

Institutional Equity Research

Aurobindo Pharma

Pharmaceuticals | India

Event Update | October 09, 2019

CMP* (Rs)	459
Upside/ (Downside) (%)	25
Bloomberg Ticker	ARBP IN
Market Cap. (Rs bn)	269
Free Float (%)	48
Shares O/S (mn)	586

BUY 

Target Price: Rs575

US FDA Issues Form 483 with Seven Observations to Unit-VII

The US FDA has issued Form 483 with seven observations to Aurobindo Pharma's (ARBP) Unit-VII facility. This is an important facility of ARBP, which contributes ~20% to its US sales with 139 final approvals and 33 pending ANDAs (including tentative approvals). Earlier, the US FDA inspected the facility between during September 19-27, 2019. As per the Management, as there is no data integrity issue, the possibility of import alert is very minimal. As per a regulatory expert, the first two observations are of very serious nature, which may lead to issuance of OAI status in the near-term. Also, he expects the US FDA may ask ARBP to review full data generated at the plant for >100 products to third party, which means this will take more than one year for CAPA. We note that first observation is common in ARBP's recent Form 483s, which the US FDA considers as serious. Certainly, there will be delay in new product approvals from the facility. Notably, ARBP's cumulative ANDA filings stood at 551 (approved: 412; pending: 139).

Other Facilities Face Regulatory Issues Too

ARBP's three facilities (API: Unit I and XI; Intermediates: Unit IX; inspection conducted in Feb-19; sartan impurity) have OAI status. Out of which Unit-XI received warning letter with 3 observations from the US FDA, while Unit I and IX have pending 6 and 5 observations (one common observation with Unit XI). OAI status means regulatory actions will be recommended and the US FDA may withhold approval of any pending applications from the facility. Though this action indicates that there is high probability of getting WL for the said plant, which will have considerable impact on future product approvals from the said facility. However, it is unlikely to have any impact on existing sales contribution. During 1QFY20 earnings con-call, the management highlighted that all the remedial measures will be done by the end of CY19, subsequent to which it expects the US FDA re-inspection at all three units. It also indicated that total 15 products (including injectables) were awaiting approvals over the next two years. On Unit-III (10 observations; inspection conducted in May-19; no new filings from the plant), ARBP is sending periodic updates to the US FDA post detailed CAPA. Unit-III has 115 final approvals, while 12 ANDAs are pending.

Elevated Concerns over ARBP's Ability in Dealing with Regulatory Issues

Current US FDA pending issues such as: (1) three OAI status plants including one warning letter (WL); (2) 7 observations to Unit-VII; (3) 10 observations to Unit-III and high possibility of getting WL to existing two OAI status plants (Unit-I and IX) raises concerns over ARBP's ability to deal with the US FDA-related issues. Though these facilities would not have any significant financial impact on ARBP, it will involve incremental remedial cost for ARBP, which may impact its operating margin, going ahead.

Outlook & Valuation

Back-to-back Form 483s/OAI status/Warning Letter raises concerns over ARBP's ability to deal with the US FDA-related issues. Also, there is high possibility of getting WL for 2 facilities (Unit I and IX). At CMP, stock trades at 10.1x and 8.0x of FY20 and FY21 earnings, respectively (heavy discount to its peers; historical 5-yr avg. PE at 13x). **Reducing our valuation multiple to 10x (from 15x earlier) owing to these US FDA concerns, we maintain our BUY recommendation on the stock with a revised Target Price of Rs575 (from Rs860 earlier).**

Financial Summary (Rs mn)	FY18	FY19	FY20E	FY21E
Sales	164,998	195,635	236,908	282,518
EBITDA	37,885	39,525	48,515	58,533
Adj. PAT	24,229	23,647	26,620	33,692
P/E (x)	11.0	10.7	10.1	8.0
EV/EBITDA (x)	8.0	8.1	7.7	6.2
ROE (%)	20.9	18.1	16.2	17.2
ROCE (%)	20.3	16.3	13.4	16.0

Source: Company, RSec Research

Share price (%)	1 mth	3 mth	12 mth
Absolute performance	(25.8)	(21.6)	(37.4)
Relative to Nifty	1.6	(3.7)	7.5

Shareholding Pattern (%)	Jun-19	Mar-19
Promoter	51.9	51.9
Public	48.1	48.1

1 Year Stock Price Performance

Note: * CMP as on Oct 07, 2019

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Unit-VII Form 483: Key Observations

- ▶ There's a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.
- ▶ There are no written procedures for production and process controls designed to assure that the products have identity, strength, quality, and purity they purport or are represented to possess.
- ▶ Control procedures are not established, which may be responsible for causing variability in the characteristics of in-process material and the product.
- ▶ Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.
- ▶ The responsibilities and procedures applicable to the quality control unit are not fully followed.
- ▶ Equipment and utensils are not cleaned at appropriate intervals to prevent contamination.
- ▶ Written production and process control procedures are not followed in the execution of production and process control functions.

Risks to view

- ▶ Inordinate delay in getting approval for new products in the US.
- ▶ Escalation to pending USFDA issues.

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Profit & Loss Statement

Y/E March (Rs mn)	FY18	FY19	FY20E	FY21E
Net sales	164,998	195,635	236,908	282,518
% yoy change	9.3	18.6	21.1	19.3
Raw Material cost	67,527	87,120	104,239	122,896
Employee cost	21,308	25,850	30,798	37,857
Other expenses	38,277	43,140	53,355	63,233
Total operating expenditure	127,113	156,110	188,392	223,986
EBIDTA	37,885	39,525	48,515	58,533
EBIDTA margin (%)	23.0	20.2	20.5	20.7
Depreciation	5,580	6,680	10,243	10,975
Other income	1,020	1,160	1,000	1,000
EBIT	33,325	34,005	39,272	48,558
Interest costs	777	1,630	4,278	3,667
PBT	32,548	32,375	34,994	44,890
Taxes	8,180	7,270	8,399	11,223
Tax rate (%)	25.1	22.5	24.0	25.0
Minority interest	(29)	(25)	(25)	(25)
Foreign Exchange	-168	-1483	0	0
Reported PAT	24,229	23,647	26,620	33,692
% yoy change	5.3	-2.4	12.6	26.6
EPS (Rs)	41.6	42.9	45.4	57.5

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Balance Sheet

Y/E March (Rs mn)	FY18	FY19	FY20E	FY21E
SOURCES OF FUNDS				
Equity Share Capital	586	586	586	586
Reserves & Surplus	116,218	138,322	163,403	195,147
Shareholders Funds	116,804	138,908	163,989	195,733
Minority Interest	18	16	41	65
Total Loans	47,700	69,667	128,867	107,867
Deferred tax liability	2,353	2,810	2,810	2,810
Total Liabilities	166,875	211,401	295,707	306,475
APPLICATION OF FUNDS				
Gross Block	72,617	99,921	167,921	179,921
Less: Acc. Depreciation	13,741	20,228	30,471	41,446
Net Block	58,876	79,693	137,450	138,475
Capital Work-in-Progress	13,995	13,420	30,420	33,420
Goodwill on consolidation	8,166	8,330	8,330	8,330
Investments	3,120	3,610	3,971	4,368
Current Assets	121,878	153,710	170,535	188,225
Inventories	58,584	72,460	72,460	87,747
Sundry Debtors	30,844	34,140	41,342	49,302
Cash and Bank	12,620	19,570	23,241	11,237
Loans and Advances	140	160	389	464
Other Current Assets	19,690	27,380	33,102	39,475
Current liabilities	44,145	53,144	61,177	72,955
Net Current Assets	77,733	100,566	109,358	115,271
Deferred tax asset	1,588	1,830	1,830	1,830
Other non-current assets	3,397	3,952	4,347	4,782
Total Assets	166,875	211,401	295,707	306,475

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Cash Flow Statement

Y/E March (Rs mn)	FY18	FY19	FY20E	FY21E
Profit before tax	32,412	30,910	34,994	44,890
Depreciation	5,580	6,680	10,243	10,975
Interest provided	629	1,510	4,278	3,667
Change in Working Capital	(11,220)	(15,100)	(5,517)	(18,351)
Tax Paid	(6,990)	(7,700)	(8,399)	(11,223)
Others	(860)	(80)	-	-
Cash Flow from Operations	19,550	16,220	35,600	29,960
(Inc.)/ Dec. in Fixed Assets	(15,300)	(15,590)	(85,000)	(15,000)
(Inc.)/ Dec. in Investments	(678)	(460)	(361)	(397)
Others	(3,294)	(12,720)	-	-
Cash Flow from Investing	(19,271)	(28,770)	(85,361)	(15,397)
Issue of Equity	2	1	-	-
Inc./(Dec.) in loans	(206)	(3,940)	59,200	(21,000)
Dividend Paid (Incl. Tax)	(2,190)	(1,460)	(1,539)	(1,948)
Interest provided	(742)	(1,520)	(4,278)	(3,667)
Others	11,772	26,104	49	49
Cash Flow from Financing	8,636	19,185	53,432	(26,566)
Inc./(Dec.) in Cash	8,915	6,635	3,671	(12,004)
Opening Cash balances	3,183	12,620	19,570	23,241
Closing Cash balances	12,620	19,570	23,241	11,237

Key Ratio

Y/E March	FY18	FY19	FY20E	FY21E
Valuation Ratio (x)				
P/E	11.0	10.7	10.1	8.0
P/CEPS	9.0	8.4	7.3	6.0
P/BV	2.3	1.9	1.6	1.4
Dividend yield (%)	0.5	0.5	0.6	0.7
EV/Sales	1.8	1.6	1.6	1.3
EV/EBITDA	8.0	8.1	7.7	6.2
Per Share Data (Rs)				
EPS	41.6	42.9	45.4	57.5
Cash EPS	51.2	54.3	62.9	76.2
DPS	2.5	2.5	2.6	3.3
Book Value (BV)	199.4	237.1	279.9	334.1
Returns (%)				
RoCE	20.3	16.3	13.4	16.0
RoE	20.9	18.1	16.2	17.2
Turnover ratios (x)				
Asset Turnover (Gross Block)	2.3	2.0	1.4	1.6
Asset Turnover (Net Block)	2.8	2.5	1.7	2.0
Inventory (days)	130	135	135	135
Receivables (days)	68	64	64	64
Payables (days)	52	50	50	50

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Rating History

Date	Reco	CMP	TP
08-Aug-19	BUY	600	860
29-May-19	BUY	685	860
11-Feb-19	BUY	754	860
21-Jan-19	BUY	780	876
13-Nov-18	BUY	775	876
07-Sept-18	BUY	760	876
10-Aug-18	BUY	611	712
30-May-18	BUY	566	712

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Rating	Expected absolute returns (%) over 12 months
BUY	>10%
HOLD	-5% to 10%
REDUCE	>-5%

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