

FIDENT FINEPRINT

BIOTECH, CDMO AND GLP-1

EDITION 1



JULY 2025



As we mark the completion of our *1st year* at Fident AMC, we are pleased to present the **inaugural edition of Fident Fineprint - a research-led view on emerging megatrends.**

Fident Fineprint is a focused lens on structural megatrends shaping India's growth story. In each edition, we explore sectors undergoing meaningful transformation, highlight listed companies aligned with these themes, and share how our portfolios are positioned to participate in these long-term opportunities.

In our first edition, we probe into the Pharmaceutical sector.

Why are we overweight on pharma?

- Our philosophy at Fident is straight-forward
 - We like businesses which we believe we understand, which are difficult to be disrupted and having favourable long-term prospects.
 - We prefer companies which have strong capital allocation, robust cash flows and are run by competent management.
 - We believe the risk-reward is favourable.
- Pharma as a sector is an ideal confluence of our philosophy, as strong tailwinds, robust capital allocation and favourable risk makes in one of the sectors where we are overweight on.
- Our due-diligence on the sector which encompassed meeting listed and unlisted companies, interacting with experts on the subject and our in-house analysis results in popping up of 3 megatrends where we see significantly higher growth
 - I. Biotech (Novel Drug Discovery)
 - II. Contract Development and Manufacturing Organization (CDMO)(Innovator focused)
 - III. GLP-1 (Glucagon-like Peptide)

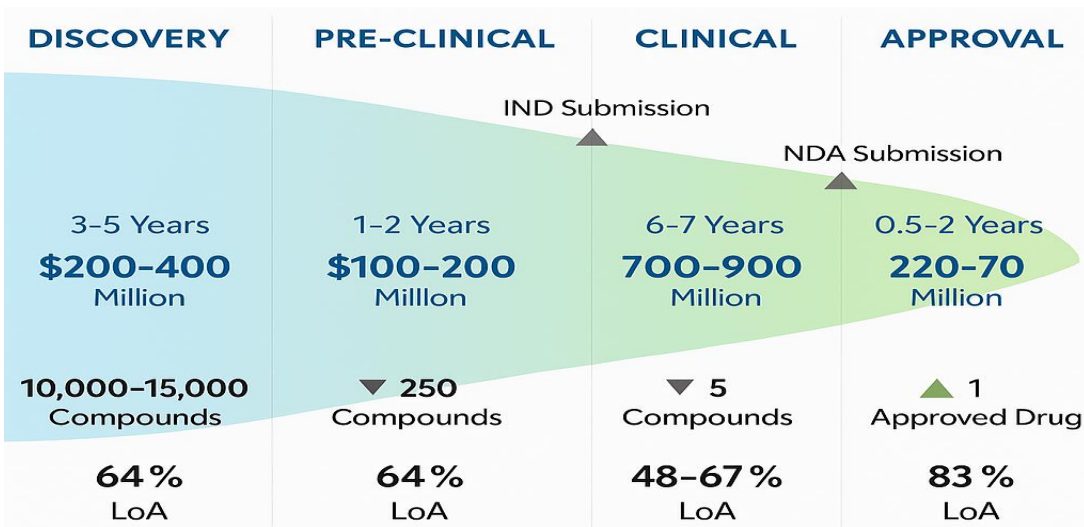
Fident Fineprint does a comprehensive deep-dive in these megatrends with the sole purpose of **identifying listed companies best structured to ride multi-year tailwinds.**



I. Biotech (Novel Drug Discovery)

- When we look at domestic listed universe, a comprehensive majority of businesses reflect either a linear growth (in-line with capacities available) or cyclical growth (where spurts of exponential growth are often offset by declines when the cycle turns unfavourable).
- Biotech (Novel Drug Discovery) (NCE or NBE) (New Chemical Entity or New Biological Entity) is an exciting business to be in, as it is among the very few domains where successful commercialization of a new drug can yield exceptionally high rewards.
- However, the cost for innovating and commercializing a new drug is high, a lengthy, costly and risky process.
- Innovator drugs are the first version of NCE or NBE to be developed, approved, and marketed, that usually contain a new active ingredient and require extensive clinical development and a patent approval process for use.

Drug Development Lifecycle



Total	Small Molecules
Cost (USD bn)	1.5-2 bn
Time for development	12-15
Probability Success	18%

Source – Anthem Biosciences DRHP



- The cost of developing a new drug typically ranges from ~1-2 billion USD with success rates at 9% to 18% for small molecules and biologics, with bulk of costs in clinical phases ranging from ~700-900 million USD.
- Historically, Indian companies have historically focused more on generic molecules rather than innovations, with innovative molecules markets dominated by US (~45% MS), China (~35% MS) and Europe (~13% MS).
- Some of the largest global innovators are Roche, Pfizer, Eli Lilly, Novo Nordisk, Johnson and Johnson and Jiangsu Hengrui Pharmaceuticals.

India and Innovation

- In the history of Indian biotech there is only one New Chemical Entity (NCE) innovated by Indian company and approved by US FDA which was **Orchid Pharma's Cefipime - Enmetazobactam**.
- Sun-Pharma has not yet developed an-inhouse NCE, though it has multiple molecules which it acquired from other bio-tech companies. (Refer Exhibit below)
- However, we believe the limited presence of India in novel drug discovery is likely to change materially over the next few years, as several Indian pharma companies have interesting assets in different stages of development. (Refer Exhibit below)



New Chemical Entity	Therapy	Innovator	Stage
Approved			
Enmetazobactam (Exblifep)	Infections (UTI and Kidney)	Orchid Pharma (Licensed to Allecra Therapeutics)	US FDA approved
Tildrakizumab-asmn (Ilumya)	Plaque psoriasis.	Merck/ MSD (NCE takeover by Sun Pharma post Phase 2 development)	US FDA approved
Deuruxolitinib (Leqselvi)	Severe alopecia areata	Concert Pharma (Company acquired by Sun Pharma)	US FDA approved
Cosibelimab - ipdl (Unloxcyt)	Cancer (metastatic cutaneous squamous cell carcinoma (cSCC))	Checkpoint Therapeutics (Company acquired by Sun Pharma)	US FDA approved
In Progress			
Zaynich (WCK5222)	Infections	Wockhardt	Global Phase III completed, US FDA approval expected in FY26-27
Saroglitazar Magnesium (Lipaglyn)	Metabolic and liver-related disorders	Zydus LifeSciences	USFDA - Phase II(b)/III for PBC
ZYIL1 (Usnoflast)	Inflammatory and auto-immune diseases	Zydus LifeSciences	Phase II
SUVN-502 (Masupirdine)	Alzheimers and Dementia	Suven Life Sciences	Completed Phase 2A / Currently phase 3
GL0034 - Utreglutide	Type 2 diabetes and Obesity	Sun Pharma	Phase 2
WCK4282 (Foviscu)	Infections	Wockhardt	Phase 2
JB1 - 802	Essential Thrombocythemia	Jubilant Pharmova	Phase 2
NRC-2694	EGFR tyrosine kinase inhibitor for late-stage cancers	Natco Pharma	Phase 2
MKP-10241	Diabetes type 2 and Obesity	Mankind Pharma	Phase 2 (India)
JB1 - 778	Non-small Lung Cancer	Jubilant Pharmova	Phase 1
ISB-2001	Multiple Myeloma	Glenmark Pharma (Out-licensed to Abbvie)	Phase 1
Failed			
Umbralisib	Cancer (Lymphoma)	Co-developed by Rhizen Pharmaceuticals (50% owned by Alembic Pharma) & TG Therapeutics	Received an accelerated US FDA approval but was withdrawn in 2022 owing to safety concerns.
Vibozilimod	Auto-immune and inflammatory diseases	Sun Pharma Advanced Research Centre	Failed US FDA Phase 2, discontinued



Listed universe

- Pureplay biotech companies – Focus primarily on innovation, no major ancillary businesses.
- There are 2 pureplay listed biotech companies in India, Sun Pharma Advanced Research Centre (SPARC) and Suven Pharmaceuticals.
- Suven Pharma has spent over INR 3,000 crores over the last 2 decades, with no commercial molecules yet and the most promising molecule (Suven 502 - Masupirdine which focuses on Agitation and Aggression in Alzheimer's Dementia) is undergoing Phase 2 clinical trials.
- Similarly, one of the most promising candidate of SPARC (SCD-044 or Vibozilimod developed for the treatment of psoriasis and atopic dermatitis) failed Phase 2 trials.
- Pharma companies with NCE pipeline's as part of their product portfolio:

In the listed universe, several Pharma companies i.e. Wockhardt, Zydus Lifescience, Sun Pharma, Jubilant Pharmova, Natco Pharma, Glenmark, Lupin and Mankind Pharma (primarily India) have NCE assets at different stages of development along with their existing businesses.

Outsourcing

Indian companies have a history of outsourcing early stage NCE assets to innovators:

- The most prominent is the recent outsourcing for Glenmark's early stage NCE – ISB 2001 for 700 million USD upfront payment.
- Glenmark Pharma's outsourcing to Abbvie for \$700 million upfront payment, with potential milestone payments totalling up to \$1.225 billion, and tiered double-digit royalties on net sales.
- Lupin had outsourced 2 molecules in 2018 (MALT1) and 2019(LNP3794) to Abbvie and Boehringer for an upfront of 30 and 20 million USD respectively. In addition, to the same Lupin was eligible for milestone payments of 947 / 700 million USD respectively.
- With Wockhardt's NCE likely to be approved in FY26/27, and other assets at advanced stages of development primarily from Zydus and Suven Life Sciences, along with Glenmark's record licensing deal we see a new era of biotech companies and NCE development for Indian pharma companies.
- Although we are actively exploring ideas in the space, our current portfolio has minimal exposure to biotech or NCE-focused companies, given the high-risk nature of drug development despite its potential for outsized returns.



II. Contract Development and Manufacturing Organisation (CDMO)

- Contract manufacturing is often misclassified by analysts and companies alike. A contract manufacturer having a long history of supplying material & having a relationship with innovator is often misclassified in the same breath with a generic contract manufacturer.
- While there are merits to both business models, we strongly believe that contract manufacturers who work with customers both in discovery and pre-clinical stages have a higher likelihood of growing materially faster (CDMO) than generic contract manufacturers (CMO).
- CDMO sector is sitting **on trifecta of strong structural tailwinds, strong innovator relationships and track record of delivering molecules.**
- In the past, pharmaceutical companies often installed dedicated manufacturing capacities for innovative drugs in development, only to see them fail during phase III of clinical research trials. Thus, the additional manufacturing capacity for the specific drugs was no longer needed, resulting in poor return ratios.
- In addition, given the high costs in development (~1-2 billion USD) (see above), pharma companies are looking to outsource parts of their R&D to convert fixed costs into variable costs.
- The growing number of U.S. biotech firms and rising capital flows into the sector have led smaller players to often outsource significant portions of their research to CDMOs, driving structural tailwinds for the industry
- Indian companies have long standing relationship with marquee clients such as Merck, Pfizer, GSK, Zoetis, Eli Lilly, Gilead, Aspen, Fermion amongst others.
- While Indian companies have lagged in NCE's, Indian companies been more successful in providing to patented molecules, below is the list of Indian companies with large contracts from innovators both in pharma and agro-chemical space.
- Several Indian companies both in Chemical and Pharma have been beneficiaries of strong tailwinds in innovator molecules such as Pyroxasulfone, Bempedoic Acid, Darolutamide, Valsartan-Sacubitril amongst others.



Company	Innovator	Drug	Annual revenue (FY25 Estimates in INR Cr)
PI Industries	Kumiai Chemicals	Pyroxasulfone	3000-3500
Divis Laboratories	Novartis	Valsartan- Sacubitril	1000-1200
Syngene	Zoetis	Librela	400-450
Blue Jet	Espion Therapeutics	Bempedoic Acid	450
Neuland Laboratories	BMS	Xanomeline + Trospuim chloride	100-150
Acutaas Chemicals	Fermion / Bayer	Darolutamide	200-300
Sai Lifesciences	Faes Pharma	Bilastine	100-120

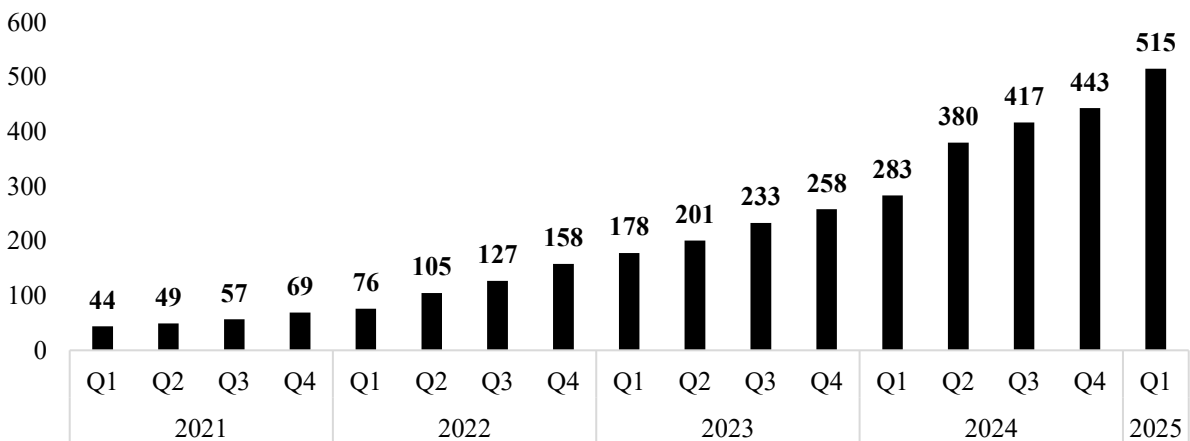
- We like CDMO companies as they offer a disproportionate payoff when a new drug commercializes, however the risk of failure is materially lower vis-à-vis biotech companies. Hence, we continue to be overweight on CDMO.
- At the time of writing in our portfolios across FAIR and FIBER strategies we own Syngene, Acutaas Chemicals, Cohance Life Sciences and Laurus Labs
- Our thesis of attractive asymmetry - disproportionate growth at limited risks played out well in Acutaas Chemicals (earlier Ami Organics) and we believe a similar trend is likely to play out across several companies over the next few years.



Acutaas Chemicals

- Acutaas Chemicals is primarily an intermediate manufacturer with presence in chemicals space.
- In early 2010’s, Acutaas Chemicals provided intermediates for Darolutamide (Nubeqa) to innovator (co-developed by Orion and Bayer).
- The drug was initially approved for **non-metastatic CRPC** (July 2019), it gained additional **FDA approvals** for **mHSPC** (Aug 2022) and **mCSPC** (June 2025), significantly widening its patient base.
- Fermion’s capacities for key intermediates were fully utilized owing to better than expected demand.
- Fermion had been working with Acutaas Chemicals for over a decade and Fermion decided to outsource 1 intermediate to Acutaas Chemicals in November 2022.
- Another key intermediate was outsourced to Acutaas Chemicals in September 2023 and 2 more intermediates to be used for captive consumptions were outsourced to Acutaas in December 2023.
- In the meanwhile, Nubeqa’s sales rose more than 12x from Q1 CY 2021 to Q1 CY2025 to 515 million Euros and continues to grow strong.

Nubeqa (Darolutamide) sales (in mn Euros)



Source – Bayer Investor Presentations

- Acutaas Chemicals was a big beneficiary of growth in end-user molecule in FY25 with the company delivering a 40% / 81% / 109% growth in Revenue / EBITDA / PAT in FY25.
- Acutaas Chemicals continues to maintain strong relationships with Boehringer Ingelheim, Takeda and Angelini Pharma paving the way for future CDMO opportunities.
- We continue to remain positive on Acutaas Chemicals.



III. GLP-1 (Glucagon-like Peptide)

- Most people have heard of Ozempic and Mounjaro. No drug has reached such high consumer awareness in such a short time.
- GLP-1's are a sizable market globally with market size of ~53 billion USD, however market is expected to open up in 2026 in countries like Canada, India, Brazil, China and multiple smaller markets (~100 countries) which will result in higher patient coverage.

What are GLP-1's ?

- GLP 1 (glucagon-like peptide 1) agonists are used primarily for treatment for type 2 diabetes & obesity
- They mimic the naturally occurring GLP 1 hormone, boosting insulin release, suppressing glucagon, delaying gastric emptying, and promoting satiety to lower glucose and reduce weight.
- GLP-1 drugs have a market size of around 53 billion USD as of 2024.
- Currently, GLP-1 drugs are dominated by 2 molecules - Semaglutide (Novo Nordisk) and Tirzepatide (Eli Lilly). (See chart below)

Large GLP - 1 drugs	CY24 sales (Billion USD)	Innovator	Efficacy (Weight loss)	Users (million)
Semaglutide (Ozempic) - Injectable for type 2 diabetes	17.5	Novo Nordisk	15%	7
Semaglutide (Wegovy) - Injectable for weight loss	8.4	Novo Nordisk	15%	1
Semaglutide (Rybelsus) - Solid Format	3.4	Novo Nordisk	5%	2
Novo's New Age- GLP's Revenues	29.3			
Liraglutide (Victoza and Saxenda)	1.8		5%	1
Novo Nordisk GLP-1 Revenues	31.1	Novo Nordisk		11
Tirzepatide (Mounjaro) - Injectable for type 2 Diabetes	11.5	Eli Lilly	18-22%	3
Tirzepatide (Zepbound) - Injectable for Obesity	4.9	Eli Lilly	18-22%	1
Eli Lilly's New Age - GLP'S Revenues	16.4			
Dulaglutide (Trulicity) - Injectable for Diabetes	5.2	Eli Lilly	3-5%	3
Eli Lilly's GLP-1 Revenues	21.6			7
Others				1
Exenatide	0.25	AstraZeneca	3-5%	
Lixisenatide	0.25	Sanofi	3-5%	
Market size	53			19



- Semaglutide injectables has an average weight loss of around 15% whereas the same for Tirzepatide is around 18-22%.
- While the current market size of Semaglutide is higher, efficacy of Tirzepatide is higher.
- It's widely expected that in the future Tirzepatide will be larger than Semaglutide.
- Innovators such as Pfizer, Roche, Amgen, AstraZeneca, and Boehringer Ingelheim are expected to launch their GLP-1 drugs in the next 5-7 years along with existing versions.

Where is the opportunity for Indian companies?

- Novo Nordisk's patent for Semaglutide expires in 2026 in key countries such as Canada, China, Brazil and India.
- In addition to the same, Semaglutide is not registered in majority of semi-regulated and frontier markets which will open-up in CY26.

Off-patent	Country	Year	Company
Semaglutide	Canada, China, Brazil and India	2026	Novo Nordisk
Dulaglutide	US	2027	Eli Lilly
Dulaglutide	EU, Japan	2029	Eli Lilly
Semaglutide	EU, Japan	2031	Novo Nordisk
Semaglutide	US	2032	Novo Nordisk
Tirzepatide	US	2036	Eli Lilly
Tirzepatide	EU	2037	Eli Lilly
Tirzepatide, Duraglutide	Canada	2039	Eli Lilly
Tirzepatide	Japan	2040	Eli Lilly

GLP-1 opportunity for Indian companies is three-fold

1. GLP-1 generics in India
2. GLP-1 generics for Exports
3. Contract manufacturing opportunities

1. GLP-1 generics in India

- Indian opportunity is expected to be reasonably large. Both Novo Nordisk (Ozempic and Wegovy) and Eli Lilly (Mounjaro) have launched products in the last few months.
- Mounjaro (Type 2 diabetes) is currently priced at INR 3,500-4,375 per injection (once a week injection) and has INR ~26 crores of revenue in the month of June 2025 and has swiftly risen to over 50 crores within 3 months on launch.
- Novo Nordisk has recently launched Wegovy (weight loss drug) which is priced at 4,366-6000 per injection (once a week). Wegovy launched in June had sales of 2.53 crores in July.
- Novo Nordisk's oral semaglutide Rybelsus did INR~412 crores of revenue in MAT 2025.
- A Host of Indian companies will be launching semaglutide generics in India when the patent expires (see list below).



2. GLP-1 generics for Exports

- Dr. Reddy and Biocon are expected to be amongst the first to launch in Canada, Brazil and other markets. Other companies with decent presence in overseas are likely to follow.
- Below are Indian companies who have announced their GLP-1 pipelines in India & overseas

Company	Launch
Dr. Reddy	Planning to launch in 87 markets including Canada, India, Brazil, China.
Natco Pharma	Has received FTF on certain strengths in US, clinical trial ongoing in India
Eris LifeSciences	Launched Liraglutide in India, will launch Semaglutide in FY27
Abbott India	Distributing Novo Nordisk's Rybelsus (Oral semaglutide) with revenues of ~45 crores monthly
Sun Pharma	Developing its own GLP-1 treatment, utreglutide, for weight loss and type 2 diabetes. Launch planned in 4-5 years
Mankind Pharma	Developing own solid GLP-1, GPR 119 for weight management
Biocon	Selling Liraglutide in UK, EU launch in FY26. Launch planned for markets including Canada, India, Brazil and China
Glenmark	Biosimilar for Liraglutide
Torrent Pharma	Expects to launch Semaglutide in Brazil and India.
Cipla, Alkem, Zydus	Will launch Semaglutide in first wave in India
Lupin	Expects to launch Liraglutide in few markets.

3. Contract manufacturing opportunity

Contract manufacturing opportunity is two-fold for Indian companies.

- CDMO For Innovators
- Contract manufacturing for generics

i. CDMO for innovators

- **Novo Nordisk (semaglutide):**

- CDMO opportunity for Novo Nordisk is limited as Novo Nordisk manufactures the API in-house and Novo also acquired CDMO Catalent for 16.5 billion USD, Catalent's expertise in fill-finish manufacturing was one of the key reasons for the same.
- Currently, Novo Nordisk only outsources small fill-finish capacities and is unlikely to benefit Indian CMO /CDMO's.

- **Eli Lilly (Tirzepatide)**

- Eli Lilly has outsourced GLP-1 API manufacturing to Corden Pharma.
- Divis has announced INR ~1400 crores capex for supply of both intermediates and API's to GLP-1 innovator (most likely Eli Lilly) marking India's CDMO entry into GLP-1 drugs



ii. Contract manufacturing for generics

- Globally there has been active shortage of both pens (devices) and fill-finish capacities. With semaglutide going off patent in over 100 countries, a sizable opportunity opens up.
- In India there are 3 companies who have capacities for both pens and fill-finish.
- One Source Specialty Chemicals which focuses on fill-finish has a capacity of 40 million cartridges but is expecting to ramp up to 220 million cartridges. One Source has tied up with companies like Dr. Reddy for its launch in Canada and other countries.
- Gland Pharma has a capacity of 40 million cartridges but is expecting to ramp up capacities to 140 million cartridges by FY26. It has secured two GLP-1 contracts for three products.
- Shaily Engineering which focuses on pens (device IP and manufacturing) has capacity of ~40 million pens which will be expanded to ~90 million pens by FY26.

Where do we stand ?

- We see GLP-1's as a long-term story with decadal long tailwinds. As the space is rapidly evolving, we see merit in companies who are ready to take advantage of this massive opportunity.
- While we currently we have limited direct exposure to GLP-1, primarily because we see limited merit in being super early for the valuations of some of the companies we like.
- While we are closely tracking the space, we believe we will have a meaningful direct exposure to GLP-1 drugs in the future where we see favourable risk-reward.

Conclusion

- ✓ While broader Listed pharmaceutical space has multiple segments comprising of Domestic Pharma, Generics (regulated and semi-regulated markets), Biotech, API and Intermediates, Hospitals, Diagnostics, Contract manufacturers (CMO and CDMO), Equipment manufacturers and a combination of the above.
- ✓ We at Fident are currently invested in API and Intermediates, Contract Manufacturers (Both CMO and CDMO) and domestic pharma proxies.
- ✓ We believe the risk-reward profile for our portfolio companies is slightly better than Biotech or GLP-1 drugs at the time of writing. We do believe as the thesis of hyper growth in the above segments play out, our portfolios will align to what we write.



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