AXIS DIRECT

03 OCT 2017 | Company Update

DIVI'S LABORATORIES

PHARMACEUTICALS

BUY

Target Price: Rs 1,080

Quick resolution a positive surprise; BUY

We are positively surprised on fast remediation by Divi's followed by quick USFDA re-inspection. Form 483 observations issued in Dec'16 on Unit 2 facility (under Import Alert) have been confirmed as completed and resolved (EIR awaited) after USFDA re-inspection. We believe this could be due to large dependence of innovator/generic companies for key drugs on Divi's. However, Divi's has received another form 483 with 6 new observations (largely procedural as per the management).

As some remediation activity is going on and with closure of Import Alert/EIR awaited, we expect earnings to start improving from end FY18/FY19. We increase FY19E EPS by 15%. With improved visibility on USFDA resolution, we raise multiple to its historical level (on strong chemistry skills/manufacturing excellence) **upgrading Divi's to BUY** with a revised TP of Rs 1,080 (24x FY19E) vs. Rs 625 (16x FY19E) earlier.

CMP	: Rs 943
Potential Upside	: 15%

MARKET DATA

No. of Shares	: 265 mn
Free Float	: 48%
Market Cap	: Rs 250 bn
52-week High / Low	: Rs 1,355 / Rs 533
Avg. Daily vol. (6mth)	: 2.2 mn shares
Bloomberg Code	: DIVI IB Equity
Promoters Holding	: 52%
FII / DII	: 15% / 16%

- **Positively surprised on fast remediation** by Divi's, followed by quick USFDA re-inspection (Form 483 in Dec'16, import alert in Mar'17, warning letter in Apr'17). USFDA conducted cGMP (Good Manufacturing Practices) inspection for verification of all proposed corrective actions at Divi's Unit -2 Visakhapatnam facility from Sep 11-19, 2017, resulting in resolution of Form 483 observations issued in Dec'16 – which required significant and comprehensive corrective actions in our view. USFDA had also laid out a comprehensive remediation plan in the WL and mandated global corrective action and preventive action plan
- **Upside to management guidance:** Post Q1FY18 results, Divi's guided for 10% YoY constant currency revenue decline for FY18 (vs. 19% YoY revenue decline in Q1FY18, 8% YoY growth in FY17) with EBITDA margin of ~32-33% (vs 29.8% in Q1FY18, 37.1% in FY17) factoring in ~18-24 months remediation timeline. However, earlier than expected remediation of Unit 2 will result in upward revision of management guidance with further pick-up in earnings from FY19. US sales from Unit 2 contributed ~21-22% to Divi's FY17 sales, with ~17% contributed by the exempted products. We build in 16% revenue growth, coupled with 250 bps EBITDA margin improvement in FY19

Financial summary (Consolidated)

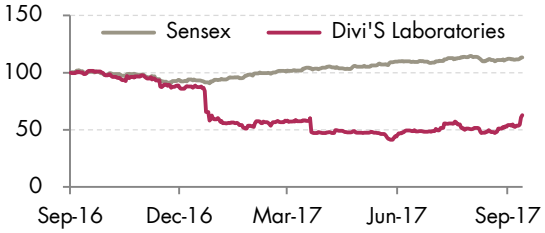
Y/E March	FY16	FY17	FY18E	FY19E
Sales (Rs mn)	38,049	41,063	38,925	45,138
Adj PAT (Rs mn)	11,258	11,396	9,373	11,771
Con. EPS* (Rs)	-	-	35.2	39.0
EPS (Rs)	43.0	43.6	35.8	45.0
Change YOY (%)	29.8	1.2	(17.7)	25.6
P/E (x)	21.9	21.6	26.3	20.9
RoE (%)	28.9	23.6	16.8	19.3
RoCE (%)	34.7	29.8	21.2	24.5
EV/E (x)	17.1	15.3	18.1	14.5
DPS (Rs)	10.0	10.0	15.0	20.0

Source: *Consensus broker estimates, Company, Axis Capital

Key drivers

(%)	FY17	FY18E	FY19E
Revenue growth	8	-5	16
EBITDA margin	37.1	32.8	35.3
Gross margin	62.6	60.0	60.5

Price performance



- **Greenfield capex delayed; expanding existing capacity:** Divi's greenfield capex plans have been delayed (Vizag & Kakinada). Divi's is maneuvering its existing capacities to derive higher yields, in the interim. Over FY12-17, Divi's increased its reactor capacities by 2-14% across plants, which helped it yield higher output without substantial capex, and ensured higher RoI
- **Potential special dividend/buyback:** Divi's has high net cash of Rs 18 bn as of end Jun'17 (vs. Rs 17.1 bn as at Mar '17), which could potentially be distributed to shareholders given delay in capex (above the annual dividend payout – Rs 2.6 bn in FY17)
- **Raise multiple:** Resolution of Form 483 issued in Dec'16 will certainly improve sentiment and restore customer confidence in Divi's quality and speedy delivery mechanism along with competitive cost structure. Accordingly, we increase the multiple to historical level of 24x (from earlier 16x) given it is in a sweet spot with its strong chemistry skills/manufacturing excellence (ability to improve manufacturing yields) and big pharma's focus on R&D productivity/cost reduction

Exhibit 1: Form 483 observations issued by USFDA in Dec'16

Sr. No	Observations	FDA view	Our view
1	Proper controls not being exercised over computerized systems used for analytical testing to ensure drug products meet their specified quality attributes	The FDA has pointed out 2 separate observations. ♦ Several instances wherein unknown impurities are not accurately assessed or not reported. FDA has cited several instances wherein a product with unknown/higher than specified impurities was released into the market ♦ FDA cited that the R&D Division's chromatographic systems did not have audit trails enabled or enabled audit trails on Nov 27, 2016, or enabled audit trails on Nov 27, 2016	Observation 1A seems serious in nature
2	Facilities, Equipment not maintained to ensure Purity, Quality, Strength and Identity of the API	The FDA has pointed out 2 separate observations. ♦ FDA has pointed out 4 instances wherein it observed unexplained colored residue in API's intended for the US market. Additionally FDA had concerns relating to cross contamination of the residue with the API ♦ FDA cited 2 specific instance relating to improper cleaning maintenance of equipment used to manufacture API for the US market	
3	R&D division guides Quality, Production to commence activities Inconsistent with CGMP's	The FDA has pointed out 9 specific instances where R&D division guided Quality/production team to neglect test results with Out of Specific result or to perform the test again .Concerns also relating to inadequate investigation into root cause for OOS results	Observation seems serious in nature
4	Failure to conduct a thorough investigation	Concern relating to inadequate investigation into 2 customer complaints relating to presence of foreign particles. Additionally concerns relating to improper/inadequate cleaning procedures for manufacturing equipment used to manufacture intermediate/starting material for 7 products	
5	Documentation and Records are either not maintained or inaccurate/Falsified	FDA has pointed out 1 specific instance wherein documents relating to inter office memorandum between QCD and R&D were falsified, IOM's were incinerated. Also concerns relating to Customer complaint log not accounting for customer complaints, and discrepancy in cleaning status of Equipment status tag and Usage log	Observation seems serious in nature

Source: USFDA, Axis Capital

Divi's had sent a detailed response to the Form 483 issued by the USFDA in Dec'16 outlining its corrective and preventive actions.

Exhibit 2: 483 observations – Divi's has outlined responses to USFDA issues including product impurities and falsification of data

Sr. No	Observations	Divis initially proposed corrective actions
1	Proper controls not being exercised over computerized systems used for analytical testing to ensure drug products meet their specified quality attributes	♦ Extended impact assessment for inhibit integration of 1950 batches to be performed. (As of date 60 % of the batches completed). ♦ Part 11 compliance for non-chromatographic systems and connection of chromatographic systems to server in GMP process support lab. ♦ To segregate roles and responsibilities for GMP process support lab and QC.
2	Facilities, Equipment not maintained to ensure Purity, Quality, Strength and Identity of the API	♦ Appropriate batch records are modified for identifying discolored product at inter batch cleaning and increasing the illumination levels for better visual inspection. ♦ Protocols being initiated to study the quality of discolored product, if any ♦ All glass lined reactors are being spark tested to check integrity of glass lining
3	R&D division guides Quality, Production to commence activities Inconsistent with CGMP's	♦ Review of company's quality systems being done by external consultants. ♦ Startup of process support lab.
4	Failure to conduct a thorough investigation	♦ Review of process filter installation procedures for break through resulting in OOS for metals and assessing the effectiveness of equipment. ♦ Monitoring of effectiveness of corrective and preventive actions (CAPAs) through self-inspections.
5	Documentation and Records are either not maintained or inaccurate/Falsified	♦ Upgrading existing systems by implementation of electronic data management systems (eDMS) and electronic quality management systems (eQMS) ♦ Monitoring the effectiveness of corrective and preventive actions (CAPAs) through self-inspections

Source: Company

Exhibit 3: Divi's Warning Letter observations

Sr. No	Observations	FDA view	Divi's remediation response	FDA guided remediation measure
1	Failure to ensure that test procedures are scientifically sound and appropriate to ensure that your API conform to established standards of quality and/or purity.	♦ FDA investigators observed that the software used to conduct high performance liquid chromatography (HPLC) analyses of API for unknown impurities was **configured to permit extensive use of the "inhibit integration" function without scientific justification**	♦ Updated its procedure "Peak Integration Techniques for Chromatography" to include controls on the use of inhibit integration events	♦ USFDA is not satisfied with the summary data provided by Divi's Lab as in its view, it does not demonstrate that previously released lots do not contain excessive levels of unknown impurities
		♦ FDA is concerned that Inhibiting integration at various points during release testing for commercial batches **can mask identification and quantitation of impurities in API,** which may result in releasing API that do not conform to specifications	♦ Extended impact assessment for inhibit integration of 1950 batches to be performed.	♦ USFDA has communicated **to Divi's to provide updated analyses of all lots within expiry** that take into account any changes to specific test methods and chromatographic parameters.
2	Failure to prevent unauthorized access or changes to data and failure to provide adequate controls to prevent manipulation and omission of data.	♦ FDA investigators discovered a lack of basic laboratory controls to prevent changes to and deletions from Divi's electronically-stored data in laboratories where it conducts CGMP activities.	♦ Enabled audit trail functionality for all chromatographic systems in its laboratories	♦ As per the USFDA, Divi's response does not demonstrate how the specific controls it has implemented prevent deletion or alteration of data,
		♦ Specifically, **audit trail functionality** for some systems used to conduct CGMP operations **was enabled only the day before the inspection**, and there were no quality unit procedures in place to review and evaluate the audit trail data.	♦ Procedural updates requiring review and evaluation of the data generated by these systems.	♦ FDA is also concerned on how Divi's Labs will ensure that these controls are documented, implemented, and followed.
		♦ USFDA also found **use of uncontrolled systems to conduct out-of-specification (OOS) investigations** for in-process materials used to manufacture API.		
3	Limiting access to or copying of records	♦ FDA investigators **were given limited access** to certain records, Specifically audit trail data from all chromatographic systems used to test drugs for the U.S. market at facility. ♦ The files ultimately provided by Divi's were in the form of Excel spread sheets rather than direct exports from its chromatographic software, and were not the original records or true copies, and showed signs of manipulation. ♦ FDA investigators explained to the company, that failure to provide the requested original audit trail records would be documented as a refusal, to which the personnel acknowledged the refusal. ♦ At multiple times during the inspection, FDA requested records of CGMP activities performed in Divis R&D laboratories at the behest of its quality unit. However, **the company limited the inspection by providing only a subset of the requested records** ♦ **Additionally investigators found at least one of the requested records shredded in the trash.**		

Source: USFDA, Axis Capital

Exhibit 4: Divi's garnered ~73% of FY17 revenue from clients in America and Europe

Region	2016-17 Sales (Rs mn)	% share	2015-16 Sales (Rs mn)	% share
Asia	4,728	12%	3,944	11%
Europe	16,283	40%	16,035	43%
America	13,381	33%	11,858	32%
Rest of the World	946	2%	808	2%
India	5,210	13%	4,780	12%
Total	**40,547**	**100%**	**37,425**	**100%**

Source: Company, Axis capital

Exhibit 5: ~87%of Divi's FY17 revenue were from exports

Particulars	FY17	FY16
Exports	87%	87%
Imports (% of material consumption)	58%	55%
Largest Product (Naproxen)	16%	18%
Top 5 Products	43%	43%
Top 5 Customers	41%	38%
Exports (USD)	85%	83%
Exports (GBP)	11%	14%
Exports (EUR)	4%	3%

Source: Company, Axis Capital

Exhibit 6: Divi's has 4 dedicated manufacturing facilities - increased its reactor capacities by 2-14% over FY12-17

Facility	Location	Reactors						CAGR	Capacity (m^3)
		FY12	FY13	FY14	FY15	FY16	FY17	FY12-17	FY17
Unit 1	Lingojigudem (Telangana)	322	342	356	362	362	362	2%	1,762
Export Oriented Unit (Unit 2)	Chippada (Andhra Pradesh)	175	186	186	195	192	232	6%	1,721
SEZ Unit (Unit 2)	Chippada (Andhra Pradesh)	253	299	324	342	420	487	14%	3,244
DSN SEZ Unit (Unit 2)	Chippada (Andhra Pradesh)	186	205	234	276	254	299	10%	2,846

Source: Company, Axis Capital

Exhibit 7: Asset turnover has been consistently above 1.5x over last 5 years

	FY12	FY13	FY14	FY15	FY16	FY17
Asset Turnover (x)	1.7	1.6	1.5	1.6	1.7	1.7

Source: Company, Axis Capital

Financial summary (Consolidated)

Profit & loss (Rs mn)

Y/E March	FY16	FY17	FY18E	FY19E
Net sales	38,049	41,063	38,925	45,138
Other operating income	-	-	-	-
Total operating income	**38,049**	**41,063**	**38,925**	**45,138**
Cost of goods sold	(17,679)	(18,830)	(19,268)	(21,666)
Gross profit	20,370	22,232	19,657	23,472
Gross margin (%)	*53.5*	*54.1*	*50.5*	*52.0*
Total operating expenses	(6,196)	(6,981)	(6,909)	(7,561)
EBITDA	**14,174**	**15,252**	**12,748**	**15,911**
EBITDA margin (%)	*37.3*	*37.1*	*32.8*	*35.3*
Depreciation	(1,182)	(1,233)	(1,450)	(1,646)
EBIT	**12,992**	**14,018**	**11,298**	**14,265**
Net interest	(38)	(23)	(25)	(23)
Other income	974	749	900	1,046
Profit before tax	**13,928**	**14,745**	**12,173**	**15,287**
Total taxation	(2,671)	(3,349)	(2,800)	(3,516)
Tax rate (%)	*19.2*	*22.7*	*23.0*	*23.0*
Profit after tax	11,258	11,396	9,373	11,771
Minorities	-	-	-	-
Profit/ Loss associate co(s)	-	-	-	-
Adjusted net profit	11,258	11,396	9,373	11,771
Adj. PAT margin (%)	*29.6*	*27.8*	*24.1*	*26.1*
Net non-recurring items	-	(791)	-	-
Reported net profit	11,258	10,604	9,373	11,771

Balance sheet (Rs mn)

Y/E March	FY16	FY17	FY18E	FY19E
Paid-up capital	531	531	531	531
Reserves & surplus	42,402	53,043	57,695	63,171
Net worth	42,933	53,574	58,226	63,702
Borrowing	419	357	357	357
Other non-current liabilities	731	1,228	1,228	1,228
Total liabilities	**44,083**	**55,160**	**59,811**	**65,288**
Gross fixed assets	21,961	24,398	27,398	31,398
Less: Depreciation	(7,573)	(8,806)	(10,257)	(11,903)
Net fixed assets	14,388	15,592	17,142	19,495
Add: Capital WIP	2,639	4,436	4,436	4,436
Total fixed assets	17,027	20,028	21,577	23,931
Total Investment	8,025	16,307	16,307	16,307
Inventory	12,078	13,199	11,731	13,603
Debtors	8,809	8,985	9,065	11,130
Cash & bank	738	787	4,198	3,954
Loans & advances	1	3	3	3
Current liabilities	4,897	6,390	5,311	5,882
Net current assets	19,031	18,825	21,927	25,050
Other non-current assets	-	-	-	-
Total assets	**44,083**	**55,160**	**59,811**	**65,288**

Source: Company, Axis Capital

Cash flow (Rs mn)

Y/E March	FY16	FY17	FY18E	FY19E
Profit before tax	13,928	14,745	12,173	15,287
Depreciation & Amortisation	1,182	1,233	1,450	1,646
Chg in working capital	*(1,550)*	*(371)*	*309*	*(3,366)*
Cash flow from operations	**10,888**	**11,114**	**9,357**	**7,983**
Capital expenditure	*(3,957)*	*(3,767)*	*(3,000)*	*(4,000)*
Cash flow from investing	**(4,629)**	**(12,049)**	**(3,000)**	**(4,000)**
Equity raised/ (repaid)	-	-	-	-
Debt raised/ (repaid)	*158*	*(62)*	-	-
Dividend paid	*(6,390)*	*(3,147)*	*(4,721)*	*(6,295)*
Cash flow from financing	**(6,241)**	**(3,231)**	**(4,746)**	**(6,318)**
Net chg in cash	18	(4,166)	1,611	(2,335)

Key ratios

Y/E March	FY16	FY17	FY18E	FY19E
OPERATIONAL				
FDEPS (Rs)	43.0	43.6	35.8	45.0
CEPS (Rs)	38.5	35.8	30.3	38.7
DPS (Rs)	10.0	10.0	15.0	20.0
Dividend payout ratio (%)	23.2	24.7	41.9	44.4
GROWTH				
Net sales (%)	22.6	7.9	(5.2)	16.0
EBITDA (%)	22.9	7.6	(16.4)	24.8
Adj net profit (%)	29.8	1.2	(17.7)	25.6
FDEPS (%)	29.8	1.2	(17.7)	25.6
PERFORMANCE				
RoE (%)	28.9	23.6	16.8	19.3
RoCE (%)	34.7	29.8	21.2	24.5
EFFICIENCY				
Asset turnover (x)	1.2	1.1	1.0	1.1
Sales/ total assets (x)	0.8	0.7	0.6	0.7
Working capital/ sales (x)	0.4	0.4	0.5	0.4
Receivable days	84.5	79.9	85.0	90.0
Inventory days	184.7	186.7	163.6	169.9
Payable days	35.6	54.3	35.7	36.6
FINANCIAL STABILITY				
Total debt/ equity (x)	-	-	-	-
Net debt/ equity (x)	(0.2)	(0.3)	(0.4)	(0.3)
Current ratio (x)	4.9	3.9	5.1	5.3
Interest cover (x)	343.7	623.0	451.9	620.2
VALUATION				
PE (x)	21.9	21.6	26.3	20.9
EV/ EBITDA (x)	17.1	15.3	18.1	14.5
EV/ Net sales (x)	6.4	5.7	5.9	5.1
PB (x)	5.7	4.6	4.2	3.9
Dividend yield (%)	1.1	1.1	1.6	2.1
Free cash flow yield (%)	-	-	-	-

Source: Company, Axis Capital

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