

**About the Industry:**

**Indian Pharmaceutical Market (IPM):** India ranks 3rd worldwide for pharmaceutical production by volume and 14th by value (as per IBEF, 2021). The contribution of the Indian Pharma market to one of the leading economic indicators i.e. GDP stands at 2% and around 8% to the country's total merchandise exports. The pharmaceutical export market turnover stood at USD24.4bn in 2020-21, growth of 18.1% on a y-o-y basis. India's domestic pharmaceutical market is estimated to grow to USD65bn by 2024 and further expected to reach USD130bn by 2030. The Indian domestic Pharma market which was at about USD18bn during FY17 has exhibited a CAGR of about 4.5% to reach USD21bn during FY21. Further, the Pharma exports which contributed about USD17bn during FY17 have reported a CAGR of about 10% to reach USD24bn during FY21. The exports growth of 18% in FY21 was primarily attributed to increased demand for Covid-19 related drugs. Thus, on account of better export growth rate, the ratio of contribution of domestic to exports has changed from 52:48 during FY17 to 47:53 during FY21.

**Active Pharmaceutical Ingredients (API) Market:** As per recent media articles, the Indian API market stood at USD11.80bn in FY21 and is anticipated to report a CAGR of 12.24% during the forecast period 2021-2027. The growth is expected to be driven by high growth of the biopharmaceutical sector in the country; the increasing geriatric population in India which is further expected to boost the demand through FY27E, growing prevalence of chronic diseases such as cardiovascular diseases, diabetes, cancer, respiratory disorders, among others is going to boost the market. India continues to be an importer of API (~78% in 2020), on account of abundant supply of low cost API imports available outside India, thereby leading to higher dependency on the imports. The import of raw materials for FY20 stood at Rs28,528cr of which 68% came in from China while for FY21 the imports stood at Rs49,436cr as against the exports of Rs180,551cr indicating the strong capacity of domestic manufacturing. While India continues to be an importer, the pandemic served as an eye opener for the Indian Pharma industry that led to the adoption of China + 1: de-risking from a single geography. The GOI stepped in with the launch of PLI schemes as a part of Atmanirbhar Bharat (self-reliance) to encourage the industry to build capacity in India. India needs a holistic and conducive ecosystem to rebuild its API manufacturing capabilities, which would require favourable policies from the government and a supportive financial ecosystem to boost private and foreign investment.

**The IPM Trend:** The IPM has seen a swing of growth trend across months led by sale of Covid related drugs, growth in therapeutic areas and gradually with cases seen on a receding trend; a slight pick-up was observed in the non-Covid portfolio. IPM growth stood at 6.6% y-o-y in Nov'21 v/s 5% y-o-y in Oct'21. IPM growth was 1% y-o-y in Nov'20. On a MAT basis, industry growth stood at 15.2% y-o-y. Acute therapies such as gastro, respiratory and pain/analgesics witnessed sales growth of 13.1% (y-o-y), 16.3% (y-o-y) and 17.3% (y-o-y) respectively. Improvement was observed in chronic therapies during the month, with cardiac growing 6.3% (y-o-y) and anti-diabetic reporting 6.0% (y-o-y) growth. As per Ind-Ra, the growth of 6.6% on a y-o-y basis was led by improving growth trends in chronic therapies, namely cardiac 6% (y-o-y) {October 2021: down 1% (y-o-y)} and anti-diabetic 6% (y-o-y) {October 2021: up 1% (y-o-y)}. Acute therapies namely gastro-intestinal, respiratory and pain/analgesics continued to witness strong growth, aided by the low base impact. During November 2021, volumes were flat (y-o-y) {October 2021: declined 1.6% (y-o-y)}, while price growth was 5.4% (5.3%) and new products launches were 1.2% (1.4%), driven by acute therapy products. Ind-Ra expects IPM revenue growth of over 12% (y-o-y) for FY22E.

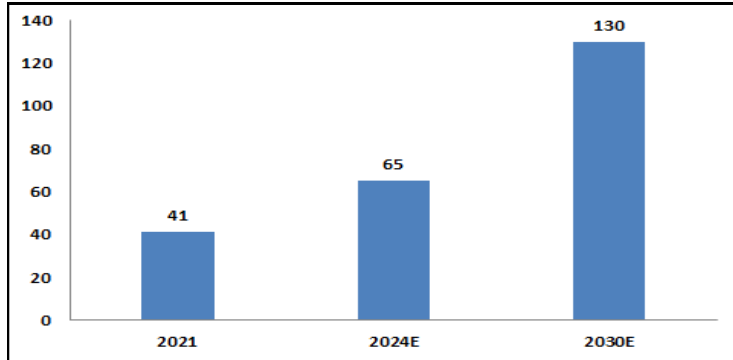
SNAPSHOT				
52 week H / L		Mcap (INR mn)		
4068/2544		440,794		
Face value: 2				
BSE Code		NSE CODE		
539523		ALKEM		
Annual Performance				
(Rs mn)	FY19	FY20	FY21	FY22E
Total Revenue	73,572	83,444	88,650	100,770
EBITDA	11,148	14,734	19,424	21,162
EBITDA (%)	15.2	17.7	21.9	21.0
Other Income	877	1,042	2,332	1,754
Interest	546	651	589	585
Depreciation	1,932	2,528	2,746	2,737
PBT	9,547	12,598	18,421	19,594
PAT	7,736	11,493	16,178	17,341
Equity (Rs mn)	239	239	239	239
EPS (INR)	64	94	133	142
Quarterly Performance				
Parameters (Rs mn)	Dec-20	Mar-21	June-21	Sept-21
Sales (Net)	23,181	21,922	27,314	28,000
EBITDA	5,291	2,911	5,929	6,244
EBITDA (%)	22.8	13.3	21.7	22.3
Other Income	964	463	467	420
Interest	131	107	129	120
Depreciation	690	685	705	728
PAT	4,516	2,494	4,805	5,620
Equity (Rs mn)	239	239	239	239
Ratio Analysis				
Parameters (Rs mn)	FY19	FY20	FY21	FY22E
EV/EBITDA (x)	40.1	30.9	23.5	21.5
EV/Net Sales (x)	6.1	5.5	5.1	4.5
M Cap/Sales (x)	6.0	5.3	5.0	4.4
M Cap/EBITDA (x)	39.5	29.9	22.7	20.8
Debt/Equity (x)	0.1	0.3	0.2	0.4
ROCE (%)	18	21	26	24
Price/Book Value (x)	8.1	7.2	6.0	5.2
P/E (x) (TTM)	40.2	38.8	30.1	25.4
Shareholding Pattern as on 30th September, 2021				
Parameters	No of Shares	%		
Promoters	70,355,621	58.8		
Institutions	23,097,160	19.3		
Public	26,112,219	21.8		
TOTAL	119,565,000	100.0		

Source: Annual Report, Progressive Research

Note: Data is calculated as on 07th Jan, 2022

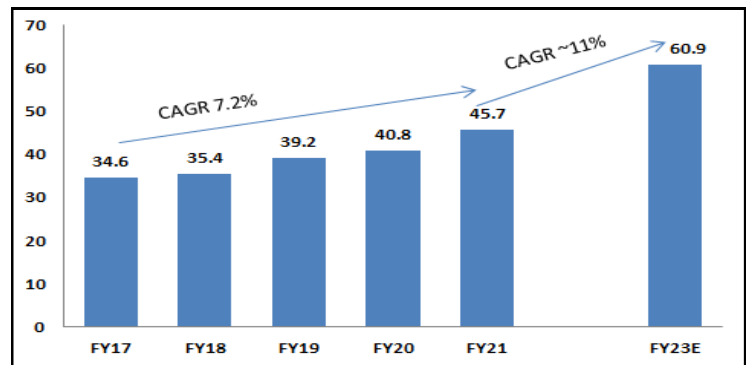
About the Industry (contd.):

Exhibit 01: IPM Growth (USD bn)



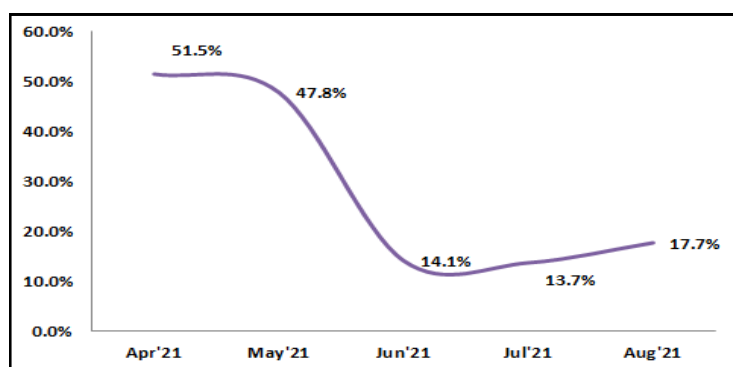
Source: RBI Docs, Progressive Research

Exhibit 02: Market Size of Indian Pharma Industry (USD bn)



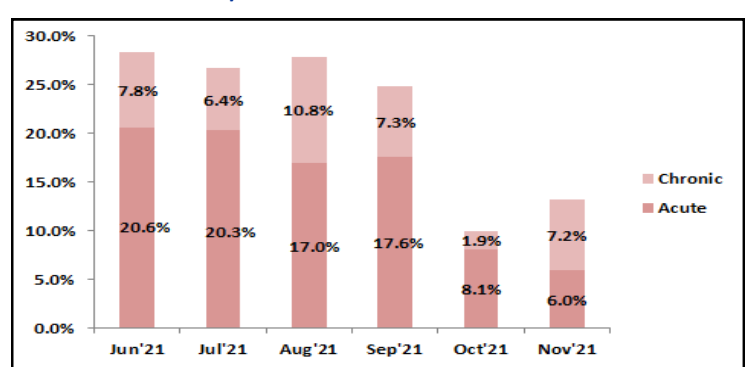
Source: CARE Reports, Progressive Research

Exhibit 03: IPM Growth across months



Source: Market Reports, Progressive Research

Exhibit 04: Acute v/s Chronic Trend



Source: Ind-Ra Reports, Progressive Research

About the Company:

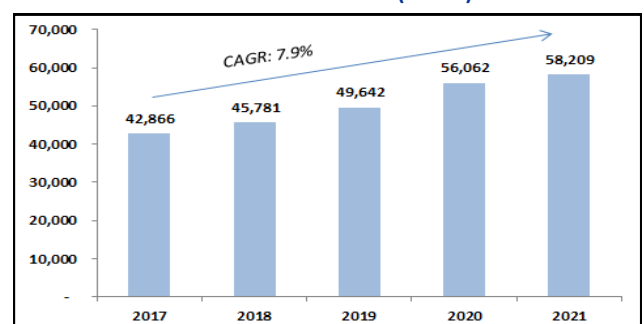
Alkem Laboratories Limited (Alkem) is the seventh largest branded Pharma company in India with global operations. Besides being a strong domestic company, Alkem's business operations are spread in more than 40 international markets, with the US being the key market. The company develops, manufactures and sells pharmaceutical and nutraceutical products in India and overseas. With a broad portfolio of more than 800 brands and a highly proficient management team, Alkem is amongst the leaders in its major therapy areas of anti-infective, gastrointestinal (GI), vitamins and minerals (VMN), and pain; that account for ~75% of its branded sales. For more than a decade now, Alkem has maintained the number 1 position in anti-infective (~38% of domestic sales; ~13% market share) by successfully tapping the largest sub therapy area, i.e. anti-bacterial. It holds a strong positioning in the GI and VMN segments as well. Dominantly an acute player, the company has slowly diversified its revenue base in chronic/semi-chronic therapies such as Neuro/CNS, derma, cardiac and anti-diabetic. It has 20 state-of-the-art manufacturing facilities that are approved by various regulatory agencies like the USFDA, WHO, MHRA (UK), TGA (Australia), ANVISA (Brazil), and MCC (South Africa) and six R&D centres. Mr. Sandeep Singh is the Managing Director of the company.

Investment Rationale:

(A) Business Mix:

The business of Alkem majorly has the domestic business and international operations (which is further bifurcated into US and Other International markets). The domestic business has a major revenue share of ~66%; while the balance is accounted from the international business. From FY17-21, the **domestic business** has grown at a CAGR of 7.9% with consolidated revenues earned at Rs42,866mn in FY17 to reach levels of Rs58,209mn in FY21. As per November, 2021 MAT growth trend; Alkem recorded a growth of 18.1% as compared to its counterparts with a market share of 3.5%. (Ranking 7<sup>th</sup> in the IPM).

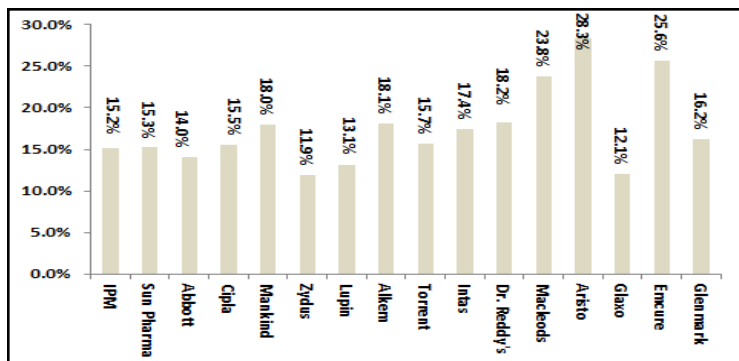
Exhibit 05: Domestic Revenue Trend (Rs mn)



Source: AR 2021, Progressive Research

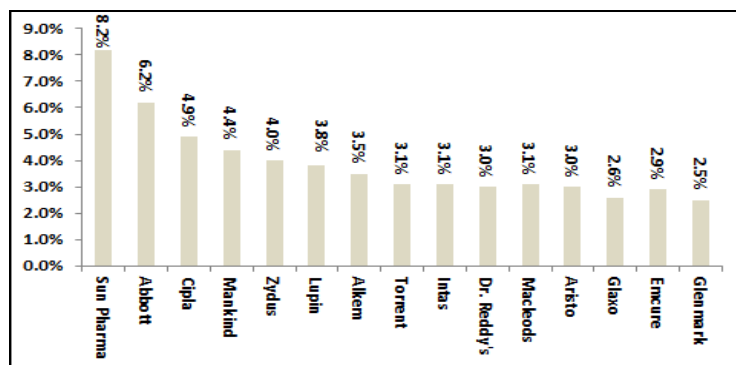
Investment Rationale (contd.):

Exhibit 06: MAT Growth– Nov'21



Source: Ind-Ra Reports, Progressive Research

Exhibit 07: MAT Nov'21 Market Share



Source: Ind-Ra Reports, Progressive Research

(B) Therapeutic Base Portfolio:

In the domestic market, the company caters to various therapeutic areas (with the most significant ones being under the acute segment namely anti-infective, gastro-intestinal, pain/analgesics, vitamins/minerals/nutrients) having a strong brand portfolio at its disposal. Therapy wise, anti-infective (35% of sales) continues to be the largest contributor to overall sales, followed by GI (19%) and VMN (15%). Over the years, Alkem's share of acute: chronic has been in the range of 85:15. Alkem continues to be **ranked No. 1** in the **anti-infective** segment in India over the past 15 years and **ranks No. 3** in the **GI and analgesic** therapies in India. Apart from catering to the acute areas, the company also has its presence in the fast growing chronic therapies that include neuro/CNS, cardiology, anti-diabetic, dermatology and oncology. Alkem has always been ahead of the curve and has surpassed the industry growth rate across FY17-21. Even in H1FY22, Alkem outperformed the IPM with growth of 40.4% y-o-y as compared to IPM growth of 26.4% y-o-y; attributed majorly to the growth in acute therapies like anti-infective, VMN and pain management. Apart from growth in the acute space, chronic therapies of neuro/CNS, anti-diabetes, cardiac and derma also grew faster than the segment growth rate, thereby gaining market share and improving their market rankings. The company has also ventured into the OTC segment that caters to women care, cough & cold, gastrointestinal, pain management and the sexual wellness category. Products under this division include Pregakem, Livoerb, Playguard, Tiger Balm to mention a few. Alkem has strong market capability, 800+ brands, 40+ sales depots/warehouses in India, 7000+ stockists. The domestic demand for products is catered through the field force that visits the prescribers across specialties in addition to the pharmacies and distributors to ensure that the brands are adequately stocked. The MR strength has increased from the levels of 8,000 in FY18 to more than 13,000 in FY21; with almost a PCPM range of Rs8-10 lakhs under the anti-infectives and antibiotics segment and ~Rs3.5-4 lakhs in the evolving business of the chronic space. This enables Alkem to cater to the strong brand recall established across different segments.

Exhibit 08: Therapeutic Share across financial years

Therapy Area	Company's Rank				Contribution (%)				Market Share (%)				Company's Growth (%)			
	FY18	FY19	FY20	FY21	FY18	FY19	FY20	FY21	FY18	FY19	FY20	FY21	FY18	FY19	FY20	FY21
Anti-infective	1	1	1	1	40.0	40.0	41.0	37.3	11.2	12.0	12.7	13.1	2.7	13.7	21.4	(9.5)
GI	3	3	3	3	18.0	19.0	18.0	18.6	5.9	6.5	6.6	6.5	6.7	17.9	10.8	7.4
VMN	4	4	4	4	8.0	8.0	9.0	11.1	3.7	3.9	4.2	4.9	11.5	15.4	20.7	27.4
Pain/Analgesics	3	3	3	3	12.0	12.0	11.0	10.8	5.5	5.4	5.4	5.3	10.6	7.7	10.8	(1.9)
Neuro/CNS	9	7	7	8	4.0	4.0	4.0	3.8	2.4	2.5	2.6	2.3	12.1	13.7	13.6	(3.5)
Anti-diabetic	25	22	21	20	2.0	3.0	3.0	3.6	0.9	1.0	1.2	1.3	20.3	34.2	29.4	18.3
Cardiac	28	26	26	27	2.0	3.0	3.0	3.1	0.7	0.8	0.8	0.9	17.6	29.2	23.7	15.4
Derma	18	17	15	18	4.0	3.0	3.0	2.9	1.6	1.6	1.7	1.4	19.4	13.0	14.7	(13.7)
Gynaecology	NA	NA	NA	11	NA	NA	NA	3.8	NA	NA	NA	2.8	NA	NA	NA	20.0
Respiratory	NA	NA	NA	17	NA	NA	NA	2.7	NA	NA	NA	1.3	NA	NA	NA	(14.1)
<b>Alkem</b>	<b>6</b>	<b>6</b>	<b>5</b>	<b>5</b>	-	-	-	-	<b>3.5</b>	<b>3.6</b>	<b>3.8</b>	<b>3.6</b>	<b>7.2</b>	<b>14.3</b>	<b>21.4</b>	<b>0.3</b>

Source: Annual Reports, Progressive Research

Jan 10, 2022

PICK OF THE MONTH

VOL-8, NO-02

Industry: Pharmaceuticals

Alkem Laboratories Limited

ACCUMULATE

CMP: Rs.3687

TARGET PRICE: Rs.4299

TIME : 12 months

**Investment Rationale (contd.):**

**Exhibit 09: Quarterly Trend-Acute Therapy**

Acute Therapies	Growth (in %, y-o-y basis)									
	Q2FY21		Q3FY21		Q4FY21		Q1FY22		Q2FY22	
	Alkem	Industry	Alkem	Industry	Alkem	Industry	Alkem	Industry	Alkem	Industry
Anti-infective	(12.2)	(13.5)	(3.9)	(5.9)	(0.5)	(5.8)	88.5	93.6	32.8	30.6
Gastro-intestinal	6.0	4.3	12.5	12.9	17.3	17.4	32.8	33.2	11.6	14.6
Pain/Analgesics	(5.4)	(2.5)	3.2	3.1	9.8	8.0	43.7	36.3	22.2	21.9
VMN	30.3	12.9	39.6	16.3	36.0	16.4	86.6	46.8	16.0	8.2

Source: Quarterly Reports, Progressive Research

**Exhibit 10: Quarterly Trend-Chronic Therapy**

Chronic Therapies	Growth (in %, y-o-y basis)									
	Q2FY21		Q3FY21		Q4FY21		Q1FY22		Q2FY22	
	Alkem	Industry	Alkem	Industry	Alkem	Industry	Alkem	Industry	Alkem	Industry
Neuro/CNS	(9.8)	9.5	(2.2)	12.2	12.8	12.1	38.9	13.4	38.2	12.3
Derma	(19.2)	5.5	(11.2)	8.3	9.4	12.6	51.1	23.8	40.8	9.4
Cardiac	17.1	14.6	17.6	15.2	13.1	9.9	24.9	19.0	10.0	6.9
Anti-diabetic	13.2	9.3	21.2	10.5	27.0	6.8	34.3	11.2	27.8	5.7

Source: Quarterly Reports, Progressive Research

**Exhibit 11: Industry v/s Alkem Growth Trend**

Therapy Area	Company's Growth (%)						Industry Growth (%)					
	FY17	FY18	FY19	FY20	FY21	H1FY22	FY17	FY18	FY19	FY20	FY21	H1FY22
Anti-infectives	9.4	2.7	13.7	21.4	(9.5)	54.9	4.8	1.5	6.6	13.3	(11.9)	55.5
GI	14.2	6.7	17.9	10.8	7.4	21.3	8.5	5.3	7.9	8.7	6.2	23.4
VMN	10.2	11.5	15.4	20.7	27.4	45.2	9.0	6.0	12.0	10.0	10.5	25.5
Pain/Analgesics	12.8	10.6	7.7	10.8	(1.9)	31.5	7.8	3.5	9.0	11.6	(0.7)	28.3
Neuro/CNS	19.3	12.1	13.7	13.6	(3.5)	38.6	10.2	3.8	10.3	9.0	9.7	12.9
Anti-diabetic	27.5	20.3	34.2	29.4	18.3	30.9	17.6	11.8	14.9	11.8	8.7	8.5
Cardiac	14.6	17.6	29.2	23.7	15.4	17.2	8.4	6.0	12.0	11.8	12.9	13.0
Derma	15.1	19.4	13.0	14.7	(13.7)	45.0	16.3	13.8	13.1	8.6	5.7	16.0
Gynaecology	NA	NA	NA	NA	20.0	NA	NA	NA	NA	NA	2.2	NA
Respiratory	NA	NA	NA	NA	(14.1)	NA	NA	NA	NA	NA	(8.4)	NA
<b>Alkem</b>	<b>11.4</b>	<b>7.2</b>	<b>14.3</b>	<b>21.4</b>	<b>0.3</b>	<b>NA</b>	<b>9.1</b>	<b>6.3</b>	<b>10.5</b>	<b>10.8</b>	<b>4.3</b>	<b>NA</b>

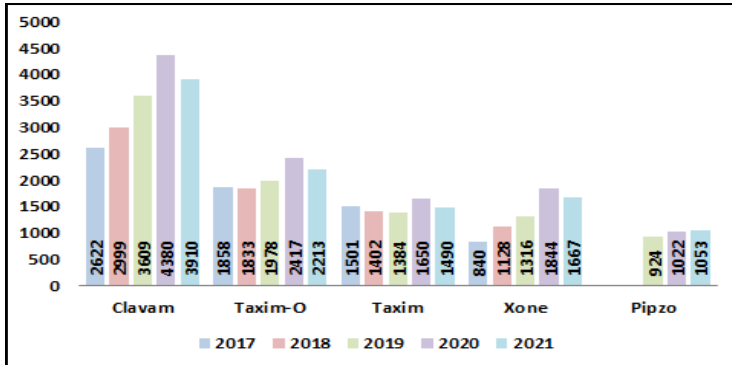
Source: Annual Reports and Q2FY22, Progressive Research

**Acute Therapies:**

(i) **Anti-infective:** Under the anti-infective space, Alkem has immense expertise across the wide range of formulations that include tablets, dry syrups and sterile dosage forms. It has been the leader in the anti-infective segment (~12.75% of IPM), having 13.1% market share (in FY21) in the therapy. The major brands of the segment are **Clavam, Taxim, Zone and Swich**. The top 8 brands of the company contribute ~80% of the anti-infective sales. Also, the company enjoys leadership in 6 out of 10 brands in the anti-infective market. The strategy would be to increase the market share in the represented markets.

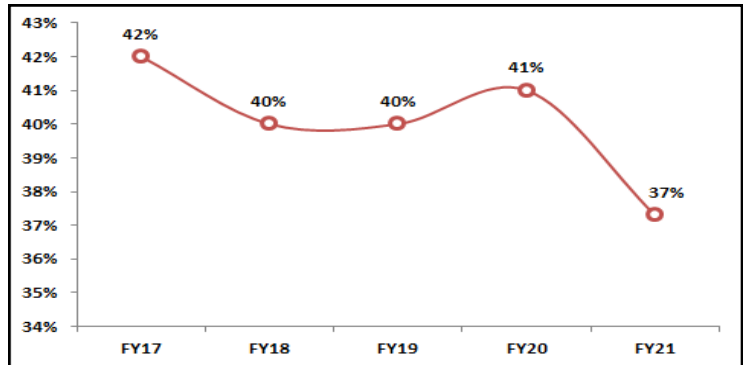
**Investment Rationale (contd.):**

**Exhibit 12: Anti-infective Revenue Trend (Rs mn)**



Source: Annual Reports, Progressive Research

**Exhibit 13: Anti-infective Acute Contribution**

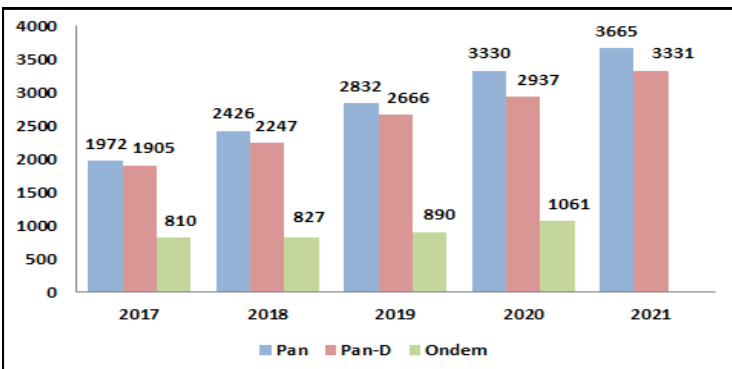


Source: Annual Reports, Progressive Research

**National List of Essential Medicines (NLEM) Effect:** The National Pharmaceutical Pricing Authority (NPPA) panel has fixed the retail price (at Rs3.36 per ml excluding GST) of each 5ml of the reconstituted suspension containing amoxicillin in trihydrate plus potassium clavulanate diluted manufactured by Alkem Health Science and marketed by Alkem Labs. As per the provisions of DPCO 2013, the retail price of each 5ml of the reconstituted suspension is required to be calculated as per the formula for new drugs provided in DPCO, based on the April 2021 database. As per CARE Ratings, Alkem has ~25-30% of its products under NLEM list, and hence the recent increase in the pricing pressure in the US markets along with rise in cost of KSMs and APIs are likely to depict some moderation on the operating margins in the medium term.

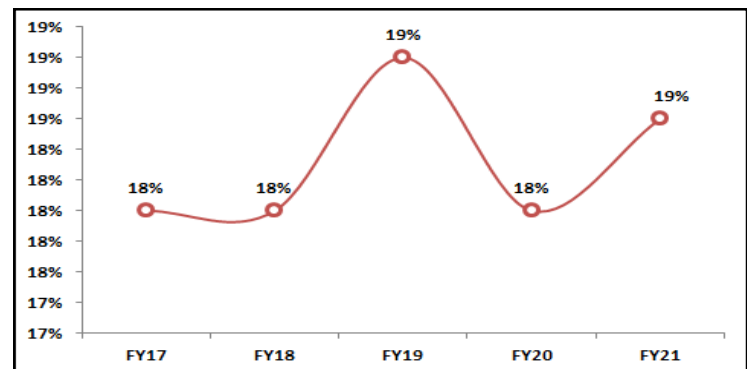
(ii) **Gastro Intestinal (GI):** In the GI therapy, Alkem provides products for disorders related to Gastroesophageal Reflux Disease (GERD), gastric ulcers, constipation, hyperacidity, diarrhoea, worm infestation, etc. The second most important segment in the acute space is the GI which is ~19% of the total domestic sales with market share of ~6.5% (in FY21) making it the category leader. This segment has also outperformed (7.4% growth reported in FY21) when compared to the therapy growth of 6.2% in FY21. Majorly the top 3 brands namely **PAN, PAN D and ONDEM** contribute around 75% of the GI sales.

**Exhibit 14: GI Revenue Trend (Rs mn)**



Source: Annual Reports, Progressive Research

**Exhibit 15: GI Acute Contribution**



Source: Annual Reports, Progressive Research

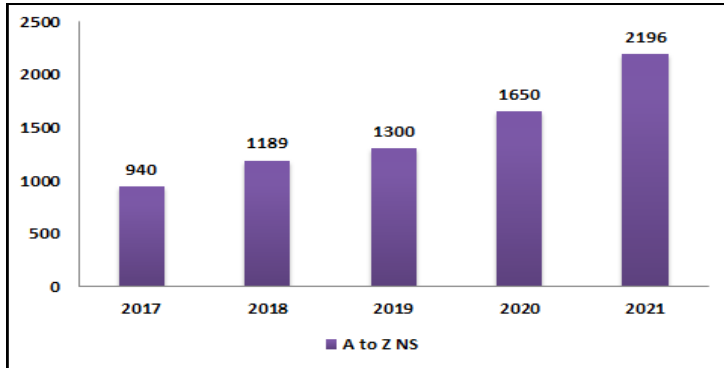
**Chronic Therapies:** The chronic therapies include anti-diabetic, cardiac and neuro/CNS which are ~14% of the overall domestic sales. The target of doubling chronic sales in every 3 years would be largely led by cardiac and anti-diabetes segment. Growth in the chronic space would aid the domestic margins betting on the MR addition already done.

**Anti-Diabetic /Cardiac/CNS:**

The anti-diabetic segment growth is majorly led by the top brand **Glucoryl-M and Glucoryl-MV** which account for ~40% of the total anti-diabetic sales. The other key brands of the category include Olymrix M, Elucide M and Olymrix. In the cardiac segment, the top-5 brands are **Olkem, Olkem trio, Diabictot, Jupiros, and Fondakem** which form ~40% of the total cardiac sales. This segment has consistently outperformed the industry growth rate over FY17-21. The Neuro/CNS portfolio too has outperformed the industry growth except in FY21. Some of the top brands **Ceham, Donep, Levenue, Pentanerv-NT and Donep M** in this segment. As far as Glucoryl-M is considered, the management has indicated to report sales of over Rs1,000mn (from the current Rs600mn) over a period of 2-3 years coupled with new launches that are under its radar.

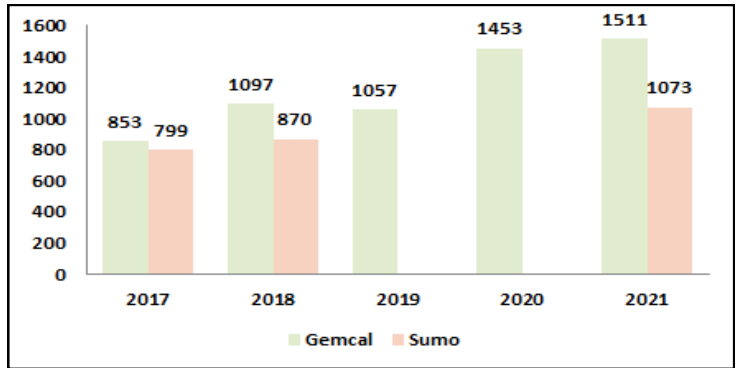
**Investment Rationale (contd.):**

**Exhibit 16: VMN Revenue Trend (Rs mn)**



Source: Annual Reports, Progressive Research

**Exhibit 17: Pain/Analgesics Revenue Trend (Rs mn)**



Source: Annual Reports, Progressive Research

Alkem's **top 10 brands** are featured amongst the **top 2 selling brands** in their respective molecular category. The company has earned around 38% of its domestic revenues from the top 10 brands in FY21 as against 39% in FY20. Additionally, its 12 brands have earned revenue of more than Rs1bn each during FY21; of which 6 are featured amongst the top 100 domestic formulation brands in FY21. Furthermore, Alkem has developed a robust pan-India network, invested in brand building and marketing with a large workforce at its disposal.

**Exhibit 18: Top 10 Brands**



Source: Annual Reports, Progressive Research

**Exhibit 19: Therapeutic Sales**

Brand	Therapeutic Base	Branded Sales (Rs mn)					CAGR (%)
		FY17	FY18	FY19	FY20	FY21	
Clavam	Anti-infectives	2622	2999	3609	4380	3910	10.5
Pan	Gastro-intestinal	1972	2426	2832	3330	3665	16.7
Pan-D	Gastro-intestinal	1905	2247	2666	2937	3331	14.9
Taxim-O	Anti-infectives	1858	1833	1978	2417	2213	4.4
Taxim	Anti-infectives	1501	1402	1384	1650	1490	NA
A To Z NS	Vitamins/Minerals/Nutrients	940	1189	1300	1650	2196	23.6
Gemcal	Pain/Analgesics	853	1097	1057	1453	1511	15.7
Kone	Anti-infectives	840	1128	1316	1844	1667	18.6
Ondem	Gastro-intestinal	810	827	890	1061	NA	14.4
Sumo	Pain/Analgesics	799	870	NA	NA	1073	15.8
Pipzo	Anti-infectives	NA	NA	924	1022	1053	6.7

Source: Annual Reports, Progressive Research

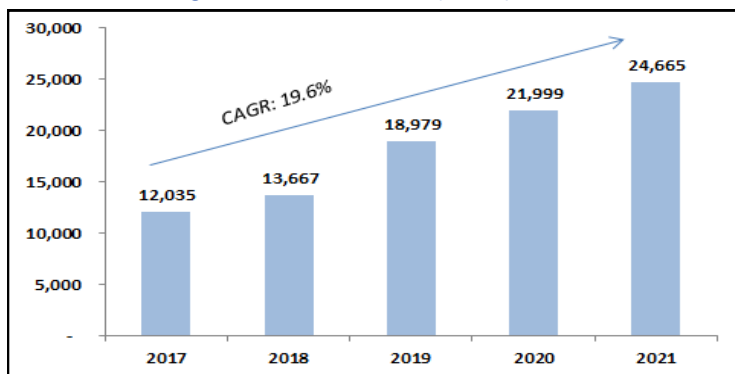
**(C) Transitional Shift:** With the onset of the pandemic followed by a series of phases faced across the globe in terms of lockdowns, re-opening of cities in a phased manner, devastating second wave and now the new variant spread; the industry has witnessed multiple up and downswings in terms of power shortages, concerns related to raw material availability, supply chain issues etc. In the past several months, on account of forced social isolation, home food and home remedies, very fewer people had complains of generic cold, cough and gastric related problems which essentially had led to subdued sales in the acute therapeutic portfolio across. While on the other hand, the chronic therapy had delivered growth even during the peak Covid months albeit at a reduced pace on account of slowdown in doctor and patient visits that had taken a backseat. However, as per media articles, the Indian Pharma company sales are anticipated to show a robust growth in FY22 attributed to normalized sales in categories that were affected by the pandemic in the previous year. Additionally, acute therapies and elective procedures are expected to recover in FY22 with a caution of keeping in mind the uncertainties hovering around the third wave which has set in across the nation. Although Alkem is the market leader in the acute base, the positive industry triggers depending on the seasonality and how the pandemic shapes up in the near future coupled with growth in Alkem's large mega brands, new launches would vouch for the growth in this area.

**(D) International Operations:** Revenues from the international operations are bifurcated into US business (contributing ~26-27% of the total revenues) and Other International business (contributing ~6-7% of the total revenues). The US business has been the second largest market for Alkem over the past financial years. Alkem's products are sold in 40+ countries, either directly through subsidiaries or indirectly, through supply, distribution and other arrangements with various global companies and local distributors in the US markets under its acquired brand **Ascend**. Alkem was a late entrant into the US markets in FY11 and adopted the inorganic route with acquisitions, that enabled it establish its presence in US and also diversify its manufacturing capabilities in dosage form like semi-solid, liquid and nasal formulations.

**Investment Rationale (contd.):**

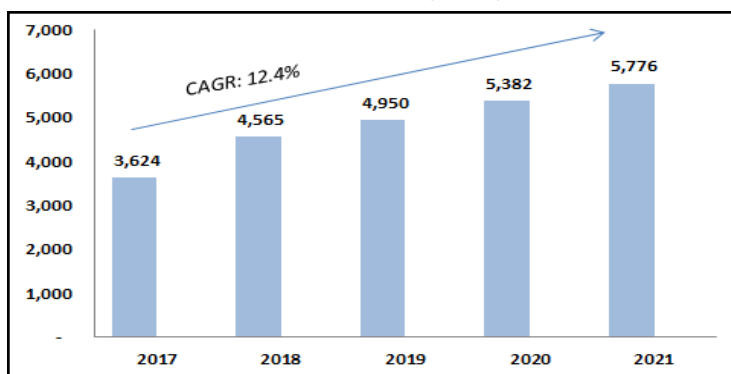
**(D) International Operations (contd.):** Revenues from the US business have shown a sharp surge from Rs12,035mn in FY17 to reach levels of Rs24,665mn in FY21; reporting a CAGR of 19.6% over the same period. This healthy growth over the years has been on account of the increase in product launches and market share gains in the existing product base. The company preferred to participate in selected biosimilar opportunities through its subsidiary Enzene Bioscience rather than going the complex generic route in injectables or inhalers. Alkem is working on a monoclonal antibody for the developed markets which can potentially be launched post FY25-26E. Apart from the US base, the company has an onshore presence in selected key international markets viz; Australia, Philippines, Chile, UK and Kazakhstan. It sells its products either directly through its own subsidiaries or indirectly through active engagement with other companies in Australia, Chile, the Philippines, Kazakhstan, Europe, Middle East, and East Africa. The Other international business revenues clocked a CAGR of 12.4% over FY17-21; attributed to new product launches (including in-licensed products) and improving market share in existing products. As of FY21, the company has over 1,100 dossier filings and 700 approvals across international markets, and continues to build its worldwide presence in the pharmaceutical industry.

**Exhibit 20: Strong Growth in US Business (Rs mn)**



Source: Annual Reports, Progressive Research

**Exhibit 21: Other International Business (Rs mn)**



Source: Annual Reports, Progressive Research

**Plant Inspections and ANDA Update:**

Alkem is committed to deliver high quality products and adhere to regulatory compliance. It continues to invest in its systems, processes and people to keep up with the evolving GMP norms. By end of FY21, all the 6 facilities had received an EIR with no pending observations indicating cGMP compliant status. As of Q2FY22, St. Louis facility in the US received 2 observations and the company has already responded in order to undertake corrective steps, while the status of the remaining 5 facilities stands with an EIR check in comparison to the respective last inspections being undertaken at these facilities. Additionally, the USFDA also had conducted a remote and virtual bio-analytical inspection at Alkem’s bioequivalence centre at Taloja (in July 2021) with a zero Form 483 issued at the closure of the inspection.

**Exhibit 22: Facilities Inspection Status**

Manufacturing Facility	Capability	Last Inspection	Status Post Last Inspection
St. Louis (US)	Formulations	June 2021	Received 2 observations. Already sent a detail response to the USFDA on the corrective and preventive actions being taken
Baddi (India)	Formulations	February 2020	EIR received in March 2020
Daman (India)	Formulations	August 2019	EIR received in October 2019
California (US)	APIs	August 2018	EIR received in October 2018
Ankleshwar (India)	APIs	December 2016	EIR received in March 2017
Mandva (India)	APIs	September 2015	September 2016

Source: Quarterly Reports, Progressive Research

**Recent Approvals:**

During Q2FY22, Alkem filed 6 ANDAs with the USFDA and received 7 approvals (including 2 tentative approvals). For H1FY22, the company filed 8 ANDAs and received 12 approvals (including 2 tentative approvals). As on 30<sup>th</sup> September, 2021, the company has filed a total of 157 ANDAs and 2 NDAs. Of these, it has received approvals for 116 ANDAs (including 14 tentative approvals) and 2 NDAs.

Jan 10, 2022

PICK OF THE MONTH

VOL-8, NO-02

Industry: Pharmaceuticals

Alkem Laboratories Limited

ACCUMULATE

CMP: Rs.3687

TARGET PRICE: Rs.4299

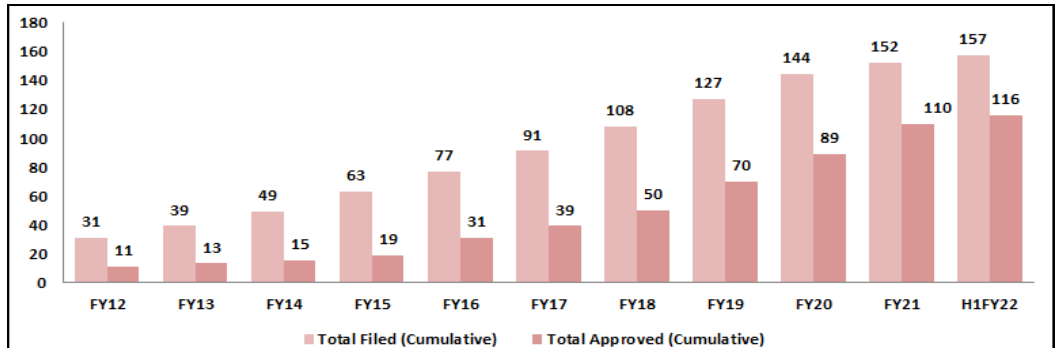
TIME : 12 months

**Investment Rationale (contd.):**

**Some of the key events:**

- **Alfuzenza:** for management of mild to moderate cases of Covid-19
- **Anti-epileptic drug:** Brivasure, 25mg for Rs79.50/strip, Brivasure 50mg for Rs148.50/strip, Brivasure 75mg for Rs230/strip, Brivasure 100mg for Rs295/strip
- **Perampil (Perampanel) tablets 2mg (Rs49 per strip), 4mg (Rs180 per strip) and 6mg (Rs300 per strip):** indicated as an adjunctive therapy in treatment of partial onset seizures in patients with epilepsy aged 4 years and older
- **Ibuprofen and Famotidine tablets (800mg/26.6mg):** After a long pending litigation (initiated by Horizon Medicines) that turned out to be in the favor of Alkem Labs; the latter launched the generic version of Duexis: Ibuprofen and Famotidine (800mg/26.6mg) in the US markets; considered as 'launch at risk' drug. This combination medication is used to relieve pain from rheumatoid arthritis and osteoarthritis while decreasing the risk of developing an ulcer from Ibuprofen use. As per IQVIA, these drugs have an estimated market size of USD765mn, July 2021 data; while for Alkem it represents a market share of ~20-25%; the company intends to garner as much share as they can. This would be a key molecule to watch out for in the US business
- **Pulmocare division:** launched to enhance awareness, diagnosis and management for lung diseases like asthma, COPD, allergy, advanced lung diseases and lung infections through a wide range of products for lung care

**Exhibit 23: ANDA Count**



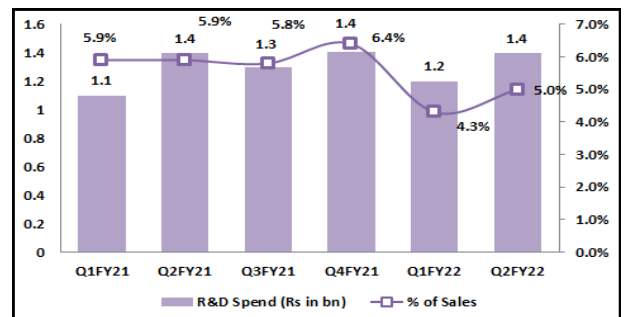
Source: Annual Reports, Progressive Research

**(E) Biosimilars Focus:** Enzene Biosciences Ltd is a wholly owned subsidiary of Alkem Labs and operates as an independent centre with Alkem. Enzene is a technology driven company based in Pune; having products in pre-clinical and clinical development stages. Enzene has invested in world class R&D infrastructure, has end to end development platform, comprehensive drug product development capabilities backed by state of the art advanced analytical technological support. Alkem has made investments in the biosimilars space through its subsidiary Enzene. Alkem has been spending ~Rs800mn as an annual operating expense for the working of biosimilars. Enzene had 3 approvals in its hands for the biotech space, 2 of them in peptides and 1 being in Monoclonal antibody (Mab). In Q2FY22, Alkem launched 2 products in the Indian market Denosumab (indicated for treatment of osteoporosis) and Romisplostim (indicated for treatment of low platelet counts); with plans to further expand the portfolio going ahead. So far the company has invested ~Rs6,500mn on biosimilars and has maintained flexibility in terms of business scale up for any further incrementals, if any, likely to happen in the near future. As far as product licensing to Theramex is concerned, Enzene has entered into an agreement to develop, register and commercialise a biosimilar drug of Roche's reference medicine RoActemra (Tocilizumab). Tocilizumab, in combination with Methotrexate (MTX), is indicated for the treatment of rheumatoid arthritis. It is planned to be commercialised from 2026 in Europe, UK, Switzerland and Australia. Alkem has been making good progress towards few products to cater to the regulated markets over the next 5 years which would enable it to unleash the potential in the biosimilars segment.

**Research and Development (R&D):** Alkem has remained committed in order to make substantial investments and thus strengthen the R&D base. It has an R&D team of 500+ scientists who develop new products with cutting edge technology at its 6 R&D centers spread across the US and India; all of them having an accreditation by international regulatory authorities. As bioequivalence and bioavailability studies are essential to prove the efficacy and effectiveness of dosage forms, the company has a clinical research facility comprising more than 100 beds. For FY21, the company invested Rs5,322mn (6% of the revenues) as against Rs4,726mn (5.7% of revenues in FY20).

**Connect2Clinic:** During the testing times of Covid-19, Alkem introduced its telemedicine/tele-consultation platform viz; **Connect2Clinic**. This served the medical professionals and healthcare staff to communicate with patients, irrespective of the physical location. It has user-friendly modules for e-prescription generation, secured e-payment facility for consultation; auto-reminder messages so that patients do not miss out on their e-consultation and a centralized dashboard to access all the important information during consultation. Currently, more than 20,000 doctors across 30+ specialties are on-board and are making their services available to patients located at different parts of India.

**Exhibit 24: Quarterly R&D Spend Trend**



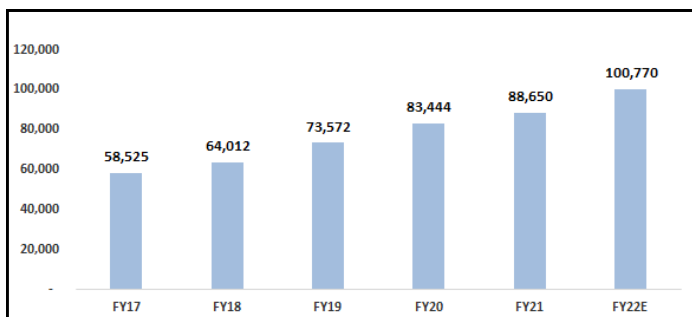
Source: Quarterly Reports, Progressive Research



**Financials:**

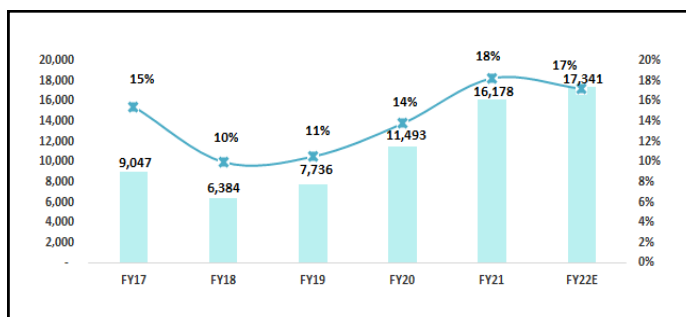
**Therapy Driven Growth:** Alkem has been purely a domestic driven company with focus laid on acute therapies and a higher MR strength catering to the acute base portfolio. Over the past financial years (FY17-21), the domestic business has grown at a CAGR of 7.95%, maintaining the contribution to the overall revenues at ~67-70%. For H1FY22, the business reported a growth of ~43% on a y-o-y basis attributed to factors of strong volume growth in the therapeutic areas of anti-infective, VMN, pain management and GI. As far as the chronic portfolio is concerned, areas of neuro, derma and anti-diabetes reported more than 30% growth in H1FY22 as per IQVIA; reporting 2x the industry therapy growth rate. On an overall basis, the revenues have grown at a decent CAGR of 11.92% from FY16-21. As per the Management, as far as the India business is concerned, they envision a growth of ~12-15% in the near term. In the international business, on account of pricing pressure concerns in the base portfolio which was however offset by product launches, decent launch pipeline, good performance in the RoW markets and expanding the biosimilars portfolio should garner decent growth in these markets barring any external headwinds.

**Exhibit 25: Revenue Trend (Rs mn)**



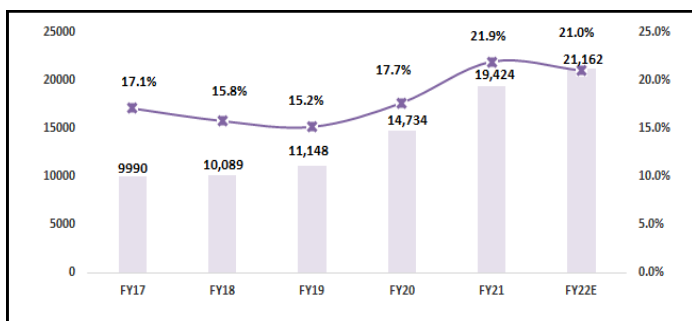
Source: Annual Reports, Progressive Research

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



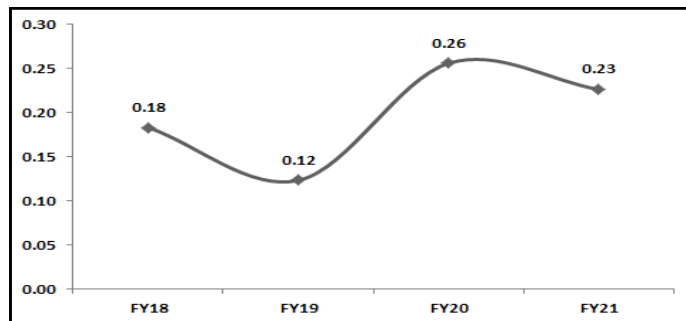
Source: Annual Reports, Progressive Research

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



Source: Annual Reports, Progressive Research

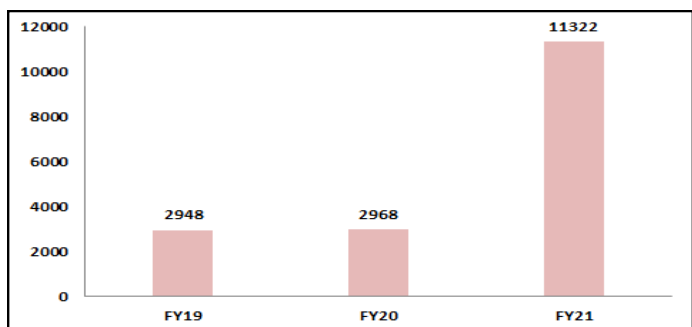
**Exhibit 28: D/E Trend**



Source: Annual Reports, Progressive Research

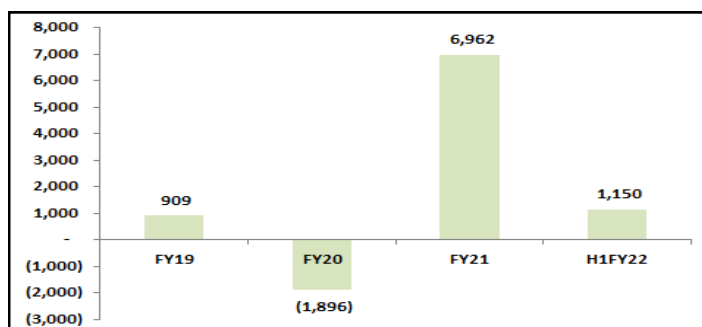
**FCFF Generations and Cash Reserves:** Alkem has already made significant capex investments through FY17-20 which it will look to leverage to drive future growth and profitability. For H1FY22, the company had made an investment to the tune of ~Rs2,000mn. The guidance for FY22E is around Rs4,500-5,000mn. Despite huge capex investments, the company has been able to generate good FCFF from FY19-21. On the other hand, Alkem stood at a net cash position of Rs6,962mn in FY21 and Rs1,150mn as on 30<sup>th</sup> Sept, 2021.

**Exhibit 29: FCFF Generation (Rs mn)**



Source: Annual Reports, Progressive Research

**Exhibit 30: Cash Generation (Rs mn)**

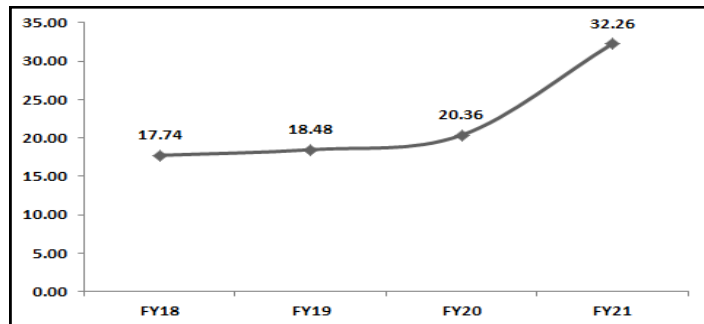


Source: Annual Reports, Progressive Research

**Financials (contd.):**

**Sikkim Tax Benefit:** Tracing back a decade, as per the North-East Industrial and Investment Promotion Policy (NEIIPP), 2007, Pharma majors captured huge benefits in terms of quick ROI, 10 year tax exemption from the date of commencement of commercial production, interest and capital subsidy amongst others. Based on this, even Alkem is eligible for government grants which are conditional upon construction of new factories in the Sikkim region. One of the grants, received in FY15 amounted to Rs72.4mn with respect to the Kumrek facility. The factory has been constructed and in operation since August 2007. The second grant is with respect to Samardung facility in Sikkim amounting to Rs122.1mn for which the company has received the claim amount in FY19. The factory has been constructed and in operation since October, 2012. These grants, recognized as deferred income, are being amortized over the useful life of the plant and machinery in proportion in which the related depreciation expense is recognised. The unamortised grant as on 31<sup>st</sup> March, 2021 amounts to Rs80.9mn (non-current stands at Rs69.3mn and current portion at Rs11.6mn) as against Rs92.6mn in FY20 (non-current: Rs80.9mn and current portion: Rs11.7mn). As per latest Q2FY22 concall, the management has indicated the benefit to continue till March 2026. The domestic base of ~65-70% of the revenues is catered from its Sikkim plant that has a fiscal benefit wherein the profits are exempted from taxation and based on the same, the management has changed the dynamics for effective tax for the entire year; revising the guidance for the year from the earlier 15% to the current being at ~10-11%.

**Exhibit 31: ICR Trend**



Source: Annual Reports, Progressive Research

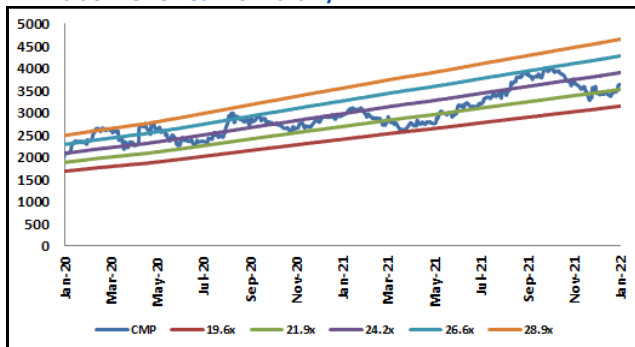
**Risks and Concerns:**

- Weak anti-infective season critical for overall growth in revenues
- Slowdown in ANDA approvals due to regulatory action
- Pricing regulations by the NPPA in India could impact the revenues and the margins
- Price erosion in the US generics business
- Delay in approvals and launches of new products

**Outlook and Recommendations:**

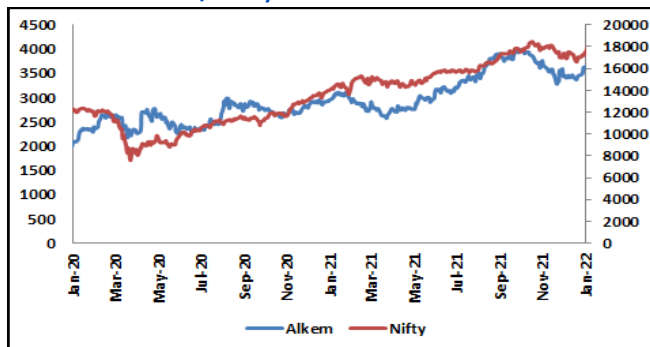
There are equal opportunities of growth for Alkem both in the acute and chronic segments. Alkem has been outperforming the IPM driven by consistent launches in the acute therapies like anti-infective, pain/analgesic and vitamins, while growing its presence in high growth chronic therapies like CNS, cardiac, derma and anti-diabetic. The company enjoys leading position in most of its key brands across the different therapeutic segments catered through the increasing MR productivity. The brand recall has been the key to the domestic sales growth. Collectively it places the company on an overall strong foothold in the domestic market. The other key contributor being the US market has also been in focus through the ANDA pipeline and product launches. Instead of the complex generics path, biosimilars lead the way which would boost the international revenues of the company. On the back of strong domestic growth, improving chronic presence and the US market giving the leverage, the company is expecting earnings to grow at a CAGR of 14.46% over the next 2-3 years. This would be supported by revenue CAGR of 12.42% over next 2-3 years with 51% expansion over FY17-21. Overall, we bet on Alkem’s margins expansion visibility, rich return ratios and improving business profile and would recommend to Accumulate the stock with any declines for a target of Rs4299.

**Exhibit 32: One Year Forward P/E**



Source: Ace Equity, Progressive Research

**Exhibit 33: Price v/s Nifty**



Source: Ace Equity, Progressive Research

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