

Aurobindo Pharmaceuticals

USFDA Update

Aurobindo Pharmaceuticals (APL) has a big relief in form of Establishment Inspection report (EIR) for Unit-4 facility in which the USFDA has closed issued Form 483. The Form 483 is issued to a firm's management at the conclusion of an inspection when an investigator(s) has observed any conditions that may constitute violations of the Food Drug and Cosmetic (FD&C) Act and related Acts. USFDA had inspected Unit 4 facility in December and issued Form 483, with two observations. Unit 4 EIR is very important for the company, as it has filed totally 101 products from this facility of which 58 are approved by the USFDA (as on 31 Dec'2018). As on December'2018, the company had filed 519 US ANDA's with 369 already approved.

Injectable segment, which contributes around 6-7% of sales (FY2018), is a key growth driver for the company expected to grow at 20-25% in the short to medium term. In addition, on the profitability front, the injectable business have ROE higher than the company business ROE on an average 25-26%. The main reason behind the same is lack of any big Indian player in the segment, which enables the main integrated players to enjoy better profitability. Currently according to Management, the segment in USA enjoys limited completion from 3-4 players. **Thus, the approval of the facility is good relief for the company.**

According to our interaction with the company, we have understood that the company is building another complex injectable facility in USA; which will in future de-risk its Injectable business. The facility will be functional by end of FY2020.

However, in another development, company's Unit 16 has received 11 observations and was inspected from February 22- March 1'2019. This facility makes sterile products and the observations pertain to procedural lapses and not providing adequate training to employees, among others. Currently the unit does not contribute significantly and hence will not have a material impact on the numbers of the company.

Since we have already built in the numbers the potential from the Injectable business we are not changing our estimates and maintain our Buy with a revised target of `890.

BUY

CMP	`773
Target Price	`890

Investment Period 12 Months

Stock Info

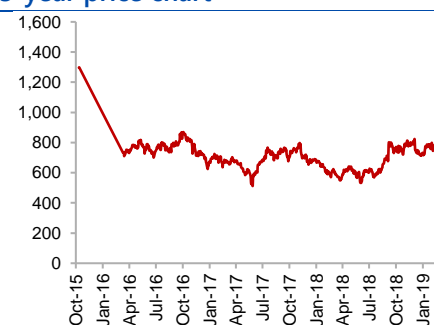
Sector	Pharmaceuticals
Market Cap (₹ cr)	45,251
Net Debt (₹ cr)	2,579
Beta	1.1
52 Week High / Low	830/527
Avg. Daily Volume	52,572
Face Value (₹)	1
BSE Sensex	37,565
Nifty	11,301
Reuters Code	ARBN.BO
Bloomberg Code	ARBP.IN

Shareholding Pattern (%)

Promoters	51.9
MF / Banks / Indian FIs	17.7
FII / NRIs / OCBs	20.6
Indian Public / Others	9.8

Abs.(%)	3m	1yr	3yr
Sensex	4.6	11.0	52.0
Aurobindo Pharma	3.6	33.0	5.5

3-year price chart



Source: Company, Angel Research

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Disclosure of Interest Statement	Aurobindo Pharma
1. Financial interest of research analyst or Angel or his Associate or his relative	No
2. Ownership of 1% or more of the stock by research analyst or Angel or associates or relatives	No
3. Served as an officer, director or employee of the company covered under Research	No
4. Broking relationship with company covered under Research	No

Ratings (Returns):

Buy (> 15%)
Reduce (-5% to -15%)
Accumulate (5% to 15%)
Sell (< -15%)
Neutral (-5 to 5%)