Recent media article on GLP-1

WHO adds GLP-1 drugs for diabetes, others to essential medicines list

Wegovy maker Novo Nordisk to cut 9,000 jobs amid increased competition

Pricing group says weight-loss drugs becoming more cost-effective

GLP-1 Manufacturing: Scaling capacity ahead of Semaglutide patent expiry

India's CDMO ecosystem and innovators are preparing for a multi-fold surge in demand for injectables and oral formulations

We visited the peptide API plant of Biocon (BIOS) and the peptide manufacturing plant of OneSource Specialty Pharma to understand the manufacturing aspects of GLP-1 products:

- **Demand for Semaglutide is expected to reach 50-60 tons after patent expiry in emerging markets compared to the current innovator sales equivalent of 2 tons of API per annum.**
- **While formulators are procuring API from Chinese sources, they are working on in-house manufacturing to de-risk the supply.**
- **Companies are utilizing multiple business models, such as - a) in-house development/manufacturing and establishing their own front-end across multiple geographies; and b) being a CDMO company for supplying API/formulation. The timely approval is vital for business success, given that the cost of manufacturing is significantly lower than the price of the innovator.**
- **The injectable (Wegovy) and the oral solid dosage (Rybelsus) of Semaglutide are expected to witness patent expiry in Mar'26 in India.**
- The injectable Semaglutide would have a higher offtake than the oral solid, as the injectable is used for weight management and Type II diabetes control, while the oral solid is primarily used for Type II diabetes.

Key highlights

- The cost of manufacturing the API through the synthetic route (~USD200/g) is higher than that of the biological route (~USD50/g).
- The synthetic route comprises solid phase peptide synthesis (SPPS) with chemical modifications. The biological route comprises fermentation using recombinant DNA technology using engineered microbe, followed by purification and chemical conjugation.
- Synthesis is typically a 21-day process for a batch. The critical aspect in the process is stabilizing the addition of amino acids and maintaining impurities within the permissible limit.
- API developers/manufacturers are using the synthetic route due to higher control over purity and sequence accuracy. The synthetic route also has flexibility to incorporate unnatural amino acids/modification (Lipidation with C18 fatty acid chain).
- Having said this, the synthetic route also has challenges. For example, it is expensive to scale up beyond 10kg of Semaglutide per batch, and the purification is solvent and energy-intensive.
- The challenges in the biological route include the appropriate folding of peptide and the prevention of degradation in host cell. Chemical modification (Lipid conjugation) still needed after biological production.
- Regulatory complexity is higher in the biological route vs. the synthetic route as it may need to be developed and filed under the BLA route with the USFDA.
- The difference between Semaglutide and Liraglutide is one amino acid. This becomes a significant factor for better efficacy as well. Most of the generic applications are filed using Chinese API as source.

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- Having said this, BIOS has set up its own API/formulation manufacturing and has made the process efficient to lower the cost compared to Chinese suppliers.
- Notably, the capacity of BIOS would be suitable to cater to business for the next 2-3 years.
- BIOS expects to file soon in Canada (Ozempic and Wegovy), and expects its approval in 2HCY26. Given that no GLP-1 generic has been approved so far by Health Canada, including Liraglutide, we believe that there could be a downside risk to the projected Semaglutide approval timeline for BIOS in Canada.
- Almost 25 customer inspections are being done at Unit II (drug device combination) of OneSource.
- OneSource manufactures drug product, drug substance and drug device combination at Unit II. While Semaglutide API is not manufactured at this site, the rest of the process to make Semaglutide injectable is done at Unit II. In addition, OneSource is utilizing this facility to manufacture biosimilars and innovative biologics.
- OneSource has strengthened its position in GLP-1, with more than 20 customers tied up till date.
- The CDMO market opportunity in GLP-1 is expected to increase at 20%+ CAGR to USD12b by FY28. The biologics CDMO opportunity is expected to increase at 14% CAGR to USD38b by FY28.
- OneSource's facility features a Bausch + Ströbel filling line integrated with isolator technology to deliver high-precision cartridge and PFS fill finish.
- The capacity is expected to scale up from 40m units currently to 100m units in FY27 and 200m units from FY28 onward.
- Customers of OneSource would be catering to emerging and developed markets.
- OneSource has capacity tie-ups with customers in multiple aspects. Some customers have a tie-up in the capex program, some have take-or-pay contracts, and some have given reservation fee with a long-term forecast.
- Canada, Brazil and India markets are opportunities for OneSource customers over the near term. Other countries (~60-80) are expected to witness patent expiries from CY26 onward, driving opportunities for CDMO companies like OneSource.
- OneSource has drug-device combination manufacturing capability for non-GLP as well as GLP products. Overall ~10 products are in the pipeline in the drug-device combination.
- **OneSource has site approval for the Brazil market. It is awaiting customer approval to manufacture products for this market.**
- Interestingly, with EU and USFDA approvals for its site, the Canadian health authority would not require inspection for product approval.

Story in charts

Exhibit 1: Comparing synthetic and biological routes to manufacture Semaglutide

Step	Synthetic Route (SPPS)	Biological Route (Recombinant)
Starting Material	❖ Protected amino acids, resins, solvents	❖ Gene construct, host cells (E. coli / Yeast), media
Core Process	❖ Solid Phase Peptide Synthesis (30+ coupling cycles)	❖ Fermentation for peptide precursor expression
Intermediate Handling	❖ Cleavage from resin, followed by HPLC purification	❖ Purification and refolding of peptide
Modification	❖ Chemical lipidation with C18 fatty acid	❖ Chemical lipidation with C18 fatty acid
Final Output	❖ High-purity Semaglutide API	❖ High-purity Semaglutide API
Cost Impact	❖ High cost (reagents, solvents, purification)	❖ Lower cost once optimized at scale
Scalability	❖ Limited to kg-scale; prohibitively expensive beyond that	❖ Highly scalable (multi-ton fermentation possible)
Key Challenges	❖ Yield drops with peptide length; solvent-intensive	❖ Protein folding/refolding complexities; host cell impurities
Overall Yield	❖ ~20–30% (multi-step losses)	❖ ~40–60% (after fermentation and refolding)
Estimated Cost per Gram (commercial scale)	❖ USD 200–400 / g	❖ USD 20–50 / g
Scalability Range	❖ Up to ~10–20 kg batches; costly beyond	❖ 100s of kg to tons feasible

Source: Industry

Exhibit 2: Timeline for Patent expiry for Semaglutide

Geography	Injectable (Ozempic/Wegovy)	Oral (Rybelsus)
United States	❖ Dec 5, 2031 (earliest generic entry); some patents extend to 2032	❖ Mar 15, 2033 (earliest generic entry)
European Union (EU/EEA)	❖ 2031 (with SPC / term adjustments)	❖ Early 2030s (aligned with SPC framework)
Japan	❖ 2031	❖ Early 2030s (likely aligned with injectables)
China	❖ 2026 (substance patent expiry; litigation ongoing)	❖ 2026 (substance expiry; formulation/device patents may extend)
India	❖ 2026 (substance expiry; domestic firms preparing generics)	❖ 2026 (substance expiry; oral-specific patents may vary)
Brazil	❖ Mar 2026 (substance expiry; local firms planning launches)	❖ 2026 (substance expiry; formulation patents may affect timing)
Canada	❖ Jan 4, 2026 (main patent expired / lapsed)	❖ 2026 (substance expiry; oral entry possible)
UK	❖ 2031 (aligned with EU SPC framework)	❖ Early 2030s (aligned with EU SPC framework)

Source: Industry

Exhibit 3: Comparison of oral and injectable dosage of Semaglutide

Aspect	Oral Semaglutide (Rybelsus)	Injectable Semaglutide (Ozempic / Wegovy)
Formulation	❖ Tablet (daily, with SNAC enhancer)	❖ Subcutaneous injection pen (weekly)
Indications	❖ Type 2 Diabetes	❖ Type 2 Diabetes + Obesity
Absorption	❖ Low (~1%), requires empty stomach	❖ High, consistent, no food effect
Efficacy	❖ Effective but slightly lower	❖ Stronger HbA1c & weight loss efficacy
Convenience	❖ No needles, but dosing restrictions	❖ Once-weekly, but requires injection
Manufacturing	❖ Tablet formulation with peptide stability challenge	❖ API + fill-finish + cartridge/device assembly

Source: Industry

Exhibit 4: Global/Local capacities to manufacture cartridges for GLP

Region	Company	Offering (GLP-1 cartridges)	Key Sites	Current Capacity (est.)	Planned Capacity / Timeline	GLP-1 Experience (1-5)	Notes	Standardized Capacity (m units/yr)
India	OneSource Specialty Pharma	❖ Cartridge fill-finish + device assembly (GLP-1 DDCs)	❖ India (multiple sites)	❖ ~40M cartridges/yr	❖ Ramp to 200–220M/yr (18–24 months)	4	❖ Scaling aggressively; end-to-end pen program support	40
India	Gland Pharma	❖ GLP-1 pen/cartridge fill-finish	❖ Hyderabad; Vizag (India)	❖ ~40M units/yr	❖ Ramp to 140M/yr (~FY27)	4	❖ Flexible bulk line usable for insulin/GLP-1	40
India	Shilpa Medicare (Hybrid CDMO)	❖ Peptide API + cartridge/device fill-finish	❖ Raichur, Jadcherla (India)	❖ ~20M cartridges/yr	❖ N/A disclosed	3	❖ Also ~40 kg/yr peptide API (scale marker)	20
Europe	Vetter Pharma	❖ Cartridge fill-finish + device assembly	❖ Ravensburg/Langenargen (DE)	❖ Undisclosed (large-scale)	❖ Ongoing expansions	5	❖ Deep GLP-1 combo device experience	
Europe	Recipharm	❖ Sterile RTU cartridge & PFS fill-finish	❖ EU/US network	❖ High-speed; 100M+ vials/yr (indicator)	❖ New RTU lines	4	❖ Cartridge capability via isolator lines	100
Europe	PCI Pharma Services	❖ Cartridge/PFS fill-finish + assembly/packaging	❖ León (ES) + US	❖ Undisclosed	❖ Investing in high-speed isolators	4	❖ Device assembly + cold-chain expertise	
Europe	Stevanato Group	❖ Primary packaging (cartridges) + pen/autoinjector platforms	❖ Italy + global	❖ Large (packaging/device)	❖ Multiple expansions	5	❖ Pairs with DP CDMOs for fill-finish	
Europe	Gerresheimer	❖ Cartridges/syringes + device mfg	❖ DE/MX/US	❖ Expanding RTF capacity	❖ Multiple site investments	4	❖ GLP-1 called out as growth driver	
Europe	SCHOTT Pharma	❖ RTU sterile cartridges (cartriQ®)	❖ Lukácsháza (HU)	❖	❖ €100M+ Hungary expansion (2025)	4	❖ RTU focus; partner for DP fill-finish	
US/EU	Catalent (Novo-owned sites)	❖ GLP-1 aseptic fill-finish & pen capacity	❖ Bloomington (US), Anagni (IT), Brussels (BE)	❖ Large (undisclosed)	❖ Novo expansion in-house	5	❖ Benchmarks for GLP-1 network capacity	
US/Global	Thermo Fisher (Patheon)	❖ Sterile cartridge & PFS fill-finish	❖ Greenville (US), Swindon (UK), Singapore	❖ Undisclosed	❖ New high-speed PFS lines	4	❖ Flexible networks; cartridges by site	
US/EU	Simtra BioPharma Solutions	❖ Sterile injectables incl. PFS/cartridges	❖ Bloomington (US), Halle (DE)	❖ Large (undisclosed)	❖ Ongoing expansions	3	❖ Combo product support	
Korea	Samsung Biologics	❖ Drug-product fill-finish (adding PFS/cartridge)	❖ Songdo (KR)	❖ Undisclosed	❖ Capacity additions	3	❖ High throughput DP ops; cartridge emerging	
China	Tonghua Dongbao	❖ Cartridge & vial manufacturing (insulin heritage)	❖ China	❖ 300M+ cartridges/vials (combined)	❖ Further growth planned	3	❖ Not GLP-1-specific; capacity marker	300
US/EU	CordenPharma	❖ GLP-1 peptide API (upstream supply)	❖ Colorado (US) + EU	❖ Large (undisclosed)	❖ €900M multi-year expansion	5	❖ Long-term GLP-1 contracts	
CH/US	Bachem	❖ GLP-1 peptide API (upstream)	❖ Switzerland, US	❖ Large (undisclosed)	❖ Multiple 2024–25 expansions	5	❖ Key GLP-1 supplier	

Source: Company, MOFSL

Exhibit 5: One source specialty pharma: Key capacities

Key capacities	Capability & Capacity
DDC Integrated Biologics and drug products site	❖ Microbial: 1x1KL SS
	❖ Mammalian: 2x 2KL SUB Cartridges: 40 million
	❖ PFS: 28 million
	❖ Vials: 12 million
Soft gelatin capsules	❖ Capsules: 2.4 billion
Sterile Injectables	❖ PFS: 10 million
	❖ Vials: 16 million
Penicillin fill-finish	❖ Vials: 18 million
Multi-modal Biologics development center	❖ Microbial: 1x 50L
	❖ Fill-finish: Clinical supplies

Source: Company, MOFSL

NOTES

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