Cadila Healthcare

Refer to important disclosures at the end of this report

Striving for a place in Innovators' club

CMP	Target Price
Rs 465 as of (January 22, 2021)	Rs 655 (▲) 12 months
Rating	**Upside**
BUY (▲)	40.8 %

- We upgrade Cadila to Buy from Hold and raise the TP to Rs655 from Rs430. Our bullish view is based on 1) consistent double-digit revenue growth in the core business, coupled with 200bps EBITDA margin expansion during FY20-23E; 2) upside from Saroglitazar in PBC and NASH; and 3) potential success of Covid-19 vaccine, ZyCoV-D.
- In our view, the current share price ascribes NIL success probability to innovation efforts due to the lack of precedents for in-house new chemical entity (NCE) and vaccine development, and also in view of Sun Pharma's initial challenges in specialty.
- In our SOTP, the core business contributes 80% (Rs520/share, valued by us at 20x forward P/E), PBC/NASH add 14% (Rs90, NPV) and ZyCov-D accounts for the remaining 7% (Rs45, NPV). Our bull case scenario yields a fair value of Rs835/share, assuming higher market share in PBC and NASH, favorable gRevlimid settlement and Covid-19 vaccine becoming an annual shot.
- Key downside risks are: 1) Higher-than-expected competition in Mesalamine franchise; 2) Adverse regulatory outcome on plants; 3) Failure to get FDA approval for Saroglitazar.

Innovative medicines and vaccine efforts underappreciated: Saroglitazar, the company's lead NCE, offers a significant opportunity (USD30bn market size) as competitors are small development-stage companies and PBC is a rare disease offering good pricing dynamics. The company has successfully completed the Phase-2 trial for PBC and Phase-2 proof of concept trial for NASH. However, current valuations ascribe nil success probability to these developments. Our NPV analysis suggests a base case upside of Rs50/share for PBC and Rs40/share for NASH. Similarly, ZyCoV-D offers a base case upside of Rs45/share, assuming it is a three-year opportunity (Exhibits 4-17).

Well positioned to sustain multi-year growth in the core business: The one-off bump in US revenues in FY18 driven by Mesalamine, Sentynl and Tamiflu has since moderated. Hereon, we expect US revenues to grow at a 10% CAGR through FY23E, backed by a strong product pipeline (110 ANDAs + 154 products under development plus nine 505(b)2 products), and launch of 25-30 products annually. We expect the India formulations business (25% of revenue) to grow at a 12% CAGR over FY20-23E, thus outperforming the market after several years of underperformance; this we believe would be driven by renewed focus on 'mandate brands', comprising new product launches and resource redeployment (Exhibits 18-36).

Improving FCF and profitability: We forecast consol. FCFE to grow to Rs33.6bn by FY23E from Rs16.1bn in FY20, driven by Rs7bn FCF increase in the core business. Further, with likely improvement in asset-turns (1.1 to 1.4 in FY23E) and expansion of 300bps in EBIT margin, we expect core ROIC to improve well above the cost of capital to ~19% in FY23E from 11% in FY20.

Compelling valuation: The stock is trading at a 1-year forward P/E of 16.4x on our consolidated forecast, and 21x on core earnings in line with the historical average. Our Rs655 TP includes core business value of Rs520 (20x forward P/E), Saroglitazar NPV of Rs90 and ZyCoV-D upside of Rs45.

Please see our sector model portfolio (Emkay Alpha Portfolio): Pharmaceuticals (page 35)

Financial Snapshot (Consolidated)

(Rs mn)	FY19	FY20	FY21E	FY22E	FY23E
Net Sales	131,656	142,531	153,723	203,946	223,303
EBITDA	29,731	27,420	33,606	47,028	51,145
EBITDA Margin (%)	22.6	19.2	21.9	23.1	22.9
APAT	18,488	14,406	20,645	30,625	34,797
EPS (Rs)	18.1	14.1	20.2	29.9	34.0
EPS (% chg)	3.0	(22.1)	43.3	48.3	13.6
ROE (%)	17.9	12.3	16.5	20.9	19.9
P/E (x)	26.1	33.5	23.4	15.8	13.9
EV/EBITDA (x)	18.3	19.7	15.6	10.8	9.3
P/BV (x)	4.7	4.7	4.0	3.3	2.7

Source: Company, Emkay Research

Change in Estimates	
EPS Chg FY21E/FY22E (%)	-/-
Target Price change (%)	52.3
Target Period (Months)	12
Previous Reco	HOLD

Emkay vs Consensus

EPS Estimates

	FY21E	FY22E
Emkay	20.2	29.9
Consensus	18.5	19.9
Mean Consensus TP (12M)	Rs 472	

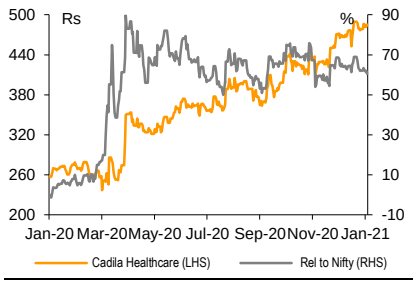
Stock Details	
Bloomberg Code	CDH IN
Face Value (Rs)	1
Shares outstanding (mn)	1,024
52 Week H/L	509 / 202
M Cap (Rs bn/USD bn)	483 / 6.62
Daily Avg Volume (nos.)	4,603,682
Daily Avg Turnover (US$ mn)	28.6

Shareholding Pattern Dec '20	
Promoters	74.9%
FIIs	5.2%
DIIs	11.7%
Public and Others	8.2%

Price Performance

(%)	1M	3M	6M	12M
Absolute	4	11	29	76
Rel. to Nifty	(5)	(9)	(1)	47

Relative price chart



Source: Bloomberg

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Table of contents

Upgrade to BUY with a revised TP of Rs655 3

Innovative medicines efforts are underappreciated 5

ZyCoV-D offers Rs45/share upside 9

US business poised to grow at double digit CAGR 12

India branded business to outperform IPM growth rate 15

Core EBITDA margins to improve meaningfully 17

Improving FCF and profitability 19

Valuation is compelling 20

Bull case TP of Rs835 21

Downside risks are largely priced in CMP 24

Appendix-1 25

Appendix-2 28

Upgrade to Buy with a revised TP of Rs655

We upgrade Cadila to Buy from Hold with a revised Mar'22 TP of Rs655 (Rs430 previously). Our bullish view is based on 1) consistent double-digit revenue growth in core business, coupled with 200bps EBITDA margin expansion; 2) upside from Saroglitazar in PBC and NASH; and 3) likely success of Covid-19 vaccine, ZyCoV-D. Our revised TP is based on a P/E multiple of 20x on our core FY23E earnings, with Saroglitazar NPV of Rs90/ share and ZyCoV-D NPV of Rs45/share.

Exhibit 1: We revise our TP to Rs655/share

	FY23E EPS	P/E multiple	Equity value
Cadila core business	26	20	520
Saroglitazar NPV			90
Vaccine NPV			45
Target price			**655**

Source: Company reports; Emkay research

Our headline numbers bake in a positive impact from ZyCoV-D and negative impact from Saroglitazar development for PBC and NASH in the US. However, we exclude these to arrive at core business metrics for Cadila. Our core revenue, EBITDA and PAT are expected to grow at a CAGR of 10%, 13% and 21%, respectively.

Exhibit 2: Cadila's core earnings is expected to grow at a CAGR of 21% through FY23

Particulars	FY20	FY21e	FY22e	FY23e
Segment revenues (Rs mn)				
Core	142,531	153,723	171,546	187,303
Sp	-	-	-	-
Vaccine	-	-	32,400	36,000
Total	**142,531**	**153,723**	**203,946**	**223,303**
Total growth (y-y)	-	*7.9%*	*32.7%*	*9.5%*
Segment EBITDA (Rs mn)				
Core	28,120	33,606	36,453	40,645
Sp	-	-	-5,625	-7,500
Vaccine	-	-	16,200	18,000
Total	**28,120**	**33,606**	**47,028**	**51,145**
Total growth (y-y)	-	*19.5%*	*39.9%*	*8.8%*
Segment EBITDA margin				
Core	19.7%	21.9%	21.3%	21.7%
Sp				
Vaccine			50.0%	50.0%
Total	**19.7%**	**21.9%**	**23.1%**	**22.9%**
Change (y-y)	-	*213bps*	*120bps*	*-16bps*
Segment EPS (Rs)				
Core	14.6	20.2	22.0	26.0
Sp	-	-	-4.3	-5.7
Vaccine	-	-	12.2	13.7
Total	**14.6**	**20.2**	**29.9**	**34.0**
Total growth (y-y)	-	*38.0%*	*48.3%*	*13.6%*

Source: Company reports; Emkay research

Exhibit 3: Risk-reward is highly favorable

	Bear case	Base case	Bull case	Comments
Core business	**425**	**520**	**520**	**Base case: Mesalamine EPS of ~Rs5 in FY23e down from ~Rs7 in FY20**
EPS	21	26	26	Bull case: Mesalamine EPS of ~Rs5 in FY23e down from ~Rs7 in FY20
P/E multiple	20	20	20	Bear case: Minimal Mesalamine EPS contribution in FY23e
PBC NPV	**0**	**50**	**54**	**Base case: Success probability of 65% and peak market share of 10%**
Success probability	0%	65%	65%	Bull case: Success probability of 65% and peak market share of 15%
Market share	NA	10%	15%	Bear case: Saroglitazar fails to gain US FDA approval
NASH NPV	**0**	**40**	**56**	**Base case: Modest market share of 5% due to high competitive intensity**
Success probability	0	25%	25%	Bull case: Modestly higher market share of 7%
Market share	NA	5%	7%	Bear case: Saroglitazar fails to gain US FDA approval
ZyCoV-D	**10**	**45**	**165**	**Base case: Vaccine to be 3 year opportunity @Rs1,200 per person**
Opportunity window	3 years	3 years	Annuity	Bull case: Annual vaccination hence terminal value @Rs1,200 per person
Price per person	750	1,200	1,200	Bear case: 3 year opportunity @750 per person
Revlimid	**0**	**0**	**40**	**Bull case: Para IV court case settlement with innovator with allocated share of 5% in 1st year increasing to 9% in final year**
Settlement	No	No	Yes	
Terms	NA	NA	In line with Alvogen	
Total	**435**	**655**	**835**	
Upside/ (downside) from CMP	**-5%**	**44%**	**83%**	

Source: Emkay Research

Innovative medicines efforts underappreciated

We believe that Cadila's specialty efforts are underappreciated by the investor community due to lack of precedent for an in-house NCE or vaccine development, and in view of Sun Pharma's initial challenges in specialty efforts. Saroglitazar, the company's lead NCE, offers a significant opportunity as competitors are small development-stage companies and PBC is a rare disease offering good pricing dynamics. Our NPV analysis yields an upside of Rs50/share for PBC and Rs40/share for NASH in the base case.

Saroglitazar, the company's lead molecule, has successfully completed the Phase 2 trial for PBC and received a fast-track designation from the US FDA. The company has also successfully completed a Phase 2 proof of concept trial for NASH. Hereon, Cadila has three options to develop these indications further: 1) Own development, 2) Strategic partner or 3) Financial partner.

Exhibit 4: Saroglitazar upside of Rs90/share is not reflecting in the share price

	Upside (Rs/share)
PBC	50
NASH	40
Total upside	**90**

Source: Company reports; AASLD; Younossi et al., Emkay Research

Saroglitazar is a novel Peroxisome Proliferator-activated receptor (PPAR) α/γ agonist. The PPARs play a critical physiological role as lipid sensors and regulators of lipid metabolism. It is approved for treatment of Hypertriglyceridemia and diabetic dyslipidemia in India, Mexico, Myanmar and Kenya. It is also approved for Type 2 diabetes mellitus and NASH in India. Saroglitazar's candidature for NASH as well as PBC is well supported by multiple clinical trials in emerging markets.

Exhibit 5: Saroglitazar has received multiple approvals in Emerging markets

Year	Geography	Approved/ ongoing Indications
2013	India	Hypertriglyceridemia, Diabetic Dyslipidemia
2017-2018	Mexico and Kenya	Hypertriglyceridemia, Diabetic Dyslipidemia
2019-20	India	T2DM, Pre-cirrhotic NASH
2019-20	Myanmar	Hypertriglyceridemia, Diabetic Dyslipidemia
2023	US	Expected NDA filing for PBC in US; Phase 2 completed
2025	US	Expected NDA filing for Pre-cirrhotic NASH; Phase 2 PoC completed

Source: Company presentation; Emkay research

PBC represents NPV of Rs50/share in base case

Based on the incidence, prevalence and mortality, we estimate there are ~132,000 PBC patients in the US, growing at a ~5% CAGR. Based on the current treatment protocol and prices of available treatments, we estimate PBC market is ~USD5bn, growing at a 5% CAGR.

Exhibit 6: We estimate PBC market size of USD5bn

PBC market size	
PBC patient pool	132,000
Price of treatment (US$)	79,000
Ursodiol treatment cost per annum (US$)	3,000
Patients controlled on Ursodiol	66,000
Estimated market size (USD bn)	**5.4**

Source: AASLD; Bloomberg; Emkay Research

For Cadila, the addressable patient pool is 50% of total PBC patients as the remaining 50% is controlled on an affordable drug, Ursodeoxycolic acid. Based on the competitive landscape, we believe that Cadila could garner a peak market share of ~10%. Assuming annual treatment cost of ~USD79,000 per patient (in line with the current second line treatment, Ocaliva), steady state gross to net adjustment of 65%, upfront R&D expense of USD160mn, sales force of 50-60 representatives, commercialization probability of 65% and WACC of 12%, we estimate NPV of Rs50/share for PBC indication.

Exhibit 7: We estimate NPV of Rs50/share for PBC indication

Saroglitazar NPV for PBC indication	FY23E	FY24E	FY25E	FY26E	FY27E	FY28E	FY29E	FY35E	FY36E
PBC patient pool	148,236	156,354	164,472	172,590	180,708	188,826	196,944	245,652	253,770
Patients controlled on Ursodiol	50%	50%	50%	50%	50%	50%	50%	50%	50%
Addressable patient pool	74,118	78,177	82,236	86,295	90,354	94,413	98,472	122,826	126,885
Cadila Market share	0%	1%	3%	5%	7%	8%	9%	10%	10%
Treatment price ($)		79,000	79,790	82,184	84,649	87,189	89,804	107,231	110,448
Net realization (%)		35%	40%	50%	60%	65%	65%	65%	65%
Potential gross revenue ($ mn)	-	22	79	177	321	428	517	898	956
Gross profit @ 99% ($ mn)	-	21	78	176	318	424	512	889	946
Other expenses ($ mn)	-	63	83	135	181	170	175	218	221
R&D expenses ($ mn)	160	-	-	-	-	-	-	-	-
EBITDA ($ mn)	-160	-42	-5	40	137	254	337	671	725
EBITDA *(1-t) ($ mn)	-126	-33	-4	32	109	201	266	530	573
Change in WC ($ mn)	0	6	17	30	43	32	27	16	17
FCF ($ mn)	**-126**	**-40**	**-21**	**2**	**65**	**169**	**239**	**514**	**556**
Discount rate	12%								
Discount factor	1.00	0.89	0.80	0.71	0.64	0.57	0.51	0.26	0.23
PV of FCF ($ mn)	-126	-35	-17	2	42	96	121	132	127
NPV ($ mn)	1,051								
NPV per share (Rs)	77								
Success probability	65%								
Risk adjusted NPV per share	**50**								

Source: AASLD; Bloomberg; Company reports; Emkay Research

Exhibit 8: There are 8 molecules in pipeline for PBC including Saroglitazar

Company	Drug name	Class of Drug	Comment	Phase of development
Genfit	Elafibranor	a dual agonist of PPARα and PPARδ	Targeting PPAR receptors may result in a reduction of bile acid synthesis, improved detoxification of bile in the bile duct and anti-inflammatory activity. The use of drugs targeting PPAR receptors has been shown to reduce blood levels of Alkaline Phospahatase (ALP), and improve biochemical measures of cholestasis and pruritus (itching) in patients with PBC.	Phase 3 enrolment
CymaBay Therapeutics	Seladelpar	orally active peroxisome proliferator-activated receptor δ (PPARδ) agonist	Regulates genes involved in bile acids synthesis, inflammation, fibrosis and lipid metabolism, storage and transport.	Phase 3
Cadila	**Saroglitazar**	**A novel dual PPAR α/γ agonist**	**The drug aims to control Alkaline Phosphotase (ALP) or bilirubin, reduces strong side effects of existing drugs such as pruritus or increase in LDL-cholesterol and brings in better tolerance and efficacy.**	**Phase 2 complete**
Genkyotex	Setanaxib	a NOX1 and NOX4 inhibitor	-	Phase 2 complete
Novartis	Tropifexor	Farnesoid X receptor (FXR)	Activation of FXR inhibits bile acid synthesis and increases bile acid conjugation, transport, and excretion, thereby protecting the liver from the harmful effects of bile accumulation.	Phase 2 ongoing
HighTide Biopharma	HTD1801 (BUDCA)	-	-	Phase 2 ongoing
Pfizer/Mirum Pharmaceuticals	LUM001	Sodium-bile acid cotransporter inhibitors	LUM001 is a potent, apical, sodium- dependent, bile acid transporter competitive inhibitor with minimal systemic absorption.	Phase 2
Biogen Idec/Genentech	Rituximab	Antibody-dependent cell cytotoxicity; T lymphocyte stimulants	-	Phase 1

Source: Company reports; AASLD; Emkay Research

NASH NPV of Rs40/share in base case

The company has completed the Phase 2 Proof-of-Concept trial for Saroglitazar in the NASH Indication in the US and has applied for the Phase 2b trial to the US FDA. NASH is a large market due to high prevalence and research suggests 25%+ of US population has NASH precursor condition, Non-alcoholic fatty liver disease (NAFLD). Of the 95mn having NAFLD, 20% have NASH, putting the addressable patient pool at ~20mn. Within this, approximately 40% of patients have progressed to the advanced fibrosis stage and are the prime target for treatment, suggesting patient pool of ~8-9mn. Assuming 30-40% of patients with advanced fibrosis will be treated and treatment cost of ~USD9,000 per patient, in line with average diabetes/ blood pressure management cost in US, we estimate NASH Market of ~USD25bn in the US, growing at a high single digit.

Exhibit 9: We estimate US NASH market size of USD25bn

NASH addressable market size	
NASH patient pool (mn)	20.2
Fibrosis patient who require treatment (mn)	8.4
Actual patients treated (mn)	2.7
Annual treatment cost (US$)	9,000
Total addressable market size ($bn)	**25**

Source: Younossi et al., CDC, Emkay Research

Based on the above, the peak market share of 5-7% for Cadila, upfront R&D cost of USD350mn, gross to net adjustment of 65%, sales force of ~150 representatives, WACC of 12% and success probability of 25%, we estimate NPV of Rs30/share for Saroglitazar in NASH Indication.

Exhibit 10: We estimate NPV of Rs40/share for NASH indication

Saroglitazar NPV for NASH Indication									
Particulars	**FY23E**	**FY24E**	**FY25E**	**FY26E**	**FY27E**	**FY28E**	**FY29E**	**FY37E**	**FY38E**
US Population (mn)	338	339	341	343	344	346	348	362	364
	28%	28%	28%	28%	28%	28%	29%	29%	29%
NALFD prevalence (mn)	94	95	96	97	97	98	99	106	107
	25%	25%	25%	25%	25%	25%	25%	26%	27%
NASH prevalence (mn)	21	21	21	22	22	23	23	27	27
	22%	22%	22%	23%	23%	23%	23%	25%	25%
Fibrosis prevalence (mn)	8	9	9	9	9	9	10	11	12
	41%	41%	41%	41%	41%	41%	41%	42%	42%
% treated		33%	34%	35%	36%	37%	38%	46%	47%
Treatable population (mn)	-	2.85	3.00	3.15	3.31	3.48	3.65	5.23	5.46
Market share	-	0.0%	0.0%	0.5%	1.0%	2.0%	3.0%	5.0%	5.0%
Patients treated with Saroglitazar	-	0	0	15,759	33,121	69,556	109,466	261,476	272,796
Treatment cost p.a. ($/patient)	-			9,000	9,270	9,502	9,739	11,866	12,163
Realization				35%	40%	50%	60%	70%	70%
Net price realised ($)	-			3,150	3,708	4,751	5,844	8,306	8,514
Potential gross revenue ($ mn)	-	-	-	50	123	330	640	2,172	2,323
Gross profit ($ mn)	-	-	-	47	117	314	608	2,063	2,206
Other expenses ($ mn)	-	-	-	110	158	258	316	451	478
R&D expenses ($ mn)	100	100	100	-	-	-	-	-	-
EBITDA ($ mn)	-100	-100	-100	-62	-42	56	292	1,612	1,728
EBITDA (1-t) ($ mn)	-79	-79	-79	-49	-33	44	231	1,274	1,365
Change in WC ($ mn)	-	0	0	15	22	62	93	43	45
FCF ($ mn)	**-79**	**-79**	**-79**	**-64**	**-55**	**-18**	**138**	**1,231**	**1,320**
Discount rate	12%								
Discount factor	1.00	0.89	0.80	0.71	0.64	0.57	0.51	0.23	0.23
PV of FCF ($ mn)	-79	-71	-63	-46	-35	-10	70	285	306
NPV ($ mn)	2,159								
No of shares (mn)	1,024								
NPV per share ($)	2.1								
NPV per share (Rs)	158								
Phase 2 Proof of Concept to Launch probability	25%								
Risk adjusted NPV	**40**								

Source: Younossi et al., CDC, Emkay Research

Our assumption of a 5% market share is well supported by the current competitive landscape. Additionally, our pricing assumption of USD9,000 per patient annually is also well supported by the fact that there is a high overlap between diabetes market and NASH. Hence, we see the existing diabetes market serve as a staging ground for pricing NASH related drugs. Our assumption of sales force of 150 people is based on Intercept pharma's plan for the launch of their drug for NASH indication. For the success probability, we depend on a research which suggests only 25% of molecules for the metabolic disease in the early Phase 2 trial were successfully commercialised between 2006 and 2015.

Exhibit 11: NASH is expected to be competitive market given many molecules under development

Product	Company	Mechanism of Action	Phase
Aramchol	Galmed	SCD-1 modulator	Phase 3
Cenicriviroc	Allergan	CCR2/5 antagonist	Phase 3
GR-MD-02	Galectin	Galectin-3 inhibitor	Phase 3
Resmetirom	Madrigal	THR-β agonist	Phase 3
Firsocostat (GS-0976)	Gilead	ACC inhibitor	Phase 2b
NGM-282	NGM	FGF19 analog	Phase 2b
Pegbelfermin (BMS-986036)	BMY	FGF21 analog	Phase 2b
MK-3655 (NGM-313)	NGM	FGFR1c/βKlotho agonist	Phase 2b
Cilofexor (GS-9674)	Gilead	FXR agonist	Phase 2b
Tropifexor	Novartis	FXR agonist	Phase 2b
Lanifibranor	Inventiva	Pan-PPAR (α/δ/γ) agonist	Phase 2b
Seladelpar	Cymabay	PPAR-δ agonist	Phase 2b
VK2809	Viking	THR-β agonist	Phase 2b
Saroglitazar Mg	**Cadila**	**PPAR α/γ agonist**	**Phase 2b**
NGM-282	NGM	FGF19 analog	Phase 2a
AKR-001	Akero	FGF21 analog	Phase 2a
EDP-305	Enanta	FXR agonist	Phase 2a
Coladutide (MEDI-0382)	AZN	GLP-1 agonist	Phase 2
Semaglutide	Novo Nordisk	GLP-1 agonist	Phase 2

Source: Back bay advisors; Emkay Research

Exhibit 12: We assume a 25% probability of success due to a history of unsuccessful NALFD/NASH programs

Company name	Drug name	Class of drug	Phase
Intercept Pharmaceuticals	Obeticholic Acid	Farnesoid X Receptor	Registration
Immuron	IMM 124-E	Anti-Inflammatory Anti-Fibrotic Other Metabolic	Phase 2
Arisaph Pharmaceuticals	ARI-3037MO		
Novartis Pharmaceuticals	LCQ908		
Cempra	Solithera		
Boehringer Ingelheim	BI 1467335		
Conatus Pharmaceuticals	Emricasan		
Gilead Sciences	Simtuzumab		
AstraZeneca	AZD4017		
Mirum Pharmaceuticals	SHP626		
Gilead Sciences	Selonsertib		Phase 3
Gilead Sciences	Firsocostat	Thyroid Hormone Receptor Modulator	Phase 2
Genfit	Elafibranor	Ppar Modulator	Phase 3
Polysan Scientific & Technological Pharmaceutical	Runihol		Phase 2
CymaBay Therapeutics	Seladelpar		
AstraZeneca	Epanova, Fenofibrate	Combination Treatments/ Multiple Moa	Phase 2
AstraZeneca	Roflumilast And Pioglitazone		
Gilead Sciences	Selonsertib, Firsocostat, Cilofexor		
Gilead Sciences	GS-9674	Bile Acid Receptor Modulator	Phase 2
Phenex Pharmaceuticals AG	PX-104		
Novartis Pharmaceuticals	LMB763		

Source: Back bay advisors; Emkay Research

ZyCoV-D offers Rs45/share upside

Cadila's Covid-19 vaccine ZyCoV-D has several advantages over currently available vaccines in India in terms of storage, transportation and administration. Additionally, it is the second vaccine (after Bharat Biotech) with full-fledged clinical trials (1,048 volunteers in Phase 2 and 28,000+ in Phase 3) in India. Given its advantages and the supply shortage, we believe that its 150mn annual doses will likely be fully absorbed for the next three years at least. Our detailed model points to an upside of Rs45/share in the base case. Our analysis assumes the vaccine price of Rs1,200 per person (Rs400 per dose), net-realization of 60%, EBITDA margin of 50%, and discount rate of 12%. We expect the vaccine to be launched in Q1FY22.

Exhibit 13: We estimate Zycov-D NPV of Rs45/share with zero terminal value

Covid vaccine NPV				
	FY21E	**FY22E**	**FY23E**	**FY24E**
Cadila vaccine capacity (doses) (mn)	100	100	100	100
Contract manufacturing (doses) (mn)		50	50	50
Total capacity (doses) (mn)	100	150	150	150
Doses per person	3	3	3	3
Persons immunized	33	50	50	50
Vaccine price per person (Rs)	**1,200**	**1,200**	**1,200**	**1,200**
Realization		60%	60%	60%
Number of years		0.9	1.0	1.0
Vaccine revenue (mn)		32,400	36,000	36,000
EBITDA margin		50%	50%	50%
EBITDA (Rs mn)		16,200	18,000	18,000
EBITDA * (1-t) (Rs mn)		12,122	13,469	13,469
Working capital (Rs mn)		2,663	2,959	0
Change in working capital		2,663	296	-2,959
FCF (Rs mn)		**13,537**	**17,704**	**20,959**
Discount rate		12%		
Discount factor		1.00	0.89	0.80
PV of FCF (Rs mn)		13,537	15,807	16,708
Total NPV (Rs mn)		46,053		
NPV per share (Rs)		**45**		

Source: Company reports; Emkay Research

Exhibit 14: We believe entire Indian population will be vaccinated in 3 years

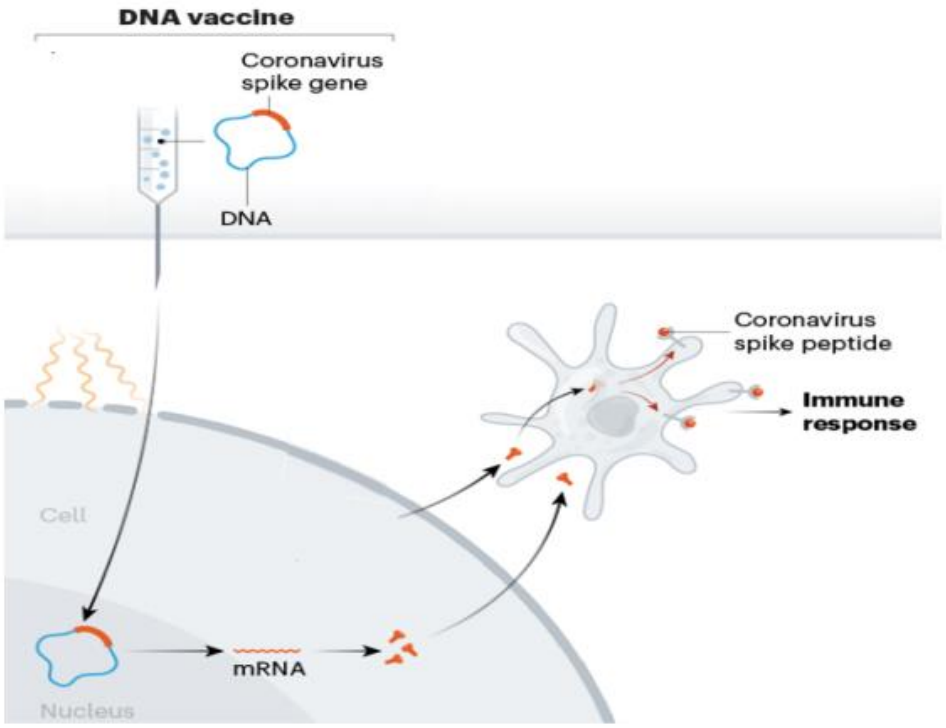
Vaccine supply and demand dynamics in India (no. of people – mn)						
Vaccine	**Company**	**FY22**	**FY23**	**FY24**	**Total**	**Comments**
Covaxin	Bharat Biotech	140	140	140	420	The company has capacity of ~600-700mn doses per annum, of which we believe half will be used for domestic consumption.
Covishield	Serum Institute of India	240	240	240	720	The company has annual capacity of 1.2bn doses, of which we believe half will be used for domestic market.
ZyCov-D	Zydus Cadila	40	40	40	120	The company has capacity of 150mn doses which will be fully utilized for Indian market.
Sputnik - V	Dr Reddy's labs	40	40	40	120	DRL will import initial 100mn doses from Russia followed by manufacturing by Hetero.
Total		**460**	**460**	**460**	**1,380**	

Source: Company reports; Emkay research

What is ZyCoVD?

ZyCoVD is a DNA-based Covid-19 vaccine developed by Cadila's in-house R&D team. In this type of vaccines, genetic material encoding the antigen or antigens against which the immune response is required is introduced into the body. The body's own cells then use this genetic material to produce the antigens against which immune systems generate a response. This immune response is primarily of two types: 1) Humoral (sensitization of B cells and production of neutralizing antibodies) and 2) Cellular (sensitization of natural killer and memory T cell for cell-mediated immunity and future protection). A good vaccine typically generates both Humoral as well as Cellular response.

Exhibit 15: DNA vaccine mechanism of action



Source: Company presentation

Pros and Cons of ZyCoV-D

ZyCoV-D has significant edge over other vaccines in terms of logistic requirement as the vaccine remains stable at room temperature for ~3 months. Additionally, ZyCoV-D offers administration ease as it is an intradermal vaccine vs. intramuscular route for other vaccines. The vaccine could also be quickly modified for any virus mutation. On the other hand, three dose schedule is a slight disappointment given all other approved/underdevelopment vaccines are one/two dose vaccines.

Exhibit 16: ZyCoV-D has significant advantages

Indicator	ZyCoV-D	Covishield	Covaxin	Sputnik
Type of vaccine	Plasmid DNA vaccine; introduces the DNA sequence encoding the antigen	Recombinant Covid-19 vaccine based on viral vector technology	Whole-virion inactivated corona virus	Two-part adenovirus-based vector vaccine
Route	**Intradermal injection; used with the needle free injection: Pharmajet**	**Intramuscular Injectable**	**Intramuscular Injectable**	**Intramuscular Injectable**
Dose	0.2 ml each dose	0.5 ml each dose	0.5 ml each dose	0.5 ml each dose
Course of vaccine	3 doses	2 doses	2 doses	2 doses
Schedule	4 and 8 weeks apart	4 weeks apart	4 weeks apart	21 days apart
Storage and transportation	**Thermostable at 25^0 C for 3 months**	**+2^0C to +8^0C at all levels**	**+2^0C to +8^0C at all levels**	**Stored at -18^0C or below; a freeze-dried version can be stored at 2-8^0C**

Source: Company reports; Emkay Research

Safety and Immunogenicity

According to the Phase 2 study conducted by the company in 1,048 healthy volunteers, it is found to be extremely safe with no grade 3/4 adverse events and no serious adverse events with follow up for ≥3 months. While the company has not released immunogenicity data, it has said that the vaccine has demonstrated high levels of neutralizing antibodies and cellular immune response, which is comparable to international standards.

Our analysis of Inovio's (DNA vaccine developer in the US) Phase 1 immunogenicity data suggests that it generated humoral and/or cellular response in 100% of the volunteers who were vaccinated in the US.

Exhibit 17: Inovio's vaccine data suggests good immunogenicity for its DNA vaccine

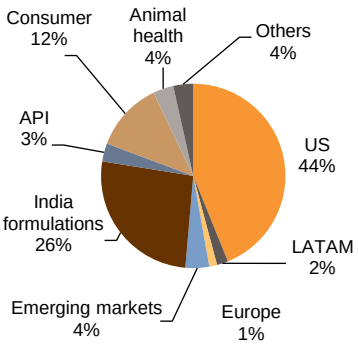
Inovio vaccine data		
Vaccine arm	1mg dose	2mg dose
Vaccine type	DNA vaccine	
Number of doses	2	
Number of subjects	19	19
Dose administration	Day 0, Day 28	
Evaluation time frame	Seroconversion 6 weeks post first dose, cellular immune response 8 week post first dose	
Spike protein binding antibody response rate (RR)	**89%**	**95%**
Spike protein binding antibody titre - Median	665	994.2
Neutralization antibody RR	**78%**	**84%**
Neutralization antibody titre	102.3	63.5
IFN Gamma ELIspot RR - Cell mediated immunity	**74%**	**100%**
IFN Gamma ELIspot level	45.6	71.1

Source: New England Journal of Medicine, Emkay research

US business poised to grow at double-digit CAGR

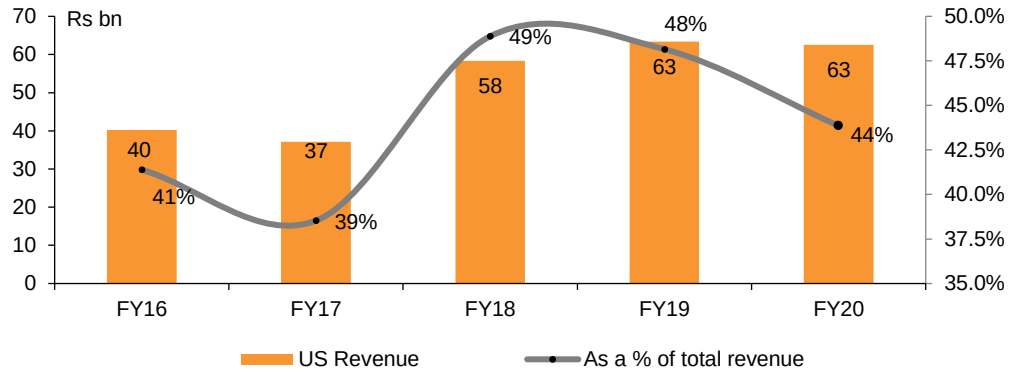
The one-off bump in US revenue in FY18 was driven by Mesalamine, Sentynl and Tamiflu and has since moderated. Hereon, US revenue will grow at a 10% CAGR through FY23, backed by a strong product pipeline (110 ANDAs + 154 products under development + 9 505 (b)2 products) and launch of 25-30 products annually.

Revenue break-up FY20



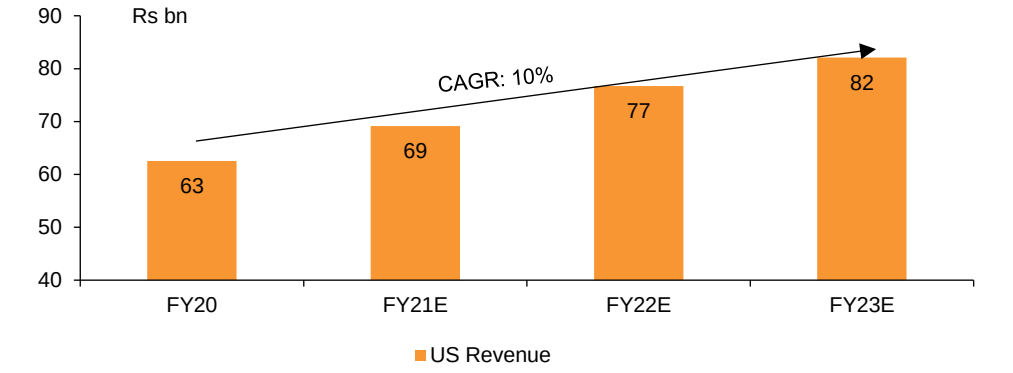
Source: Company

Exhibit 18: US contributed ~44% of total revenue in FY20



Source: Company reports

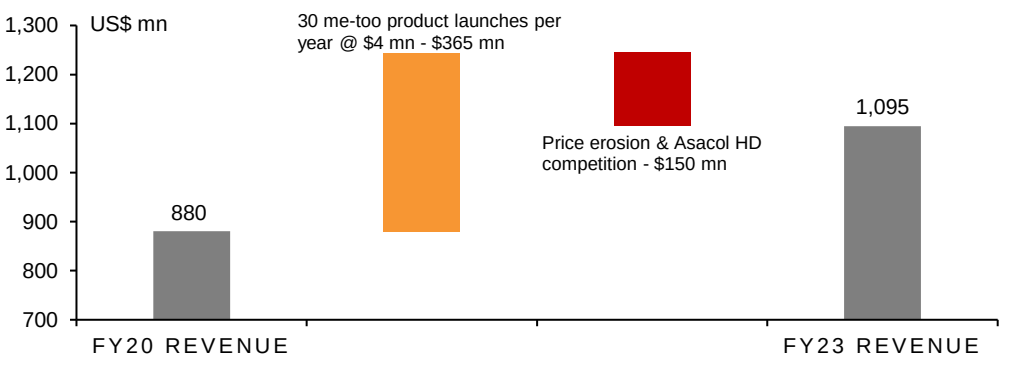
Exhibit 19: US revenue is expected to grow at 10% CAGR through FY23



Source: Company reports; Emkay Research

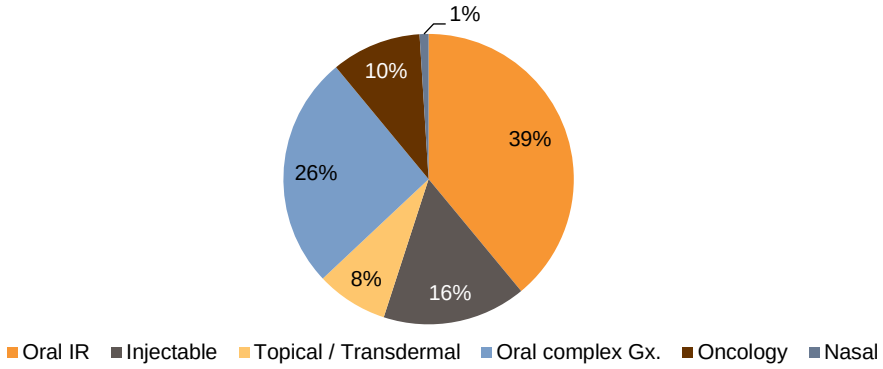
We believe that the company can continue to launch 25-30 products annually, based on its current pipeline of 110 ANDAs and 154 products under development. The company has recently suggested that it will be filing 40 ANDAs annually for the next three years, providing an ample buffer to our estimate of 25-30 product launches. Assuming USD4mn per product launch, generic launches could add USD100-120mn annually. In addition to this, we believe that gTamiflu revenue of ~USD30mn will come back in FY22. This will be partially offset by single-digit price erosion on the base business and competition in Asacol starting Nov'21. Overall, we expect US business revenue to grow at a low double-digit CAGR through FY23.

Exhibit 20: US revenue growth drivers



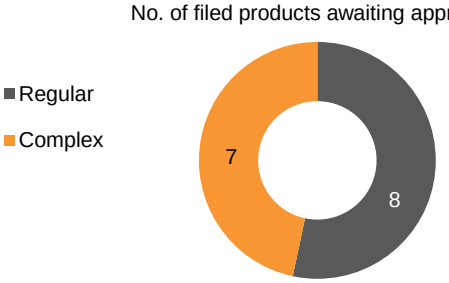
Source: Company reports; Emkay research

Exhibit 21: Diversified product pipeline with 110 ANDAs & 154 products under development



Source: Company reports; Emkay Research

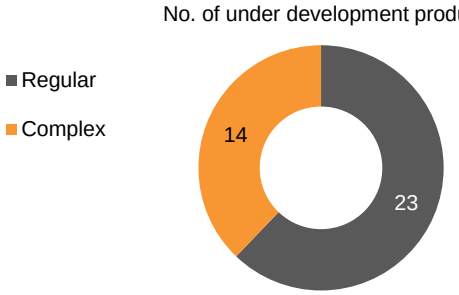
Exhibit 22: 50% of the filed injectables are complex injectables



Opportunity size - $6bn

Source: Company reports

Exhibit 23: ~50% of injectables under development are also complex



Opporunity size - $19bn

Source: Company reports

Exhibit 24: 505(b)2 pipeline focusing on orphan disease and specialty will complement generic pipeline

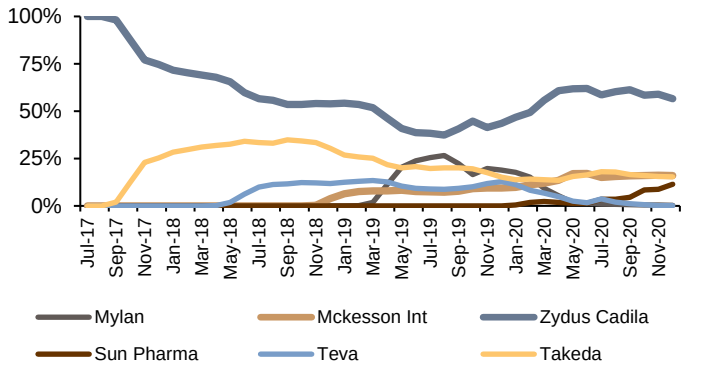
	Product	Indication	Stage
Late stage Clinical study to NDA filing to Approval	Product 1 - Metabolic Disorder	Other	NDA filed in Oct'20, earliest launch in 2022
	Product 2 - Pain	Pain	NDA-Ready to File
	Product 3 - Spasticity	CNS	PK ongoing
Early- Stage Concept / Research: Pre-clinical / pIND	Product 4 - Sickle cell anemia	Blood disorder/ orphan indication	Pre- IND Jan'21
	Product 5 - Oncology	Oncology	pIND submitted
	Product 6 - Migraine	CNS	PoC completed
	Product 7 - Oncology	Oncology	PoC Ongoing
	Product 8 - HRS	Liver disease	PoC Ongoing
	Product 9 - PAH	Other	Prototype

Source: Emkay Research, Company

Mesalamine franchise risk adequately built into our estimates and valuation

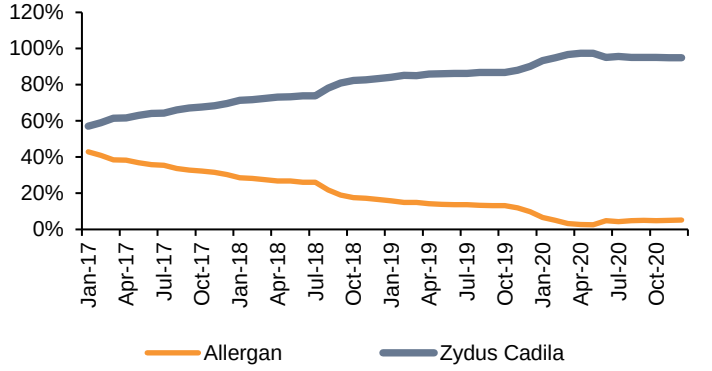
We believe that concerns on Mesalamine franchise is overblown, as competition in products such as Lialda and Asacol HD is expected to remain limited. Our expectation is based on 1) manufacturing complexity and variable yield, and 2) requirement of a dedicated production line. That said, we build in a ~USD50mn decline in Asacol revenue as Sun Pharma will launch its generic post Nov'21, while Allergan regains its lost ground. **We forecast Mesalamine earnings contribution to go down from an estimated Rs7-8 per share in FY20 to ~Rs5 per share in FY23.**

Exhibit 25: Generic players have failed to gain market share



Source: Bloomberg, Emkay Research

Exhibit 26: Innovator has also faced supply issues



Source: Bloomberg, Emkay Research

Contrary to the popular view that Cadila's Mesalamine revenue and earnings could go down drastically, we believe that genericization of additional Mesalamine brands such as gApriso, gDelzicol and gSFRowasa could offer an upside.

Exhibit 27: Genericization of additional Mesalamine brands could offer an upside

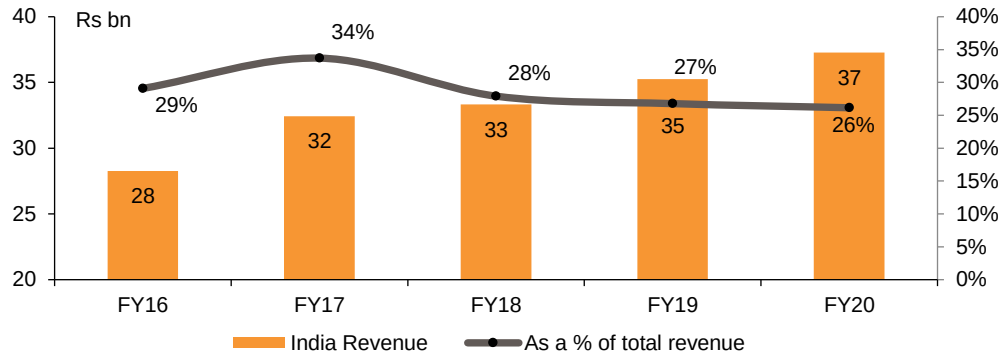
Brand Name	Innovator Name	Revenue	Patent Expiry	Para IV Filers
Apriso	Valeant Pharmaceuticals Intl	$145 mn	01-May-30	Lupin, Mylan, Novel Labs, Teva
Delzicol	Allergan, Inc.	NA	13-Apr-20	Teva, Mylan, Zydus Cadila
SfRowasa	Mylan Speciality	NA	24-Jul-27	NA

Source: Company reports, FDA, Emkay Research

India branded business to outperform IPM growth rate

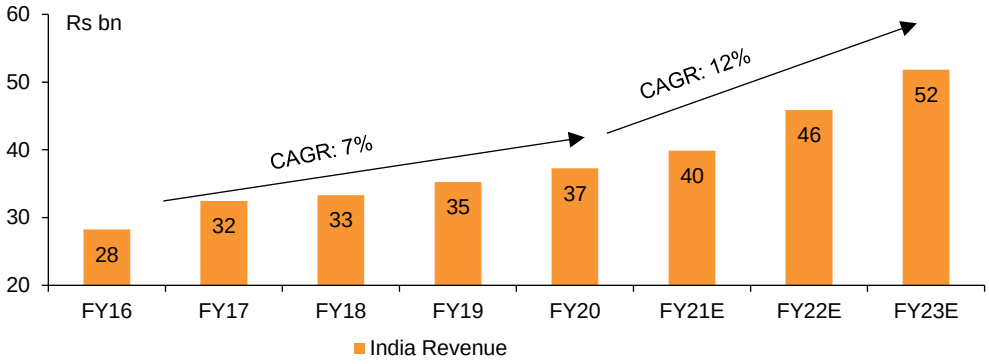
We expect the India formulations business (25% of revenues) to grow at a 12% CAGR over FY20-23E, outperforming the market after several years of underperformance. This will be driven by 1) new products in the mandate brands category, 2) strengthening of existing therapies such as Cardio, Gynae, Respiratory and Oncology, and 3) 12-15 new molecule launches including Saroglitazar.

Exhibit 28: India formulations business contributed ~26% of total revenue in FY20



Source: Company reports; Emkay Research

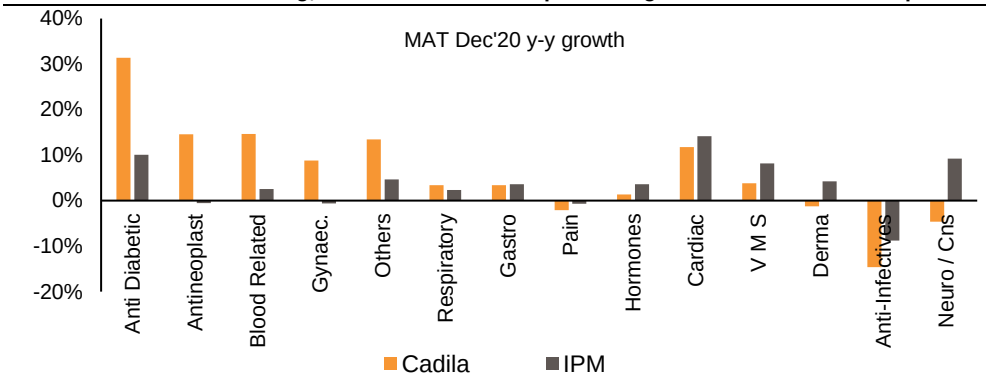
Exhibit 29: We expect India revenue to grow at 12% CAGR through FY23E vs. 7% historically



Source: Company reports; Emkay Research

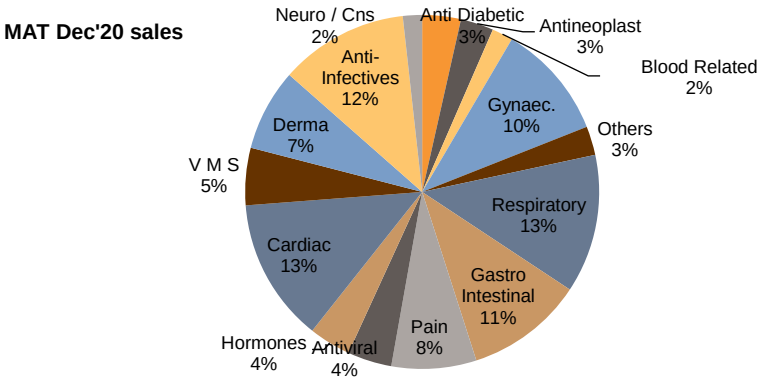
The company has restructured its India business into Mass and Specialty segments and also discontinued tail brands. This has resulted in improved growth momentum as reflected in recent secondary sales data. According to the IMS IQVIA data, the company has posted 5% MAT (Dec'20) sales growth, outperforming the industry growth by ~60bps.

Exhibit 30: After restructuring, Cadila has started outperforming IPM in most of the therapies



Source: IMS IQVIA, Emkay Research.

Exhibit 31: Strengthening of existing therapies to drive growth



Source: IMS IQVIA; Emkay Research,

The company has suggested that new launches and renewed focus in its mandate brands would drive their revenue contribution from ~53% to 60% in the next 3 years. Even assuming sub market growth of 6% in the rest of the brands, Cadila's India revenue is expected to grow at a 12% CAGR through FY23.

Exhibit 32: Mandate brands are expected to grow significantly

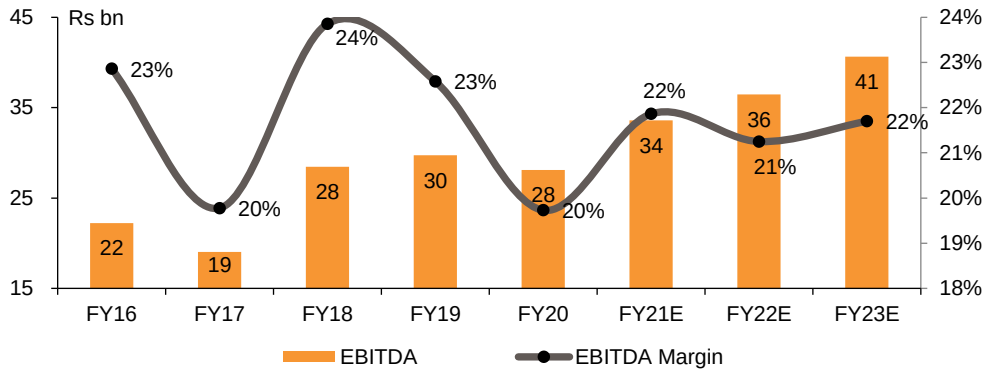
Growth in non-mandate brands	Implied growth in mandate brands	Implied Cadila India growth
4%	14%	10%
5%	15%	11%
6%	**17%**	**12%**
7%	18%	13%
8%	19%	14%

Source: Company reports; Emkay Research

Financials—core EBITDA margins likely to improve

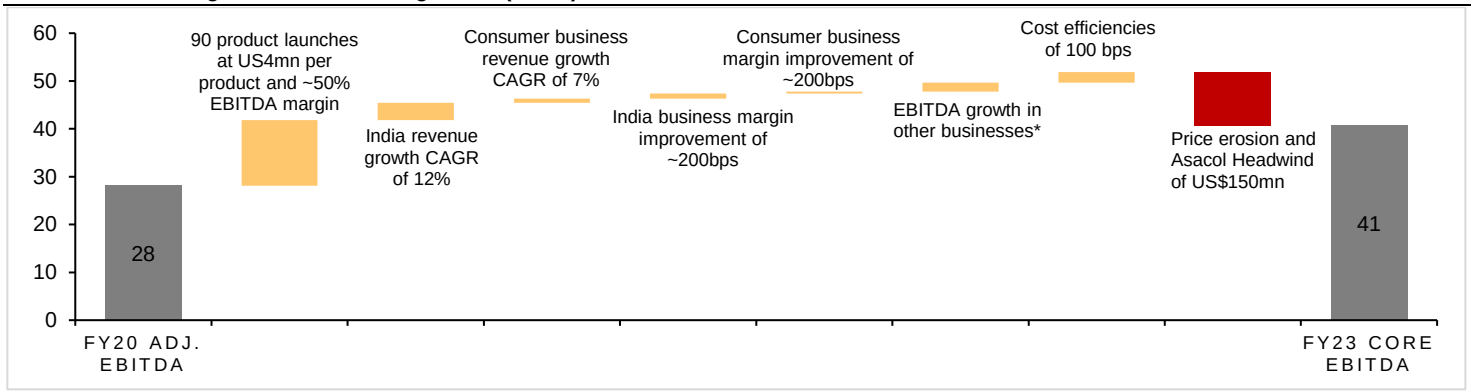
We calculated that the EBITDA margin boost in Mesalamine franchise in recent years was more than offset by higher competition in the US business and Heinz acquisition. Hereon, we expect core EBITDA to grow at a 13% CAGR and margin expansion of ~200bps through FY23. Margin improvement will be driven by 1) 100bps structural EBITDA improvement from cost efficiencies, 2) 40-50bps margin expansion due to an increase in field force productivity in the India business and 3) modest margin improvement across other businesses.

Exhibit 33: We expect core EBITDA margin improvement of ~200 bps in the medium term



Source: Company reports; Emkay Research

Exhibit 34: EBITDA growth drivers through FY23 (Rs bn)



Source: Company reports, Emkay Research
**Other business includes Europe, LATAM, Emerging markets & API*

The company plans to achieve a sustainable improvement of 1% in EBIDTA margins with governance on 5 work streams, including 1) optimization of manpower, 2) throughput improvement through OEE improvement, 3) facilitating the enhanced throughput with reduced shift of operation, 4) drive cost optimization in utilities and consumables and 5) digitally enabled manufacturing and quality operations. While we expect more details on the company's plan for EBITDA improvement given their previous track record, we believe that they will be able to achieve the 100bps EBITDA margin improvement target in the medium term.

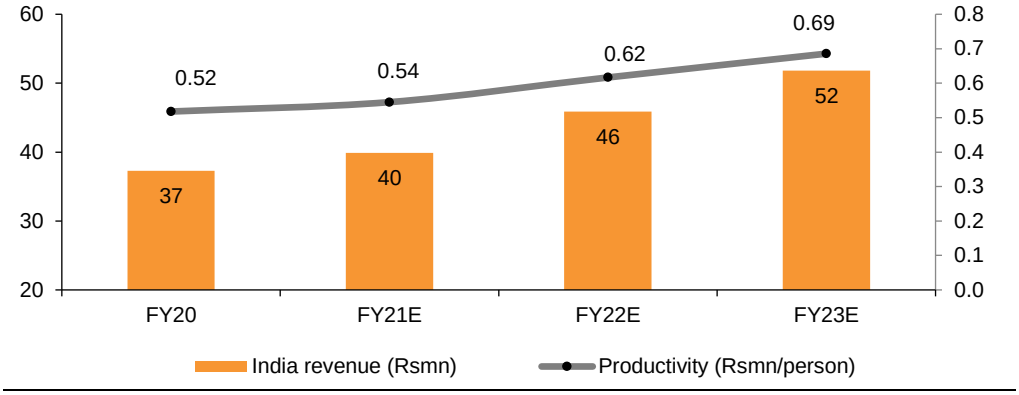
Exhibit 35: Cost optimization to drive margin improvement of ~100 bps

Journey so far	Journey ahead
Cumulative savings of over US$ 80 Mn. over a decade through Productivity & Cost improvement	To achieve a sustainable improvement of 1% in EBIDTA margins with governance on 5 Work streams
Simplification of quality systems and Compliance improvement	Optimization of manpower through the Spans & Layers to release and throughput improvement through OEE improvement
Paperless QMS activities	Facilitating the enhanced throughput with reduced shift of operation
AR & VR based Remote/Self assistance and training on guided maintenance, operations and changeover.	Drive cost optimization in utilities & consumables and digitally enabled manufacturing & quality operations

Source: Emkay Research, Company

In our view, field force productivity improvement in India could drive margin expansion of 40-50bps. Cadila's current field force productivity is around Rs0.5mn PCPM. With field force expected to remain stable in the medium-term, India business revenue growth will likely drive the PCPM to nearly Rs0.7mn. This, in our view, will drive 150-200bps margin improvement in the India business, translating to 40-50bps of consolidated EBITDA margin improvement.

Exhibit 36: PCPM to improve 30% over FY20-23E

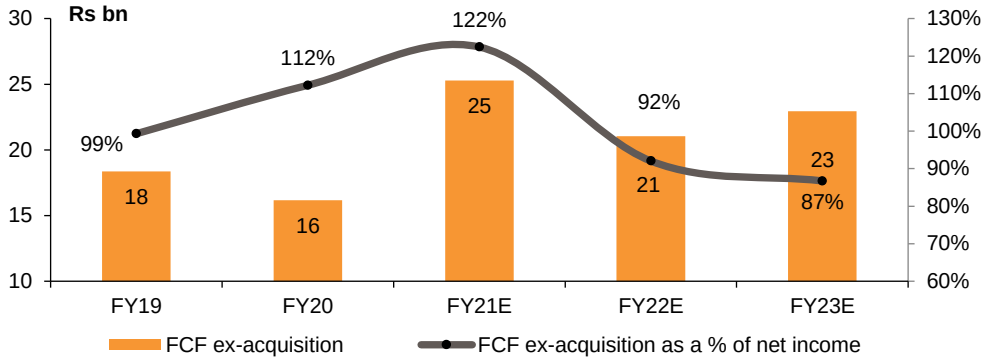


Source: Company reports; Emkay Research

Improving FCF and profitability

We forecast consolidated FCFE to grow to Rs33.6bn by FY23 from Rs16.1bn in FY20, driven by a Rs7bn FCF increase in the core business. Further, with improving asset-turns (1.12 to 1.4 in FY23) and likely expansion of 300bps in EBIT margin, we expect core ROIC to improve well above the cost of capital to ~19% in FY23E from 11% in FY20.

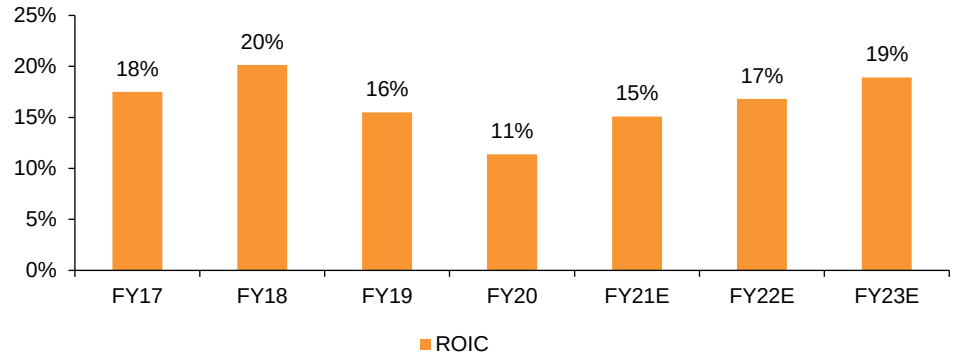
Exhibit 37: Core business FCF (excl. acquisitions) generation remains strong and stable



Source: Emkay Research, company reports

ROIC declined in FY19 and FY20 primarily due to Heinz acquisition of ~Rs46bn, by its 64% owned subsidiary Zydus wellness. The acquisition and related costs led to a decline in asset turnover from 1.6 in FY18 to 1.1 in FY20. Also, EBITDA margin compressed by ~450bps due to the acquisition and competition in Cadila's specialty molecule Levorphanol in the US. With improving asset turnover and margins, return ratios are also expected to improve.

Exhibit 38: Core business Pre-tax ROIC has bottomed out and expected to improve through FY23e



Source: Company reports; Emkay Research

Valuation is compelling

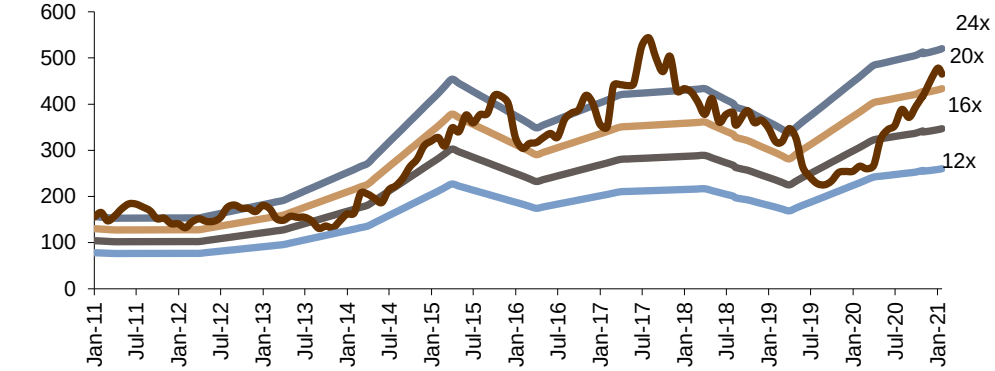
The stock is trading at 1-year forward P/E of 16x on our consolidated forecast and 21x on core earnings in line with the historical average. Our Rs655 TP includes core business value of Rs520 (20x forward P/E), Saroglitazar NPV of Rs90 and ZyCoV-D upside of Rs45. Catalysts: Positive news on Saroglitazar trials, positive read out on Covid-19 vaccine and clearance of the Moraiya plant. Downside risks: Higher-than-expected competition in mesalamine franchise, adverse regulatory outcome.

Exhibit 39: We revise our TP to Rs655/ share

	FY23 earnings	P/E multiple	Equity value
Cadila core business	26	20	520
Saroglitazar NPV			90
Vaccine NPV			45
Target price			**655**

Source: Company reports; Emkay research

Exhibit 40: The stock is trading at P/E of 21x on 1-year forward earnings



Source: Bloomberg; Emkay Research

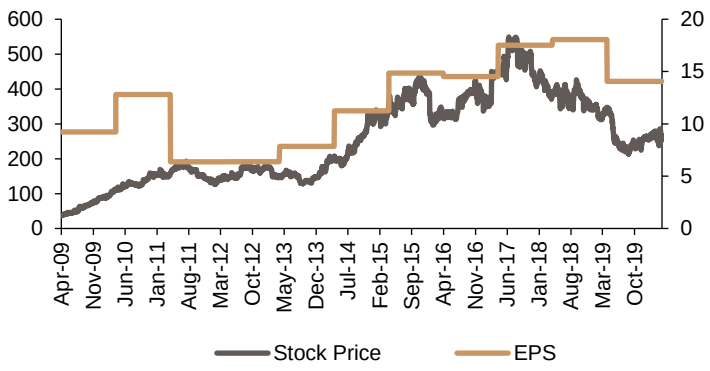
If we assume that the current market price has already factored in the upside from Saroglitazar and ZyCoV-D, the core business is trading at a compelling P/E of 16x.

Exhibit 41: Core business is trading at compelling 1-year forward P/E of 15x, excluding Saroglitazar and ZyCoV-D NPV

Current market price	**465**
Saroglitazar NPV (Mar'22E)	90
Saroglitazar NPV discounted to Mar'21E	80
ZyCoV-D NPV (Mar'22E)	45
ZyCoV-D NPV discounted to Mar'21E	40
Implied value of core business in CMP (Mar'21)	**345**
Core business 1-year forward EPS (Rs)	21.7
Core business 1-year forward P/E (x)	**16x**

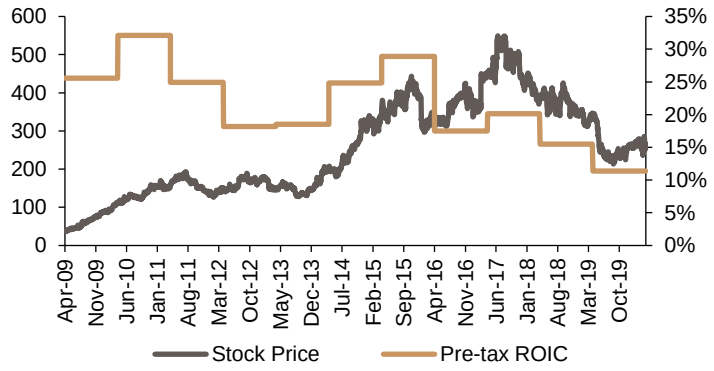
Source: Emkay research. Bloomberg.

Exhibit 42: Historically, stock price has been by earnings growth…



Source: Company reports; Bloomberg; Emkay Research

Exhibit 43: …and ROIC; both of them will likely improve drastically



Source: Company reports; Bloomberg; Emkay Research

Bull case TP of Rs835

There are multiple upsides to our base case TP of Rs655/share. All put together, our bull case scenario yields a fair value of Rs835/share, which includes 1) additional upside of Rs120/share from ZyCoV-D, 2) additional upside from Saroglitazar of Rs20/share and 3) Revlimid upside of Rs40/share. Other upsides, which are difficult to quantify at this point in time, include higher-than-expected penetration of Saroglitazar in India and success of other NCE such as Desidustat.

Additional Rs120 upside from ZyCoV-D if vaccination becomes annual exercise

Current research suggests that people who were cured after Covid-19 infection could only remain immune for only 3-6 months against reinfection, meaning those who were already infected also needs to take the vaccine. Additionally, data from leading vaccines suggest that neutralizing-antibodies generated in response to the vaccine tend to decline gradually over a period of time. Hence, we believe that the Covid-19 vaccine could become an annual vaccine drive, which means Cadila may continue to sell its limited supply of vaccine for many years in the future. Accordingly, we estimate ZyCov-D vaccine represents an additional upside of Rs120/share on the NPV basis.

Exhibit 44: ZyCoV-D could offer an additional upside of Rs120/share

Covid vaccine NPV				
	FY21	**FY22**	**FY23**	**FY24**
Cadila vaccine capacity (doses) (mn)	**100**	**100**	**100**	**100**
Contract manufacturing (doses) (mn)		50	50	50
Total capacity (doses) (mn)	100	150	150	150
Doses per person	3	3	3	3
Persons immunised	33	50	50	50
Vaccine price per person (Rs)	1,200	1,200	1,200	1,200
Realization		60%	60%	60%
Number of years		0.9	1.0	1.0
Vaccine revenue (Rs mn)		**32,400**	**36,000**	**36,000**
EBITDA margin		50%	50%	50%
EBITDA (Rs mn)		16,200	18,162	18,162
EBITDA * (1-t) (Rs mn)		12,122	13,591	13,591
Working capital (Rs mn)		2,663	2,959	0
Change in working capital (Rs mn)		2,663	296	-2,959
FCF (Rs mn)		13,537	17,866	21,121
Discount factor		1.00	0.89	0.80
PV of FCF (Rs mn)		13,537	15,952	16,837
Terminal value (Rs mn)		140,312		
Total NPV (Rs mn)		**169,801**		
NPV per share (Rs)		165		
NPV already baked in our TP (Rs)		45		
Additional upside if vaccine becomes an annual shot		**120**		

Source: Company reports; Emkay research

Saroglitazar offers an additional upside of Rs20/share

We have assumed conservative market share of 10% in PBC market and 5% in NASH market for Saroglitazar in the US. If the market share would rise by 5% in PBC and 2% in NASH, it could represent an upside of Rs20/sh.

Exhibit 45: PBC NPV sensitivity

		Peak market share				
	50.07	**5%**	**8%**	**10%**	**13%**	**15%**
Treatment price	**63,200**	35	37	38	40	41
	71,100	41	43	44	46	48
	79,000	47	49	**50**	52	54
	86,900	53	55	57	59	61
	94,800	58	61	63	65	67

Source: Emkay research

Exhibit 46: NASH NPV sensitivity

		Peak market share				
	39.54	**3%**	**4%**	**5%**	**6%**	**7%**
Annual treatment cost (US$)	**7,200**	17	23	30	36	43
	8,100	20	27	35	42	49
	9,000	23	31	**40**	48	56
	9,900	26	35	44	53	62
	10,800	30	39	49	59	69

Source: Emkay research

Generic Revlimid could offer an upside of Rs40/share

Generic Revlimid could offer an additional upside too. We estimate gRevlimid NPV of Rs40/share assuming settlement terms in line with Alvogen.

Exhibit 47: Revlimid NPV for Cadila

Base case (settlement terms in line with Alvogen)				
2022e US sales (US$mn)	8,454			
	FY23	**FY24**	**FY25**	**FY26**
Volume allowance	5%	7%	8%	9%
Price erosion	35%	50%	70%	85%
Potential revenue (US$mn)	275	296	203	114
Gross margin	98%	98%	97%	93%
FCF (US$mn)	211	226	153	83
WACC	10%			
	0.91	0.83	0.75	0.68
PV (US$mn)	192	187	115	57
NPV	550			
NPV per share (Rs)	**40**			

Source: Emkay Research, Company

Desidustat, another NCE, represents additional upside

Saroglitazar is not the only new chemical entity the company is working on. The second molecule in the pipeline is Desidustat, for which the company has received US FDA approval to initiate clinical trials in cancer patients receiving chemotherapy-induced anemia. Currently, there are ~1mn cancer patients receiving chemotherapy in the US, offering a decent market. Apart from this, the company is conducting Phase 3 clinical trial of Desidustat for treatment of Anemia in chronic kidney disease (CKD) in India. The company has a licensing agreement with China Medical System Holdings Ltd (CMS) for development and commercialization of Desidustat in anemia induced CKD.

Exhibit 48: Desidustat development will continue simultaneously with Saroglitazar

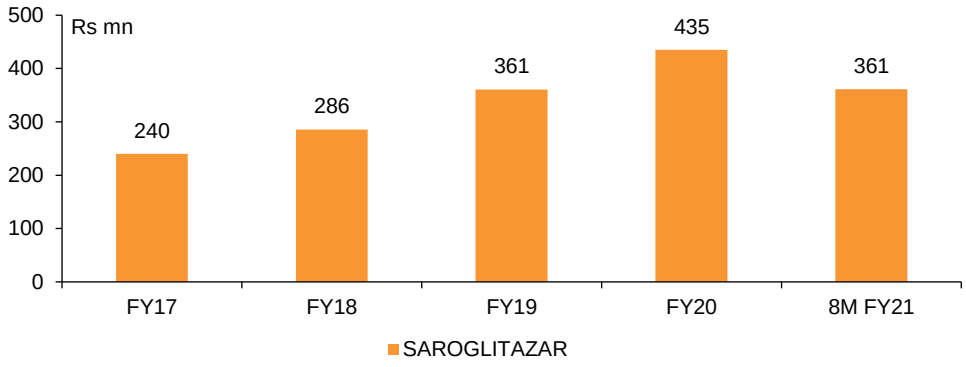
Desidustat	Market opportunity	Key milestones in 2019-20
Desidustat is a novel, oral, hypoxia inducible factor prolyl hydroxylase inhibitor (HIF-PH inh.), currently undergoing Phase 3 trials for treating anemia in chronic kidney disease patients	Global Renal anemia market is expected to reach ~$6bn by 2027	US drug regulator's approval to initiate clinical trials of Desidustat in cancer patients receiving chemotherapy induced anemia
Chronic kidney disease (CKD) is the patient pool for Desidustat	Potential for Renal anemia in emerging market is expected to reach ~$500-600mn by 2027	Initiated Phase II (b) trial of Desidustat in Mexico for the management of patients with COVID-19
CKD is a serious medical condition involving gradual loss of functioning of kidneys eventually leading to kidney failure	~1mn cancer patients in the US receiving chemotherapy develop anemia	Started Phase III clinical trials of Desidustat targeted at treating anemia in dialysis (n=392) and nondialysis (n=588) dependent CKD patients
Anemia is one of the frequent complications of CKD	>120 mn people are estimated to be living with CKD in China; Prevalance of CKD patients in India is ~17%	-

Source: Company, Emkay Research

Saroglitazar sales in India could surprise positively

While Saroglitazar has tasted limited success in India for Type 2 Diabetes Mellitus and Hypertriglyceridemia indications, NASH indication could be a game changer. If Saroglitazar reaches Rs2.5bn revenue mark given the approval for NASH indication, it could add another rupee to earnings, representing a ~4% upside to FY23 earnings.

Exhibit 49: Saroglitazar revenue in India has grown rapidly (other than NASH indications)



Source: IQVIA IMS, Emkay Research

Downside risks appear to be largely priced in

Failure to progress on Innovative medicines, vaccines as well as high competition in mesalamine represent downside to our base case TP. Our bear case scenario suggests Mar'22 fair value of Rs435, which is largely in line with the current market price.

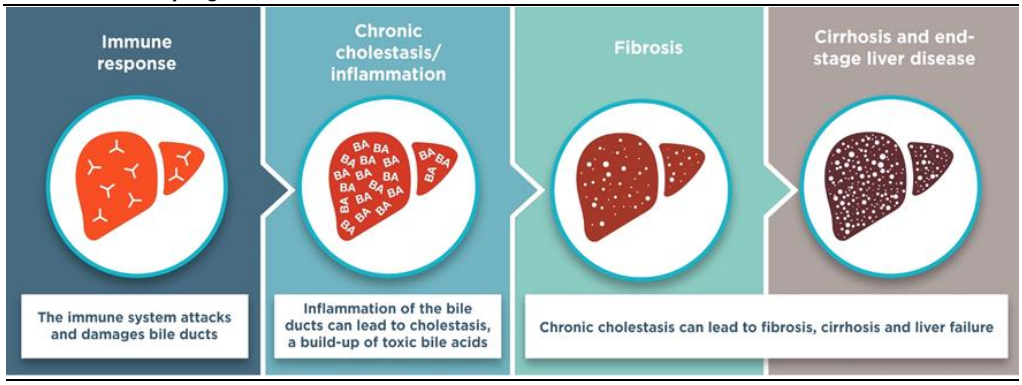
If we assume that Cadila fails to garner any approval for Saroglitazar in the US, it represents a downside of Rs90/share. Similarly, a lower price (Rs600 per person) for ZyCoV-D would represent a Rs35 downside to our base case scenario. On the core business, competition in Mesalamine franchise is the biggest risk. If we assume that Asacol and Lialda revenue and earnings go down drastically, it could represent an EPS downside of ~Rs5 in the worst case scenario. At a P/E multiple of 20x, it represents a downside of Rs95/sh.

Appendix-1

What is Primary Biliary Cholangitis?

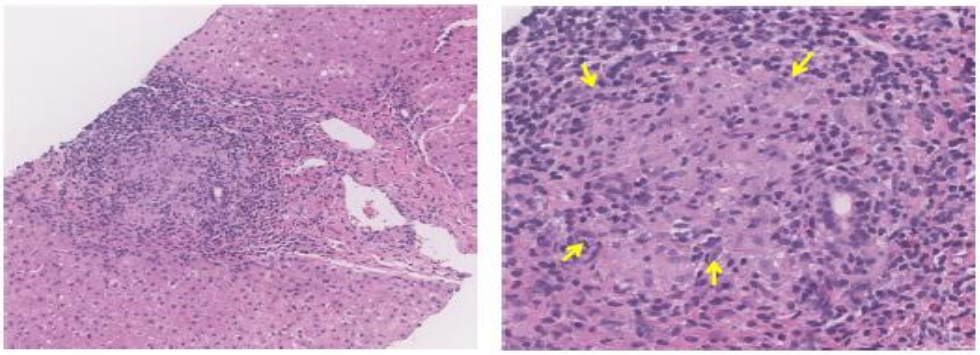
Primary biliary cholangitis (PBC) is a rare liver disease caused by an autoimmune reaction resulting from progressive destruction of the bile ducts in the liver. Human liver produces bile, a digestive liquid, which travels through the bile ducts in the liver to the small intestine where it breaks down toxins and aids in digestion. Cholestasis is a condition where that bile flow is reduced, meaning that bile cannot flow into the small intestine leading to a build-up of bile in the liver. As a result, the ducts are damaged causing inflammation and scarring (fibrosis) as scar tissue replaces healthy liver tissue. PBC is progressive meaning that the damage gets worse over time. Starting with inflammation, the damage can cause fibrosis, and then cirrhosis.

Exhibit 50: PBC progression



Source: AASLD; Emkay research

Exhibit 51: Typical liver histology of PBC demonstrating portal-based duct-centric inflammation, with prominent bile duct injury



Source: Emkay Research, AASLD
Note the overlapping and disorganized appearance of the cholangiocyte nuclei, cytoplasmic eosinophilia, and intraepithelial lymphocyte (right upper and lower arrow). A loose aggregate of histiocytes (left upper and lower arrows) forms a vague granuloma adjacent to the bile duct.

Exhibit 52: Symptoms of PBC

Source: Emkay Research, AASLD

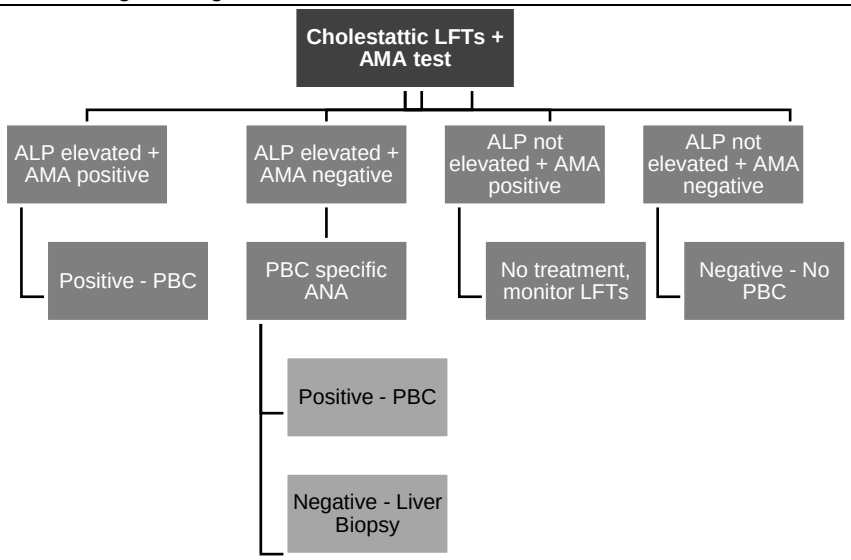
Epidemiology

With prevalence of ~400 patients per million population, we estimate there are ~132,000 people in the US living with PBC, which is expected to grow by a 5% CAGR to ~205,000 by FY30E. The growth will be driven by PBC incidence of 27 patients per million population, partially offset by a PBC mortality rate of 2.4 patients per million population. It is estimated that 75-90% of patients who are diagnosed with PBC are women. Majority of the patients who are diagnosed with PBC are between 40-60 years of age.

Diagnosis

Many people with chronic cholestatic liver disease have no symptoms for months, or even years, the condition is often discovered incidentally when a raised level of alkaline phosphatase (ALP) is noticed during routine blood tests. ALP is an enzyme that is produced by liver cells and found in the blood. It is one of several key markers for overall liver health and function. Once PBC is suspected, a blood test to check for antimitochondrial antibody (AMA) is done. Although this test is positive in nearly all people with PBC, it can be absent in ~10% of the people. AMA negative patients are tested for antinuclear antibodies (ANAs) and are often found positive on the test. Liver biopsy may be considered in cases when a concomitant liver disease such as autoimmune hepatitis (AIH) or nonalcoholic fatty liver disease is suspected and is required to confirm the diagnosis of AMA-negative PBC when PBC-specific autoantibodies are also lacking. Imaging studies may be used to rule out other diseases, or to further evaluate patients once they have been diagnosed with PBC.

Exhibit 53: PBC Diagnosis algorithm



Abbreviations – Alkaline phosphatase (ALP), Antimitochondrial antibodies (AMA), Antinuclear antibodies (ANA)

Source: AASLD, Emkay Research

Treatment

There is currently no cure for primary biliary cholangitis, but medications are available that can help slow the disease progression and manage symptoms. Ursodeoxycholic acid (UDCA), also known as ursodiol, is commonly used as the first line treatment that helps move bile through the liver. UDCA does not cure PBC but is known to improve liver function and reduce liver scarring. UDCA is effective in more than 50% of the patients, but up to 40% of them do not achieve an adequate reduction in ALP, while 5-10% are unable to tolerate it and require a different treatment option.

In May 2016, obetacholic acid (brand name Ocaliva) was approved by the US FDA, offering an additional treatment option for PBC patients. Ocaliva is indicated for the treatment of PBC in combination with UDCA in adults with an inadequate response to UDCA, or as a single therapy in adults unable to tolerate UDCA. Obeticholic acid increases bile flow from the liver and suppresses bile acid production in the liver, thus reducing the exposure of the liver to toxic levels of bile acids. Other alternative therapies in patients who are incomplete responders to UDCA include fenofibrate/ bezafibrate. Medications to suppress the immune system may also be prescribed including prednisone or azathioprine in PBC patients with the “overlap syndrome” with autoimmune hepatitis. Liver transplantation is considered when medical treatment no longer sufficiently controls the disease. When a person has end-stage liver disease, a liver transplant is necessary for survival.

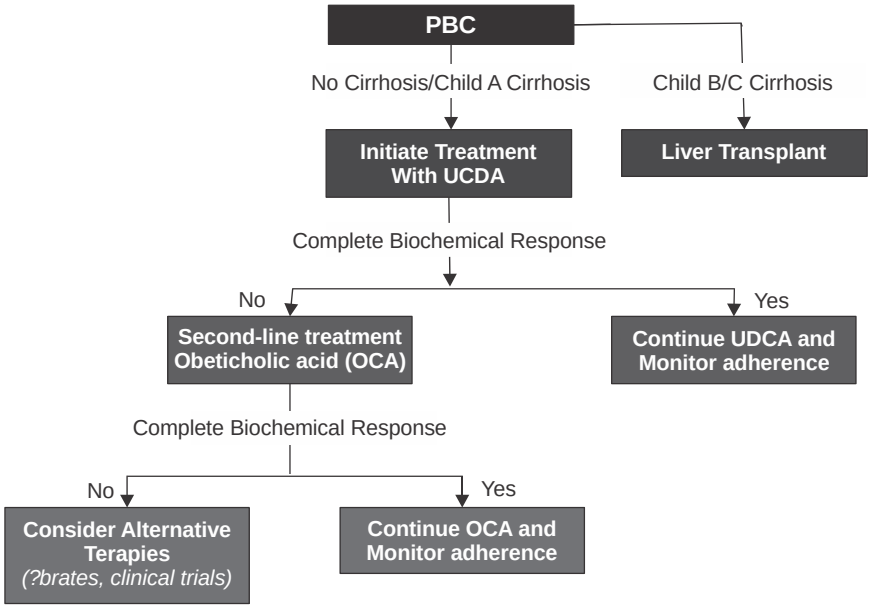
Initial treatment begins with UDCA in all patients with PBC. Biochemical response is assessed 6 to 12 months after starting UDCA. Patients with an inadequate biochemical response or who do not tolerate UDCA are considered for treatment with Ocaliva + UDCA/ Ocaliva alone or referred to clinical trials. Patients with advanced cirrhosis are considered for liver transplantation.

Exhibit 54: Treatment options for PBC patients

Therapeutic Agent	Mechanism	Effects
UDCA	Secondary bile acid	Improves liver biochemical tests
		Delays progression of hepatic fibrosis
		Improves time to liver transplantation
		~30%45% have an inadequate response
		Less effective in patients with PBC with latestage disease
OCA	Farnesoid X receptor agonist	Improves serum ALP and TB in patients with PBC who had an incomplete response or were intolerant to UDCA alone
		May improve liver histology
Fibrates	Peroxisome proliferator-activated receptor agonists	Decrease in ALP, ALT, and Gammaglutamyl transferase
		May arrest the progression of liver stiffness
Budesonide	Glucocorticoid	Improves serum ALP in patients with PBC who have active interface hepatitis
		Results in reduced bone mineral density

Source: AASLD, Emkay Research

Exhibit 55: PBC treatment algorithm



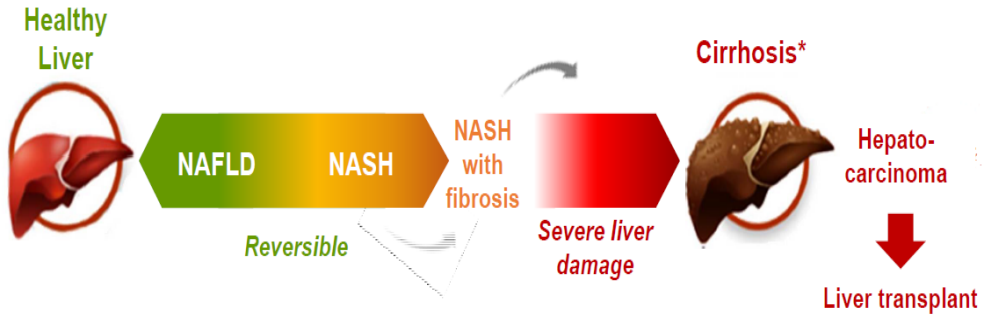
Source: AASLD, Emkay Research

Appendix-2

What is NASH?

Non-Alcoholic Steatohepatitis (NASH) is a chronic, progressive liver disease that occurs when excessive amounts of fat build up in the liver, damaging hepatocytes. NASH is a progressive form of Non-alcoholic Fatty Liver Disease (NAFLD), developing in about 20% of NAFLD patients. The earliest of manifestation of NAFLD is non-alcoholic fatty liver when there is excessive hepatic fat without inflammation. When the excess of liver fat is accompanied by cell ballooning, inflammation and cell damage, NASH often progresses slowly with no obvious or visible symptoms and can lead to liver scarring known as fibrosis. Further inflammation can lead to progressive degeneration of liver cells which are replaced by scar tissue. Fibrosis severity is measured on a scale ranging from no liver scarring or F0 to cirrhosis or severe liver scarring at F4. As NASH progresses without detection and intervention in earlier stages, severe and irreversible liver damage in the form of cirrhosis, liver failure and even hepatocellular carcinoma (HCC) may occur in some patients. While only 10% of all patients with NASH have cirrhosis, cirrhosis accounts for >80% of annual direct medical costs.

Exhibit 56: NASH is an inflammation of liver cells due to excess fat deposition

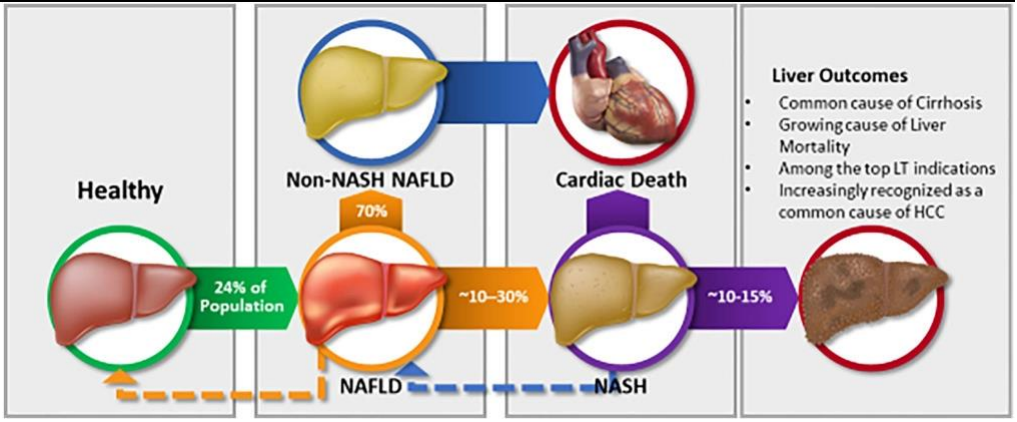


Source: AASLD

Epidemiology

As the global rates of obesity increase, obesity related complications are on the rise. Of these NAFLD is becoming one the major causes of liver disease throughout the world. NAFLD population in the US is estimated to be ~90-100 mn or ~25% of the US population. Further, estimates suggest that ~21% of the NAFLD population or ~20mn have NASH currently. The prevalence of NASH has continued to increase and it is estimated to rise to ~23-24mn by FY30. We currently estimate ~7.8mn people with F2/F3 grade of fibrosis which is expected to grow to ~10mn by FY30. We estimate ~500,000 patients who are at an advanced stage of fibrosis currently with a high mortality risk. It is generally observed that it takes 7 years for NASH patients to progress one fibrosis stage. In the absence of lifestyle related changes, liver inflammation associated with NASH may persist and lead to progressive fibrosis, thus leaving patients at an increased risk of liver related mortality. Progression to cirrhosis (F4 grade of fibrosis) has the highest risk liver related mortality resulting from liver failure requiring transplantation.

Exhibit 57: NASH epidemiology

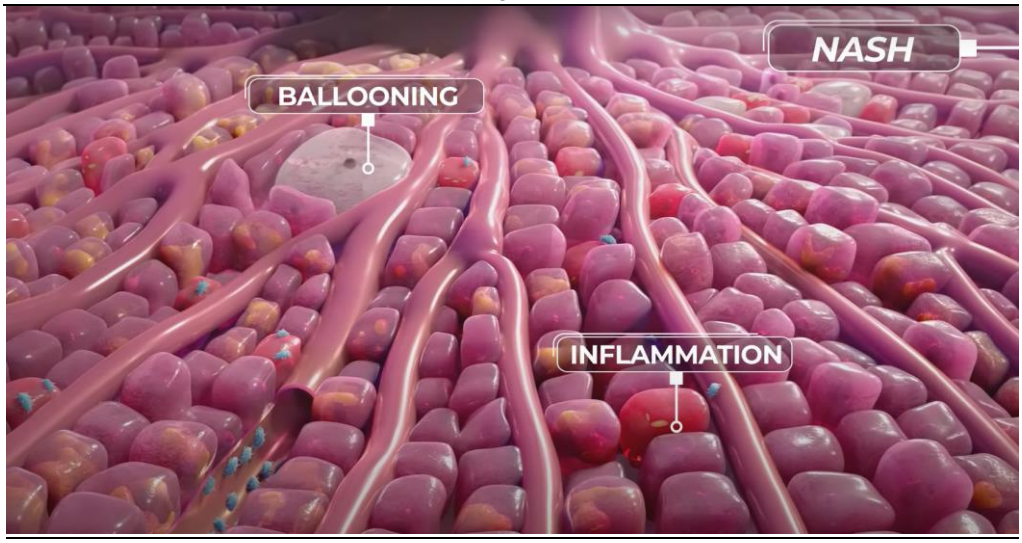


Source: AASLD

Pathogenesis

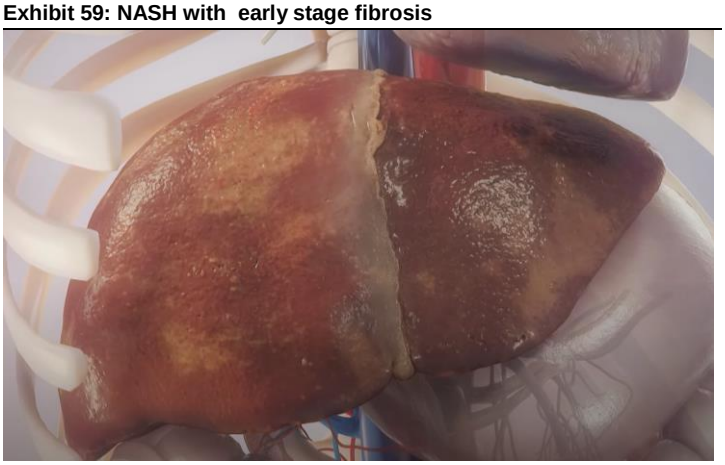
Liver fat can arise from numerous sources including delivery from fat tissue in other parts of the body and the creation of new fat from foods high in fat and sugar. If fat build-up and removal is unbalanced, it can lead to an abnormal amount of liver fat accumulation called steatosis. Risk factors such as obesity, type 2 diabetes, insulin resistance, metabolic syndrome, and a genetic predisposition can lead to metabolic changes in the liver causing excessive fat accumulation or steatosis. Elevated BMI/obesity and excessive caloric intake can also cause steatosis and contribute to the development of the disease. While the exact cause of NASH has not been fully elucidated, it is largely caused by factors mentioned here.

Exhibit 58: Excess liver fat causes cell ballooning and inflammation



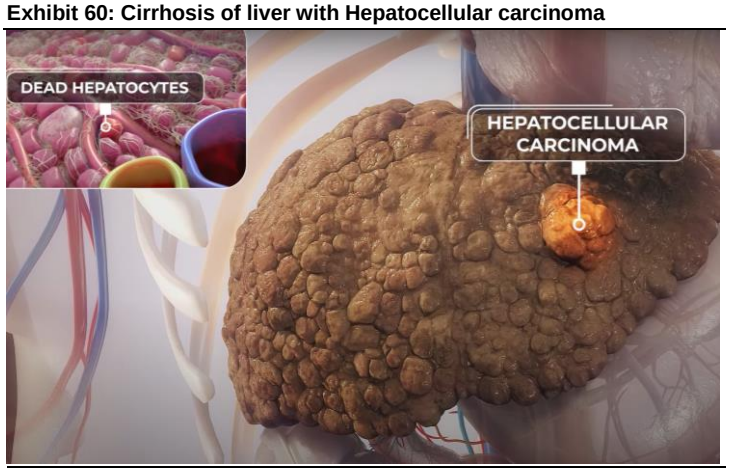
Source: Pfizer company reports

Exhibit 59: NASH with early stage fibrosis



Source: Pfizer company reports

Exhibit 60: Cirrhosis of liver with Hepatocellular carcinoma



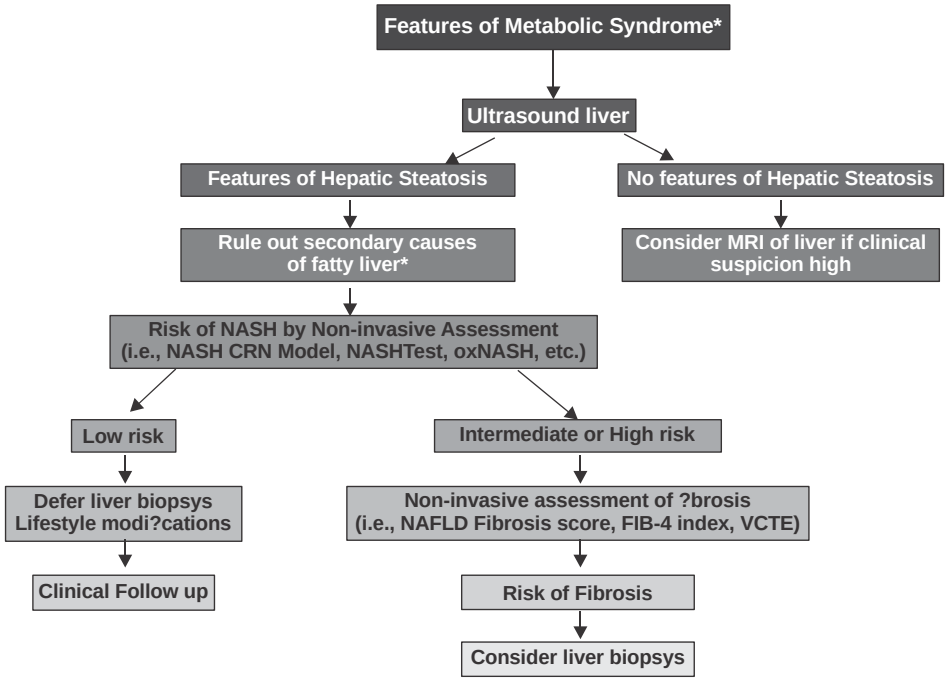
Source: Pfizer company reports

Diagnosis

As early disease is often asymptomatic, fatty liver disease may be incidentally discovered during a routine blood test or screening for another medical condition. NAFLD patients would have elevated level of enzymes on their liver function tests (LFT). The cells in the liver contain proteins called enzymes, which are chemicals that aid the liver do its functions. When the liver cells are damaged, the enzymes in the cells flow in the blood where they can be measured by the blood tests. LFT usually checks the blood for the two main enzymes: Alanine transaminase (ALT) and Alkaline phosphatase (ALP) test. If the liver is damaged due to inflammation, enzyme levels on these tests would be elevated. However, ALT and ALP tests do not usually indicate the level of fibrosis/scarring in the level.

Once high levels of ALP and ALT are found on the LFT, Fibrosis assessment tests such as Fibrosis-4 (Fib-4) are conducted to estimate the level of fibrosis/liver scarring. Additionally, there are other types of non-invasive imaging tests such as transient elastography and MRE that are used to determine the stiffness in the liver. Liver stiffness indicates scarring: the more scarring that is present, the stiffer the liver is. However, these tests can only confirm the presence of fatty liver/steatosis but cannot distinguish NASH. As a result, liver biopsy, although invasive, remains the gold standard for the diagnosis NAFLD/NASH and provides information about hepatocellular inflammation and the grade of fibrosis. However, there are host of companies trying to bring non-invasive diagnostic tests for detection of NASH. For more details in tests, refer to Appendix.

Exhibit 61: NASH diagnosis algorithm



Source: AASLD; Emkay research

Exhibit 62: Noninvasive tests for detection of Liver Fibrosis

Test	Diagnostic Ability	Comments
Enhanced liver fibrosis panel	0.87	Detects markers of matrix turnover, which includes tissue inhibitor metalloproteinase 1, N-terminal propeptide of type III procollagen, and hyaluronic acid
Fibrometer	0.82	Includes ALT, AST, GGT, platelets, prothrombin time index, α2-macroglobulin, hyaluronic acid, ferritin, glucose, and urea
FibroTest	0.81	Components include age, sex, bilirubin, GGT, haptoglobin, α2-macroglobulin, and apolipoprotein A1
BARD score	0.81	Components include BMI, AST/ALT ratio, and diabetes
NFS	0.84	Validated scoring system; components include age, diabetes, BMI, AST, ALT, platelets, and albumin
FIB-4 index	0.84	Reliably excludes advanced fibrosis because of high NPV. Components include age, AST, and platelets
APRI	0.67	Initially developed for use in hepatitis C virus. Not specific for NAFLD
VCTE	0.83-0.95	Results may be invalid in obese patients (BMI >35 kg/m2); hence a FibroScan XL probe is developed to overcome this problem
MRE	0.92	Widespread clinical adoption is limited because of its high cost and low availability

Source: Emkay Research

Exhibit 63: Noninvasive tests to determine the presence of NASH

Test	Diagnostic Ability	Comments
CK-18 biomarker	0.82	Breakdown product during apoptosis of hepatocytes. Modest sensitivity/specificity in multiethnic cohort (58%-68%). Not commercially available alone
NASHTest	0.78	Components include age, sex, height, weight, cholesterol, triglycerides, AST, ALT, bilirubin, haptoglobin α2-macroglobulin, apolipoprotein A1
NASH CRN model	0.79	Components include AST level, ALT level, AST/ALT ratio, demographics (age, race, gender, and ethnicity), comorbidities (hypertension, type 2 diabetes, BMI, waist circumference, waist/hip ratio, and acanthosis nigricans), and other laboratory tests
NICE model	0.83	Components include metabolic syndrome, ALT, and CK-18
NAFLD diagnostic panel	0.81	Based on diabetes, gender, BMI, triglycerides, M30 (CK-18 fragments as a marker of apoptosis), and M65 plus M30 (total CK-18 and CK-18 fragments as a marker of necrosis)
OxNASH risk score	0.79	Score is calculated from age, BMI, AST level, and the ratio of 13-hydroxy octadecadienoic acid to linoleic acid

Source: Emkay Research

Key Financials (Consolidated)

Income Statement

Y/E Mar (Rs mn)	FY19	FY20	FY21E	FY22E	FY23E
Net Sales	**131,656**	**142,531**	**153,723**	**203,946**	**223,303**
Expenditure	101,925	115,111	120,117	156,917	172,159
EBITDA	**29,731**	**27,420**	**33,606**	**47,028**	**51,145**
Depreciation	5,986	6,965	7,023	7,270	7,336
EBIT	**23,745**	**20,455**	**26,583**	**39,758**	**43,809**
Other Income	2,011	1,139	772	609	1,676
Interest expenses	1,935	3,418	2,112	1,601	1,438
PBT	**23,821**	**18,176**	**25,243**	**38,766**	**44,047**
Tax	5,303	3,780	5,123	8,529	9,690
Extraordinary Items	0	(2,640)	0	0	0
Minority Int./Income from Assoc.	(30)	10	526	388	440
Reported Net Income	**18,488**	**11,766**	**20,645**	**30,625**	**34,797**
Adjusted PAT	**18,488**	**14,406**	**20,645**	**30,625**	**34,797**

Balance Sheet

Y/E Mar (Rs mn)	FY19	FY20	FY21E	FY22E	FY23E
Equity share capital	1,024	1,024	1,024	1,024	1,024
Reserves & surplus	102,839	102,733	119,592	146,292	177,217
Net worth	**103,863**	**103,757**	**120,616**	**147,316**	**178,241**
Minority Interest	**12,929**	**13,347**	**12,821**	**12,433**	**11,993**
Loan Funds	**76,583**	**75,333**	**58,297**	**52,847**	**42,969**
Other Liabilities	5,117	4,922	4,922	4,922	4,922
Total Liabilities	**193,375**	**192,437**	**191,733**	**212,596**	**233,203**
Net block	**59,431**	**61,937**	**76,782**	**77,512**	**78,176**
Investment	**19,841**	**19,992**	**19,992**	**19,992**	**19,992**
Current Assets	**84,981**	**87,154**	**89,091**	**123,944**	**149,984**
Cash & bank balance	6,493	9,649	7,618	20,952	40,565
Other Current Assets	12,100	12,983	13,835	17,335	17,864
Current liabilities & Provision	**41,456**	**44,429**	**48,047**	**62,767**	**68,863**
Net current assets	**43,525**	**42,725**	**41,044**	**61,178**	**81,120**
Misc. exp	0	0	0	0	0
Total Assets	**193,375**	**192,437**	**191,733**	**212,596**	**233,203**

Cash Flow

Y/E Mar (Rs mn)	FY19	FY20	FY21E	FY22E	FY23E
PBT (Ex-Other income)	**21,810**	**17,037**	**24,471**	**38,157**	**42,371**
Depreciation & Amortisation	5,986	6,965	7,023	7,270	7,336
Chg in working cap	6,378	1,294	(350)	(6,799)	(330)
Operating Cashflow	**29,137**	**26,453**	**28,658**	**32,088**	**41,565**
Capital expenditure	(10,464)	(8,888)	(8,000)	(8,000)	(8,000)
Free Cash Flow	**18,673**	**17,565**	**20,658**	**24,088**	**33,565**
Investments	(13,876)	0	0	0	0
Other Investing Cash Flow	0	0	0	0	0
Investing Cashflow	**(24,340)**	**(8,888)**	**(8,000)**	**(8,000)**	**(8,000)**
Equity Capital Raised	0	0	0	0	0
Loans Taken / (Repaid)	23,955	(3,489)	(17,036)	(5,450)	(9,878)
Dividend paid (incl tax)	(4,314)	(8,569)	(4,313)	(4,313)	(4,313)
Other Financing Cash Flow	(33,047)	(1,235)	772	609	1,676
Financing Cashflow	**(14,201)**	**(14,409)**	**(22,689)**	**(10,754)**	**(13,952)**
Net chg in cash	**(9,404)**	**3,156**	**(2,031)**	**13,334**	**19,613**
Opening cash position	15,897	6,493	9,649	7,618	20,952
Closing cash position	**6,493**	**9,649**	**7,618**	**20,952**	**40,565**

Source: Company, Emkay Research

Key Ratios

Profitability (%)	FY19	FY20	FY21E	FY22E	FY23E
EBITDA Margin	22.6	19.2	21.9	23.1	22.9
EBIT Margin	18.0	14.4	17.3	19.5	19.6
Effective Tax Rate	22.3	20.8	20.3	22.0	22.0
Net Margin	14.1	10.1	13.1	14.8	15.4
ROCE	14.4	10.9	14.2	20.2	20.1
ROE	17.9	12.3	16.5	20.9	19.9
RoIC	15.5	11.4	14.9	21.7	23.4

Per Share Data (Rs)	FY19	FY20	FY21E	FY22E	FY23E
EPS	18.1	14.1	20.2	29.9	34.0
CEPS	23.9	20.9	27.0	37.0	41.2
BVPS	101.5	101.4	117.8	143.9	174.1
DPS	3.1	3.6	3.6	3.6	3.6

Valuations (x)	FY19	FY20	FY21E	FY22E	FY23E
PER	26.1	33.5	23.4	15.8	13.9
P/CEPS	19.2	22.0	17.0	12.4	11.2
P/BV	4.7	4.7	4.0	3.3	2.7
EV / Sales	4.1	3.8	3.4	2.5	2.1
EV / EBITDA	18.3	19.7	15.6	10.8	9.3
Dividend Yield (%)	0.7	0.8	0.8	0.8	0.8

Gearing Ratio (x)	FY19	FY20	FY21E	FY22E	FY23E
Net Debt/ Equity	0.6	0.6	0.4	0.2	0.0
Net Debt/EBIDTA	2.1	2.1	1.3	0.5	(0.1)
Working Cap Cycle (days)	102.7	84.7	79.4	72.0	66.3

Growth (%)	FY19	FY20	FY21E	FY22E	FY23E
Revenue	10.3	8.3	7.9	32.7	9.5
EBITDA	4.4	(7.8)	22.6	39.9	8.8
EBIT	2.9	(13.9)	30.0	49.6	10.2
PAT	4.1	(36.4)	75.5	48.3	13.6

Quarterly (Rs mn)	Q2FY20	Q3FY20	Q4FY20	Q1FY21	Q2FY21
Revenue	33,666	36,381	37,521	36,399	38,200
EBITDA	6,256	6,932	7,912	8,154	8,634
EBITDA Margin (%)	**18.6**	**19.1**	**21.1**	**22.4**	**22.6**
PAT	1,072	3,739	4,351	4,540	4,734
EPS (Rs)	**1.0**	**3.7**	**4.2**	**4.4**	**4.6**

Source: Company, Emkay Research

Shareholding Pattern (%)	Dec-19	Mar-20	Jun-20	Sep-20	Dec-20
Promoters	74.9	74.9	74.9	74.9	74.9
FIIs	4.6	4.4	4.6	4.4	5.2
DIIs	12.6	12.9	12.6	12.5	11.7
Public and Others	7.9	7.8	8.0	8.2	8.2

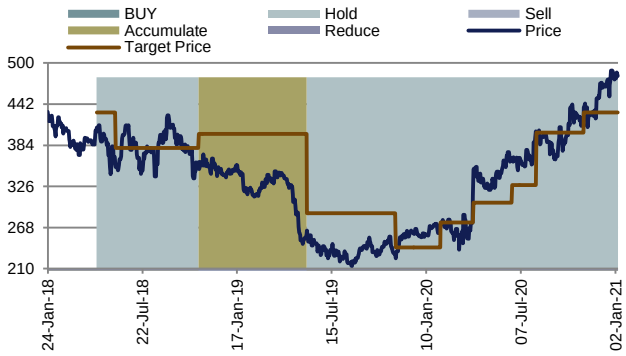
Source: Capitaline

RECOMMENDATION HISTORY TABLE

Date	Closing Price	TP	Period (months)	Rating	Analyst
16-Dec-20	469	430	12m	Hold	Kunal Dhamesha
03-Nov-20	438	430	12m	Hold	Kunal Dhamesha
05-Aug-20	396	402	12m	Hold	Praful Bohra
20-Jun-20	362	328	12m	Hold	Praful Bohra
08-Apr-20	350	303	12m	Hold	Praful Bohra
06-Feb-20	273	275	12m	Hold	Praful Bohra
16-Dec-19	261	240	12m	Hold	Praful Bohra
14-Nov-19	234	240	12m	Hold	Praful Bohra
13-Nov-19	225	240	12m	Hold	Praful Bohra
19-Aug-19	219	288	12m	Hold	Praful Bohra
29-May-19	264	288	12m	Hold	Praful Bohra
05-Nov-18	360	400	12m	Accumulate	Jatin Kotian
19-Sep-18	408	380	12m	Hold	Jatin Kotian
11-Jul-18	371	380	12m	Hold	Jatin Kotian
10-Jul-18	381	380	12m	Hold	Jatin Kotian
29-Jun-18	377	380	12m	Hold	Jatin Kotian
01-Jun-18	353	380	12m	Hold	Jatin Kotian
10-May-18	399	430	12m	Hold	Jatin Kotian
26-Apr-18	409	430	12m	Hold	Jatin Kotian

Source: Company, Emkay Research

RECOMMENDATION HISTORY CHART



Source: Bloomberg, Company, Emkay Research

Emkay Alpha Portfolio – Pharmaceuticals

Analyst: Dr. Kunal Dhamesha

Contact Details

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Sector

Pharmaceuticals

Analyst bio

Dr. Kunal Dhamesha holds an MBA from IIM Lucknow and completed his MBBS from B.J. Medical College. As an equity analyst he has tracked multiple healthcare verticals for 8+ years. His team currently covers 7 stocks.

EAP sector portfolio

Company Name	BSE200 Weight	EAP Weight	OW/UW (%)	OW/UW (bps)	EAP Weight (Normalised)
Pharmaceuticals	**2.99**	**2.84**	**-5%**	**-16**	**100.00**
Aurobindo Pharma	0.31	0.29	-9%	-3	9.55
Cadila Healthcare	0.15	0.12	-20%	-3	3.95
Cipla	0.51	0.53	4%	2	17.75
Dr. Reddy's Lab	0.76	0.83	10%	7	27.77
Ipca Lab	0.17	0.14	-21%	-4	4.61
Lupin	0.32	0.31	-1%	0	10.44
Sun Pharma	0.78	0.62	-20%	-16	20.70
Cash	**0.00**	**0.16**	**NA**	**16**	**5.23**

Source: Emkay Research

** Not under coverage: Equal Weight*

High Conviction/Strong Over Weight High Conviction/Strong Under Weight

Sector portfolio NAV

	Base					Latest
	01-Apr-19	23-Jan-20	23-Jul-20	22-Oct-20	22-Dec-20	21-Jan-21
EAP - Pharmaceuticals	100.0	97.9	131.6	153.6	163.8	166.4
BSE200 Neutral Weighted Portfolio (ETF)	100.0	94.7	121.0	137.4	148.7	152.1

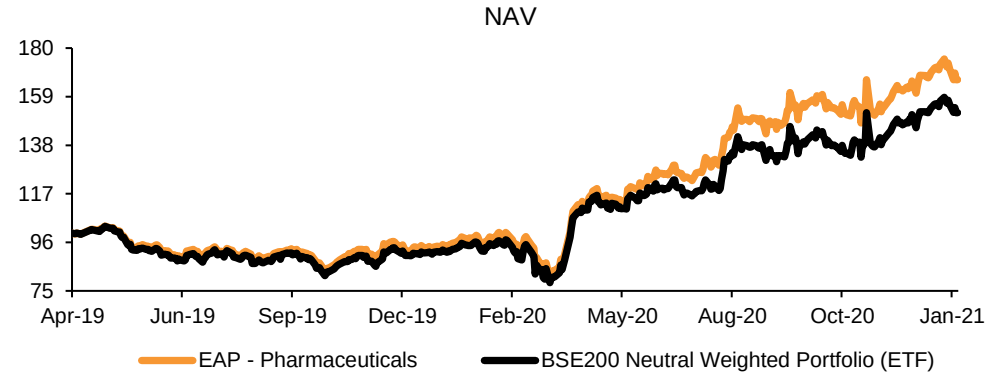
**Performance measurement base date 1st April 2019*
Source: Emkay Research

Price Performance (%)

	1m	3m	6m	12m
EAP - Pharmaceuticals	1.6%	8.3%	26.4%	70.0%
BSE200 Neutral Weighted Portfolio (ETF)	2.3%	10.7%	25.7%	60.7%

Source: Emkay Research

NAV chart



Source: Emkay Research

Please see our model portfolio (Emkay Alpha Portfolio): Nifty

Please see our model portfolio (Emkay Alpha Portfolio): SMID

"Emkay Alpha Portfolio – SMID and Nifty are a supporting document to the Emkay Alpha Portfolios Report and is updated on regular intervals"

Emkay Rating Distribution

Ratings	Expected Return within the next 12-18 months.
BUY	Over 15%
HOLD	Between -5% to 15%
SELL	Below -5%

Completed Date: 22 Jan 2021 23:51:41 (SGT)
Dissemination Date: 22 Jan 2021 23:52:41 (SGT)

Sources for all charts and tables are Emkay Research unless otherwise specified.

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