May 06, 2021 | **PICK OF THE MONTH** | **VOL-7, NO-05**

Industry: Pharmaceuticals

Aurobindo Pharma Limited

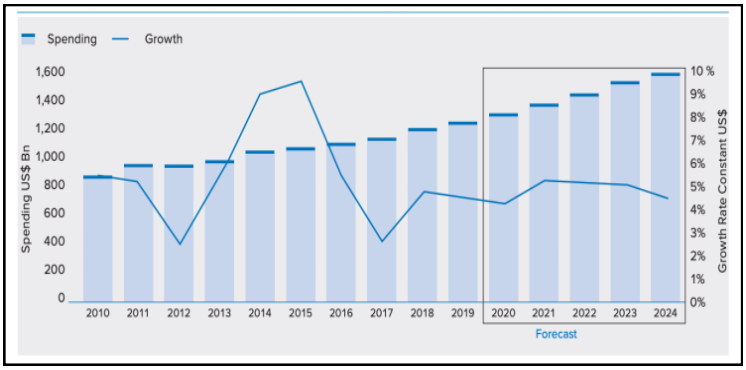
BUY

CMP: Rs.1018 | **TARGET PRICE: Rs.1250** | **TIME : 12 months**

OVERVIEW: Indian Pharma Industry:

In the past decade there has been a considerable increase in the use of medicines majorly for chronic and high priority segments on the global front. Pharma spending stood at USD1,25tn in 2019, and is expected to reach USD1.5-1.6tn by 2024 growing at a CAGR of 3-6%. Increased usage coupled with changes in the speciality and innovative product composition of new brands has led to the increased spending. As per the IQVIA, developed markets are expected to see enhanced spending from USD821.6bn in 2019 to USD985-1,015bn in 2024, growth of 2-5% CAGR. On the other hand, pharmerging markets are likely to grow from USD357.7bn in 2019 to USD475-505bn in 2024, at 5-8% CAGR. US, China, Japan, Germany, Brazil, Italy, France, the UK, India and Spain would be the front-ranking nations in pharma spending in 2024.

Exhibit 01: Global medicine spending and growth



Source: Annual Report, IQVIA Dec 2019, Progressive Research

US Generics:

US has been the largest export destination for Indian Pharma with exports worth over USD8bn and the share being 34-35%. However, due to intense generic competition and stringency of compliance related to facilities and approvals; there has been stagnancy witnessed in the US exports which hampered the Indian Pharma performance.

Over the last four years, formulations exports to US from India clocked a muted 3% CAGR to touch USD7.9bn in FY20. Covid led supply disruptions and trade issues increased the concerns about the future of exports to the US even a little more. However, there was a reverse trend witnessed with increased dependence on Indian Pharma during the pandemic. Indian Pharma's formulations exports to the US grew 13% to USD5.31bn during April-January 2021. Value growth due to improved realizations clocked in backed by drug shortages and disruptions.

Although the second wave of Covid leads to uncertainty, key factors like:

- Recovery signs visible through stabilizing pricing environment
- Rising share of specialty/complex drugs on the low base
- Drug filing/approval momentum gaining steam

All of these indicate sustained value growth for Indian Pharma in the US market going forward.

EU as a market for Indian Pharma:

Tender based pricing was one of the main reasons for the Indian Pharma companies to stay away from EU as an exports opportunity. In order to cut down public health expenditure as well as drug prices, the European government had resorted to harsh measures which ultimately led to commodisation (lowest price in reference countries formed the base of drug pricing making it a commodity) across the markets. Drugs were procured based on tender pricing, in order to cut the prices by major EU players like Germany, UK, France, etc.,

SNAPSHOT	
52 week H / L	**Mcap (INR mn)**
1025/627	596,544
Face value: 1	
BSE Code	**NSE CODE**
524804	AUROPHARMA

Annual Performance				
(Rs mn)	**FY19**	**FY20**	**FY21E**	**FY22E**
Total Revenue	195,636	230,985	248,230	262,004
EBITDA	39,519	48,643	54,114	58,951
EBITDA (%)	20.2	21.1	21.8	22.5
Other Income	1,553	1,919	3,565	1,565
Interest	2,626	3,051	2,461	1,711
Depreciation	6,680	9,667	10,983	13,207
PBT	31,767	37,843	44,235	45,597
PAT	23,645	28,295	*32734	33,742
Equity (Rs mn)	586	586	586	586
EPS (INR)	40	48	*56	58

Quarterly Performance				
Parameters (Rs mn)	**Mar-20**	**Jun-20**	**Sept-20**	**Dec-20**
Sales (Net)	61,584	59,248	64,834	63,649
EBITDA	13,398	12,574	14,328	13,686
EBITDA (%)	21.8	21.2	22.1	21.5
Other Income	326	1156	538	1,334
Interest	318	211	157	195
Depreciation	2324	2555	2573	2,765
PAT	10213	8418	7623	*9494
Equity (Rs mn)	586	586	586	586

Ratio Analysis				
Parameters (Rs mn)	**FY19**	**FY20**	**FY21E**	**FY22E**
EV/EBITDA (x)	16.3	12.8	11.0	9.5
EV/Net Sales (x)	3.3	2.7	2.4	2.1
M Cap/Sales (x)	3.0	2.6	2.4	2.3
M Cap/EBITDA (x)	15.1	12.3	11.0	10.1
Debt/Equity (x)	0.6	0.5	0.3	0.2
ROCE (%)	26	26	23	19
Price/Book Value (x)	4.3	3.5	2.6	2.3
P/E (x) TTM	20.8	14.4	18.2	17.7

Shareholding Pattern as on 31st March, 2021		
Parameters	**No of Shares**	**%**
Promoters	304,315,471	51.94
Institutions	220397769	37.61
Public	61,225,369	10.45
TOTAL	**585,938,609**	**100**

Source: Annual Report

Note: All the data is calculated as per Market Price on 05 May, 2021
**EPS/PAT : adjusted for the Exceptional Income during Dec20*

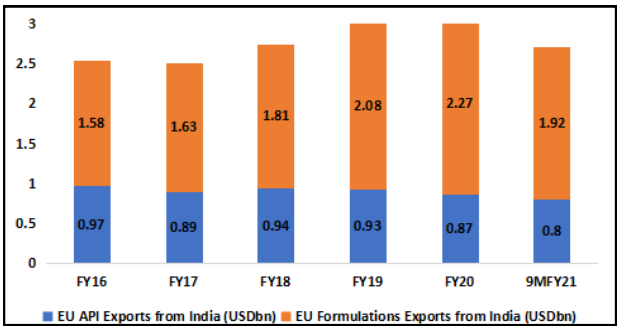
OVERVIEW: Industry (contd.)

EU as a market for Indian Pharma (contd.):

However, with US generics taking a hit due to intense price competition and channel consolidation, there has been improvement in the growth momentum from EU markets. EU's target during Covid times was to reduce over-dependency on China period which deviated exports to Indian pharma manufacturers (clocking a growth of ~20% in 9MFY21), one of the strongest displays over the last decade, further supported by a 27% growth in API and intermediate exports. (China has always been a strong competitor for India as far as EU markets are concerned. Its API/intermediate exports to the EU stands at 9x that of India's at USD9.5bn) Hence, we feel EU, with its aim to de-risk from China, offers to be one of the fastest growth opportunity for Indian pharma exports, for APIs and intermediates as well as formulations.

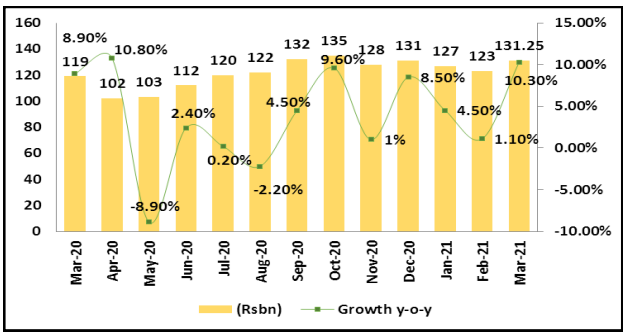
IPM Growth in Past Few Months: In recent months, there have been signs of improvement and growth in IPM indicating that domestic formulations are getting back on track. With branded formulations being the key, IPM, enjoys better and higher margins compared to other segments, and thereby indicates that there should be volume and value growth both for Indian pharma space going forward. Earnings growth would be complemented further by the savings in costs led by the digital expansion.

Exhibit 02: EU Markets for Indian Pharma



Source: Industry Reports, Progressive Research

Exhibit 03: IPM Recovery



Source: PharmaBiz, Progressive Research

Vaccines and Indian Companies: There has been immense uncertainty hovering around the development of vaccines; finally which seems to have ended with many globally approved vaccines available currently. However, questions around the side effects or for that matter the efficacy of the vaccines still persists across the recipients. But with the increase in case loads across the world, as well as in India, vaccines now have become of prime importance. Of the total 9 vaccines approved globally; AstraZeneca/Serum's Covishield and Bharat Biotech's Covaxin are already being administered in India. Cadila (in-house R&D), Dr. Reddy (partnership with Russia's Sputnik), Aurobindo (for its own vaccine and another in-licensed one from US-based Covaxx), Strides (from Russia's Sputnik), Gland (from Russia's Sputnik) are some of the potential beneficiaries of vaccines in the listed Pharma space.

Working towards self-reliance: With the pandemic and the subsequent supply-side challenges faced, many countries witnessed shortfall of critical medical supplies for which they were relying on overseas suppliers. This has led to increased focus to make the supply-chain more localized. US has been quite vocal about shifting base of essential medicines from countries like India / China to US. India is also looking to reduce dependence on China in sourcing APIs and KSMs.

Indian Pharma sector deserves an upgrade: Over the last 3-5 years, Indian Pharma sector had showcased subdued valuations led by intense pricing competition and USFDA stringency. However, during the pandemic, despite the initial disruptions, Indian Pharma did pretty well catering to the super normal demand, providing earnings visibility through the strong export trend that is being witnessed led by the pandemic.

(a) Indian pharma, now known as the 'Pharmacy of the World' catering to more than 40% of the global generics volume demand, emerges as a one-stop-shop for the world pharma markets. In fact, its end-to-end integration across the value chain makes it a reliable manufacturing partner across the entire pharma value chain.

(b) Indian pharma exports had clocked moderate growth due to challenges faced by US generics. However, there has been a reversal in trend witnessed due to structural disruptions led by Covid and supply chain de-risking initiatives taken by global pharma.

(c) The GOI has announced two Production-linked Incentive Schemes (PLIs) for pharma, amounting to a total of Rs219.4bn (USD3bn) over a period of 6 years, starting from FY23E. PLI-1 targets self-reliance and attempts to reduce import dependence in critical drug raw materials by manufacturing KSMs/drug intermediates and APIs, while PLI-2 aims to drive an upgrade in pharma manufacturing to specialty from generics.

(d) While the exports-supply opportunity look strong, companies that are cost efficient, integrated, having large-scale manufacturing base and a leadership offering model would be the key beneficiaries in the cost-efficient post-Covid global market.

(e) There exists potential opportunity to supply Covid vaccines over the medium term (as the vaccine has already become as a necessity and its longevity is still not clear could prove to be a value opportunity for different players).

Summarizing, growth across the Indian Pharma would be led by self reliance i.e. reducing dependency for raw material, robust exports opportunity, supply chain de-risking by global pharma from China, strategic end-to-end integration, PLI schemes, enhanced specialty, drug efforts, recovery of global pharma demand post Covid. **All this gives us the confidence that the Indian Pharma Industry is all set for Structural Growth definitely led by Structural Changes.**

May 06, 2021 | PICK OF THE MONTH | VOL-7, NO-05

Industry: Pharmaceuticals | **Aurobindo Pharma Limited** | BUY

CMP: Rs.1018 | TARGET PRICE: Rs.1250 | TIME : 12 months

About the Company: Aurobindo Pharma Limited (Aurobindo) was incorporated in 1986 and manufactures generic formulations and APIs. The company's robust product portfolio spreads over 6 major therapeutic/ product areas encompassing Antibiotics, Anti-Retroviral, CVS, CNS, Gastroenterological, Pain management and Anti- Allergic, supported by an outstanding R&D set-up. Aurobindo generates more than 90% of its sales from international markets. With a dedicated focus on me-too generics, it has already emerged as the second-largest US-generic company in terms of Rx dispensing (with USD1.6bn US sales in FY20, i.e., 50% of its total sales) and the seventh-largest generic company globally. It has a strong US franchise with well-diversified R&D pipeline. Over last few years, 100+ launches and scale-up in base business have placed Aurobindo as a leading generic player in US. The company also holds a strong position in many European countries, including France and Italy, where it ranks among the largest generic companies. Aurobindo entered Poland and the Czech Republic with the acquisition of Apotex's commercial operations. The company also strengthened its US presence with the acquisition of dermatology and oral solid businesses from Sandoz. The company has K Nithyananda Reddy as the Vice-Chairman and Whole-time Director and N Govindarajan as the Managing Director. Aurobindo is a vertically integrated company, meeting 70% of its API requirements in-house. It has the edge of having a well equipped manufacturing base spread across the different segments served. The company has 29 manufacturing facilities for its API (11 units) and formulations businesses (11 in India, 4 in USA and 1 each in Brazil, Portugal and the Netherlands), which have requisite approvals from various regulatory authorities, including the USFDA, UK MHRA, Japan PMDA, WHO, Health Canada, MCC South Africa and ANVISA Brazil.

Exhibit 04: USFDA Status- Key Plants

Inspection Date	Facility	No. of Observations	Facility Status
Feb-20	Aurolife New Jersey US	9	WL (Oct-20) OAI (June-20)
Nov-19	Unit-4	14	VAI (April-20)
Oct-19	Unit-5	4	-
Oct-19	Unit-8	4	VAI (Feb-20)
Sept-19	Unit-7	7	OAI (Jan-20)
May-19	Unit-3	10	-
Feb-19	Units-1,9 and 11	6 (Unit-1) 5(Unit-9) 3(Unit-11)	WL for Unit-11 (Jun-19) OAI for all 3 (May-19)

Source: Company Intimations/PR, Progressive Research

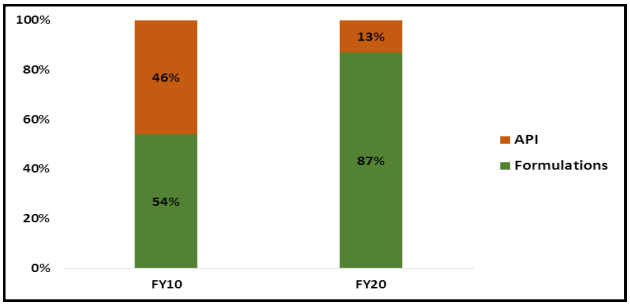
INVESTMENT RATIONALE:

The business model of the company is broadly categorised across Generics and Branded Generics with focus on high margin specialty generic formulations. Aurobindo has been catering to the needs of global customers through the contract manufacturing base as well as products outlicensed with the strong R&D support, complying with the highest regulatory standards.

Exhibit 05: Business Model-Key Segments

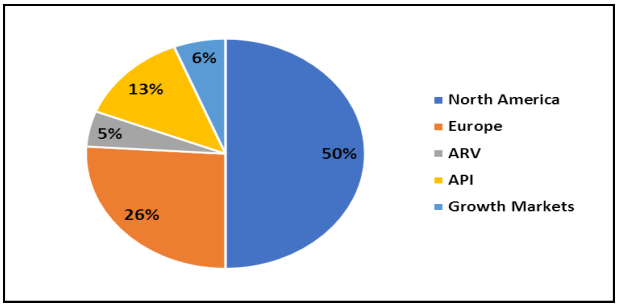
Source: Company Website, Progressive Research

Exhibit 06: Revenue Mix Shift Towards Formulations



Source: Company Progressive Research

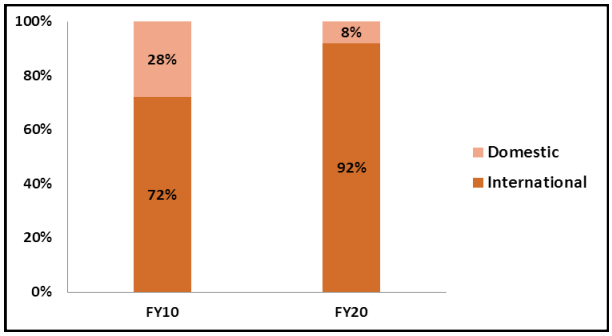
Exhibit 07: Geographical Breakup



Source: Company, Progressive Research

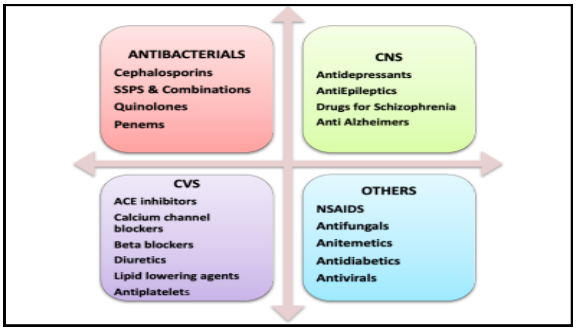
Formulations: business contributed 87% to the company's consolidated 9MFY21 revenues. Aurobindo commands a large portfolio in formulations with 1,200+ products and has 18 formulations manufacturing facilities in India (11), the Netherlands (1), Portugal (1), Brazil (1) and the US (4).

Exhibit 08: Geographical Revenue Mix



Source: Company, Progressive Research

Exhibit 09: Range of Formulations



Source: Company Website, Progressive Research

INVESTMENT RATIONALE (contd.)

A. US Formulations Business:

Aurobindo has a sizeable presence in the US pharma markets which constitutes ~50% of the overall revenues, with a strong product pipeline which would unfold going ahead and provide the impetus for growth. Its product portfolio in the injectables space comprises of almost 70 assets under development, 50 filed and under review and 80 approved products, thus pointing towards a sturdy product pipeline. Aurobindo is on track to achieve its guidance of launching 50 new products in the US in FY21 and sees the new launch momentum to continue in FY22E. Its focus on injectable business to drive growth ahead should augur well.

New Facility: Aurobindo is setting up a new facility aimed at the US markets, with a focus on high value and low volumes products. The new facility would enable it diversify its risk related to Unit 4, as it's the only plant catering to the US markets as of now. The new facility would also enable the company to benefit from local tenders, if any.

With regards to injectables, Aurobindo is targeting revenues of around USD650-700mn over the next three years from the injectables (which accounts for 22% of the US portfolio) from around USD380mn currently led by new launches in the US (54 pending ANDAs + 87 approved ones; taking the total to 141 injectable ANDAs as of 31st Dec, 2020)/Europe (penems and oncology injectables), and two additional injectable plants (one for the US, and one for EU and growth markets).

Apart from the injectables, the complex generics space is also gaining traction and different industry reports suggests that the overall market for complex generics is expected to be around USD20bn over the next 3 years from ~USD15-16bn currently. Aurobindo has a small presence in the complex generics space, but is looking to enhance its presence gradually by focusing on areas of biosimilars, inhalers, transdermal patches and injectables.

Collectively, a strong overall new product pipeline, focus on injectables business, key launches from complex pipeline (oncology, derma, nasal asset over FY21-22; inhalers, transdermal, depots and biosimilars from FY22) and acquisitions in niche areas, would be the key growth drivers for the US business over the next 3-4 years.

The US Business can be categorised into:

Oral Solids (Aurobindo USA):

- This business accounts for 65.4% of the US business as of 9MFY21
- It filed 31 ANDAs in 9MFY21 and is awaiting final approval for 135 ANDAs
- The future pipeline includes controlled substances with ADF, Oncology and 505b2 products for select patient segments.

Branded Oncology Injectables: (Acrotech)

- This business accounts for 14.3% of US business in 9MFY21
- It has filed 13 ANDAs in 9MFY21 and awaiting final approval for 54 ANDAs
- The future pipeline includes complex injectables including depot injections, Oncology, Hormones
- It has acquired portfolio of seven marketed oncology injectable products from Spectrum Pharmaceuticals
- Acrotech will continue building out its commercial infrastructure to maximize the value of its current and future products
- It has launched in-licensed product HEMADY.

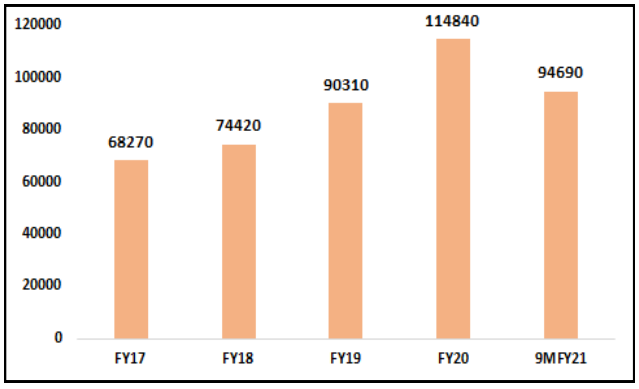
OTC: (Aurohealth)

- This business is 2.6% of US business in 9MFY21
- It is awaiting final approval for 11 ANDAs
- The future pipeline includes Rx to OTC switch opportunities and Branded OTC

Dietary supplements (Natrol):

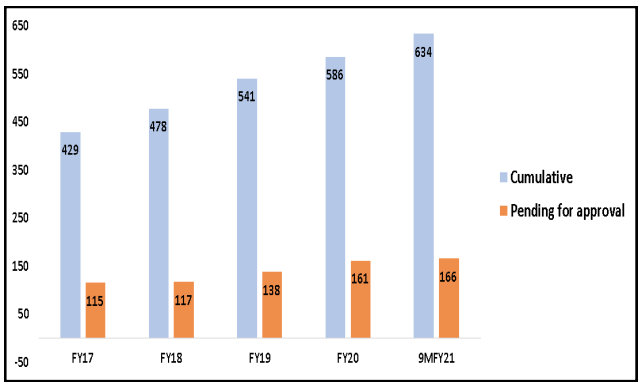
- This business was divested in Dec, 2020 which accounted for 11.6% of US business in 9MFY21

Exhibit 10: US Revenues (Rs mn)



Source: Company Presentations, Progressive Research

Exhibit 11: Cumulative ANDA filings & Approvals



Source: Company Presentations, Progressive Research

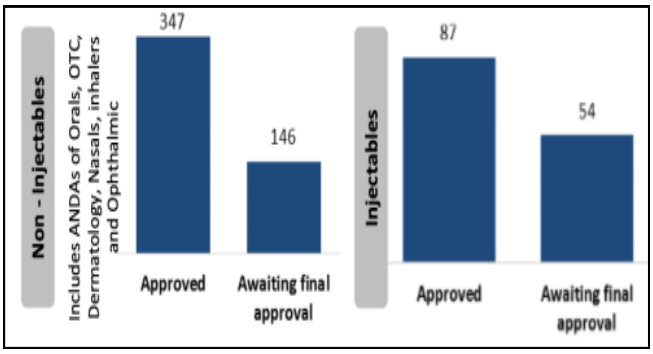
INVESTMENT RATIONALE (contd.):

Exhibit 12: ANDA Status

ANDA Filings	Cumulative	Final	Tentative	Under Review
FY16	398	215	36	147
FY17	429	276	38	115
FY18	478	327	34	117
FY19	541	377	26	138
FY20	586	397	28	161
9MFY21	634	434	29	171

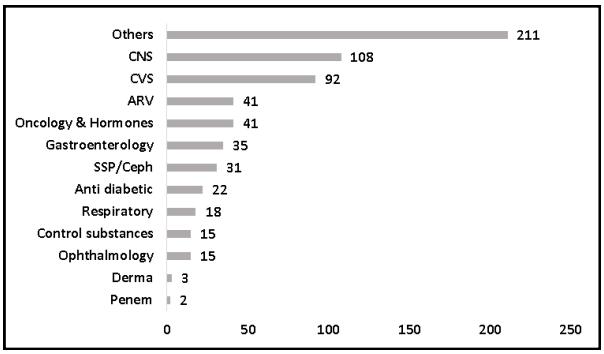
Source: Company Presentations, Progressive Research

Exhibit 13: Filings Mix



Source: Company Presentation

Exhibit 14: ANDA Filings Across Different Segments

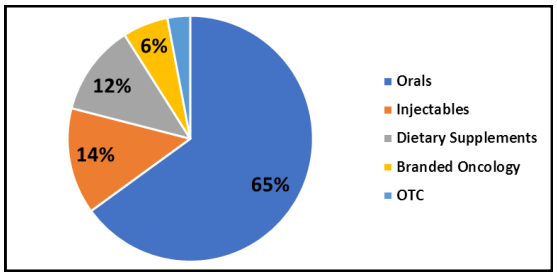


Source: Company PPT, IQVIA MAT Dec 2020 Data, Progressive Research

Tracked back to FY16, orals segment was the key contributor to the revenues of the company. It stood at 78% of the total revenues while the remaining being from dietary supplements (12%) and injectables (10%). Gradually with the business focus tilting towards specialty, and the conscious effort of reducing dependency on a single contributing segment, oral segment now stand at 65% of the total sales, thereby the revenue contribution risk well dealt by the company.

Going forward with new product approvals and launches across the key geographies, the other segments should also start contributing to revenues of Aurobindo.

Exhibit 15: US Generics Revenue Breakup:



Source: Company Presentations, Progressive Research

Exhibit 16: Addressable Market Size Across ANDA Filings In Different Therapeutic Segments

Therapeutic Segment	Addressable Market Size (USD bn)	Therapeutic Segment	Addressable Market Size (USD bn)
Ophthalmology	3.4	CVS	30.5
Control substances	1.1	CNS	23.3
Respiratory	1.3	Others	18.7
Anti-diabetic	20.4	SSP/Ceph	0.6
Gastroenterology	3.3	Derma	0.9
Oncology & Hormones	13.4	Penems	0.3
ARV	3.5		

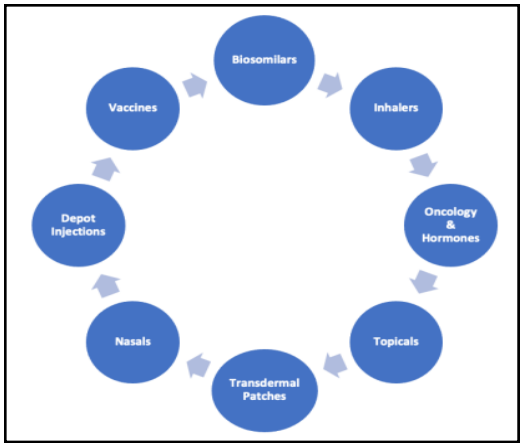
Source: Company PPT, IQVIA MAT Dec 2020 Data, Progressive Research

INVESTMENT RATIONALE (contd.):

B. Product portfolio upgrade to drive sustained value growth: The company is creating a diversified product basket by identifying complex molecules across therapeutic areas. Each of the following product groups enhances the business mix and strengthens the company's market presence.

i) Oncology and Hormones: Eugia's (Aurobindo's JV) product portfolio comprises of 84 products prescribed for Oncology, Hormone and Immunosuppressant indications. During FY20, it filed 12 ANDAs for US, of which nine were injectables and filed 11 dossiers for other markets, with 8 being injectables. Eugia filed a total of 34 ANDAs and received approval for 13 products, including tentative approvals for 3 ANDAs as on 31st March 2020. The market size of Eugia's 74 oncology products, which are under development, stands close to USD40bn and have applications across prostate cancer, lung cancer, multiple myeloma, metastatic melanoma, Hodgkin's lymphoma, acute myeloid leukemia, sickle cell disease and thrombocythaemia. The current hormonal portfolio includes 10 products with market size of USD1.1bn. Industry parse, the overall oncology spending will reach USD220–250bn, growing 9-12% by 2023E.

Exhibit 17: Diverse Specialty Products Portfolio



Source: Company Website, Progressive Research

(ii) Dermatology: Aurobindo is working on both topicals and transdermal.

Topicals: There are 37 products identified to be developed under the topical segment. These are developed in both India as well as US-based R&D centres. As on 31 Dec 2020, it has filed 3 ANDAs with the USFDA and received tentative approval for one product. The total market size of the products under development is more than USD4bn.

Transdermal Patches: Aurobindo is working on developing 8 transdermal patches with the total market size for the products under development being more than USD3bn. The endpoint studies for the first set of products will begin in FY22E.

(iii) Respiratory: Aurobindo is developing metered dose **inhalers** (MDIs) and dry powder inhalers (DPIs) for the treatment of asthma and Chronic Obstructive Pulmonary Disease (COPD). It is in the process of building a diversified product basket with 6 MDIs and 2 DPIs which have a market size of more than USD10bn in the US. It has successfully filed the first MDI. The company is setting up a state-of-the-art manufacturing facility in North Carolina, USA and that would be ready in CY21. Aurobindo is in the process of developing six **nasal spray** products. It has filed and received approval for first set of products while would be filing remaining products over the course of next two years. The current US market size is estimated to be USD1.3bn.

(iv) Depot Injections: It is working on 3 depot injections which have global market size of USD3.3bn

(v) Peptides: The company has invested in developing peptide development laboratory and set up four manufacturing sites for its commercial production and has the capability to produce peptides from milligrams to multi-kilogram. It has developed the process for manufacturing 20 peptides including small and large volume products. As on 31st Dec 2020, it has filed 10 DMFs with USFDA and is in the process of filing DMFs for other products. The APIs developed by Auro Peptides are used for developing complex injectables and oral products by the company. Aurobindo has filed 5 ANDAs both for injectables and orals using Auro Peptides APIs having a global market size of ~USD2.5bn.

(vi) Biologics: division is fully integrated with expertise in cell line development, process and analytical development, bulk manufacturing of mammalian and microbial products, filling in vials and pre-filled syringes, packaging and dispatch. The company has a portfolio of 14 biosimilars, including five molecules acquired from TL Biopharmaceuticals AG. In the first wave of development, it is working on 5 products that have a combined market size in excess of USD20bn. Through CuraTeQ Biologics it continues to develop biosimilars with a portfolio of products covering a market size of over USD50bn. The four therapeutic areas namely Oncology, Immunology, Ophthalmology and Respiratory are being focused on for development efforts. It has also initiated early stage development of immuno-oncology assets to become part of the opportunity in anti-PD1 biosimilars space. In total, Aurobindo is developing 13 biosimilars in two phases (first and second wave). The clinical trials spend on biosimilar was around USD3-4mn in the last quarter and around USD17mn for full year FY21E. Two of the products, one each in oncology and immunology segments, have been tested in animal toxicity studies awaiting the study report and would be on track to advance these programs to Phase-1 clinical trials in the next fiscal year.

Exhibit 18: Details of first wave Biosimilars Under Development

Molecule (market size in USD bn)	Therapy	Current Status
BP01 (6.5bn)	Oncology	Phase I completed; Started receiving approvals to conduct Phase III trials and expects the first subject to be dosed in the next 2-3 months
BP14 (5.1bn)	Oncology	Expect clinical trials to conclude in Q1FY22
BP13 (1.7bn)	Oncology	Expect clinical trials to conclude by late Q1FY22 or early Q2FY22
BP02 (6.2bn)	Oncology	Phase III clinical trials are on-going and expect to complete recruitment of all subjects by Sep 2021
BP05 (4.3bn)	Ophthalmology	Expect to receive permissions for carrying out Phase III clinical trials by early Q1FY22
BP06 (7.4bn)	Immunology	Completed pre-clinical trials; Expect to start Phase I clinical trials in Q2FY22

Source: Q3FY21 PPT, Progressive Research

INVESTMENT RATIONALE (contd.):

B. Product portfolio upgrade to drive sustained value growth (contd.):

For BP13 and BP14; the company will start first with Europe only as it has done with extended Phase 1, which would then be followed by US later.

UB-612: The Indian government has asked Aurobindo to submit the protocol after approved by ANVISA. It expects to start trial in Brazil for Phase-II/III. The first set of data from Phase-II/III is expected by July. In fact, the conclusion will be by September. As far as efficacy is concerned, Phase-II and III has not happened and any efficacy to be talked about would be after the trial is concluded. Overall, yield and the front end, gives the company the confidence of sustaining good market share.

Vaccines: Aurobindo's vaccines pipeline consists of both bacterial and viral vaccines. It is developing Pneumococcal Conjugate Vaccine (PCV) vaccine through its JV with Tergene Biotech. It is developing viral vaccines in Hyderabad

Bacterial Vaccines: The company is developing PCV (global market size of USD6.2bn) and is awaiting the approval to start manufacturing. It has presented the data to the SEC and is awaiting clearance from them for starting Phase-III. From the day it starts; one can take approx 9-12 months to complete it and approximately same timeline to get the approval and start launching the product in India and then move it to the Gavi market. The revenues are expected to start flowing in over a period of next 18 months.

Viral Vaccines: Aurobindo forayed into viral vaccines segment with an acquisition through its step down subsidiary Auro Vaccines in Feb 2020. Auro Vaccines is developing four viral vaccines including one for Covid-19.

Covid-19 Vaccine: With regard to Covid, multiple vaccines are under development leveraging the inherent execution capabilities and collaborative strengths. Aurobindo has entered into an exclusive license agreement with COVAXX, a US based company to develop, commercialize and manufacture UB-612, first Multitope Peptide-based vaccine for Covid-19 in India market and to UNICEF. There have been promising results for safety and immunogenicity in COVAXX's Phase-I clinical trial that was conducted in Taiwan. **The company is doubling the capacity from current 220million doses in multi-dose presentation to a capacity of 480million doses by June 2021.** There is an in-house vaccine as well being developed (SARS COV-2 vaccine candidate) based on the company's proprietary, attenuated, recombinant vesicular stomatitis (VSV, VesiculoVax) vaccine. The company has collaborated with Council of Scientific and Industrial Research (CSIR) to develop multiple vaccines for Covid-19.

Acquired R&D assets of US clinical stage viral vaccine development firm Profectus BioSciences Inc.: Through Auro Vaccines LLC, 100% subsidiary of Aurobindo Pharma USA Inc, Aurobindo has acquired certain R&D assets from Profectus BioSciences Inc., USA, a clinical stage vaccine development company in the design and development of preventive and therapeutic vaccines for an upfront cash consideration USD11.29mn (~Rs80cr). This acquisition provides access to Proprietary & Innovative technology platforms for prophylactic use & therapeutic use along with global R&D center to develop newer vaccines from basic discovery research into FDA-approved product. BIRAC (Department of Bio Technology, Ministry of Science and Technology in India) has evaluated the platform extensively and informed that the vaccine has been shortlisted for funding initial development upto conducting the Phase I/II trial in India.

Strong US business, but USFDA overhang concerns: Aurobindo has one of the best product approval rates and launch pipelines in the US. Despite pricing pressures, the company is one of the few to mitigate this risk led by the continuous product launches and approvals. However, currently it is grappling through the USFDA scrutiny at its various plants and continued regulatory glitches are a concern, likely to impact the performance going ahead, as more than 50% of the company's filings are from plants that are under USFDA scrutiny. The company is putting in the necessary efforts to mitigate risk and resolve the issues at the earliest.

Exhibit 19: Injectables Approval Portfolio

Filing Profile	Filed		*Approved		Pending	
	Dec-19	Dec-20	Dec-19	Dec-20	Dec-19	Dec-20
Total Orals	391	444	317	313	86	105
Unit III	126	130	124	116	2	5
Unit VI B (Cephalosporins)	12	12	11	11	1	1
Unit VII (SEZ)	167	170	149	136	18	21
Unit X	53	76	11	20	42	53
Aurolife	33	35	22	23	11	11
APL Healthcare	0	21	0	7	12	14
Total Injectables	113	125	67	83	47	43
Unit IV (Inj. And Ophthalmics)	111	123	65	81	46	42
Auronext (Penems)	2	2	2	2	0	0
Others	56	46	36	24	20	22
Eugia (Oncology/ Hormones)	30	40	10	18	20	22
Total	572	634	418	617	154	171

***Approved ANDAs include tentative approvals (TA)**

Source: Company Data, Progressive Research

In April-2020, Aurobindo Pharma received EIR from USFDA and VAI status for its injectable formulation facility, Unit IV. The clearance of this unit released the overhang on potential earnings. Unit IV is one of the most critical plants from an organic growth perspective for the company. Resolution of Unit IV gives confidence on growth as it paves way for future approvals.

Aurobindo Sandoz Deal Called off: Aurobindo and Sandoz Inc. mutually announced the termination of the deal through which the company was buying US generic oral solids and dermatology businesses from Sandoz. The primary reason identified was failure to obtain the required transaction approval from the US Federal Trade Commission (FTC) during anticipated timelines. The deal meant revenues of nearly USD750-850mn with operating profit margin at ~25-27%.

INVESTMENT RATIONALE (contd.):

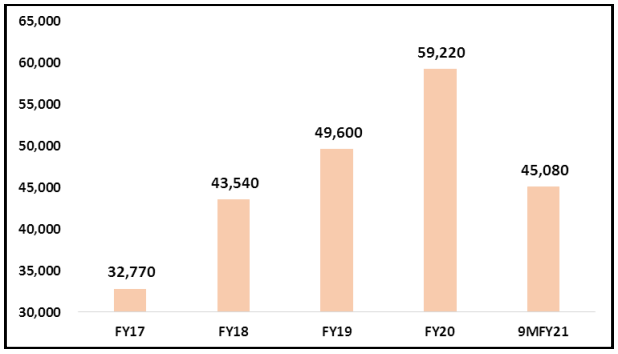
C. Europe:

Aurobindo has been expanding its European footprint since 2006 both organically and through acquisitions. It derives ~30% of its revenues from the European regions and RoW countries. It has operations in 11 countries with full-fledged Pharmacy, hospital and tender sales infrastructure with commercialized 450+ INNs. It ranks amongst the Top 10 generic companies in 7 countries including four of Top-5 EU countries. **France & Germany are the top 2 markets for the company.** The company has managed to turn around loss-making business units through switching to cost-competitive manufacturing locations and working on operational efficiencies.

The Apotex Acquisition: The recent acquisition of **Apotex business** (Aurobindo acquired Apotex Inc's operations in 5 European countries in Feb 2019.) strengthened Aurobindo's presence in existing markets of Spain, Netherlands and Belgium and provided entry into newer markets of Poland and Czech Republic. The portfolio includes 200 Rx and 88 OTC products with a pipeline of 20 launches in the next two years. Aurobindo has established itself as one of the leading generics companies in Europe with significant value opportunity through multiple avenues for revenue growth and cost synergies. Going forward, decent growth is expected backed by increased market access, market share gains in own and acquired portfolio and new launches. There shall be expansion across the Ebitda margins led by the operational synergies through combined business infrastructure; lowering COGS by transferring products to Aurobindo's own manufacturing in India and ramp-up in own filings and day-one launches.

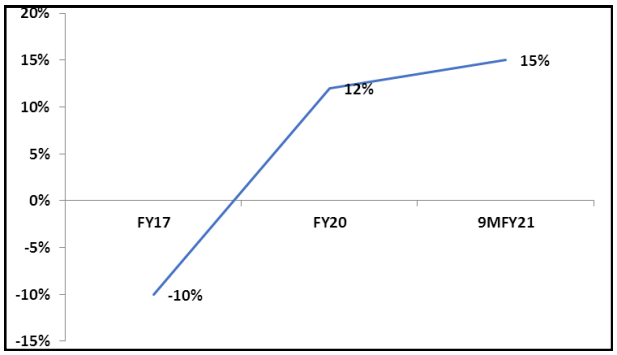
Setting-up New Plant: With regard to the plant being put up in Europe, it is known that the main general injectable plant, Unit IV, is catering exclusively to US and doesn't have capacity to supply to Europe. Aurobindo has close to 20 products, which are filed or approved, but has not been able to capitalize on the same. It has been meeting some part of meropenem demand, but otherwise, it is outsourcing from Europe and from Aurobindo India it supplies Piptaz and one more ampicillin + sulbactam. So, once it is done with the new plant, which is for Europe and the other growth markets, Aurobindo will be able to immediately supply those 20 products, which are approved or filed. It will further add another 30 products, which adds up to 50 products which will be a fair size of potential to supply general injectables.

Exhibit 20: EU Sales (Rs in mn)



Source: Company PPT, Progressive Research

Exhibit 21: EU Ebitda Margins (%)



Source: Company, Progressive Research

Aurobindo sees Europe being impacted by a second wave of the Covid-19 pandemic, but expects the situation to improve on the back of vaccination drive which has commenced across major markets of the globe. Further, given the improved growth prospects from Europe and emerging markets, the company is anticipating a strong demand growth and has announced a greenfield plant setup at Vizag, which would be focused on these markets. The announcement comes on the backdrop of a strong demand traction in the US which is catered from Unit 4, thus leaving a small portion to meet the demand in the EU and other markets. The new plant is expected to be ready in the next 15 months.

Some of the key growth drivers include:

- Portfolio expansion via launches of targeted Day 1 products, oncology range, hormones, niche low volume injectables and orals.
- Pipeline of over 250 products is under development
- Opportunity of ~USD13bn of addressable sales is coming off patent in its key markets in the medium term (2021-2023)
- Future growth potential in countries like Italy, Spain, Portugal and France as the penetration of generics improves

Growth recovery in Europe is based on new launches (expects ~250 launches over next 3-4 years) and better gross margin led by backward integration in India (setting up 3 dedicated facilities including injectable facility by FY22E for Europe and EMs). The company's focus remains on filing more products on a consistent basis, diversifying its existing product portfolio, reaching out to critical markets, streamlining of sales and marketing.

D. Growth Markets Formulations: (contributed 5.9% to total revenues FY20)

The growth markets segment includes the key markets including Canada, Brazil and China. Aurobindo targets to build branded generics presence in these selected markets. It is in the process of strengthening operations and portfolio in the above identified countries. The future product launches are expected in oncology and specialty injectables. The business has clocked ~20% CAGR from FY16-20.

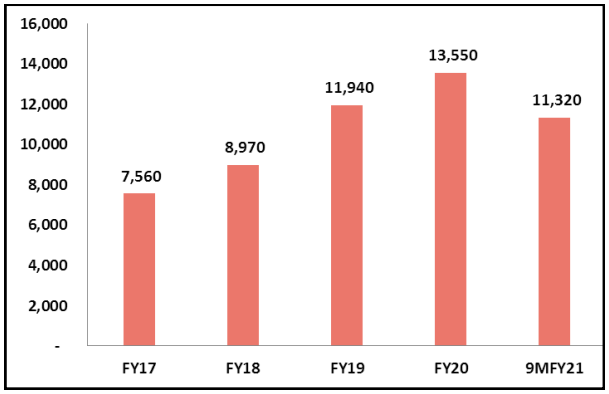
INVESTMENT RATIONALE (contd.):

D. Growth Markets Formulations: (contd.)

(i) China: is an important geography for the company going ahead. It is setting up an oral solid manufacturing facility in China and is fairly confident about the performance and has already filed 28 products and expects around 8-10 product approvals in this calendar year, which will also allow Aurobindo to participate in the tenders going forward. Aurobindo is also setting up an oral formulation manufacturing facility in China which will cater to China, Europe and US. *In 2018: Established a Joint Venture with Shandong Luoxin, Pharmaceutical Group Stock Co., Ltd., to manufacture nebuliser inhalation formulation products. In 2019, Started setting up an oral solid manufacturing facility at Taizhou for China*

(ii) Canada: In FY20, the company launched 13 products taking total launches to 113. The market share of the company in value terms increased from 1.7% to 2.4%. The company has filed 13 dossiers and plans to file another 25 products in FY21. Over the next two to three years, the company is aiming to introduce products in Inhalers and Biosimilars. The segment aims to build its presence in branded generics in select growth markets and is deepening its footprint in specific countries, with the Canadian market being the key growth driver.

Exhibit 22: Growth Market Revenues (Rs in mn)

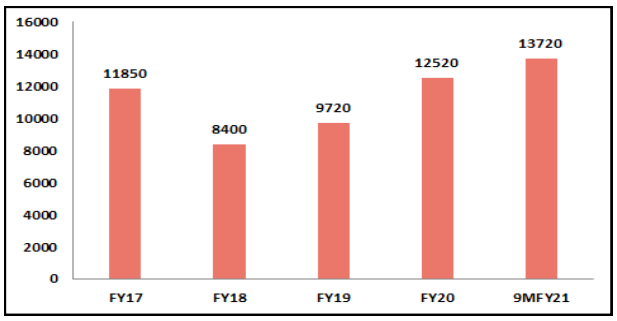


Source: Company PPT, Progressive Research

E. ARV Formulations: Aurobindo is one of the largest players in the ARV segment supplying life-saving ARV's to ~3 million HIV patients spread over 125 countries. It has a comprehensive portfolio of 32 products in 1L Adults, 2L Adults and paediatric formulations. The focus is on global tenders floated by multi-lateral organizations like Global Fund, USAID/PEPFAR and country specific MOH tenders. It has filed more than 1,100 ARV dossiers across the globe. However, the business declined by 1% over FY16-20 owing to capacity constraints and exits in low margin business. The company is leveraging on the early mover advantage in TLD (Tenofovir + Lamivudine + Dolutegravir tablets) in the institution segment. It has started supplies of Dolutegravir single dose and TLD to South Africa.

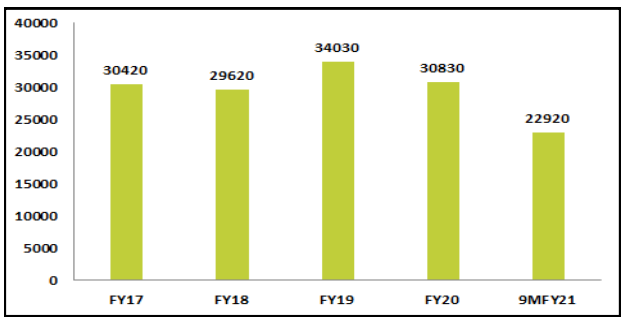
F. API Business: The company has 11 state-of-the-art API and intermediates manufacturing facilities inspected by the USFDA, UKMHRA, TGA Australia, ANVISA and other regulatory agencies. There are additional investments being made for capacity creation and capability building. The customers include innovator and large generic companies. Along with the continuous efforts to improvise manufacturing processes to meet the demand, the focus is on complex products with varying volumes. Aurobindo has sustained growth in advanced regulated markets (EU, Japan & USA). It aims to double the external sales in next 4-5 years.

Exhibit 23: ARV Formulation Revenues (Rs in mn)



Source: Company PPT, Progressive Research

Exhibit 24: API Business (Rs in mn)



Source: Company PPT, Progressive Research

G. Injectables Business: Aurobindo is among Top 4 in more than 60% of commercial injectable portfolio with regard to market share in the US. It has a comprehensive injectables portfolio (87 approved and 54 awaiting final approval) and is best placed to capitalize on the growth opportunities led by drug shortages and increased demand. It has presence in injectables across delivery systems such as liquid & lyophilized vials, bag, ampoules, prefilled syringes. The generic injectable business has sales of USD380mn which is expected to touch USD650-700mn in next 3 years. This will be predominantly driven by the new plant in US, new plant at Vizag for Europe & Emerging markets as well as expansion in Unit-IV. The injectables market is expected to grow by 12.5% as compared to 4% of the overall pharma growth over the next five years. The pending ANDAs and future filings comprise of complex opportunities viz. oncology, hormonal, liposomes, depot injectables, peptides which will improve product mix and profitability.

H. Biozymes: AuroZymes is the biocatalyst division of Aurobindo that develops and produces biocatalysts for use in the pharma and chemical industries. The company intends to produce scalable biocatalytic solutions by reducing the cost of goods in processes, whilst benefitting from Green Technology. Seamless integration with AuroSource further facilitates subsequent chemical manufacturing and product formulation, as required. With significant experience of API commercialization (over 240 projects successfully completed) the research team is completely attuned to different business needs.

INVESTMENT RATIONALE (contd.):
H. Biozymes (contd.)

Summary of the services is provided below:

- Screening of chemical transformations
- Invention of new routes utilizing biocatalysts
- Development and scale up of biochemical processes
- Supply of AuroZymes Enzyme screening panels
- Supply of AuroZymes biocatalysts to support any scale of manufacture from mg to tonnes
- Strain engineering and Fermentation development

I. Custom Synthesis: AuroSource is the custom research and manufacturing division of Aurobindo which offers the global biotech and pharmaceutical community a new approach for outsourcing of chemistry services with a dedicated focus on enhancing value for customers. AuroSource offers customer centric project-based chemistry services. It offers flexibility with five accredited API development and manufacturing facilities, most of which are USFDA, MHRA, Health Canada, TGA, ANVISA and SA MCC accredited. It has a comprehensive outsourcing option in registered starting materials, intermediates and APIs along with stability study. The portfolio includes many specialized R&D capabilities, with particular expertise in customized APIs, intermediates, starting raw materials and stability studies. It also offers solutions to manage the complete product lifecycle including extensions and regulatory support. Its contract services cover the clinical stage to manufacturing and management of the entire drug lifecycle in the API space for Penicillin's (sterile and non-sterile), cephalosporins (sterile and non-sterile) and non-beta lactams.

Financials:

Capex: Aurobindo would incur capex in the range of USD180-200mn in the current year. It is setting up a new injectables plant in the US and a new greenfield facility at Vizag aimed to cater to demand from EU and Emerging markets with commercialization expected in 15 months. In addition to this, it is also setting up a new plant for transdermal and inhalers in US, though a large part of the inhalers would continue to be supplied from India. Also the company is doubling its capacity at Unit-15 and Unit-10, both of which manufacture oral solids. The capex would be funded by internal accruals, thus avoiding any pressure on the financials. Aurobindo is looking at opportunities to take advantage from PLI scheme in API segment. PLI is a onetime expense that will come through over the next 2-3 years. Collectively, capacity expansion plans spread across the injectables as well as the oral solids provides ample visibility on growth prospects.

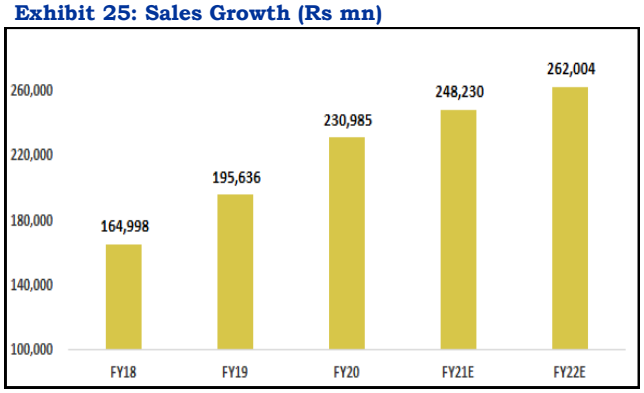
Debt Reduction: Aurobindo has reduced net debt to USD193.5mn from USD724.2mn and generating FCFF USD365mn over the last one year and being net cash after divestment of Natrol (at ~USD550mn) in Q3FY21. Strengthening of the balance sheet also provides visibility for further M&A initiatives by the company in near future.

Gross Margins Improvement: Over the last few quarters, the gross margin profile of the company has improved. The favourable exchange rates and growth in Europe business has contributed well to the gross margin expansion. The product profile has also been improving overall in all the markets.

Benefits from the PLI Scheme: Aurobindo is one of the largest beneficiary of Pharma PLI scheme; which could actually drive approx 15% Ebitda growth. The GOI has awarded three projects under PLI to Aurobindo for manufacturing three antibiotics products (Pen-G, 7-ACA, and Erythromycin) with a total value of Rs30bn. There have been certain queries put up by the company in context to these products depending on which there could be 2 or 3 products launched. These projects are through Aurobindo Antibiotics (100% subsidiary) and expected to happen over a period of 30 months and would have independent plants for these products. Aurobindo is one of the first company to have started manufacturing 6-APA in China and even developed direct crystallization process for 6-APA, which gives it an edge in product knowledge. Aurobindo itself utilizes almost 40-45% for captive consumption into own API, which is one more advantage for most of these antibiotic products, which should get into the market. This project will drive value growth with incremental sales and expand consolidated margins.

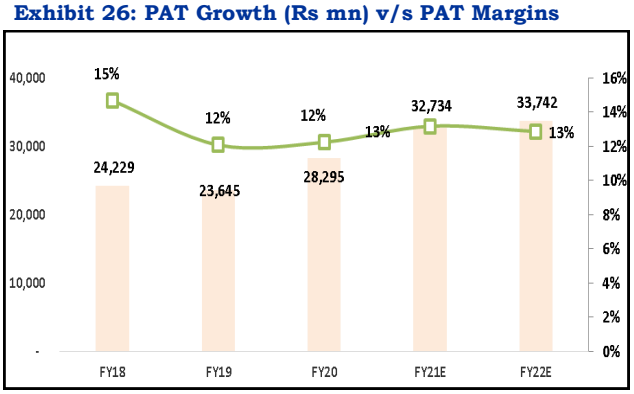
Peer Comparison and R&D Productivity: Aurobindo is one of the most efficient pharma player amongst Indian players in terms of capex and R&D productivity. Despite having one of the most capex intensive business models, it enjoys higher cumulative asset turnover of ~2.5x for cumulative incremental capex over the last five years. Similarly, in terms of the cumulative incremental sales over R&D spend (i.e. more than 8x), Aurobindo stands out over its peers.

Exhibit 25: Sales Growth (Rs mn)



Source: Annual Report, Progressive Research

Exhibit 26: PAT Growth (Rs mn) v/s PAT Margins

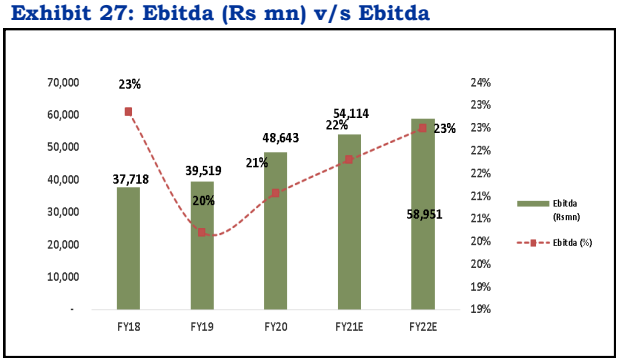


Source: Annual Report, Progressive Research

INVESTMENT RATIONALE (contd.):

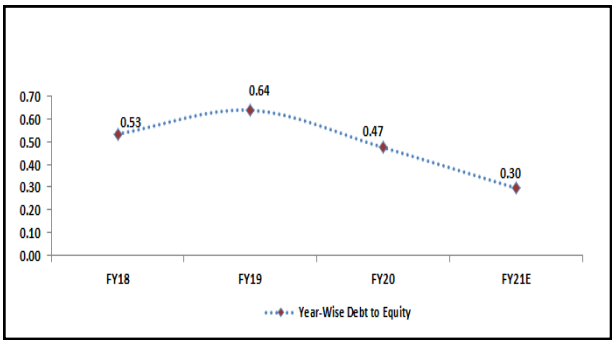
Financials:

Exhibit 27: Ebitda (Rs mn) v/s Ebitda



Source: Annual Report, Progressive Research

Exhibit 28: D/E Ratio



Source: Annual Report, Progressive Research

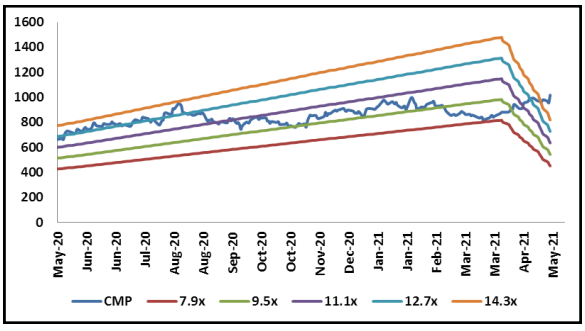
Risks and Concerns:

- Currency fluctuation could be a key risk as Aurobindo derives significant part of its revenues from international business
- Change in regulatory landscape and negative outcome of key facility inspections by the USFDA could impact the earning prospects
- Slower than expected improvement in the EU portfolio
- Delay in product approvals in US market and lower than expected contribution from new launches
- The R&D scale-up on complex filings will start contributing from FY24E. Also its inhalation and biosimilars (Avastin filing for the EU in Q1FY22) products are yet to be filed, with meaningful profit contribution unlikely before FY24E
- Decline in ARV sales due to funding squeeze by sponsors or other external factors

Outlook and Recommendations:

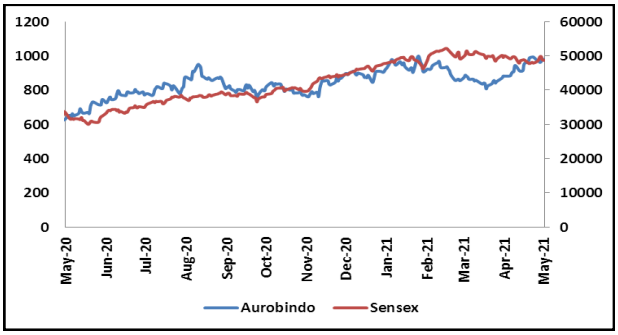
The US business stands out to be the key contributor of revenues driven by an improving traction from the generic injectables space with comparatively low competition, strong product pipeline and expected traction from the recently launched products. However, the company is awaiting clearance from the USFDA for 4 of its total 5 plants that are under the scanner after it has completed the remediation and submitted its response. Thereby, one of the key triggers for the earnings upgrade is the successful resolution of the observations. In the injectables space, the company has 70 assets under development, 50 assets under review and ~80 approved products, thus pointing towards a sturdy product pipeline which would unfold going ahead. Also, recent reports suggest a pick up in the complex generic space with the overall industry size likely to increase to around USD20bn over the next 3 years from around USD15-16bn. Aurobindo has a small presence in the complex generics space, but is looking to enhance its presence gradually in the segment by focusing on areas of biosimilars, inhalers, transdermal patches and injectables, which bodes well from a growth perspective. Furthermore, the company is expanding its capacities by setting a green field facility at Vizag aimed at Europe and emerging markets and is also setting up a facility in the US aimed at US markets. These expanded capacities are expected to be ready over the next 15 months. Over the long term, Aurobindo is looking to build a presence in the specialty segment which includes areas of biosimilars, oncology inhalers, transdermal patches amongst others which is likely to support growth. On the vaccines, Aurobindo's vaccine manufacturing plant with a capacity of 450mn doses would be ready by April 2021 and is expected to be operational by end of June 2021. The company expects a tie up for the vaccine capacity to be in place by then and would provide a new growth avenue. So Aurobindo expects strong growth momentum across the US and Europe business to sustain going ahead betting on the growth in the injectables, new facilities coming on stream, strong new product pipeline and a gradual pick up in complex generics space. We initiate a Buy on the stock with a target price of Rs1250 over a 12 months horizon.

Exhibit 29: One Year Forward P/E



Source: Ace Equity, Progressive Research

Exhibit 30: Price v/s Sensex



Source: Ace Equity, Progressive Research

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