PHARMACEUTICALS

03 March 2025

Hyderabad Visit note

- **ADC is the most effective and upcoming 2nd line of treatment in oncology. Today Oligonucleotides is where ADC was 7-8 years back**
- **Revlimid was a unique opportunity for the sector; the next equivalent big opportunity is GLP-1, led by Semaglutide**
- **The US has become very competitive; hence, companies are eyeing European regions for growth as it is a branded generic market**

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We interacted with the management of the companies largely not under our coverage during our visit to Hyderabad, and the following are the views on the companies: -

Suven Pharma – The management was positive on the ADC space and expects this segment to become 3x by 2030 from the current market size of USD 12bn. Currently there are ~400 molecules in the ADC space, where 250+ molecules are in clinical trials, 127 have been discontinued, and only 15 are approved. Amongst the ADCs, the topoisomerase inhibitor has a good success rate in the preclinical studies, with only 1 molecule discontinued from 247 molecules, and the tubulin inhibitor has the highest failure rate due to its toxic compound, resulting in 46 discontinued molecules amongst a total of 388 molecules

Aurobindo Pharma – The company has many growth levers till FY30 driven by expanding capacities in the oral solid drugs to 60-65bn from the current 50bn, backward integration for the higher yield of Pen G, 14 pipeline products of biosimilars worth USD 50bn, and commercialization of the CDMO plant. All these drivers aid in increasing EBITDA Margin every year from 22% in FY25.

Natco Pharma – The company believes it will have a blockbuster product every 3-4 years. Earlier they had a slew of blockbuster products like Lanthanum Carbonate, Copaxone, Tamiflu, and Revlimid. Post Revlimid going off patent, it believes Semaglutide to be a blockbuster product in the US region. The company is actively scouting for M&A deals, preferably in the ROW region or in the domestic/US region if the ROW deal does not get through.

Gland Pharma - The company expects Cenexi to turn profitable from 3QFY26 and expects 2Q to always slip into losses due to an annual plant shutdown in August for three weeks. However, US business is healthy as it supplies injectables to all key players like Pfizer, Hikma, Teva, etc.; hence, it is not subject to price erosion pressure in the US (maybe 1-2%) due to less competition.

Suven Pharmaceuticals

Outlook: Suven expects combined business to reach USD 1 bn over the next five years, driven by Pharma CDMO and inorganic activities. Pharma CDMO currently contributes 40% of the sales in 9MFY25, is expected to go up to 80% of sales by FY30, and 90% of sales by FY35.

China dependence: Suven has reduced its dependence on China from 40% in FY23 to 12% in FY24 and aspires to reduce below 10% as they have identified local vendors.

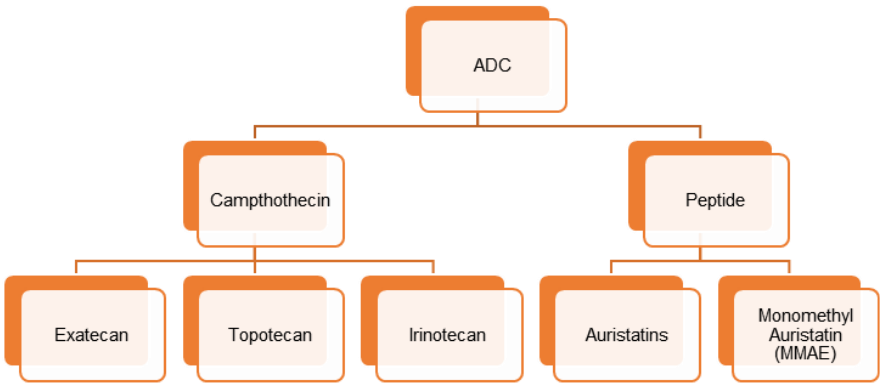
M&A: Suven is scouting for tech-driven CDMO assets for its horizon 2 to make mRNA, peptide.

Pharma CDMO:

Clients – Suven has partnered with the top 12-13 clients and expects to add 1-2 new customers on a quarterly basis.

ADC: The ADC market size has increased to USD 12bn and is expected to increase to USD 50bn by FY30, implying a CAGR of 20%. Suve has 2 products, S-Trione and SN38, which contribute 40% of the ADC. Suven is an exclusive supplier of intermediates for Enhertu (market size of USD 3.7 bn). ADC is used in oncology therapy as well as non-oncology therapy like the CNS. Suven is not dependent on China for sourcing materials for S Trione and is vertically integrated till N-1 level.

Fig 1 – ADC flow chart



Source: Company, BOBCAPS Research

NJ Bio: is the leader in ADC research and aims to become a leader in the CDMO. It has 150 people in the organization, out of which 40 employees are based in Mumbai. NJ Bio has a huge 500+ linker database with them, along with the bioconjugation capabilities.

Synergies from Suven and NJ Bio - Suven has Camptothecin-based designer payload capability, where it will make payloads and linkers in India, and NJ will make bioconjugations in the US. As there are few players in this theme, Suven is confident in capitalizing on the ADC platform.

Oligonucleotides: The market size for oligonucleotides is USD 4-5 bn. It is at a stage where ADC was 7-8 years back. Oligonucleotides can be used in various therapies.

Plant visit

Casper Formulation plant in SEZ Aviation - It has filed 17 products from this plant and received approval for 12. It was started in 2020. The plant is spread on 13 acres of land and has 2 lines operational. Its current utilization is 30% and increases up to 55% as they start manufacturing high-volume products like potassium chloride and allopurinol. This is a budding plant and has a capacity of 600 million tablets and 100 million capsules.

Cohance Unit 5 plant – This is an ADC plant that was started in 1995 and was acquired by Advent in CY2022 to merge with Cohance in FY24. This plant is a USFDA-approved plant, where it had first received USFDA approval in 2014 and later in 2017. This plant makes Eurtica, S Trione, and SN38, which run at their full capacity by running 24 hours. The plant capacity for S Trione is 3k kl; however, it makes 1500 kl annually. SN38—it makes 800-850 kg, which it supplies to Gilead Pharma for its commercial products. Strione is made for innovator Lonza.

Pharma CDMO is the key growth driver for Suven, and currently they have 5 plants.

Fig 2 – Suvven Pharma's Pharma CDMO facilities

Units	Product	Capacity
Suryapet	NA	65kl
Jeedimeta	pre clinical , development	27kl
Pashamylaram	6 Commercial products to innovators	406 kl
Nacharam	Oncology, CDMO	40kl
Parwada	Opthal products to innovators	130 KL

Source: Company, BOBCAPS Research

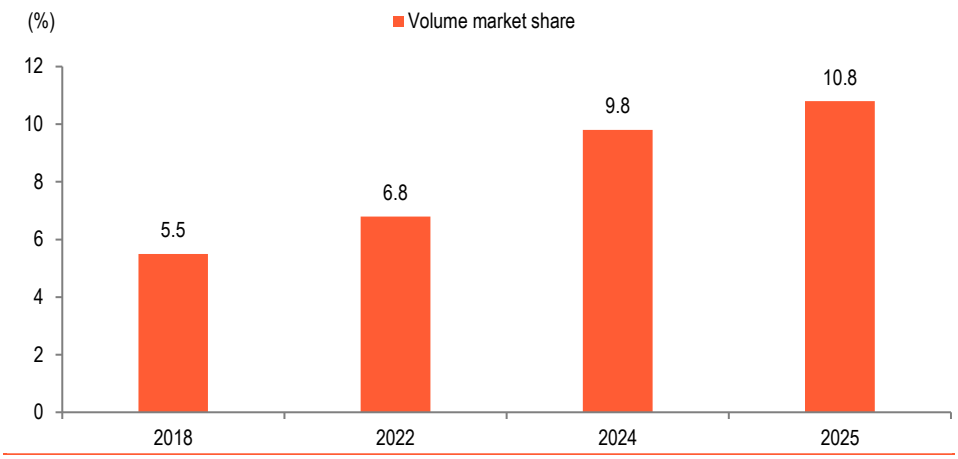
Aurobindo Pharma

Guidance: The company expects specialty and injectable sales in the US to increase to USD 100-125 million in the next 2-3 quarters from the current USD 76 million. Retains EBITDA margin guidance of 21–22% for FY25.

US: ARBP is leading in the US market as its volume market share has increased to 10%. The generic price erosion in the base products is currently nominal at 2-3%. ARBP has 3 plants in the US: the Dayton oral plant is to be commissioned by next year, and the North Carolina facility is to manufacture respiratory and transdermal products. The company envisages increase in volume market share on higher base by expanding oral solid capacity from 50bn units to 60-65 bn units

Eugia: Eugia's unit 3 capacity utilization is to increase to 60-65% by 4QFY25 from the current 50% in 3QFY25. The peak capacity utilization was 80-85%. The Eugia sterile facility has only one product, Lidocaine injection. It has recently received observations for an additional line and not for the existing lines. Demand remains strong despite supply issues, which should ease with higher capacity utilization. The ongoing growth in the US region should continue until 2030 with significant capacity at Eugia III and Vizag.

Fig 3- Aurobindo US volume market share chart



Source: Company, BOBCAPS Research

Penicillin G: The PenG plant in 3QFY25 was shut for 10 days for maintenance purposes, which led to an operational cost of Rs 600 mn. The company expects yields to be better, which would aid in EBITDA breakeven by 4QFY25. Currently, the Pen G price is USD 26. However, they are not dependent on the Pen-G sales alone, as they have created capacities across the value chain by supplying 6-APA and amoxicillin, etc. However, the company expects to consume 60-65% Pen G internally.

Biosimilars: The company has a strong portfolio of biosimilars worth USD 50 bn. However, it expects not to participate in the first wave of biosimilars and will always have 2-3 players. Currently, four biosimilars are in global Phase 3 clinical studies, so the company expects 2028–30 to be an inflection point. Currently, Filgrastim marketing approval is expected in two months in Europe with supplies beginning from Jul-25. Denosumab is likely to file in Europe in Q3FY26 and in the US in Q4FY26. Omalizumab is currently in the recruitment phase for trials, and Bevacizumab is in clinical trials currently, with filling likely in FY27.

Fig 4 - Biosimilar update

Biosimilars	Market Size (Rs bn)	Molecule	Therapy	Remarks
BP14	4.6	PEGFILGRASTIM	ONCOLOGY	Received positive opinion from European Medicines Agency
BP13	1.5	FILGRASTIM	ONCOLOGY	Received positive opinion from European Medicines Agency
BP01	6.2	BEVACIZUMAB	ONCOLOGY	Phase 1 PK/PD clinical study completed. Multi center and multi country Phase 3 study in NSCLC patients is in progress
BP02	5.2	TRASTUZUMAB	ONCOLOGY	MA received in India. Have applied for Manufacturing License. Phase 3 clinical study completed in 690 metastatic breast cancer subjects and met the clinical end points successfully
BP05	4.2	RANIBIZUMAB	OPHTHALMOLOGY	Phase 3 multi-country and multi-center trial is in progress
BP11	4	OMALIZUMAB	RESPIRATORY/DERMATOLOGY	Phase 3 clinical study is on-going in Europe in chronic spontaneous urticaria patients • Phase 3 clinical study in respiratory asthma patients is in progress in India
BP16	5.7	DENOSUMAB	ORTHOPAEDIC	Phase 3 clinical study recruitment completed in Europe and India. We are on-track for study completion by May 2025
BP08	3.5	TOCILIZUMAB	IMMUNOLOGY	Phase 3 clinical study completed in Apr/May 2024. Filing in India in Q2 FY2024-25

Source: Company, BOBCAPS Research

Europe: ARBP ranks in the top 10 positions in 8 countries, which include France, Portugal, Germany, the Netherlands, etc. It has a wide product portfolio, where last year it filed 57 products. The company's focus is on the top 10 countries and expects to achieve EUR 1bn in FY26 ex. of biosimilar sales.

CDMO – ARBP currently plans to install 2 lines of 15KL for MSD, which they are planning to expand by another 30KL. Capex for this is Rs 10 bn.

GLP-1: One active DMF for Liraglutide and likely to file another DMF for Semaglutide this year. All products are manufactured at the Vizag plant. The devices are manufactured by a third party. It also has plans to participate in the domestic GLP-1 opportunity.

China dependency – Currently 35-40% of raw material is sourced from China, and it will continue to remain at similar levels.

Oral Solid Capacity – Currently ARBP has a capacity of 50bn tablets, which is expected to increase up to 60-65 bn units.

Natco Pharma

Domestic Business - Currently the business is in the range of Rs 3-4bn, which is expected to increase to Rs 6bn by FY27. The company is present in 4 therapies in the domestic market, including oncology, cardiovascular, diabetes, and specialty pharma, out of which 70% of the sales are derived from the oncology sales.

MRs – Currently they have 1000 MRs and are expected to increase up to 1200-1250 MRs in the next 2 years.

New launches – The launch of 10 different products is estimated every year. However, expect Semaglutide and Risdiplam launches in India to be meaningful growth contributors in the domestic region.

Semaglutide - In India, Natco is to participate only in injectable form and not in oral solids. The settlement date has not been disclosed. The management has filed with DCGI and expects to be in the first wave launch post-expiry. Currently no company has received approval for Ozempic. The fill finish will be done by Stellis, and sales from Semaglutide are expected to be ~20% of the domestic sales.

US – Natco has a track record of launching blockbuster products every 3-4 years where they had exclusivity, and post-exclusivity it was only a 2-3 player market. Earlier blockbuster products were Copaxone, Tamiflu, Lanthanum Carbonate, and now gRevlimid. Post gRevlimid, the company is banking on the Semaglutide launch to be another blockbuster product.

gRevlimid - In 3QFY25, there was no sale of gRevlimid; however, they expect 4QFY25 to have some portion of gRevlimid. From Mar'25, the company expects to get 33% market share, which will increase sales despite pricing coming down due to competition. The 33% market share will lead to a 50% jump in volume; hence, they believe Q1 and Q2 to be strong quarters for gRevlimid.

Para IV filing

The company has 4-5 high market size products with sole FTF, which will increase US sales post patent expiry of gRevlimid.

Olaparib - The product has a market size of USD 1.5 billion and is a good opportunity as Natco has a sole FTF. It is expected to launch in FY28-29 and is a 50-50 JV with Alembic Pharma as the sole FTF. It is expected to launch in FY28-29 with a 50-50 JV with Alembic Pharma.

Kyprolis - The product has a market size of USD 3 bn, where Natco has sole FTF. This product is also expected to launch in FY28-29.

Imbruvica – This is also a USD 3bn market size product; however, Natco has lost litigation for this product. Natco will refile the case and hence expects the launch to be delayed to FY30-33 from the current Dec.28.

Risdiplam – Risdiplam is a USD 3bn drug opportunity, which the company has filed with Sun Pharma. It will be on a profit-sharing basis.

GLP 1 - Natco to participate in only Semaglutide (Ozempic and Wegovy) in the US market through its partner Viatris. For both the drugs, API will be sourced from the 3rd party, and fill finish would be done by One Source

Ozempic – The litigation is settled. The company will participate in 4 strengths, where it has sole FTF in two strengths and a shared FTF in the remaining two strengths

Wegovy – The company is still under litigation. The company has a sole FTF in all 5 strengths

ROW market – The current ROW market sales are in the range of Rs 4-5bn through a presence in 30 countries where the company has filed more than 300 products. In the ROW market, Saudi Arabia is the key market for Natco through its partner Boston Oncology. The company also intends to participate in the Chinese market through the tender route.

Crop Protection sales- This segment was started 1-1.5 years back with 6 products, which have now scaled up to 22 products and intend to scale up to 30 products. Currently they have partnered with Bayer Corp. for one product. Due to new launches, the company expects sales to reach Rs 2bn and EBITDA to break even as against a loss of Rs 500-600 mn.

M&A – The company has a cash balance of Rs 30bn as of 9MFY25, which is expected to increase up to Rs 50bn by FY26 due to increasing cash flows from gRevlimid. Hence, the company is actively scouting for M&A deals where it intends to deploy ~Rs 30bn cash. The company is scouting M&A deals in the ROW market; however, if there are no assets for acquisition, they are also considering the domestic and the US region.

Gland Pharma

Outlook – The company maintains its stance of Cenexi becoming profitable from 3QFY26. However, due to an annual shutdown for three weeks due to maintenance of Cenexi's plant, it is expected that 2Q will be a seasonally loss-making quarter

GLP - Gland has two customers. El Lilly (40-50 mn cartridge) and One Source (200 mn cartridge in 2-2.5 years) and three product contracts in GLP-1. Gland expects some smaller volumes for RoW and Canada markets to start from FY2026E. Higher volumes are expected to start from end-FY2027E. For auto injectors, the company's current capacity is ~40 mn units. The new line (~100 mn units) will be installed in the next two quarters

Biologics – Gland has partnered with Dr. Reddy's for CDMO collaboration. For this collaboration, Gland has set up an 8kl capacity and is evaluating scaling up to 15kl.

US region -

Price erosion – Price erosion is less for Gland at 1-2% due to less competition.

Market share of key products - Gland's market share in Enoxaparin is 6-7% and 20-25% in Heparin. For Chinese players, the market share in Heparin would be ~40%.

Volume in base business - Base business sales declined due to volume decline in some products (12% volume decline in Enoxaparin and Ketorolac) in the US. Certain products were not shipped out in 3QFY25. Gland expects to recover these volumes in the coming quarters.

Europe region

Market Outlook – For Cenexi, Europe is a strong market. Cenexi is seeing a constant flow of opportunities and RFPs.

New ampoule line production - Cenexi's new high-capacity ampoule line began production on schedule. This addition will increase ampoule manufacturing capacity by 40-50 mn units.

Plant shutdown – The company expects the Cenexi plant to shut down every August for at least 3 weeks.

ROW Market - Gland has moved its focus to the top 5-6 countries (Saudi Arabia, Mexico, and South Africa), where it wants to be aggressive in terms of partnership and filings. It has now divided the RoW into groups—high, medium, and low-value markets—with an intention to focus more on high-value markets.

R&D – Gland will maintain a 5% R&D contribution.

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