

Sector: Pharmaceuticals  
Stock Update

	Change
Reco: <b>Hold</b>	↓
CMP: <b>Rs. 608</b>	
Price Target: <b>Rs. 710</b>	↓

↑ Upgrade ↔ No change ↓ Downgrade

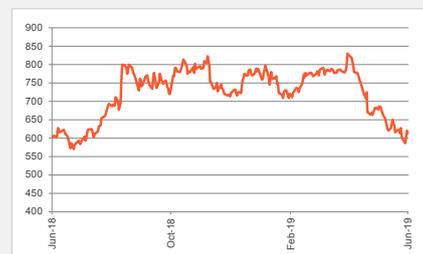
## Company details

Market cap:	Rs. 35,623 cr
52-week high/low:	Rs. 838/566
NSE volume: (No of shares)	25.1 lakh
BSE code:	524804
NSE code:	AUROPHARMA
Sharekhan code:	AUROPHARMA
Free float: (No of shares)	28.2 cr

## Shareholding (%)

Promoters	51.9
FII	22.0
DII	13.7
Others	12.40

## Price chart



## Price performance

(%)	1m	3m	6m	12m
Absolute	-10.2	-21.0	-13.8	-0.3
Relative to Sensex	-10.2	-24.2	-22.5	-12.4

Sharekhan Research, Bloomberg

A Warning Letter has been issued to Aurobindo Pharma Limited (Aurobindo) for its Unit-XI, an Active Pharmaceutical Ingredient (API) unit in Srikakulam, one of the three plants that received Official Action Indicated (OAI) status in May 2019. The letter mainly pertains to the ongoing issues regarding impurities in Sartan's. The company proposes to enter into dialogue with the US FDA over the next 15–20 days to decide a future course of action. From Unit XI, the company has ~28 filings that await approval, the delay of which may negatively impact performance ahead.

## Regulatory hurdles increase

In Feb 2019, Unit- XI received three observations as follows: 1) lack of appropriate specifications for lab controls; 2) inadequate investigations that failed to evaluate potential root causes; and 3) inadequate master production batch records for API manufacturing. The plant was designated as OAI by the USFDA in March 2019. Aurobindo received OAI for two other API plants—unit I in Sangareddy (with six observations) and unit IX in the Medak district (with five observations). As with Unit XI, these both plants have been called out for 'inadequate investigations that failed to evaluate potential root causes'. Aurobindo has also received ten observations for unit III (oral formulations plant) and 11 observations for the sterile formulations unit. An increase in potential regulatory risks for Aurobindo may impact future approvals.

## Our Call

## Downgrade to Hold with downward revised PT of Rs 710

With a pattern emerging with the issues at all the API units, threat of warning letters for its other units cannot be ruled out. Although impact on existing businesses can be ruled out because of these developments, approval for future filings from these plants are likely to get delayed. Also, the remediation and site transfer related costs are likely to put the company's near term margins under pressure. The company is considering site transfer as a precautionary measure. Thus we have revised downwards our sales/earnings estimates for FY2020/ FY2021 by 4%/13% and 7%/14% respectively. We expect the company to report sales and profit CAGR of 29% and 22%, respectively, over the next two years. The uncertainty related to regulatory hurdles at various units will weigh on the stock (until resolved successfully). Thus we downgrade our recommendation to Hold with downward revised price target of Rs 710.

## Key Risks

Delay in product approvals; Change in regulatory landscape; Negative outcome of key facility inspection by the USFDA can affect future earnings prospects.

## Valuation (Consolidated)

Particulars	Rs cr			
	FY2018	FY2019	FY2020E	FY2021E
Net sales	16499.8	19563.6	29004.5	32456.3
OPM (%)	23.0	20.2	20.0	20.0
Adj. PAT	2440	2513	3212	3762
EPS (Rs)	41.6	42.9	54.8	64.2
PER (x)	14.6	14.2	11.1	9.5
EV/Ebitda (x)	10.7	10.6	7.2	6.3
P/BV (x)	3.0	2.6	2.1	1.7
Mcap/sales	2.2	1.9	1.3	1.1
ROCE (%)	21.9	16.8	19.9	19.3
RONW (%)	23.2	19.7	20.7	19.8

Source: Company Data; Sharekhan estimates

## Recent Warning Letter increases regulatory risks

Aurobindo has received a Warning Letter for its Unit-XI, an Active Pharmaceutical Ingredient (API) unit in Srikakulam, one of the three plants that received Official Action Indicated (OAI) status in May 2019. As per the management, main reason for the warning letter is the ongoing issues pertaining to impurities in Sartan's. The company will have a dialogue with the US FDA over the next 15–20 working days to decide future course of action. From Unit XI, the company has ~28 filings that await approval (delay of which could potentially impact FY2020 and FY2021 performance).

In Feb 2019, Unit- XI had received three observations as follows: 1) lack of appropriate specifications for lab controls; 2) inadequate investigations that failed to evaluate potential root causes; and 3) inadequate master production batch records for API manufacturing. Post this, the plant was designated as OAI by the USFDA in March 2019. Along with unit XI, Aurobindo received OAI for two other API plants—unit I in Sangareddy (with six observations) and unit IX in the Medak district (with five observations). Both these plants have one observation common to unit XI ('inadequate investigations that failed to evaluate potential root causes'). Apart from these units, Aurobindo received ten observations for unit III (oral formulations plant) and 11 observations for the sterile formulations unit.

**All these put together pose potential regulatory risks for Aurobindo and could impact future approvals until successfully resolved. Although existing businesses may not get impacted due to issued warning letter (for Unit- XI), approval for future filings done from these plants are likely to get delayed.**

### Regulatory Status of various units under FDA scrutiny

Units	Manufactures	USFDA Status	Inspection Time
API			
Unit I	API	OAI (6 observations)	Jan-19
Unit IX	Intermediates	OAI (5 observations)	Jan-19
Unit XI	API	OAI (3 observations); Warning Letter in Jun-19	Feb-19
Formulation			
Bachupally Unit – III	Oral Formulations	Form 483 with 10 obs	May-19
Telangana Unit – XVI	Sterile formulations	Form 483 with 11 obs	Feb-19

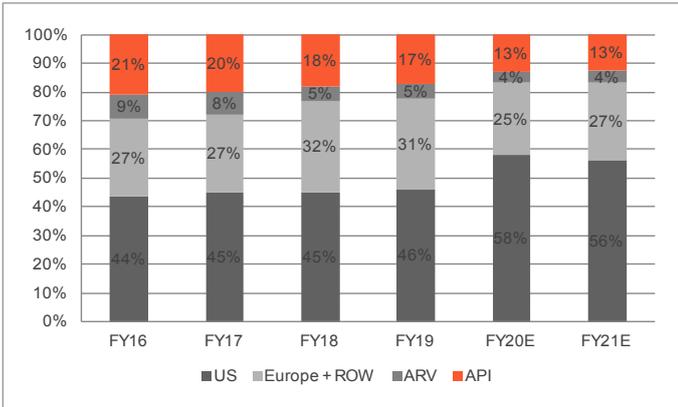
## Integration of newly-acquired assets would be crucial; margin expansion restricted

In the past six months, Aurobindo has carried out a series of acquisitions (funded by debt), namely R&D assets in Australia (for US\$12.5mn), units of Sandoz (for US\$900mn) and Apotex (for US\$82mn) with a total consideration value of ~US\$1bn. The acquired portfolio of Sandoz is expected to generate over \$0.9 billion in sales for the first 12 months after completion of the transaction for Aurobindo, before any potential FTC-led divestments. The acquisitions are yet to be completed, and a successful integration would be crucial for a short-to-mid-term perspective.

**We believe till the completion of acquisitions, margin expansion and profitability improvement would be restricted due to increase in expenses, interest cost (as acquisitions will be funded by debt) and depreciation (due to assets bought). Also, the remediation and site transfer related costs are likely to put pressure on company's near term margins.**

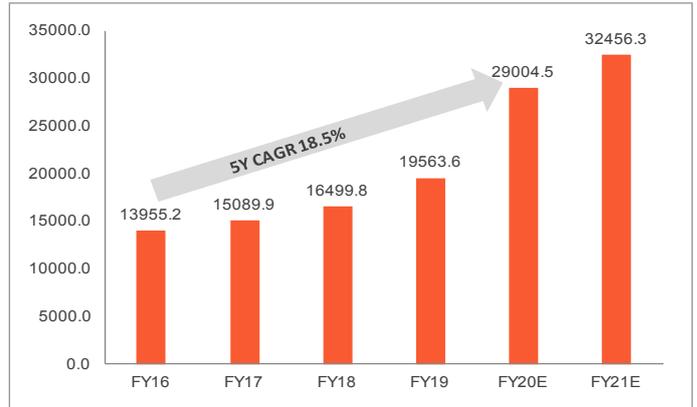
**Financials in charts**

**Sales Mix**



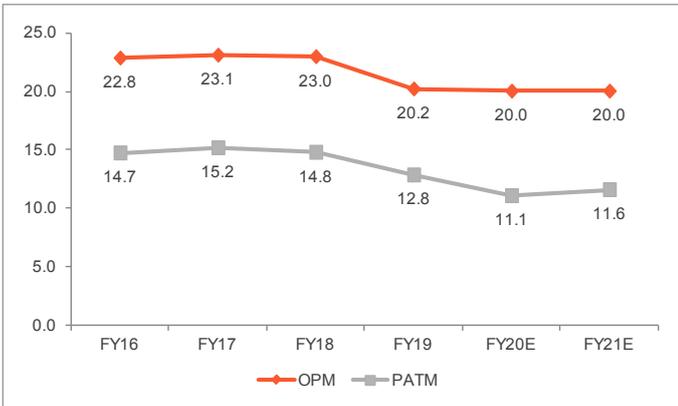
Source: Company Data; Sharekhan Research

**Sales in Crore**



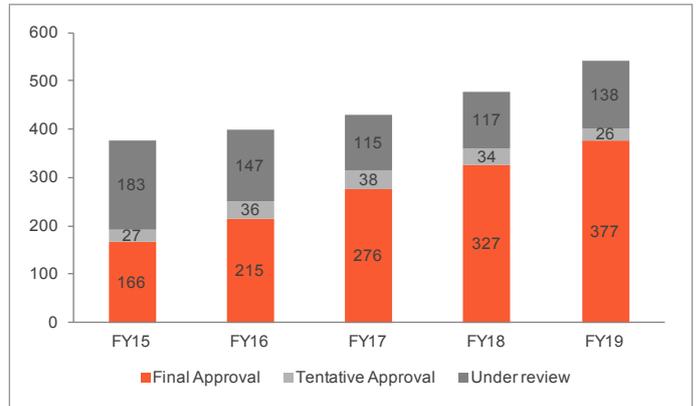
Source: Company Data; Sharekhan Research

**OPM & Adj. PATM**



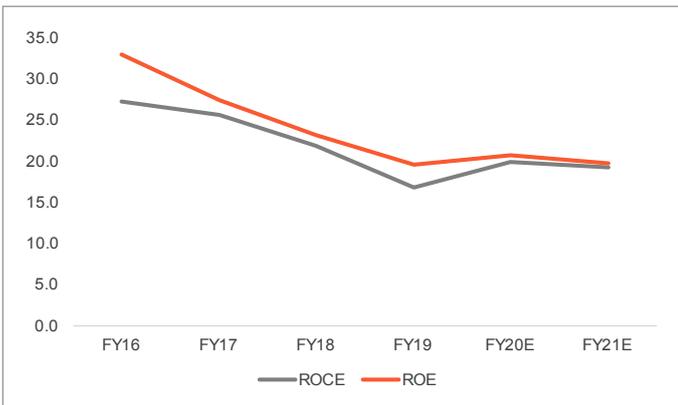
Source: Company Data; Sharekhan Research

**US Filing Snapshot**



Source: Company Data; Sharekhan Research

**Return Ratios**



Source: Company Data; Sharekhan Research

**Debt: Equity**



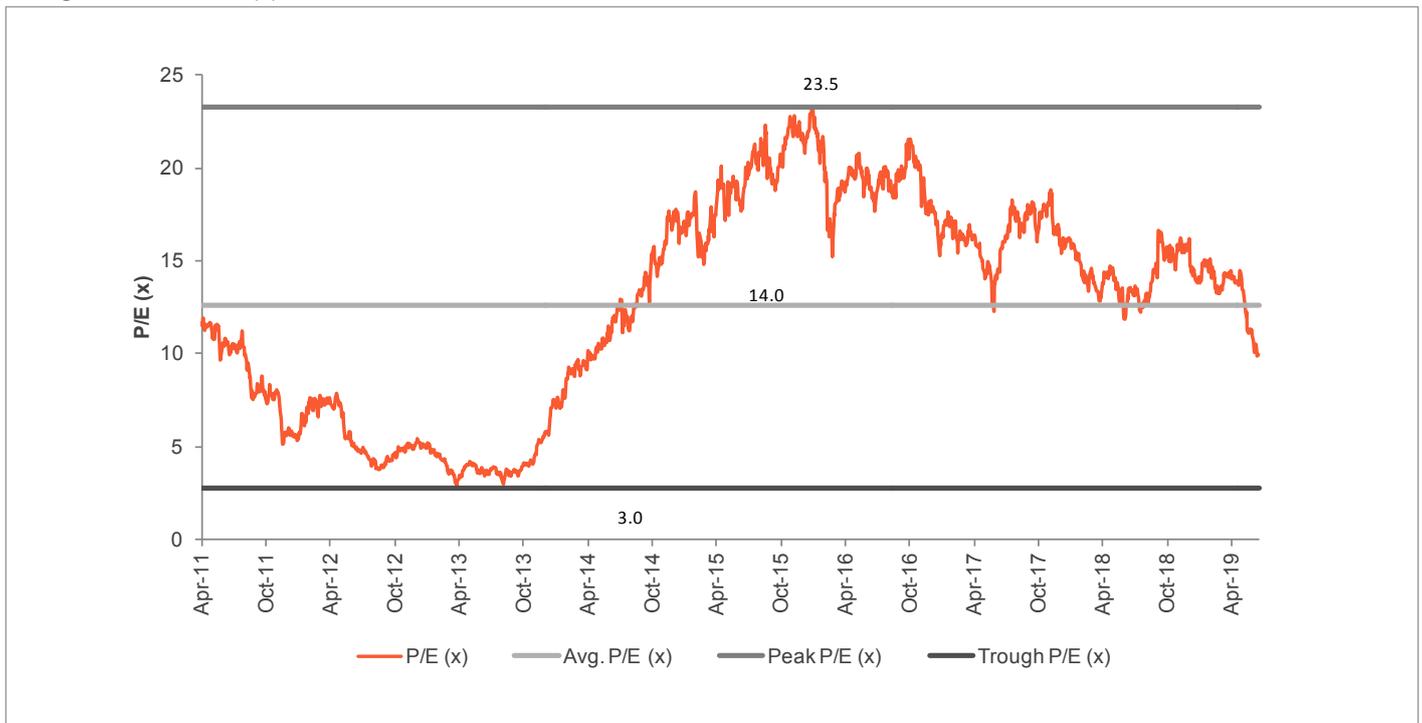
Source: Company Data; Sharekhan Research

**Valuation: Downgrade to Hold with downward revised PT of Rs 710**

With a pattern emerging with the issues at all the API units, threat of possibility of warning letters for its other units cannot be ruled out. Although impact on existing businesses can be ruled out because of these developments, may not get impacted due to issued warning letter (for Unit- XI), approval for future filings done from these plants are likely to get delayed. Also, the remediation and site transfer related costs are likely to put the pressure on company's near term margins under pressure. The company is considering site transfer as a precautionary measure. Thus we have revised downwards our sales/earnings estimates for FY2020/FY2021 by 4%/13% and 7%/14% respectively. We expect the company to report sales and profit CAGR of 29% and 22%, respectively, over the next two years.

**We feel the uncertainty related to regulatory hurdles at various units will weigh on the stock (until resolved successfully). Thus we downgrade our recommendation to Hold with downward revised price target of Rs 710.**

One-year forward P/E (x) band



Source: Sharekhan Research

## About company

Aurobindo Pharma, a Hyderabad-based pharmaceutical company, was incorporated in 1986 and is manufacturer of generic formulations and Active Pharmaceutical Ingredients (API). Aurobindo generates 90% of its sales from international markets. It currently holds a strong position in the US market, where it is the 5th largest generic pharmaceutical company as per the IMS National Prescription Audit, measured by total prescriptions dispensed for the twelve months ending Jun 2018. It also holds a strong position in many European countries, including France and Italy where it ranks among the largest generic companies. It is a vertically integrated company with around 70% of its API requirement met in-house. Aurobindo has 26 manufacturing facilities for its API and formulations business, which has the requisite approval from various regulatory authorities including the US FDA, UK MHRA, Japan PMDA, WHO, Health Canada, MCC South Africa and ANVISA Brazil. Recently, Aurobindo entered Poland and the Czech Republic with the acquisition of commercial operations from Apotex. The company also strengthened its US presence with acquisition of dermatology and oral solid businesses from Sandoz.

## Investment theme

Aurobindo has one of the best product approval rate and launch pipeline for US. Despite pricing pressure, it is one of the few companies who is able to mitigate this risk to due to continuous new launches and approvals. Also coupled with strong pipeline is low product concentration. Going ahead, progress of injectable launches is likely to sustain and be one of the key growth driver.

## Key Risks

Delay in product approvals; Change in regulatory landscape; Negative outcome of key facility inspection by the USFDA can affect future earnings prospects.

## Additional Data

### Key management personnel

Name	Designation
K Nithyananda Reddy	Vice - Chairman, Whole-time Director, One of the promoter.
N Govindarajan	Managing Director
P.V. Ramaprasad Reddy	Non-executive Director, Promoter
Santhanam Subramanian	CFO

Source: Company

### Top 10 shareholders

Sr. No.	Holder Name	Holding (%)
1	Rani Penaka Suneela	33.52
2	HDFC Asset Management Co Ltd	6.72
3	Reddy K Nithyananda	4.33
4	Reddy Kambam Kirthi	3.53
5	Reddy P V Ramaprasad	3.07
6	Penaka Venkata Ramaprasad	3.07
7	Axis Clinicals Ltd	2.97
8	Sivakumaran M	2.47
9	Vanguard Group Inc.	1.66
10	SBI Funds Management Pvt Ltd	1.62

Source: Bloomberg

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by BNP PARIBAS

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