AXIS DIRECT

DIVI'S LABORATORIES

PHARMACEUTICALS

6 JUN 2017 Quarterly Update

HOLD

Target Price: Rs 600

Weak Q4; import alert poses growth challenges

Q4 revenue declined 3% YoY in line with our estimate, while EBITDA adjusted for Rs 290 mn of forex loss at Rs 3.9 bn was 9% below our estimate. Adj. PAT declined 10% YoY at Rs 2.88 bn, 12% below our estimate. Despite import alert, Divi's has guided for 5-10% cc^ revenue growth for FY18,as USFDA has exempted Divi's 18 products giventhe company is a key supplier of these products. It guided for capex of Rs 7-8 bn over next 2-3 years. It has responded to USFDA on its Unit 2 Vizag plant warning letter within stipulated timelines.

Despite attractive valuations, we remain cautious as growth could be impacted by reactions of its customers (both innovators/generic companies across regions) given USFDA import alert on its Unit 2 plant. We maintain our FY18/19E EPS and **HOLD** rating with a revised TP of Rs 600 (16x FY19E EPS) vs. Rs 680 earlier (18x FY19E EPS).

CMP	: Rs 547
Potential Upside	: 10%

MARKET DATA

No. of Shares	: 265mn
Free Float	: 48%
Market Cap	: Rs145bn
52-week High / Low	: Rs1,380 / Rs541
Avg. Daily vol. (6mth)	: 2.2 mn shares
Bloomberg Code	: DIVI IB Equity
Promoters Holding	: 52%
FII / DII	: 17% / 14%

- **Generic: Custom Synthesis (CS)**contribution to revenue was stable at 56:44 with 6% YoY decline in generics and3% YoY decline in CS business. Neutraceuticals revenue was Rs 570 mn (Rs 2.4 bn in FY17) and grew 21% YoY/flat QoQ
- **USFDA remediation update:** Divi's has responded to theform 483 observations and to the USFDA Warning Letter (WL) within the stipulated timelines. The WL issued to Divi's Unit 2 Vizag plant citesthe deviations from current Good Manufacturing Practices (cGMP) for API's* and Divi's limiting/refusing USFDA inspection. USFDA has laid out a comprehensive remediation plan in the WL and mandated global corrective action and preventive action plan
- **Greenfield capex delayed**; **looking at another site**: Divi's greenfield capex plan has been delayed due to (1) local agitation on its 80 acre land site opposite to its existing Vizag facility (Rs 3 bn); construction expected to begin in FY18 and (2) Kakinada project (Rs 5 bn) – handover by government is complete but farmer agitation has delayed construction. Accordingly, the company is focusing on augmenting its existing capacities and also looking at another site. It has high cash balance of Rs 17.1 bn as of end FY17 (vs. 8.7 bn in FY16)

Financial summary (Consolidated)

Y/E March	FY16	FY17	FY18E	FY19E
Sales (Rs mn)	38,049	41,063	42,164	43,677
Adj PAT (Rs mn)	11,258	11,396	9,380	9,814
Con. EPS* (Rs)	-	-	42.2	42.9
EPS (Rs)	43.0	43.6	35.9	37.5
Change YOY (%)	29.8	1.2	(17.7)	4.6
P/E (x)	12.7	12.5	15.2	14.6
RoE (%)	28.9	23.6	16.7	16.2
RoCE (%)	34.7	29.8	21.7	21.1
EV/E (x)	9.6	8.4	9.6	9.0
DPS (Rs)	10.0	10.0	15.0	20.0

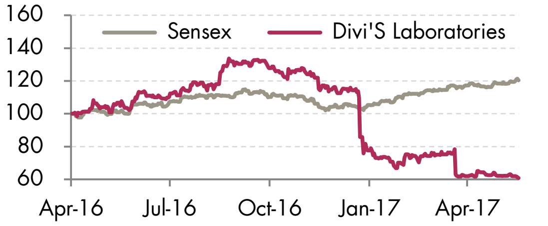
Source: *Consensus broker estimates, Company, Axis Capital

cc -constant currency;API – Active Pharmaceutical Ingredient

Key drivers

(%)	FY17	FY18E	FY19E
Revenue growth	8	3	4
EBITDA margin	37.1	31.3	32.0
Gross margin	62.6	59.5	59.6

Price performance



- **Tax rates to inch up in FY18/19:** Tax exemptions for Divi's DSN 1 facility have been cut down to 50% (fully exempted earlier). Additionally, its SEZ 1 facility would no longer enjoy tax advantages. Accordingly, Divi's expects its tax rates to inch up to 24-25% over the next 2 years

Exhibit 1: Muted growth in Q4'17

(Rs mn)	Q4'16	Q3'17	Q4'17	YoY (%)	QoQ (%)
Custom Synthesis	4,846	4,380	4,678	(3)	7
Generics	5,698	4,784	5,384	(6)	13
Neutraceuticals	470	570	570	21	-
Revenue	11,014	9,734	10,631	(3)	9
Gross Profit	6,323	6,259	6,456	2	3
Gross margin	57.4	64.3	60.7	332 bps	-356 bps
Staff Cost	987	981	999	1	2
Other Expenses	1,324	1,469	1,547	17	5
% of revenue	12.0	15.1	14.6	253 bps	-54 bps
EBITDA	**4,012**	**3,808**	**3,910**	**(3)**	**3**
EBITDA margin	**36.4**	**39.1**	**36.8**	**35 bps**	**-234 bps**
Other Income	173	178	209	21	17
Interest	22	4	10	(53)	136
Depreciation	292	310	314	8	2
PBT	3,871	3,672	3,795	(2)	3
Tax	631	996	912	45	(8)
Tax rate	16	27	24	773 bps	-309 bps
PAT (adj)	**3,240**	**2,677**	**2,883**	**(11)**	**17**
Ext. income/(exp)	(20)	7	(290)	-	-
PAT	**3,220**	**2,683**	**2,593**	**(19)**	**(3)**

Source: Company, as per Ind-AS
Q4'17 PAT/EBITDA adjusted for Rs 290 mn forex loss, Q4'16 PAT/EBITDA adjusted for Rs 20 mn forex loss
Q3'17 PAT/other income adjusted for Rs 6.5mn forex gain

Divi's Unit-2 Vizag plant was issued an Import Alert #66-40 – citing cGMP issues and Import Alert #99-32 – refusing USFDA inspection on March 20, 2017. USFDA issued a Warning Letter to Divi's Unit-2 Vizag plant on April 13,2017. Unit 2 accounts for ~65% of total sales and, US markets (direct + indirect) contribute ~35% to total sales. Accordingly, US sales from Unit 2 contribute ~22-23% to total sales. Of this, ~17% is contributed by the 10 exempted products (details in exhibit 2); with other non-exempted products contributing ~5% to total sales. Divis received exemption from USFDA for 8 more products in Apr'17

Exhibit 2: Products initially excluded from import alert

Sr no	API/intermediate
1	Levetiracetam
2	Gabapentin
3	Lamotrigine
4	Capecitabine
5	Naproxen Sodium
6	Raltegravir potassium
7	Atovaquone
8	Chloropurine
9	BOC core succinate
10	2,4-wing active ester

Source: Company, Axis Capital

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** ♦ 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	♦ Updated its procedure "Peak Integration Techniques for Chromatography" to include controls on the use of inhibit integration events ♦ Extended impact assessment for inhibit integration of 1950 batches to be performed.	♦ 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 ♦ 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. ♦ 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. ♦ USFDA also found **use of uncontrolled systems to conduct out-of-specification (OOS) investigations** for in-process materials used to manufacture API.	♦ Enabled audit trail functionality for all chromatographic systems in its laboratories ♦ Procedural updates requiring review and evaluation of the data generated by these systems.	♦ As per the USFDA, Divi's response does not demonstrate how the specific controls it has implemented prevent deletion or alteration of data, ♦ FDA is also concerned on how Divi's Labs will ensure that these controls are documented, implemented, and followed.
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 Divi's 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: 483 observations – Divi's has outlined responses to USFDA issues including product impurities and falsification of data

Sr.No	Observations	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, Productionto 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, USFDA

Financial summary (Consolidated)

Profit &loss (Rsmn)

Y/E March	FY16	FY17	FY18E	FY19E
Net sales	38,049	41,063	42,164	43,677
Other operating income	-	-	-	-
Total operating income	**38,049**	**41,063**	**42,164**	**43,677**
Cost of goods sold	(17,679)	(18,830)	(21,293)	(21,817)
Gross profit	20,370	22,232	20,871	21,860
Gross margin (%)	*53.5*	*54.1*	*49.5*	*50.1*
Total operating expenses	(6,196)	(6,981)	(7,695)	(7,906)
EBITDA	**14,174**	**15,252**	**13,176**	**13,955**
EBITDA margin (%)	*37.3*	*37.1*	*31.3*	*32.0*
Depreciation	(1,182)	(1,233)	(1,295)	(1,470)
EBIT	**12,992**	**14,018**	**11,881**	**12,485**
Net interest	(38)	(23)	(75)	(100)
Other income	974	749	700	700
Profit before tax	**13,928**	**14,745**	**12,506**	**13,085**
Total taxation	(2,671)	(3,349)	(3,127)	(3,271)
Tax rate (%)	*19.2*	*22.7*	*25.0*	*25.0*
Profit after tax	11,258	11,396	9,380	9,814
Minorities	-	-	-	-
Profit/ Loss associate co(s)	-	-	-	-
Adjusted net profit	11,258	11,396	9,380	9,814
Adj. PAT margin (%)	*29.6*	*27.8*	*22.2*	*22.5*
Net non-recurring items	-	(791)	-	-
Reported net profit	11,258	10,604	9,380	9,814

Balance sheet (Rsmn)

Y/E March	FY16	FY17	FY18E	FY19E
Paid-up capital	531	531	531	531
Reserves & surplus	42,402	53,043	58,000	61,916
Net worth	42,933	53,574	58,530	62,447
Borrowing	419	357	1,200	600
Other non-current liabilities	731	1,228	1,228	1,228
Total liabilities	**44,083**	**55,160**	**60,959**	**64,275**
Gross fixed assets	21,961	24,398	27,398	31,398
Less: Depreciation	(7,573)	(8,806)	(10,101)	(11,571)
Net fixed assets	14,388	15,592	17,297	19,827
Add: Capital WIP	2,639	4,436	4,436	4,436
Total fixed assets	17,027	20,028	21,733	24,263
Total Investment	8,025	16,307	16,307	16,307
Inventory	12,078	13,199	12,707	13,163
Debtors	8,809	8,985	9,819	10,770
Cash & bank	738	787	3,707	3,383
Loans & advances	1	3	3	3
Current liabilities	4,897	6,390	5,559	5,856
Net current assets	19,031	18,825	22,919	23,705
Other non-current assets	-	-	-	-
Total assets	**44,083**	**55,160**	**60,959**	**64,275**

Source: Company, Axis Capital

Cash flow (Rsmn)

Y/E March	FY16	FY17	FY18E	FY19E
Profit before tax	13,928	14,745	12,506	13,085
Depreciation & Amortisation	1,182	1,233	1,295	1,470
Chg in working capital	*(1,209)*	*256*	*(1,174)*	*(1,110)*
Cash flow from operations	10,897	11,409	8,176	8,874
Capital expenditure	*(3,957)*	*(4,000)*	*(3,000)*	*(4,000)*
Cash flow from investing	(4,629)	(12,282)	(3,000)	(4,000)
Equity raised/ (repaid)	-	-	-	-
Debt raised/ (repaid)	*158*	*(62)*	*843*	*(600)*
Dividend paid	*(6,390)*	*(3,147)*	*(4,423)*	*(5,898)*
Cash flow from financing	(6,241)	(3,231)	(3,656)	(6,598)
Net chg in cash	27	(4,104)	1,520	(1,724)

Key ratios

Y/E March	FY16	FY17	FY18E	FY19E
OPERATIONAL				
FDEPS (Rs)	43.0	43.6	35.9	37.5
CEPS (Rs)	38.5	35.8	30.9	31.9
DPS (Rs)	10.0	10.0	15.0	20.0
Dividend payout ratio (%)	23.2	24.7	41.8	53.3
GROWTH				
Net sales (%)	22.6	7.9	2.7	3.6
EBITDA (%)	22.9	7.6	(13.6)	5.9
Adj net profit (%)	29.8	1.2	(17.7)	4.6
FDEPS (%)	29.8	1.2	(17.7)	4.6
PERFORMANCE				
RoE (%)	28.9	23.6	16.7	16.2
RoCE (%)	34.7	29.8	21.7	21.1
EFFICIENCY				
Asset turnover (x)	1.2	1.1	1.1	1.1
Sales/ total assets (x)	0.8	0.7	0.7	0.6
Working capital/ sales (x)	0.4	0.4	0.4	0.5
Receivable days	84.5	79.9	85.0	90.0
Inventory days	184.7	186.7	160.0	161.6
Payable days	35.6	54.3	35.3	35.7
FINANCIAL STABILITY				
Total debt/ equity (x)	-	-	-	-
Net debt/ equity (x)	(0.2)	(0.3)	(0.3)	(0.3)
Current ratio (x)	4.9	3.9	5.1	5.0
Interest cover (x)	343.7	623.0	158.4	124.8
VALUATION				
PE (x)	12.7	12.5	15.2	14.6
EV/ EBITDA (x)	9.6	8.4	9.6	9.0
EV/ Net sales (x)	3.6	3.1	3.0	2.9
PB (x)	3.3	2.7	2.4	2.3
Dividend yield (%)	1.8	1.8	2.7	3.7
Free cash flow yield (%)	-	0.1	-	-

Source: Company, Axis Capital

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