ADD
TP: Rs 505 | ▲ 10%

AUROBINDO PHARMA | Pharmaceuticals | 08 October 2019

Form 483 for Unit 7: Warning letter risk largely priced in

ARBP's stock corrected 20% on 7th Oct following 483 details on Unit 7 (oral formulation unit). The unit was inspected from 19-27 Sep and received 7 observations. The inspectors were Tamil Arasu, Jogy George and Emmanuel J. Ramos. 483s cites quality issues which could delay new product approvals. This could be a near-term overhang until EIR is received. However, Stock at 10x FY21 P/E pose better risk/reward (40% dis. to peers). FDA inspection for critical units are now over. Retain ADD & revise PT to Rs505 (from Rs 700).

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Implication: Unit 7 is an important plant as it accounts for ~US$300mn in current US sales and ~8% of the total FY21 sales. It has 20 pending approvals (15% of total pending files). This should hurt near- term growth outlook. In the worst case (warning letter) we see additional 5% EPS cut on our revised FY21e if the EIR gets delayed beyond 12 months.

Observation #1 & #5 are key: These are related to lack of scientifically sound process to identify root cause for OOS results, quality control, inadequate data files. These would require more check, review of the quality/process control, training/documentation & new SOPs in few cases **(details inside)**. The US FDA previously inspected the Unit 7 in June'17 and was issued zero observations.

Retain ADD but expect another 10% downside in stock at worst: We expect likely escalation of Unit 7/483's to a warning letter given quality control lapses but largely priced in our view. We don't see any data integrity issue. Resolution could take at least 5 months meaning delay in approvals and 20-25% utilization hit. Stock post sharp fall offer better risk-reward trading at 10x FY21 EPS (40% discount to peers). Inspection for key dosage units are now over (3, 4, 7, 10, Eugia). We cut EPS /target multiple by 9%/16% and revise PT to Rs 505.

KEY FINANCIALS

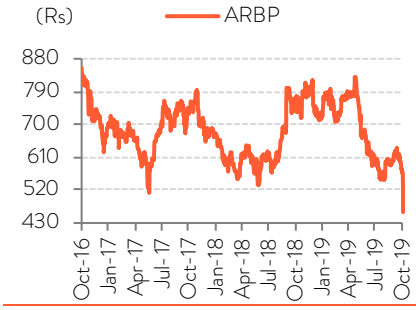
Y/E 31 Mar	FY18A	FY19A	FY20E	FY21E	FY22E
Total revenue (Rs mn)	164,630	195,634	231,311	277,291	284,116
EBITDA (Rs mn)	37,718	39,519	47,842	52,912	53,631
Adj. net profit (Rs mn)	24,227	24,126	27,071	27,276	27,397
Adj. EPS (Rs)	41.3	41.2	46.2	46.6	46.8
Adj. EPS growth (%)	5.3	(0.4)	12.2	0.8	0.4
Adj. ROAE (%)	23.1	18.8	17.9	15.5	13.7
Adj. P/E (x)	11.1	11.2	10.0	9.9	9.8
EV/EBITDA (x)	7.9	7.7	6.7	7.1	6.7

Source: Company, BOBCAPS Research

Ticker/Price	ARBP IN/Rs 460
Market cap	US$ 3.8bn
Shares o/s	586mn
3M ADV	US$ 23.0mn
52wk high/low	Rs 838/Rs 450
Promoter/FPI/DII	52%/19%/15%

Source: NSE

STOCK PERFORMANCE



Source: NSE

Detailed observations of Unit 7 below

Observation #1 Failure to thoroughly investigate unexplained discrepancy and failure of a batch to meet any of its specifications

FDA has highlighted insufficient root cause analysis to invalidate the OOS - out of specification investigation/assay failures, CAPAs does not address the identified root cause to invalidate the initial results and passing the re-test results. Generally re-testing the OOS results to invalidate the batches is a usual practice by firms but here Aurobindo needs to define and create scientifically sound SOPs to identify root cause for deviation in specification.

FDA has given instance of total OOS reported & invalidated between in last two years across Raw materials (total 112 OOS & 91% invalidated), In-process (total 85 OOS & 76% invalidated), Process validation (42 OOS & 43% invalidated), Finished product testing (172 OOS & 65% invalidated) and finished product stability (72 OOS & 100% invalidation). Hypothesis studies concluded material human errors and instrument errors as potential root causes. FDA mentions some of the instances with the products that were investigated for OOS from its Jan 19-Sep 19 and are presently marketed in US:

- Rabeprazole sodium Delayed release (standard assay should be between 90-110% at the end of 30min sonication vs hypothesis study used by Aurobindo at different time intervals showing <100% assay).
- Norgestimate and Ethinyl Estradiol (utilizing one-month hypothesis studies of acid degradation to conclude 9-month equivalent study of an unknown sulphuric acid concentration).
- **Product related multiple complaints were not investigated at the time when product left the manufacturing unit:** Broken tablets or capsules were not got adequately traced within the rejection criteria on the packaging lines or it was not adequately documented despite trace during visual inspection.

Observation #2 Instances of unaccounted documents like batch records/protocols by Quality Assurance department and inability to provides record of reconciliation for executed and unexecuted batches. However, FDA found that the firms Data storage and Retrieval system is sound. Creation of SOPs for process control would be required.

Observation #3 Deficiency in the Control procedures to run initial and commercial process validation including samples used to conduct the hold time studies. This would cause variability in the characteristics of in-process material and the final drug – Strengthening of the procedures is required.

Observation #4 Laboratory records do not include complete data derived from all tests, examination and assay necessary to assure compliance with established specification and standards. This includes failure to conduct periodic review of the audit trials for the drugs being processed. This should get address by establishing proper device connection or change of software.

Observation #5 Responsibilities and procedures applicable to the quality control unit are not fully followed: FDA cited that current reporting structure of the quality assurance department provides no confidence in maintaining the integrity of the electronic data. Plus, there is inadequate documentation & training lapses for quality personals.

Observation #6 Cleaning of equipment's and utensils to prevent contamination.

Observation #7 Warehousing procedures/rejects are not followed—the FDA found the instance of an US bound Omeprazole DR capsules which was rejected was lying in blue crates (without proper identification) which was supposed to be in Red crate.

FIG 1 – MANUFACTURING UNITS – USFDA INSPECTION DETAILS

		Segment	Last inspected	Current status
	Key Formulation Facility			
1	Unit VII (SEZ)	Orals	Sep-19	7 observation
2	Unit IV	Injectable	Mar-19	EIR*
3	Unit III	Orals	Jun-19	EIR
4	AuroLife US	Orals	Jun-18	EIR
5	Unit XII	Oral & Injectables	Mar-18	EIR
6	Unit VIB	Orals	Sep-17	EIR
7	AuroNext	Injectable	Feb-18	EIR
8	Eugia	Oral & Injectables	Jun-19	EIR awaited
9	Unit X	Orals	Apr-19	EIR
10	Unit XVI	Injectable	Mar-19	EIR
	API/Intermediates facility			
1	Unit 1	API/Intermediates	Feb-19	OAI^
2	Unit V	API	Jul-18	EIR
3	Unit VIII	API	Jun-18	EIR
4	Unit IX	Intermediates	Feb-19	OAI
5	Unit XI	API	Feb-19	WL
6	Silicon	API	Mar-18	EIR
7	AuroNext	API	Feb-18	EIR
8	AuroPeptides	API	Aug-16	EIR
9	Unit II	Intermediates		Non-FDA
10	Unit XIV	API		FDA qualification WIP
11	Unit VIA	API		Non-FDA

Source: Company, BOBCAPS Research | *Establishment inspection report | ^Official action indicated

Valuation methodology

We note that three sites will be critical to drive growth in coming years for Aurobindo i.e Unit 4, 10 and Eugia. Together these accounts for 76% of the pending ANDA and all of these units were inspected recently. Management highlighted that they expect 5-6 approvals over next 12 months from unit 7 but none of them would be meaningful. Hence, maintain ADD.

We feel Unit 7 will be an overhang on the stock in the near term until it receives EIR from USFDA/ new approvals commence. But the stock post 20% fall on 7th Oct is largely pricing in the Warning letter risk and additionally we see another 10% downside risk in the stock in the worst case. We don't see any data integrity issue.

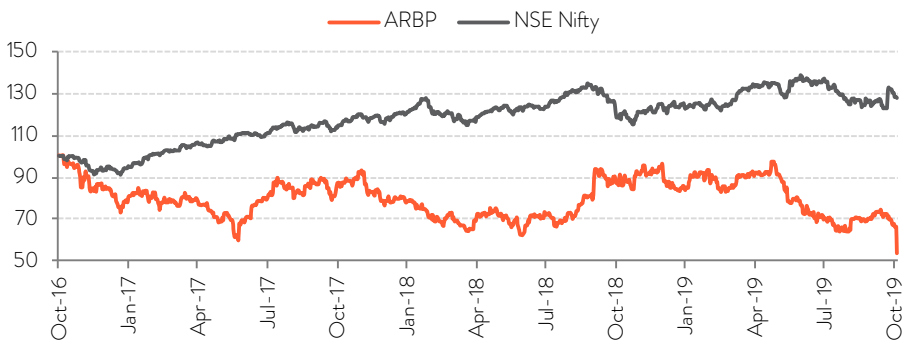
Aurobindo is trading at favorable valuation of ~10x FY21 EPS and at significant discount to peers (50% discount to Cipla, Sun, Lupin, DRL & 30% discount to Global comps Teva, Endo, Perrigo, Teva). We have cut our FY21/22 EPS estimates by 9% and target multiple by 16% (7.5x EV/EVITDA from 9x earlier) to account for tapering in the earnings growth. Other downside risks: (1) Sandoz consolidation delays, (2) penalty risk from Aceto supply-chain sabotage claim (in District court).

FIG 2 – REVISED ESTIMATES

(Rs bn)	New			Old			Change (%)		
	FY20E	FY21E	FY22E	FY20E	FY21E	FY22E	FY20E	FY21E	FY22E
Sales	231	277	284	244	279	288	(5.4)	(0.6)	(1.2)
EBITDA	48	53	54	49	55	56	(3.1)	(4.2)	(4.8)
EBITDA margin (%)	20.7	19.1	18.9	20.2	19.8	19.8	49bps	(72bps)	(93bps)
EPS (Rs)	46	47	47	47.9	50.9	51.7	(3.6)	(8.5)	(9.6)

Source: Company, BOBCAPS Research

FIG 3 – RELATIVE STOCK PERFORMANCE



Source: NSE

Key risks

- **US approval delays and Sandoz execution:** The US forms the single largest delta in our operating profit estimates for FY19-FY21 (80% of incremental profit); hence, delays in key approvals and execution hurdles in the Sandoz acquisition are key risk factors.
- **Regulatory risk:** ARBP supplies to the US from multiple plants. The key oral facilities are Unit 3 and Unit 7, Eugia unit, Unit 10 and the key injectable plant is Unit 4. FDA inspection at Unit 4/3/10/Eugia was completed (EIR received). We note that ARBP has now started most of the oral filings from the new Unit 10. Escalation of OAI (official action indicated) observations on two units (API units 1 & 9), the warning letter received for intermediate Unit 11 and Unit 7 escalation are key risks to estimates.

FINANCIALS

Income Statement

Y/E 31 Mar (Rs mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Total revenue	**164,630**	**195,634**	**231,311**	**277,291**	**284,116**
EBITDA	37,718	39,519	47,842	52,912	53,631
Depreciation	5,580	6,679	10,204	12,983	13,963
EBIT	32,138	32,839	37,638	39,929	39,668
Net interest income/(expenses)	(777)	(2,626)	(2,878)	(4,398)	(3,421)
Other income/(expenses)	1,020	1,157	1,334	837	282
Exceptional items	0	0	0	0	0
EBT	32,381	31,370	36,095	36,368	36,530
Income taxes	8,183	7,268	9,024	9,092	9,132
Extraordinary items	0	(483)	0	0	0
Min. int./Inc. from associates	(29)	(25)	0	0	0
Reported net profit	**24,227**	**23,642**	**27,071**	**27,276**	**27,397**
Adjustments	0	483	0	0	0
Adjusted net profit	**24,227**	**24,126**	**27,071**	**27,276**	**27,397**

Balance Sheet

Y/E 31 Mar (Rs mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Accounts payables	26,274	26,771	38,024	45,582	46,704
Other current liabilities	15,324	24,390	20,818	24,956	25,570
Provisions	2,567	2,273	2,688	3,222	3,301
Debt funds	47,710	69,668	122,168	97,734	73,301
Other liabilities	0	0	0	0	0
Equity capital	586	586	586	586	586
Reserves & surplus	117,001	138,686	162,812	187,158	211,626
Shareholders' fund	117,587	139,272	163,398	187,744	212,212
Total liabilities and equities	**209,462**	**262,374**	**347,095**	**359,238**	**361,088**
Cash and cash eq.	12,616	19,594	18,526	5,398	2,670
Accounts receivables	38,788	47,771	63,373	75,970	77,840
Inventories	58,584	72,456	76,048	83,567	85,624
Other current assets	15,324	17,518	20,818	24,956	25,570
Investments	3,115	3,602	3,602	3,602	3,602
Net fixed assets	47,365	56,937	120,232	121,249	121,286
CWIP	15,829	16,685	16,685	16,685	16,685
Intangible assets	17,841	27,811	27,811	27,811	27,811
Deferred tax assets, net	0	0	0	0	0
Other assets	0	0	0	0	0
Total assets	**209,462**	**262,373**	**347,095**	**359,238**	**361,088**

Source: Company, BOBCAPS Research

Cash Flows

Y/E 31 Mar (Rs mn)	FY18A	FY19A	FY20E	FY21E	FY22E
Net income + Depreciation	29,807	30,322	37,275	40,260	41,361
Interest expenses	777	2,626	2,878	4,398	3,421
Non-cash adjustments	0	0	0	0	0
Changes in working capital	(12,847)	(15,780)	(14,398)	(12,024)	(2,726)
Other operating cash flows	0	0	0	0	0
Cash flow from operations	**17,737**	**17,168**	**25,755**	**32,633**	**42,056**
Capital expenditures	(22,593)	(26,028)	(73,500)	(14,000)	(14,000)
Change in investments	(657)	(487)	0	0	0
Other investing cash flows	0	0	0	0	0
Cash flow from investing	**(23,250)**	**(26,515)**	**(73,500)**	**(14,000)**	**(14,000)**
Equities issued/Others	0	0	0	0	0
Debt raised/repaid	14,069	21,958	52,500	(24,434)	(24,434)
Interest expenses	(777)	(2,626)	(2,878)	(4,398)	(3,421)
Dividends paid	(2,641)	(2,930)	(2,930)	(2,930)	(2,930)
Other financing cash flows	2,344	(77)	(16)	0	0
Cash flow from financing	**12,995**	**16,325**	**46,677**	**(31,761)**	**(30,784)**
Changes in cash and cash eq.	**7,482**	**6,978**	**(1,068)**	**(13,128)**	**(2,728)**
Closing cash and cash eq.	**12,616**	**19,594**	**18,526**	**5,398**	**2,670**

Per Share

Y/E 31 Mar (Rs)	FY18A	FY19A	FY20E	FY21E	FY22E
Reported EPS	41.3	40.4	46.2	46.6	46.8
Adjusted EPS	41.3	41.2	46.2	46.6	46.8
Dividend per share	2.5	2.5	2.5	2.5	2.5
Book value per share	200.9	238.0	279.2	320.8	362.6

Valuations Ratios

Y/E 31 Mar (x)	FY18A	FY19A	FY20E	FY21E	FY22E
EV/Sales	1.8	1.6	1.4	1.3	1.3
EV/EBITDA	7.9	7.7	6.7	7.1	6.7
Adjusted P/E	11.1	11.2	10.0	9.9	9.8
P/BV	2.3	1.9	1.6	1.4	1.3

DuPont Analysis

Y/E 31 Mar (%)	FY18A	FY19A	FY20E	FY21E	FY22E
Tax burden (Net profit/PBT)	74.8	76.9	75.0	75.0	75.0
Interest burden (PBT/EBIT)	100.8	95.5	95.9	91.1	92.1
EBIT margin (EBIT/Revenue)	19.5	16.8	16.3	14.4	14.0
Asset turnover (Revenue/Avg TA)	28.2	26.1	23.4	24.3	24.9
Leverage (Avg TA/Avg Equity)	1.4	1.5	1.6	1.6	1.4
Adjusted ROAE	23.1	18.8	17.9	15.5	13.7

Source: Company, BOBCAPS Research | Note: TA = Total Assets

Ratio Analysis

Y/E 31 Mar	FY18A	FY19A	FY20E	FY21E	FY22E
YoY growth (%)					
Revenue	10.4	18.8	18.2	19.9	2.5
EBITDA	9.8	4.8	21.1	10.6	1.4
Adjusted EPS	5.3	(0.4)	12.2	0.8	0.4
Profitability & Return ratios (%)					
EBITDA margin	22.9	20.2	20.7	19.1	18.9
EBIT margin	19.5	16.8	16.3	14.4	14.0
Adjusted profit margin	14.7	12.3	11.7	9.8	9.6
Adjusted ROAE	23.1	18.8	17.9	15.5	13.7
ROCE	22.8	18.2	15.8	14.3	14.0
Working capital days (days)					
Receivables	86	89	100	100	100
Inventory	130	135	120	110	110
Payables	58	50	60	60	60
Ratios (x)					
Gross asset turnover	2.1	1.9	1.3	1.4	1.4
Current ratio	2.8	2.9	2.9	2.6	2.5
Net interest coverage ratio	41.4	12.5	13.1	9.1	11.6
Adjusted debt/equity	0.3	0.4	0.6	0.5	0.3

Source: Company, BOBCAPS Research

Disclaimer

Recommendations and Absolute returns (%) over 12 months

BUY – Expected return >+15%

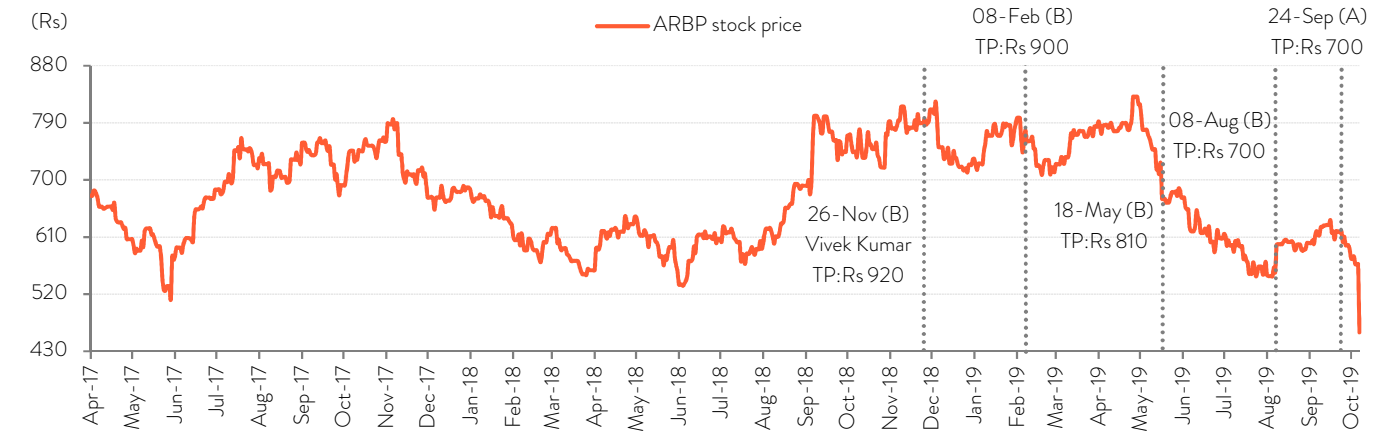
ADD – Expected return from >+5% to +15%

REDUCE – Expected return from -5% to +5%

SELL – Expected return <-5%

Note: Recommendation structure changed with effect from 1 January 2018 (Hold rating discontinued and replaced by Add / Reduce)

HISTORICAL RATINGS AND TARGET PRICE: AUROBINDO PHARMA (ARBP IN)



B – Buy, A – Add, R – Reduce, S – Sell

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