retinal disorders; the only US-approved interchangeable ranibizumab biosimilar available in both vial and pre-filled syringe formats.
- **USFDA tentative approval:** Enzalutamide Tablets, generic of Xtandi, for prostate cancer treatment.



Aurobindo Pharma*

- **USFDA final approval:** Tofacitinib Tablets (generic of Xeljanz) for autoimmune disorders; immediate US launch planned, targeting a ~USD 494 Mn market.



Astrazeneca Pharma India*

- **CDSCO approval:** Additional indication for Enhertu (trastuzumab deruxtecan) in combination with pertuzumab as first-line treatment for patients with advanced HER2-positive breast cancer.



Concord Biotech

- **USFDA approval:** Mycophenolate Mofetil Oral Suspension USP, an immunosuppressant used to prevent organ rejection in transplant patients.
- **USFDA approval:** Tofacitinib Tablets for rheumatoid arthritis, psoriatic arthritis, ulcerative colitis and other autoimmune disorders.



Alembic Pharmaceuticals*

- **USFDA final approval:** Haloperidol Tablets USP (generic of Haldol) for psychotic disorders and Tourette's disorder; addresses a ~USD 27 Mn US market.
- **USFDA final approval:** Tretinoin Cream USP 0.05% (generic of Retin-A) for acne treatment; provides access to a ~USD 76 Mn US market.
- **USFDA final approval:** Oseltamivir Phosphate Oral Suspension (generic of Tamiflu) for influenza treatment and prevention.
- **USFDA final approval:** Dapsone Gel 5% (generic of Aczone Gel) for topical treatment of acne vulgaris.
- **USFDA tentative approval:** Larotrectinib Capsules for cancer treatment; first filer with potential 180-day generic exclusivity upon final approval.
- **USFDA tentative approval:** Binimetinib Tablets 45 mg for melanoma and certain lung cancers; sole first filer for the 45 mg strength with potential 180-day exclusivity upon final approval, targeting a ~USD 259 Mn market.



Recent Report Link:

[Sun Pharma Q4FY26 Result Update](#)

[Lupin Q4FY26 Result Update](#)

* Non coverage companies



1 Cipla

- Received **USFDA Voluntary Action Indicated (VAI)** classification following routine cGMP and Pre-Approval Inspection at its Verna, Goa manufacturing facility.

2 Dr.Reddy's

- USFDA Pre-License Inspection (PLI)** at Bachupally biologics manufacturing facility concluded with **seven** Form 483 observations.

3 CONCORD BIOTECH
Biotech for Mankind...

- ANVISA inspection** at its Limbasi, Gujarat API manufacturing facility completed successfully.
- Joint Pharmacy and Poisons Board (Kenya) and National Drug Authority (Uganda) inspection** at its Unit-II formulation facility completed successfully.

4 zydus
Dedicated To Life

- Received **USFDA Warning Letter** for its Baddi formulation facility relating to purified talc not meeting current USP requirements; letter issued following records review with **no expected impact** on operations or supplies.

5 GRANULES

- Received **USFDA Establishment Inspection Report (EIR)** for its Chantilly, Virginia facility with Voluntary Action Indicated (VAI) classification following inspection with **four** Form 483 observations.

6 AUROBINDO *

- USFDA classified** Eugia Unit-III formulation facility in Telangana as **Official Action Indicated (OAI)** following inspection with **eleven** observations.
- USFDA Pre-Approval Inspection (PAI)** at Eugia Steriles facility in Andhra Pradesh concluded with **five** observations.
- USFDA Inspection** at its Andhra Pradesh API and formulation intermediates facility concluded with **two** observations.



* Non coverage companies



Lupin

- **Partnered with Laboratorios ERN to launch Luforbec** in Spain for asthma and COPD treatment, expanding its respiratory franchise in Europe.
- **Launched Azilsartan Medoxomil Tablets** (generic of Edarbi) in the US with **180-day first-to-file exclusivity**.

Zydus Lifesciences



- **Completed acquisition of Assertio Holdings**, strengthening its presence in the US specialty pharmaceuticals market.
- **Partnered with Sunshine Healthcare** to establish a pharmaceutical manufacturing facility in Sri Lanka through a joint venture with an investment of over USD 20 Mn.
- **Extended closing date for acquisition of Sterling Biotech's** API business to September 30, 2026.



Dr. Reddy's Laboratories

- **Launched Bosutinib Tablets 400 mg** (generic of Bosulif) in the US with **180-day generic exclusivity**.

Sun Pharmaceutical Industries



- **Acquired 100% stake in Innovcare Lifesciences for INR 271 crore** in an all-cash deal, strengthening its presence in the nutraceuticals, cosmeceuticals and wellness segments.



Glenmark Pharmaceuticals

- **Launched Lacosamide Injection USP** (generic of Vimpat) in the US, expanding its injectable portfolio.
- **Launched Winlevi across key European markets**, marking its first New Chemical Entity (NCE) launch in Europe.
- **Launched Methylene Blue Injection USP** (generic of ProvayBlue) in the US, strengthening its institutional injectable portfolio.

Piramal Pharma



- **Received permanent revocation of closure directions for its Dahej facility** from the Gujarat Pollution Control Board, removing the regulatory overhang.



IPCA Laboratories

- **Entered global licensing agreement with Bhami's Research Laboratory** for monoclonal antibody products targeting oncology and inflammatory diseases.
- **Approved merger of Krebs Biochemicals & Industries**, strengthening fermentation-based API capabilities and raw material security.



Marksans Pharma



- **Acquired Netherlands-based QliniQ B.V.**, strengthening front-end presence and commercial infrastructure across regulated European markets.
- **India Ratings revised outlook on bank facilities to Positive from Stable** while reaffirming IND AA-/Positive/IND A1+ ratings, reflecting improving business profile and financial strength.

Alkem Laboratories



- **Launched India's first single-shot pre-filled Semaglutide** syringes for Type-2 diabetes and obesity, strengthening presence in the rapidly growing GLP-1 market.
- **Executed supplementary agreement for acquisition of 51–55% stake in Switzerland-based Occlutech Holding AG** through subsidiary Alkem Medtech.

Ajanta Pharma



- **Promoter entity Ravi Agrawal Trust sold 2.76% stake through a block deal for INR 1,024 crore at INR 2,968 per share**; shares were acquired by Kotak Mahindra Mutual Fund and Aditya Birla Sun Life Mutual Fund with 21.02 lakh and 13.47 lakh shares, respectively.

Concord Biotech



- **Approved investment of INR 6.3 crore** to acquire a 27.38% stake in FSGE Renewable Power Pvt. Ltd in a hybrid wind-solar power project to supply green energy to its Limbasi manufacturing facility.

Biocon*



- Partner **Duopharma Biotech** secured insulin supply contracts worth **over MYR 225 Mn** from Malaysia's Ministry of Health, reinforcing Biocon's diabetes franchise.

Strides Pharma*



- **Signed strategic investment deal with an Ascent Capital-led consortium in Pivot Path to realise ~INR 1000 Mn**, enabling expansion and AI-led technology investments while retaining a ~20% stake and will inject INR 500 Mn of fresh capital.

Aurobindo Pharma*



- **Inaugurated TheraNym**, one of India's largest biologics CDMO facilities, marking entry into the biologics contract manufacturing business with MSD serving as the anchor customer.
- **Received US Federal Trade Commission clearance for acquisition of Lannett Company**, with transaction expected to close by end of June 2026.

Alembic Pharmaceuticals*



- Signed shareholders' agreement to acquire **45% stake** in a Canadian joint venture alongside Difgen Holdings LLC, focused on pharmaceutical product development and commercialization.

* Non coverage companies



CDSCO Tightens Safety Reporting: India's drug regulator has mandated stronger pharmacovigilance systems and adverse drug reaction monitoring across pharmaceutical companies. Compliance will be reviewed during inspections, reinforcing the regulator's focus on post-marketing drug safety.

1

Pharma Sector Set to Double: Commerce Minister Piyush Goyal said India's pharmaceutical industry has the potential to double in size over the next five years. Growth is expected to be driven by innovation, biosimilars, complex generics and other high-value products.

2

Input Prices Provide Relief: Prices of key APIs and petrochemical-based raw materials have declined amid easing geopolitical tensions and improving supply chains. Lower input costs are expected to provide margin support for pharmaceutical manufacturers.

3

US Turns to India for Cancer Drug Supply: The USFDA has sought support from Indian pharmaceutical companies to address shortages of the critical chemotherapy drug Ifosfamide. The move highlights India's growing importance in ensuring global medicine supply security.

4

Unified Platform Boosts Price Transparency: NPPA has integrated its Pharma Sahi Daam and Pharma Jan Samadhan portals into a single citizen-centric platform. Consumers can now check medicine prices and lodge pricing-related complaints through one interface.

5

Brazil Emerges as Export Growth Engine: Brazil has become India's second-largest pharmaceutical export market, supported by rising demand for branded generics, oncology products and biosimilars. Exports are expected to surpass USD 1 Bn in FY27.

6

CDSCO Flags Drug Quality Issues: CDSCO identified 159 drug samples as Not of Standard Quality (NSQ) and one product as spurious during May 2026. The findings reflect continued regulatory surveillance to strengthen drug quality and patient safety.

7

Semaglutide Growth Moderates: India's Semaglutide market is witnessing inventory build-up following the initial post-patent launch surge. Slower patient adoption compared with channel stocking has led to elevated inventory levels across the supply chain.

8

Biotech M&A Boom: Global biotech dealmaking has rebounded sharply in 2026 as large pharmaceutical companies seek to replenish pipelines ahead of major patent expiries. Improved investor sentiment has also supported stronger IPO activity.

9

Prescription-Only Sales Mandated: The government has restricted the sale of certain cough syrups containing regulated ingredients to prescription-only dispensing. The move aims to curb misuse while strengthening patient safety and regulatory oversight.

10



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CHOICE RATING DISTRIBUTION & METHODOLOGY

Large Cap*	
BUY	The security is expected to generate upside of 15% or more over the next 12 months
ADD	The security is expected to show upside returns from 5% to less than 15% over the next 12 months
REDUCE	The security is expected to show upside or downside returns by 5% to -5% over the next 12 months
SELL	The security is expected to show downside of 5% or more over the next 12 months
Mid & Small Cap*	
BUY	The security is expected to generate upside of 20% or more over the next 12 months
ADD	The security is expected to show upside returns from 5% to less than 20% over the next 12 months
REDUCE	The security is expected to show upside or downside returns by 5% to -10% over the next 12 months
SELL	The security is expected to show downside of 10% or more over the next 12 months
Other Ratings	
NOT RATED (NR)	The stock has no recommendation from the Analyst
UNDER REVIEW (UR)	The stock is under review by the Analyst and rating may change
Sector View	
POSITIVE (P)	Fundamentals of the sector look attractive over the next 12 months
NEUTRAL (N)	Fundamentals of the sector are expected to be in stasis over the next 12 months
CAUTIOUS (C)	Fundamentals of the sector are expected to be challenging over the next 12 months

*Large Cap: More Than INR 20,000 Cr Market Cap
 *Mid & Small Cap: Less Than INR 20,000 Cr Market Cap





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