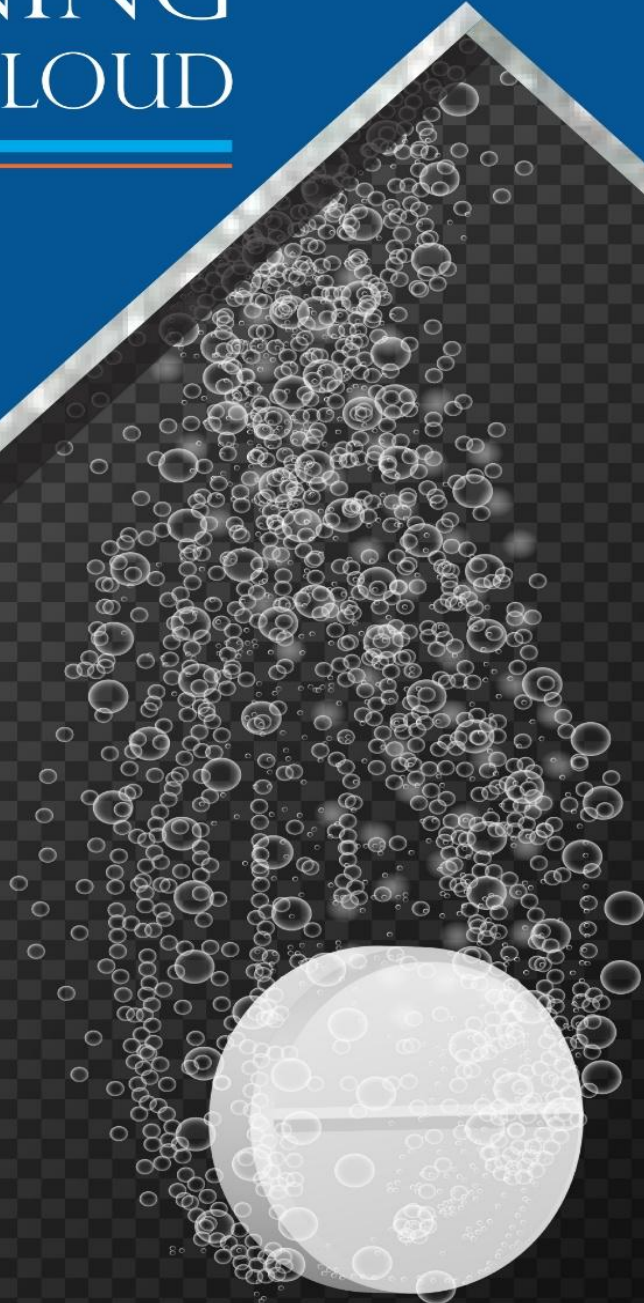




IIFL

THE
SILVER LINING
IN PHARMA CLOUD



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| Alkem laboratories– BUY | | |
|-------------------------|--------|--------|
| CMP | Target | Upside |
| 2,154 | 2,551 | 18.44% |
| Biocon – BUY | | |
| CMP | Target | Upside |
| 586 | 789 | 34.61% |
| Natco Pharma – BUY | | |
| CMP | Target | Upside |
| 785 | 1,006 | 28.2% |
| Strides Shasun – BUY | | |
| CMP | Target | Upside |
| 692 | 960 | 38.68% |
| Syngene – BUY | | |
| CMP | Target | Upside |
| 549 | 658 | 20.00% |

Prices as on 16/03/2018

March 16, 2018

Analyst-Shrikant Akolkar
research@iifl.com

The Indian pharma sector has been facing tough business environment in domestic as well as overseas markets over the past few years. This includes higher competition, pricing pressure, channel consolidation in the US, increased regulatory scrutiny by global drug regulators and rupee appreciation over the past 18 months. The environment in the Indian pharma sector (IPM) has also been challenging due to price controls announced by Drugs Price Control Orders (DPCO). Due to these challenges, valuations in the sector have come down from the highs of two years. While several companies remain impacted on regulatory fronts and have concerns over their growth, there is an opportunity for investors to cherry pick stocks in the sector having strong compliance record and earnings visibility.

Complex drugs and Biosimilars offer great value

As the plain vanilla generics continue to face high competition, companies with complex drug portfolio offer long term growth opportunity. Companies with specialty pipeline – (1) Natco Pharma (*Copaxone, Revlimid*) and (2) Strides Shasun (most filings in GDUFA regime) and Biosimilar portfolio of Biocon (*Trastuzumab, Pegfilgrastim, Glargine*, etc.) offer strong growth visibility going ahead.

Diversified geographical revenue mix will be favored

Companies with the diversified revenue streams are likely to perform much better going ahead. The Australian market is attractive considering positive industry macros, favorable for Strides Shasun. The domestic market is likely to grow at 12.5% over FY18-20E and it remains attractive for Alkem. The drug research outsourcing industry appears to be appealing due to various tailwinds in the sector, positive for Syngene International.

While earnings growth is vital, it is dependent upon strong compliance and product portfolio in pharma sector. We favor businesses which are less affected by the pricing pressure or regulatory challenges. The rupee depreciation will bring additional upside lever.

We prefer (1) Alkem Laboratories – solid domestic franchisee, clear facilities (20.3x FY20E EPS), (2) Biocon – Biosimilar play (20.8x FY20E EPS), (3) Natco Pharma – complex pipeline and clear earnings trajectory (16.4x FY20E EPS), (4) Strides Shasun – diversified business (14.0x FY20E EPS), and (5) Syngene International – innovative research model (23.4x FY20E EPS).

Double digit growth for domestic pharma

IPM, after absorbing the GST impact, has shown signs of recovery in Q3FY18 (up 16% yoy). The growing health insurance coverage, increase in lifestyle diseases like diabetes, high blood pressure, etc. and rising income levels remain the key growth drivers of the IPM. The industry growth in FY18E is likely to remain in the range of 8-9%, however by FY20E, IPM is expected to reach to ₹1.35 lakh cr from ₹94,000cr in FY17, clocking a CAGR of 12.5%.

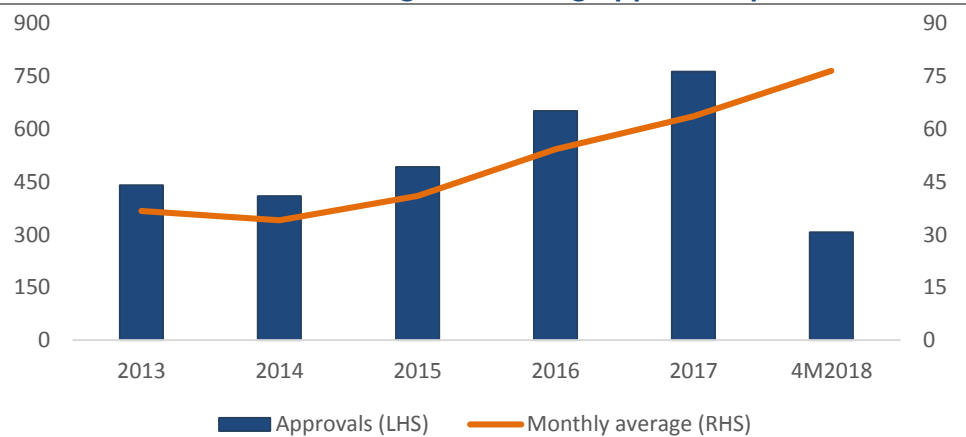
Faster approvals leading to higher competition, pricing pressure

Companies exporting their drugs to US are facing a steep challenge owing to the increase in the regulatory activities after the implementation of Generic Drug User Fee Amendments (GDUFA I) in 2012 and GDUFA II in 2017. The aim of GDUFA is to accelerate the generic drug approvals and improve the regulatory compliance according to the cGMP standards recommended by USFDA.

This is creating double whammy for the existing players by (a) loss of volumes to new players and (b) price cuts leading to lower gross margins. The GDUFA II guidelines are the aggressive form of the GDUFA I, which is leading USFDA to approve record number of drugs. The recent NADAC data shows that overall generic drug prices in the US (excluding super-inflating generics) have declined 7.6% yoy in the past six months vs. decline of 6.4% yoy in the prior six months. The pricing pressure is expected to continue for another 12-18 months as more channels consolidate and Amazon tries to enter the healthcare space.

US generic prices declined 7.6% yoy in the past six months over 6.4% yoy decline over prior six months

Exhibit 1: USFDA on record generic drug approval spree



Source: USFDA, IIFL research

Under GDUFA, approval rate is 77 ANDAs per month in 2018 vs. 64 ANDAs per month in 2017

Warning letter issues impact pharma companies significantly

In the GDUFA regime, USFDA inspections at the foreign drug manufacturing facilities have increased. India has received its fair share but has resulted in several plants put under Official Action Indicated status (OAI) through warning letter/import alert.

As per USFDA’s database, over 2012-17, cumulatively ~113 facilities in India received OAI vs. ~77 facilities in China. It is a well-known fact that plants, upon receiving OAI, cannot file any product while approvals are withheld until the plant is fully compliant. It could also impact products in the other developed markets as regulators are working together due to their data sharing pact.

Cumulatively 113 Indian facilities received OAI vs. 77 in China over 2012-17

Exhibit 2: Major Indian plants under warning letter/Import alert

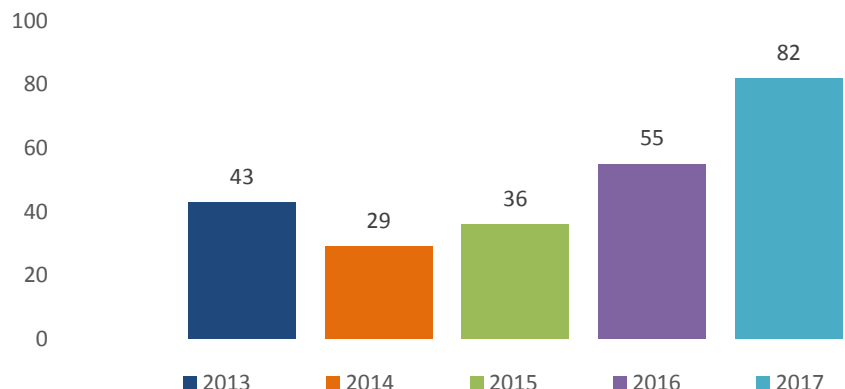
| Company | Affected plant |
|-------------------|--|
| Sun Pharma | Halol (Dec 2015), Paonta Sahib and Dewas (2008), Karkhadi (March 2014) |
| Dr. Reddy’s lab | Srikakulam and Duvvada (Nov 2015) |
| Lupin | Goa, Indore (Nov 2017) |
| Wockhardt | Waluj (May 2013), Chikalthana (Nov 2013), Ankleshwar (Dec 2016) |
| IPCA | Ratlam, Piparia and Pithampur (Jan 2016) |
| RPG Life Sciences | Ankaleshwar and Navi Mumbai (Since May 2013) |
| Aarti Drugs | Tarapur and Palghar (July 2013) |

Source: Companies, USFDA, IIFL research

Our studies indicate that out of the total 304 warning letters issued between 2013-18, only 44 plants received clearance, while rest are still under the warning letter. Those plants which received clearance, took average 400-500 days, which means a quick resolution of warning letter/import alert is a distant dream

Quick resolution of regulatory issues is a distant dream in most cases

Exhibit 3: Pending backlog of warning letters



Source: USFDA, IIFL research

USFDA also has high number of pending warning letters. For e.g. in 2013, USFDA issued warning letters on total 51 global plants. So far, only 8 of these plants have clearance, while rest 43 plants continue to remain under the warning letter. USFDA is a tough regulatory and has issued warning letters even for single observation (warning letter issued to Aztex Enterprises in Oct-17). This highlights that warning letters are not to be seen lightly and such companies, should be clearly avoided, unless they have a diversified revenue stream.

Biosimilars, next leg of growth for generic pharma

Biologics are diverse products, which are generally large and complex molecules produced through biotechnology in a living system. Biosimilars, in a simple language, are the generics of biologic drugs. The current biosimilar market is \$4bn (2017), which is expected to triple to reach ~\$11bn in 2020E. The market for the Biosimilars is well spread across US, Europe and other developed countries. We see existing Biosimilar pipeline (in Phase III) are close to approval stage within next two years, which makes Biosimilars very attractive growth opportunity.

Dr. Reddy's, Lupin, Biocon, Cadila, Natco, Aurobindo, etc. are the Indian companies having ambitious projects in the Biosimilars space. While these products are still to contribute to the Indian companies, the scenario is expected to change by 2020E.

Some opportunities still intact in the pharma space

Owing to the range of challenges faced by the pharma companies, share prices have seen a significant decline in the past two years. The large caps, which enjoyed P/E multiples of 24-25x two years ago, are currently trading below 20x. The earlier higher multiples were factoring the strong earnings growth however, the growth rates have tapered since the last two years leading to de-rating of the multiples.

Considering the low investor sentiment in the sector, we believe that there is an opportunity to cherry pick stocks with better earnings visibility vs. troubled peers. It will be a sound idea to stick to the businesses having (a) robust domestic business, (b) diversified or differentiated business model, (c) pipeline that gives strong earnings visibility and (d) strong compliance track record.

Biosimilars offer a multi-billion-dollar opportunity and Biocon is frontrunner in this market

Our stock selection is based on Compliance, product pipeline, geographical mix and earnings trajectory

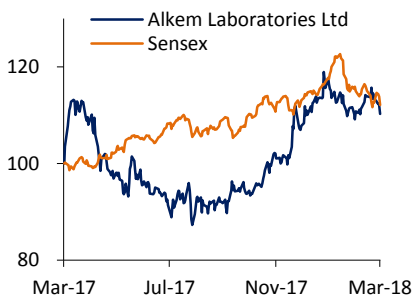
| | |
|----------------|--------|
| Sector | Pharma |
| Recommendation | BUY |
| Upside | 18.4% |

| Stock Data | |
|------------------|---------------|
| Sensex | 33,176 |
| 52 Week h/l (₹) | 2,468 / 1,578 |
| Market cap (₹Cr) | 25,752 |
| BSE code | 539523 |
| NSE code | ALKEM |
| FV (₹) | 2 |
| Div yield (%) | 0.7 |

| Shareholding Pattern | | | |
|----------------------|--------|--------|--------|
| | Jun-17 | Sep-17 | Dec-17 |
| Promoters | 66.99 | 67.02 | 65.86 |
| DII+FII | 6.65 | 6.4 | 6.59 |
| Individuals | 26.36 | 26.58 | 27.55 |

Source: www.bseindia.com

Share Price Trend



Prices as on 16/03/2018

Alkem Laboratories is a domestic focused pharma company, which enjoys a leading position in several acute therapies. Its chronic segment continues to grow faster than the industry and should help in 128bps margin expansion (FY18-20E), as MR productivity improves. In the US market, company is facing yoy price erosion of 5-7%. Company generates annual \$4.6mn revenue per product in the US (Q3FY18). With clear facilities and 48 of 96 ANDAs pending approval by Q3FY18, it has better revenue visibility in the US. We expect revenue and PAT CAGR of 11.7% and 23.6% respectively over FY18-20E and recommend BUY with target price of ₹2,551 (24x FY20E EPS).

Domestic business growing at 15%: Alkem has been consistently outperforming the domestic pharma industry. Over FY13-17, while industry grew at 12.3% CAGR, Alkem grew by 17%. This outperformance is expected to sustain owing to its leadership in the anti-infective segment, fast growing chronic franchisee and thrust to grow its mega brands such as Clavam, Pan, Taxim, etc., which generated Rs1,500cr revenue in FY17 (40% of its domestic revenue). Foray in lucrative OTC business, is expected to be positive.

Lower regulatory risk than peers, 70-80bps margin uptick likely: We believe Alkem is one of the best investment opportunities in the pharma sector due to (a) fast growing domestic business (b) lower regulatory risk and (c) small yet growing US base. Currently, all its facilities are compliant with the USFDA, which gives better revenue visibility in the US business. The margin uptick is expected due to the improving economics of scale in chronic segment and the US business.

Low risk, strong FCFs to command premium valuation: Alkem has strong balance sheet with net zero debt. In absence of major capex, it should cumulatively generate ₹1,352cr in free cash flows in FY19E/FY20E. The high MR productivity in chronic business and monetization of ANDA pipeline should aid margins by 128bps over FY18-20E. We favor Alkem given low regulatory risk, organic growth opportunities and strong acute franchisee.

Financial Summary

| Consolidated ₹cr | FY17 | FY18E | FY19E | FY20E |
|------------------|-------|-------|-------|-------|
| Revenue | 5,853 | 6,418 | 7,136 | 8,008 |
| Growth (%) yoy | 15.9 | 9.7 | 11.2 | 12.2 |
| EBITDA% | 17.1 | 19.2 | 20.4 | 20.5 |
| PAT | 892 | 832 | 1,135 | 1,271 |
| Growth (%) yoy | 20.4 | -6.8 | 36.4 | 12.0 |
| P/E (x) | 28.9 | 30.9 | 22.7 | 20.3 |
| ROE % | 20.0 | 17.0 | 19.7 | 18.9 |
| ROCE % | 17.1 | 20.6 | 19.8 | 19.5 |

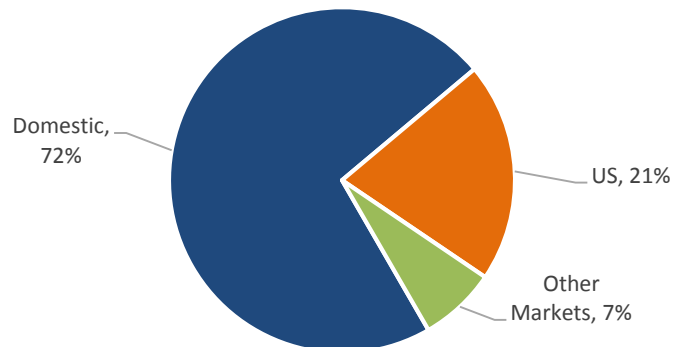
Source: Company, IIFL Research

Company Background

Alkem Laboratories is a Mumbai based pharma company. It has branded formulations business in India, US and ROW markets. It is the fifth largest pharma company (3.4% market share) in the domestic market, which contributes 72% of its total revenue (Q3FY18) and has ~6,000 medical representatives. The US and other markets contribute 21% and 7% of its total revenue respectively in Q3FY18.

Within the domestic markets, company has large base in acute therapies (85% of domestic revenues), followed by chronic (15%). In the acute therapies, company enjoys leading position in anti-infective, gastrointestinal and pain management segments. It has recently entered the OTC market with launch of male contraceptives and female pregnancy test kits. Company has 20 manufacturing facilities, of which two are located in US.

Exhibit 1: Revenue mix Q3FY18



Source: Company, IIFL Research

Outperforming the domestic industry despite large base

Alkem has a large domestic revenue base comprising of acute and chronic therapies and has recently added OTC brands. With market share of 3.4% (FY17), Alkem is a significantly large company in the domestic pharma sector. Owing to its relationships with the doctors, Alkem has constantly outperformed the domestic pharma market and all of this growth has come organically. Over FY13-17, when domestic industry grew at CAGR of 12.3%, Alkem managed to grow by 17%.

Alkem holds 3.4% market share in IPM in FY17

Company is leader in anti-infective segment and is ranked number three in Gastro Intestinal and pain management. It has several brands, which reported sales of ₹100cr+ in FY17 such as Clavam (₹262cr), Pan (₹197cr), Pan D (₹190cr), Taxim O (₹186cr) and Taxim (₹150cr). Besides, brands like Gemcal, Xone, Ondem and Sumo reported sales in the range of ₹50-100cr. Alkem’s outperformance has continued in Q3FY18 with company growing by 18.2% vs. industry growth of 10.4%.

Alkem delivered ~450bps outperformance over the industry between FY13-17

Exhibit 2: Alkem vs. Industry growth in Q3FY18

| | Segment | Q3FY18 | |
|----------------|-------------------|-----------|--------------|
| | | Alkem (%) | Industry (%) |
| Acute | Anti-infective | 19.5 | 10.5 |
| | Gastro Intestinal | 11.4 | 9.4 |
| | Pain / Analgesics | 13.3 | 7.7 |
| | Nutrition | 23.8 | 9.7 |
| Chronic | Neuro / CNS | 15.0 | 5.8 |
| | Derma | 26.7 | 16.6 |
| | Cardiac | 16.1 | 6.8 |
| | Anti-Diabetic | 31.6 | 9.8 |

Source: Company, IIFL Research

Domestic chronic business to provide margin and growth boost

Chronic therapies represent ~1/3rd of the domestic pharma industry and this market is growing by 20%+ annually. Alkem’s chronic segment is relatively new and built organically. The business is yet to attain a critical mass (FY18E base ~₹500cr), however the growth has been faster than the industry growth. In 9MFY18, Alkem, in its neuro, Derma, Cardiac and anti-diabetic segments outperformed the industry by 750bps, 770bps, 1020bps and 760bps respectively. Alkem is also outperforming the chronic therapies of IPM, which is a fast growing segment. We estimate that Alkem’s share in the chronic therapies would improve from 1.2% in FY18E to over 1.5% in FY20E.

Alkem’s market share in Chronic is likely to improve from 1.2% in FY18E to 1.5% in FY20E

Alkem’s annualized MR productivity in the chronic segment is at ~Rs30 lakh in 9MFY18 (vs. ~Rs60 lakh in the acute segment in 9MFY18). Going ahead, as company gains market share, the MR productivity should also improve. Chronic is a repeat business and has better gross margins than acute business. As revenue from chronic segment grow, absence of significant capex/opex, operating margins are likely to increase by 128bps over FY18-20E.

Alkem’s annualized MR productivity in chronic segment is ₹30lakh in Q3FY18 vs. ₹60lakh in acute segment in Q3FY18

Scale-up in the US business

While several generic companies have continued to report double digit erosion in the US business, Alkem’s erosion remains in the single digits

Alkem's US revenue is likely to grow at 11.3% CAGR over FY18-20E to reach \$250mn in FY20E

(5-7% yoy in Q3FY18). Alkem's US products generated average \$4.6mn in annual revenue in Q3FY18. By Q3FY18, Alkem has a pipeline of 96 ANDAs, with 48 ANDAs approved and 48 ANDAs awaiting approvals. With annual 8-9 ANDA launches over next two years and average \$4mn revenue per ANDA, we estimate Alkem's US revenue to grow at 11.3% CAGR from \$201mn in FY18E to \$250mn in FY20E.

Exhibit 3: Alkem's Para IV pipeline and low competition ANDAs

| Low competition drugs | | | Para IVs filed | |
|-----------------------|------------|-------------|----------------|------------|
| Brand | 2017 Sales | | Brand | 2017 Sales |
| | \$mn | Competition | | \$mn |
| gToviaz | 99 | 3 | gAmpyra | 545 |
| gSolodyn | 148 | 6 to 7 | gGilenya | 3,185 |
| gAzilect | 343 | 4 | gLyrica | 3,463 |
| gBystolic | 606 | 7 to 8 | gNucynta | 280 |
| gCrestor | 3,870 | 19 | gSensipar | 1,374 |
| gXeloda | 704 | 8 | gTecfidera | 3,294 |

Source: Company, USFDA, Bloomberg, IIFL Research

Alkem has six facilities catering to the US market and all of which have been cleared by the USFDA. These fully compliant manufacturing sites, provide the comfort that the company is on a strong track in the US market. As the company starts monetizing its pipeline, the economies of the scale should start kicking in, providing further boost to the margins.

Strong FCF generation to boost return ratios

Alkem's revenue/PAT is likely to grow at a CAGR of 11.7%/23.6% over FY18-20E due to its India focus strategy and ongoing momentum in the US pipeline monetization. Alkem has strong balance sheet with neutral net debt position by Q3FY18. With no major capex lined up over FY19-20E, the business is expected to cumulatively generate ₹1,352cr in free cash flows. Alkem's balance sheet will further strengthen with monetization of its real estate worth ₹260cr (₹21 per share) over next 12 months. Alkem's RoE will improve from 17.0% (FY18E) to of 18.9% in FY20E.

Key risk factors – (1) Lower growth in the domestic business, (2) slower monetization of the ANDA pipeline, (3) increased competition in the existing US products.

Alkem is expected generate ₹1,352cr FCF over FY19-20E

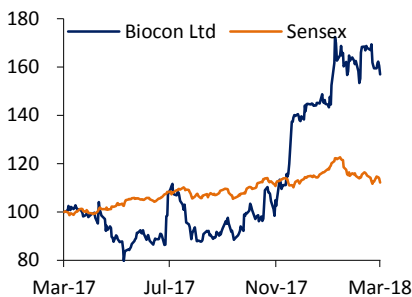
| | |
|----------------|--------|
| Sector | Pharma |
| Recommendation | BUY |
| Upside | 34.6% |

| Stock Data | |
|------------------|-----------|
| Sensex | 33,176 |
| 52 Week h/l (₹) | 658 / 295 |
| Market cap (₹Cr) | 35,169 |
| BSE code | 532523 |
| NSE code | BIOCON |
| FV (₹) | 5 |
| Div yield (%) | 0.8 |

| Shareholding Pattern | | | |
|----------------------|--------|--------|--------|
| | Jun-17 | Sep-17 | Dec-17 |
| Promoters | 60.67 | 60.67 | 60.67 |
| DII+FII | 18.80 | 19.23 | 20.39 |
| Individuals | 20.53 | 20.10 | 18.94 |

Source: www.bseindia.com

Share Price Trend



Prices as on 16/03/2018

Biocon is India's largest biotech company with presence in research business. Biocon's early entry in the Biosimilars is expected to reap huge profits. Biocon-Mylan has received an approval for biosimilar of Trastuzumab in US (Dec 2017), while 2-3 biosimilars are expected to get US and EU approval in 2018/2019. This will help Biocon to grow its profit 5-6x over next five years. Biocon's EBITDA margins are expected to improve from 27% in FY18E to 42% in FY20E. We recommend BUY on Biocon with target price of ₹789 (28x FY20E EPS).

New launches to trigger PAT growth of Biosimilars: Biocon and Mylan have made rapid progress in their biosimilar programs with Trastuzumab approval in US/Brazil and likely European approval in FY19E. Pegfilgrastim approval in US/Europe is also expected in FY19E. Both these two Biosimilars are expected to cumulatively contribute ~\$475mn (₹3,000cr) in PAT over FY19-21E. We expect Biocon's PAT to grow 3x over FY18-20E owing to these launches.

Research business back on growth track: Biocon's research business (Syngene) contributed 34% of its total revenue in Q3FY18. Syngene's growth has almost recovered from the facility damage in Q3FY17. The company has commissioned ~\$100mn capex by Q3FY18 and is on track to start contributing strongly in FY19E. The commissioning of biologics facility and extension of BMS contract in Q3FY18 are the near term triggers. The tailwinds in the CRO industry are positive for Syngene.

Strong earning visibility: Biocon has strong earnings visibility over next 5-6 years due to its biosimilar pipeline with Mylan. It has also partnered with Sandoz to develop multiple Biosimilars in immunology and oncology. This gives further boost to Biocon's biosimilar program. Considering strong earnings visibility, PAT CAGR of 69% is expected over FY18-20E,

Financial Summary

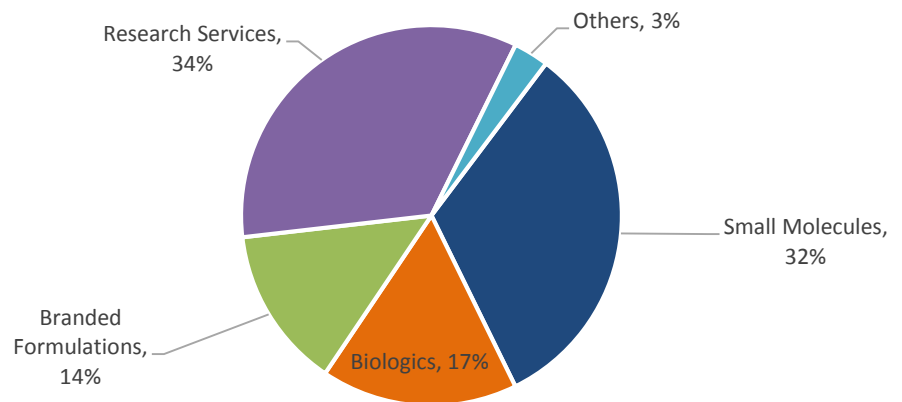
| Consolidated ₹cr. | FY17 | FY18E | FY19E | FY20E |
|-------------------|-------|-------|-------|-------|
| Revenue | 3,891 | 4,086 | 4,860 | 6,842 |
| Growth (%) yoy | 16.2 | 5.0 | 13.0 | 15.0 |
| EBITDA% | 25.2 | 27.0 | 28.8 | 41.8 |
| PAT | 612 | 592 | 733 | 1,691 |
| Growth (%) yoy | 11.2 | -3.3 | 23.8 | 130.6 |
| P/E (x) | 57.5 | 59.4 | 48.0 | 20.8 |
| ROE % | 14.2 | 12.9 | 14.8 | 27.6 |
| ROCE % | 10.1 | 9.9 | 17.3 | 35.0 |

Source: Company, IIFL Research

Company Background

Biocon is a Bangalore based fully-integrated biopharma company. It has API manufacturing facilities, a research business, strong capabilities in biologics manufacturing, innovative drug development pipeline and a branded generics business in India and UAE. In Q3FY18, its small molecules, research business, branded formulations and biologics businesses contributed 32%, 34%, 14% and 17% respectively and the rest 3% came from the other business, mainly licensing fees. In India, it is the largest biologics company and has products like Insugen, Basalog, Canmab, Alzumab, etc. Overall India contributes 30% of revenue and 70% comes from overseas markets.

Exhibit 1: Business mix Q3FY18



Source: Company, IIFL Research

Biocon's business segments:

- ✧ **Small molecules** – APIs and generic formulations, largely statins, and immune-suppressants
- ✧ **Biologics** – Biosimilars & Novel Biologics
- ✧ **Branded Formulations** – Specialty formulations Business in India and UAE, has products like Insugen, Biomab-EGFR, Basalog, Krabeva, etc.
- ✧ **Research Services** – Contract Research & Manufacturing

Global Biosimilars market to reach ~\$11bn by 2021E

Biologics are diverse products, which are generally large and complex molecules produced through biotechnology in a living system. Biologics involve complex manufacturing procedures and they are required to be maintained at pre-determined conditions, as they are highly

Biologics market is ~\$239bn in 2016, of which ~\$4bn is Biosimilars

sensitive to changes in ambience. The global biologics market was ~\$239bn in 2016 and is growing by ~4% yoy. Unlike other generics, Biosimilars require clinical trials to be completed for approval. Biosimilar market is still developing (\$3.4bn in 2016), and it will grow at 26.3% CAGR to reach \$10.9bn by 2021E.

Biocon has enviable pipeline of Biosimilars

Over the past decade, Biocon has developed a pipeline of high value, Biosimilars in Indian markets. Company has a partnership with Mylan to develop and commercialize the Biosimilars for advanced markets going ahead. Biocon’s pipeline with Mylan has reached a critical stage where it expects to commercialize the biosimilar assets over FY19E/FY20E. In Jan 2018, Biocon had signed partnership with Sandoz to develop next generation Biosimilars.

Exhibit 2: Biocon’s current Biosimilar pipeline

| Category | Molecule | Type | Status | Size in \$bn |
|--------------------------|---------------|------------------------|---|--------------|
| Insulins | Rh Insulin | Regular Acting Insulin | Pre-clinical (US), Marketed in EM | 3.2 |
| | Glargine | Long Acting Insulin | EU (+CHMP opinion). Under review in US, Australia & Canada. Marketed in Japan & Ems | 6.4 |
| | Aspart | Rapid Acting Insulin | Global Phase I | 4.5 |
| | Lispro | Rapid Acting Insulin | Preclinical | 2.8 |
| Biosimilars With Mylan | Adalimumab | Auto-Immune | Global Phase III completed | 16.1 |
| | Trastuzumab | Cancer | Approved in US. Under review in EU, Canada and Australia, Filed/ Marketed in EM | 6.8 |
| | Pegfilgrastim | Neutropenia | Filed in US, EU, Canada, Australia, EM | 4.6 |
| | Bevacizumab | Cancer | Global Phase III. Marketed in India | 6.9 |
| | Filgrastim | Neutropenia | Early development | 0.8 |
| | Etanercept | Auto-Immune | Early Development | 8.9 |
| Total Market Size | | | | 61.0 |

Biocon has a pipeline with biologic brands worth \$61bn in sales

Trastuzumab, \$95mn potential US+EU opportunity

Trastuzumab (innovator Roche, brand Herceptin) is the first biosimilar from the Biocon/Mylan pipeline, which has been approved in Dec 2017 in US; approval in Europe is also expected soon. Roche reported global Trastuzumab sales of \$6.8bn in 2017 (US \$2.5bn, EU \$2bn, other \$2.3bn). Biocon/Mylan will market Trastuzumab under their brand Ogivri in 2018E. Samsung/MSD, Celltrion/Teva, Amgen/Allergan, etc.

Trastuzumab generated global sales of \$6.8bn in 2017 for Roche

Trastuzumab likely to result in post-tax profit of ~\$195mn over FY19-21E

are the other partnerships which are also gearing for Trastuzumab competition. Of this, Samsung/MSD have US approvals, while others are in the advanced stages. Biocon/Mylan have also resubmitted this biosimilar in Europe, where it has received a positive opinion and approval is likely in 2018E. We expect Biocon to generate profit of \$195mn (~₹1,270cr) over FY19-21E from Trastuzumab in US and Europe. Company is also hopeful to launch it in emerging markets.

Pegfilgrastim, \$285mn potential US+EU opportunity

Pegfilgrastim likely to see low competition, resulting in post-tax profit of ~\$280mn over FY19-21E

Biosimilar of Pegfilgrastim (innovator Amgen, brand Neulasta) is submitted to the regulatory agencies in US and Europe by Biocon/Mylan. There are about two competitors and the drug is not expected to be as competitive as Trastuzumab. This biosimilar is filed from Bangalore facility and has received a Complete Response Letter (CRL) in October 2017. The regulator has asked for more data on chemistry as well as on the facility requalification activities. The concerns over the facility does not seem severe as Trastuzumab is also filed from Bangalore facility and has been approved in December 2017.

The European regulator has accepted the resubmission of this biosimilar in December 2017 and has given a positive opinion in Jan 2018. We believe that approval is expected in FY19E. Biocon is expected to generate profit of \$280mn (~₹1,825cr) over FY19-21E from Pegfilgrastim in US and Europe.

Glargine, \$75mn EU potential opportunity

Biocon's Glargine is under 30-month regulatory stay in US, European approval to result \$75mn post tax profit to Biocon over FY19-21E

Insulin Glargine (innovator Sanofi, brand Lantus) is \$5.6bn drug globally in 2017. Biocon/Mylan are in an advance stages of regulatory submission in the EU, Australia and Canada. Company has approval for Glargine in Russia (Q3FY18). Glargine has received positive opinion in Europe in January 2018 and approval is expected in April 2018. The US submission triggered USFDA pre-approval inspection of the Malaysian manufacturing site in February 2018, which has received six form 483 observations.

The filing led to litigation filed by Sanofi against Mylan and has triggered a mandatory 30 month stay, which ends in March 2020, (patent expiry in 2023 /2028). Company has indicated that the European review for Glargine is fairly advanced and expects possible launch in this calendar year (2018E). We expect Biocon to generate profit of \$75mn (~₹488cr) over FY19-21E from Glargine in Europe.

Company has launched Glargine in Japan, and expects to launch in Russia and three more emerging markets.

Syngene to report 22% PAT CAGR over FY18-20E

Syngene's PAT to grow at 22% CAGR over FY18-20E

Syngene is Biocon's Custom Research Organization (CRO). It has capability in new drug research from discovery to development stage. The company is also in process to set up an API manufacturing facility, which will commission in 2020E. For Q2FY18 and Q3FY18, it had reported revenue growth of 17% yoy and 14% yoy respectively indicating that the company has come out of the negative impact of the facility damage in Q3FY17. Company has also invested ~\$100mn in biologics research, viral testing and formulations facility. Aided by the new growth initiatives, Syngene's revenue and PAT is expected to grow at CAGR of 21.5% and 22.2% respectively over FY18-20E.

Biocon at sweet spot with 2.9x PAT CAGR FY18-20E

Biocon PAT to grow 2.9x over FY18-20E

With the maturing biosimilar pipeline, lower regulatory hurdles, low risk model (due to the partnerships with Mylan and Sandoz) and growing CRO business, Biocon is in the sweet spot. Biocon is expected to see revenue and PAT CAGR of 29.4% and 69% over FY18-20E. Biocon has one of the best earnings visibility over FY18-20E in the India pharma sector and with the addition of new Biosimilars, earning growth is expected to continue even beyond FY20E.

Risk factors: 1) Delay in approval of Biosimilars, 2) unfavorable outcome of litigation with Sanofi, 3) escalation of form 483 on Malaysian facility to warning letter.

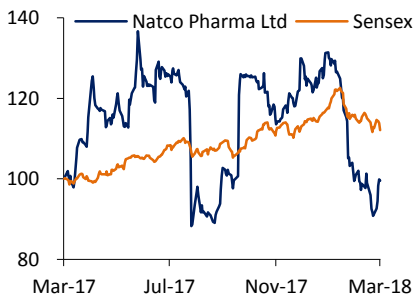
| | |
|----------------|--------|
| Sector | Pharma |
| Recommendation | BUY |
| Upside | 28.2% |

| Stock Data | |
|------------------|-------------|
| Sensex | 33,176 |
| 52 Week h/l (₹) | 1,080 / 671 |
| Market cap (₹Cr) | 14,473 |
| BSE code | 524816 |
| NSE code | NATCOPHARM |
| FV (₹) | 2 |
| Div yield (%) | 1.0 |

| Shareholding Pattern | | | |
|----------------------|--------|--------|--------|
| | Jun-17 | Sep-17 | Dec-17 |
| Promoters | 51.16 | 51.19 | 48.36 |
| DII+FII | 27.06 | 26.94 | 30.15 |
| Individuals | 21.78 | 21.87 | 21.49 |

Source: www.bseindia.com

Share Price Trend



Prices as on 16/03/2018

Natco Pharma is a Hyderabad based pharma company with focus on complex products. The launch of gCopaxone gives Natco strong earnings visibility over FY18-20E. gRevlimid, a \$8.2bn global drug in 2017 will be a big opportunity, due to settlement with Celgene (launch in 2022E). Natco should also benefit from recent launches of gDoxil, gVidaza, gForsenol and gTamiflu. We estimate CAGR of 9.6% and 20% in revenue and PAT respectively over FY18-20E. Recommend BUY on Natco with SOTP based target price of ₹1,006, which includes base business ₹862 (18x FY20E EPS) and discounted NPV of gRevlimid at ₹144/share.

Well-built portfolio of complex generics: Natco has built a pipeline of limited competition, complex, large size ANDAs. This includes drugs like gTamiflu (\$468mn in 2017), gCopaxone (20mg, 40 mg \$4.4bn in 2017), gRevlimid (8.2bn in 2017) and gLivec (1.9bn in 2017). Other limited competition drugs between the size of \$100-400mn include gDoxil, gFosrenol, gVidaza, gTracleer, etc. It has launched gCopaxone, gTamiflu, gVidaza, gFosrenol and gDoxil over last one year, which are likely to bring strong revenue/PAT growth going ahead. Company has total 29 approved ANDAs and 16 Para IVs to be launched yet.

gCopaxone to drive PAT: Copaxone is a complex drug and has seen ~30% price erosion after the first generic launch by Natco/Mylan in October 2017. The competition in gCopaxone should be limited, only two generics in FY19E and three generics in FY20E. gCopaxone is expected to generate cumulative PAT of ~₹1,250cr over FY19-20E.

Attractive valuations: The 25% fall in Natco's price since January 2018 is unwarranted, considering the huge benefits it is set to reap from its complex and high value ANDA pipeline. Natco's revenue/PAT grew 1.9x/3.1x yoy in FY17 and expected to grow further with gCopaxone ramp-up over next two years. We are positive on its plans to explore more complex generic opportunities in US market with strong balance sheet.

Financial Summary

| Consolidated ₹cr. | FY17 | FY18E | FY19E | FY20E |
|-------------------|-------|-------|-------|-------|
| Revenue | 2,065 | 1,985 | 2,407 | 2,384 |
| Growth (%) yoy | 91.2 | -3.9 | 21.2 | -0.9 |
| EBITDA% | 33.1 | 42.4 | 54.1 | 52.5 |
| PAT | 485 | 610 | 937 | 883 |
| Growth (%) yoy | 213.7 | 25.7 | 53.4 | -5.7 |
| P/E (x) | 29.8 | 23.7 | 15.4 | 16.4 |
| ROE % | 29.3 | 20.5 | 26.2 | 21.3 |
| ROCE % | 33.2 | 24.2 | 32.1 | 26.3 |

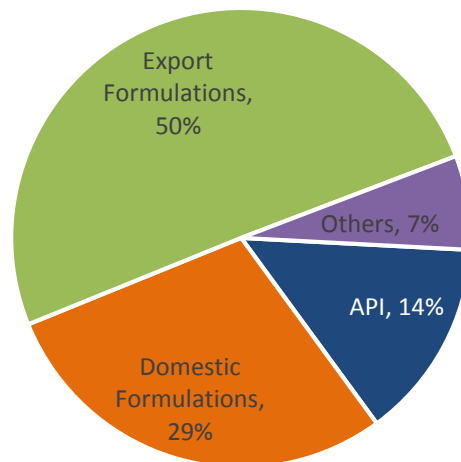
Source: Company, IIFL Research

Company Background

Natco Pharma, is a leading domestic player in oncology and derives ~36% of sales from the oncology business. The company derived revenue from international formulations (50%), domestic formulations (29%), APIs (14%) and others (7%) in Q3FY18. Domestically, company derives most of the revenue from Oncology (30 brands like Veenat, Lenalid, Bendit, etc.) and Hepatitis C drugs (13 brands like Hepcinat, Natsdac, Velpanat, etc.). The company is expanding its presence in Cardiovascular and Diabetology in India and expects to launch several products over next two years.

In the US, company has a pipeline of 29 approved ANDAs in Q3FY18. These are low competition, complex products with high dollar value. It also has a pipeline of 16 Para IVs (gGlivec, gRevlimid, gTykerb, etc). This small pipeline has been filed cautiously to focus on high value products. Company has lowered the risk of the costly litigations by partnerships with big players. It has completed a QIP of ₹915cr (Q3FY18), which will be used to invest in building pipeline of the complex generic drugs.

Exhibit 1: Business mix Q3FY18



Source: Company, IIFL Research

Domestic business - Hep-C a concern, steady growth in Onco

Natco's domestic business focuses on chronic medicines primarily Oncology and Hepatitis-C drugs. Company earlier focused on the Onco products, however in FY16, Natco launched first generics of Hepatitis C in India. The Hepatitis-C business, quickly ramped up and in FY17 became a Rs480cr franchisee (54% of domestic revenue). The increased competition in Hep-C, however has eroded the revenue from this segment to ₹320cr in FY18E (43.2% of domestic revenues). Natco expects to launch new products in Hep-C going ahead, that should give some boost to this segment.

Hep-C franchisee was ₹480cr in FY17 but has come under pressure

Onco franchisee is expected grow with new product launches

Domestic formulation business expected to clock 7% CAGR over FY18-20E

International formulation business has seen 5x growth over FY16-18E

In Onco, the company markets 30 products, which include several first generic products. The revenue from oncology segment has grown at a CAGR of 21% over FY15-18E. Company added three new products in its Onco business in Q3FY18 i.e. Pomalidomide and Carfilzomib (both multiple myeloma) and Melphalan (bone marrow transplant).

It has forayed into the Cardiology and Diabetology segments in Q1FY18. The division remains in the nascent stage but company has indicated that it will be launching first generic products in these divisions. Owing to the new product launches in Onco, but subdued growth in the Hep-C, we expect, domestic formulations business to clock 7% CAGR in revenue over FY18-20E.

Key launches have helped to scale-up US business

Natco's strategy to partner with global players to file complex, high value ANDAs has paid off handsomely. Over the past two years, company has launched low competition, high value ANDAs, with which its US business has grown significantly in base. The international formulations business has grown more than 5x over FY16-18E. US business is expected to reap benefits of the complex opportunities such as gCopaxone, gTamiflu, gTreanda, gEntocort, etc. over FY18-20E.

Exhibit 3: Natco's niche ANDA pipeline

| Recent launches | | | Known Para IVs | |
|-----------------|---------------------------------|-------------|----------------|-------------|
| Drug name | Competition | Size (\$mn) | Para IV | Size (\$mn) |
| gNuvugil | 3-4 | 450 | gJevtana | 120 |
| gCopaxone | 3 | 4,400 | gGilenya | 1,200 |
| gTamiflu | 5-6 in capsule, 3 in suspension | 700 | gNexavar | 300 |
| gEntocort | 7-8 | 400 | gRevlimid | 7,000 |
| gVidaza | 5-6 | 315 | gBosentan | 585 |
| gFosrenol | 3 | 125 | gPrevacid | 300 |
| gTreanda | 6-7 | 600 | gGlivec | 2,000 |

Source: Company, USFDA, IIFL research

gCopaxone to deliver bumper profits

Copaxone (20mg and 40mg) is a multiple sclerosis drug. Teva, which owns the brand, failed to protect the patents in 2017 and the generic was launched by Natco's partner Mylan in October 2017. Teva is aggressive in protecting its market share, however Mylan has gained market share of 15% (in 40 mg) by end of the Q3FY18. The gCopaxone (40mg) has seen entry of Sandoz in Feb 2018 (which is already present in 20mg), while Dr. Reddy's copycat is also expected in H2FY19E. We

gCopaxone would become a three player market in H2FY19E

gCopaxone should cumulatively make ~₹1,250cr post tax profit for Natco over FY19E-20E

believe that Mylan can gain market share of ~20% in FY19E (assuming a 3 player market). We estimate Natco to earn cumulative post tax profit of ₹1,250cr over FY19-20E from gCopaxone. This will help the company to strengthen its balance sheet and fund future high risk, complex products and put the company in the next growth orbit.

gRevlimid, Natco's biggest generic so far

Celgene, in 2015, has settled patent infringement litigation against Natco Pharma regarding a blockbuster multiple myeloma drug Revlimid (Lenalidomide). The settlement allows Natco to launch the generic version of Revlimid in limited volumes from March 2022 to January 2026 and in unlimited volumes afterwards. Revlimid's certain patents are expected to expire over 2018-2020 and if competition in gRevlimid intensifies, Natco will be able to bring its version of gRevlimid sooner.

gRevlimid will be a significantly large opportunity (~\$600mn PAT over FY23-26E) for Natco Pharma

Revlimid is a very aggressively priced drug and one of the most expensive drugs with a single pill priced at \$662. Revlimid holds dominant market share (48% in March 2017) in the multiple myeloma treatment which has led Celgene raising prices constantly since its launch. Celgene reported total global sales of \$8.2bn in 2017 of which \$4.4bn came from the US market. For Natco, this opportunity (~\$600mn in PAT over FY23-26E) would be bigger than gCopaxone. We value gRevlimid at ₹144/share.

Natco's cumulative PAT in FY19-20E will be higher than its PAT earned over FY11-18E

Revenue to grow 9% on a strong base, PAT CAGR to be 17%

In FY17, Natco reported revenue/PAT growth of 1.9x/3.1x yoy. Owing to the recent spate of limited competition. Moreover, with gCopaxone, Natco is further expected to report revenue/PAT CAGR of 9.6%/20.3% over FY18-20E. To put in perspective, Natco's cumulative PAT in FY19E and FY20E will be higher than its PAT earned over FY11-18E.

This strong profitability phase, over FY18-20E, will provide a huge impetus to Natco's balance sheet. The company has recently raised ₹915cr to invest in the complex generic research. Natco Pharma has demonstrated its ability to build pipeline of niche and complex products. The new R&D investments should provide further business opportunity once gCopaxone starts to fade in FY20E.

Risk factors: 1) Slowing revenue in domestic Hep-C, 2) delayed approval of gRevlimid, 3) increased competition in gCopaxone.

| | |
|----------------|--------|
| Sector | Pharma |
| Recommendation | BUY |
| Upside | 38.7% |

| Stock Data | |
|------------------|-------------|
| Sensex | 33,176 |
| 52 Week h/l (₹) | 1,173 / 640 |
| Market cap (₹Cr) | 6,196 |
| BSE code | 532531 |
| NSE code | STAR |
| FV (₹) | 10 |
| Div yield (%) | 0.6 |

| Shareholding Pattern | | | |
|----------------------|--------|--------|--------|
| | Jun-17 | Sep-17 | Dec-17 |
| Promoters | 31.36 | 31.12 | 31.12 |
| DII+FII | 50.96 | 49.59 | 48.82 |
| Individuals | 17.68 | 19.29 | 20.06 |

Source: www.bseindia.com

Share Price Trend



Prices as on 16/03/2018

Strides Shasun is rebuilding its Australia and US business after divesting Ascent Pharma Health in 2012 and Agila Specialties in 2013. With 15-20 new product launches (US/Australia) and 3-4 para IV launches in US, Strides should report revenue CAGR of 14% over FY18-20E. Divesting of low margin business in 2017 (India/Africa), API demerger (H1FY19E) and operating leverage should improve margins from 14% in FY18E to 18.3% in FY20E. This along with ₹400cr debt reduction by FY18-20E should lead to PAT CAGR of 65% over FY18-20E. We recommend Buy on Strides with target price of ₹960, implying 35% upside.

22% market share in consolidated AU generics: Strides has inorganically rebuilt its Australia business (Arrow Pharma) and has 22% market share (Q3FY18). Australia generics market (ex-OTC) is pegged at AU\$800-900mn and it is consolidated with 4-5 generic players holding 85% share in 2017. These players have partnerships with three large wholesalers, which have 95% market share. Company had 150 products in Q3FY18 and expects to add 15-20 products annually.

Niche product pipeline in the US: Strides' US business should grow at 16.5% CAGR over FY18-20E due to 15-20 launches annually. It has two para IVs, Gilenya (\$2bn, launch in Feb 2019E) and Daliresp (\$200mn launch in Jan 2020E). Company is an early filer for Rilpivirine (\$450mn, patent expiry in 2022). Strides has recently launched gViread (\$750mn, 4-5 players) and gEfavirenz (\$150mn, Para IV). Currently all its facilities are cleared by USFDA, hence there is no regulatory hangover.

2.7x PAT growth, divestments value accretive for Strides: The API business demerger and divestment of generics business in India/Africa are positive for the stock. The business will become full B2C in FY19E and should command better margins. The launches in regulated markets should lead to 2.7x growth in PAT over FY18-20E. We value Strides at ₹960 using SOTP method, core business at ₹839 (17x FY20E EPS), API business at ₹106 (10x FY20E EV/EBITDA) and Stelis Biopharma at ₹16.

Financial Summary

| Consolidated ₹cr | FY17 | FY18E | FY19E | FY20E |
|------------------|-------|-------|-------|-------|
| Revenue | 3,483 | 3,251 | 3,871 | 4,227 |
| Growth (%) yoy | 21.7 | -6.7 | 19.1 | 9.2 |
| EBITDA% | 18.5 | 14.0 | 16.6 | 18.3 |
| PAT | 400 | 163 | 325 | 442 |
| Growth (%) yoy | 268.4 | -59.3 | 100.1 | 35.7 |
| P/E (x) | 43.4 | 51.2 | 19.0 | 14.0 |
| ROE % | 15.5 | 5.4 | 10.0 | 12.1 |
| ROCE % | 7.7 | 4.5 | 7.3 | 8.9 |

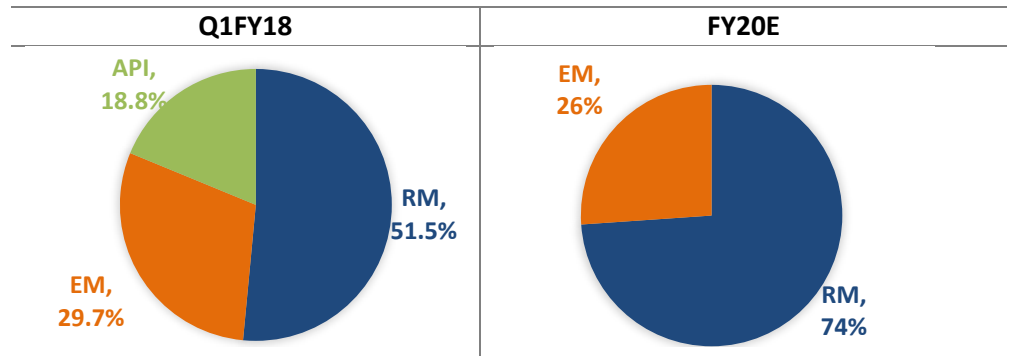
Source: Company, IIFL Research

Company Background

Strides Shasun (erstwhile Strides Arcolab) is a Bangalore based pharma company having presence in the pharma generics, branded generics, and biopharma. After divesting its stake in Australia based Ascent Pharma Health in 2012 (AU\$393mn) and US focused Agila Specialties in 2013 (\$1.75bn). Strides has re-entered Australia by serial acquisitions. It is also scaling up its US business after merger with Shasun Pharma in 2015.

The company is aiming to become a vertically integrated B2C business with a focus on branded formulations. As a part of this strategy, Strides exited the generics business in Africa in February 2017 and divested its India generics business in November 2017. Company is demerging its commodity API business in a separate entity named Solara Active Pharma Sciences in 2019E. After the restructuring, Strides Shasun will be B2C business and will be renamed Strides Pharma Limited.

Exhibit 1: Business mix



Source: Company, Bloomberg, IIFL Research

Exhibit 2: Evolution of the business from 2012

| Year | Development |
|-------|---|
| 2012 | Sale of Ascent Pharma (Australia) |
| 2013 | Sale of Agila Specialties (US) for \$1.75bn |
| 2014 | Merger with Shasun to ensure supply chain (API) security |
| 2015 | Acquired Arrow acquisition to re-enter Australia, acquired several brands in India |
| 2016 | Acquisitions 1) Generic Partners and Pharmacy Alliance in Australia 2) Universal corp. in Kenya 3) API facility from Perrigo 4) OTC brands from Moberg |
| 2017 | JV with Vivimed, capped investment in Stelis Biopharma, Divested following businesses: 1) CRAMS business 2) Africa generics business 3) India generics business |
| 2018E | Demerger of API business as Solara |

Source: Company, Bloomberg, IIFL Research

The business mix will change from formulation + API in FY18E to formulation only in FY19E

The business has evolved over several acquisitions and divestments

USFDA compliant manufacturing facilities

Strides operates formulations (solids, semi-solids) and API facilities in India, Kenya and Italy. It has also proposed to build a new Formulations facility in Singapore for regulated markets. All the facilities are having regulatory clearance from major regulators, the US focused facilities also have regulatory clearance. Indian facilities owned by Strides have been inspected in 2017, while the JV facility with Vivimed was inspected by USFDA in November 2016. The Beltapharm facility in Milan, Italy was last inspected in 2015. Its Chennai based R&D center also cleared USFDA inspection in December 2016.

Exhibit 3: Facilities have clear regulatory status

| Facility | Market | Type | Comment |
|------------------------|--------|-------------|--|
| Bangalore KRS Gardens | RM, US | OSD | 3 observations in May 2017, EIR in Sept 17 |
| Puducherry, PIMS Rd | RM, US | FDF | EIR received in April 2017 |
| Puducherry, Mathur Rd | RM, US | API | EIR received in May 2017 |
| Melakottaiyur | RM, US | R&D centre | EIR received in Dec 2016 |
| Cuddalore (Solara) | RM, US | API | EIR received in May 2015 |
| Beltapharm, Italy | RM, US | Semi-Solids | EIR received in May 2015, TGA cleared in June 2014 |
| Ambarnath | RM, US | API | Last inspection without observations |
| Alathur, (JV facility) | EM | OSD | Nov 2016, cleared |
| Chandapura | EM | OSD | |
| Bannerghatta | EM | R&D | |
| Nairobi, Kenya | EM | Semi-Solids | |

Source: Company, IIFL research, RM – Regulated markets, EM – Emerging markets, OSD – Oral solid dosages

Australia generic market dynamics positive for large players

Strides, through Arrow Pharma, has completed a few bolt on acquisitions in the Australia market (1) Generic Partners- Aug 2016, (2) Pharmacy Alliance – May 2016, (3) Amneal Pharmaceuticals Aug 2017. It also has a 10-year agreement with Sigma, the largest pharmacy wholesaler in Australia.

The Australian market is highly consolidated and it is expected to remain the same going ahead. The penetration of generic drugs in

All facilities are clear and it has one of the best compliance track record

Generic drug penetration in Australia is ~60% and industry macros are positive for generic companies like Strides Shasun.

Australia is ~60% and government is promoting the use of the generic drugs, which should further improve this share.

The company is also expecting to relocate manufacturing of the Australian drugs to India (13 products have received approval in Q3FY18), which should be positive to generate synergies from the Indian plants, driving up its margins. With the 15-20 new product launches and low cost manufacturing, the Australian business should lead to see 11.1% CAGR in the top-line, to reach AU\$299mn by FY20E.

Healthy US ANDA pipeline, accelerated approvals expected

Strides has been re-building its US business after sale of injectable business. The current pipeline is mostly in solid dosages and few in topicals. The company currently has total 82 ANDA filings (including JV ANDAs) of which 50 ANDAs are approved and 32 are pending approval.

Strides' most ANDA filings have been during the GDUFA I regime, especially in the last two years (average approval cycle of 10-40 month). These ANDAs should get faster approval as per GDUFA I timelines. Also with the new, GDUFA II timelines kicking in, ANDAs submitted between 2018-22 would get reviewed within the 10 months of submission. The company expecting to file annually 15-20 niche, low competition ANDAs. This should benefit the company to ramp-up its US business going ahead.

Strides to become B2C business with API demerger

Strides has proposed to demerge its commodity API business in Q4FY18E/Q1FY19E as Solara Active Pharma Sciences. Solara will also include Human API Business of SeQuent Scientific and will have three USFDA approved plants. API contributed 19-20% of Strides' revenue in FY17 and has EBITDA margins of ~16%.

Strides' shareholders will get 6 Solara shares per share of Strides. Solara will be run by separate management and will be listed on exchanges. We value Strides' API division at ₹105per share (10x FY20E EV/EBITDA). After the API demerger, Strides will be left with high margin, B2C business in Australia, US and Africa. The low margin India and Africa business has already been divested to Eris Life. Company also has global OTC division, which has products like Nuprin, Jointflex (pain relief cream) and Pediacare (cough, cold and allergy).

Risk factors- (1) Slower approvals in US/Australia, (2) price controls in Australia, (3) lower operating leverage in Australia business.

Relocation of manufacturing from Australia to India will see margin improvement

Strides' is focusing on low competition, niche ANDAs most of which have fewer than 10 players

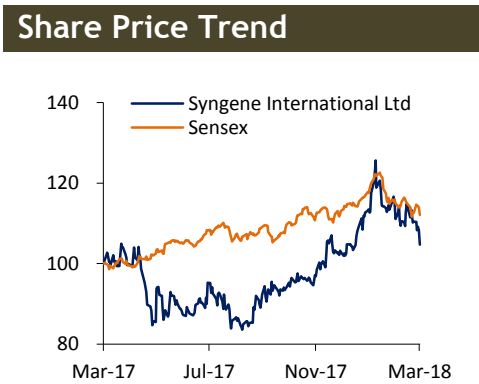
The API business is expected to continue grow 8.8% with EBITDA margins ~17% in FY20E. The demerger will be value unlocking for shareholders

| | |
|-----------------------|---------------|
| Sector | Pharma |
| Recommendation | BUY |
| Upside | 20.0% |

| Stock Data | |
|------------------|-----------|
| Sensex | 33,176 |
| 52 Week h/l (₹) | 670 / 430 |
| Market cap (₹Cr) | 10,973 |
| BSE code | 539268 |
| NSE code | SYNGENE |
| FV (₹) | 10 |
| Div yield (%) | 0.2 |

| Shareholding Pattern | | | |
|----------------------|--------|--------|--------|
| | Jun-17 | Sep-17 | Dec-17 |
| Promoters | 74.51 | 74.5 | 74.46 |
| DII+FII | 17.06 | 17.51 | 17.82 |
| Individuals | 8.43 | 7.99 | 7.72 |

Source: www.bseindia.com



Prices as on 16/03/2018

Syngene International is a full service CRO, which is expected to benefit from increasing outsourcing of innovative R&D to CROs. It has both chemicals and biologics capabilities and it should benefit from capacity augmentation over the next decade. We believe that Syngene is on its way to build a global CRO brand, while commercial manufacturing (CMO in 2020E) is its natural extension. Syngene is best for investing in the innovative drug research business, which should command better valuations. We forecast revenue/PAT CAGR 21.5%/22.2% over FY18-20E and recommend BUY with target price of ₹681 (28x FY20E).

Operates in an attractive industry with tailwinds: Syngene operates in an attractive industry, which is expected to see continued demand expansion. The global pharma companies have come under pressure due to the patent cliff and lower profitability. In order to optimize their cost structures, these companies are preferring CROs to perform their R&D. The CRO industry is growing at 7-8% CAGR and will reach \$59bn by 2020E. The CRO model is based on low costs, which makes Indian CRO industry attractive due to its huge cost arbitrage.

Syngene on strong growth path: While FY17 performance was subdued (up 8% yoy), Syngene has returned to growth path in Q3FY18. Company has been able to grow at CAGR of 23% over FY11-18E with 30%+ EBITDA margins throughout. It has commenced viral testing center, three 3,000 Kg bio-reactors, biologics center and a formulations facility. Company has also acquired bio-informatics capabilities in FY17. Syngene is on a secular growth path and margin expansion due to organic/inorganic acquisition of new capabilities.

Syngene should command premium valuations: Syngene, a low risk company, has secular growth drivers and operates in an attractive industry. With the entry in contract manufacturing (CMO), margins have much leeway to expand after 2020E. We believe Syngene has a clear long term earnings growth trajectory of 20%+. Considering this, we believe Syngene should command premium valuations.

Financial Summary

| Consolidated ₹cr | FY17 | FY18E | FY19E | FY20E |
|------------------|-------|-------|-------|-------|
| Revenue | 1,201 | 1,393 | 1,696 | 2,055 |
| Growth (%) yoy | 8.5 | 16.0 | 21.8 | 21.2 |
| EBITDA% | 33.9 | 33.2 | 34.6 | 36.8 |
| PAT | 287 | 315 | 358 | 470 |
| Growth (%) yoy | 19.3 | 9.6 | 13.7 | 31.2 |
| P/E (x) | 38.2 | 34.9 | 30.6 | 23.4 |
| ROE % | 20.3 | 18.5 | 18.1 | 20.0 |
| ROCE % | 13.3 | 13.6 | 14.6 | 16.7 |

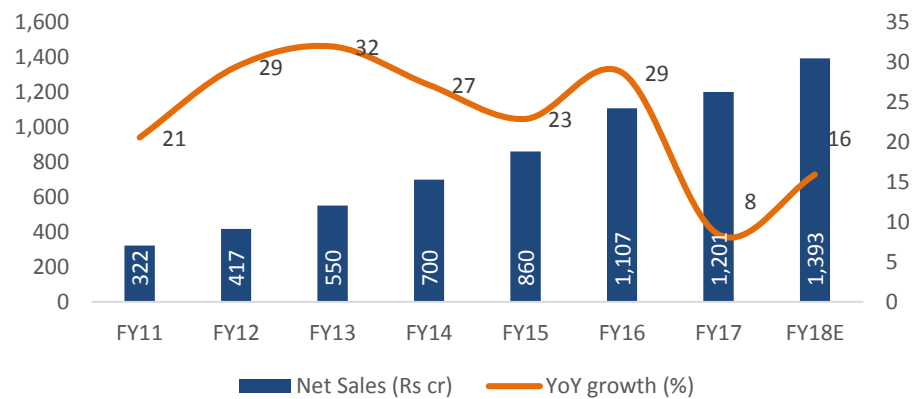
Source: Company, IIFL Research

Company Background

Established in 1994, Syngene International Limited is a subsidiary of Biocon. It is one of India’s largest Contract Research Organizations (CRO). The company is a full service CRO and provides full range of research services right from drug discovery to drug development stage. Syngene has established a robust track record and has established itself as a leading CRO. The company also has a small scale manufacturing facility, which can support clinical trial level product volumes.

The company provides research services for novel molecular entities (NMEs) across sectors like biotechnology, pharma, biopharma, etc. Syngene also offers biologics discovery and development services. It currently serves 293 international clients (Q3FY18) and has four dedicated R&D centers of Bristol-Myers Squibb (BMS), Baxter, Amgen and Herbalife (Q3FY18). The company also has a Human Pharmacology Unit (HPU), which is capable of performing clinical trials.

Exhibit 1: 23% CAGR in revenue over FY11-18E



Source: Company, IIFL Research

The CRO industry is sizable and growing

The global pharma R&D spend is expected to grow to \$160bn in 2020E from ~\$152bn in 2018E. It is also believed that ~75% of the total R&D spend can be potentially outsourced. The CRO industry was pegged to be \$49bn in 2018E, which is set to grow to \$59bn by 2020E. This means that the penetration of the CRO industry is likely to grow from ~32% in 2018E to 37% in 2020E. The CRO industry has several growth drivers such as (a) increasing generic competition for innovators, (b) lower efficiency of innovator’s R&D, (c) shrinking product pipeline amid competition even in the newer therapies and (d) the patent cliff.

CRO industry is pegged to be \$49bn in 2018E which should reach \$59bn in 2020E

Due to low cost structure (20-40% of innovator's costs), contractual nature, flexibility and higher economies of scale, penetration of the CRO industry in the global pharma R&D spending will continue to rise.

Diverse offerings and cost arbitrage - key to customer stickiness

Syngene has been in the CRO industry for the past 23 years. By Q3FY18, company has 293 clients and 4 dedicated R&D centers. It has end-to-end discovery, development and manufacturing capabilities. The company has integrated service platforms for small and large molecules, antibody-drug conjugates and oligonucleotides. Its facilities are audited successfully by USFDA, EMA, AAALAC and major life sciences partners. The global pharma companies, wouldn't work with CROs unless facilities are fully compliant with the regulators. This keeps a check on Syngene, and hence, it has low regulatory risk.

The company offers huge cost arbitrage and bills its clients at ~20% of the salary of the US R&D scientist. This low cost and high value proposition, integrated business model and availability of the talent pool in India, makes Syngene's model as very attractive. Amid the global boom in the biologic drugs, Syngene has also organically developed capabilities in the biologics research, which is expected to be a key driver of the growth going ahead. The company has recently set up an office in the US, which will help in establishing strong relationships with the customers. This will build better brand equity with its customers and get more long term contracts.

Dedicated centers, a testimony of Syngene's capabilities

Syngene has 293 clients as of Q3FY18, which itself indicates a very diverse client base (no client contributes 10% of revenue by Q3FY18). Company also has four large clients, which have set up dedicated R&D centers at Syngene's facilities. These centers provide revenue visibility for long and as drugs from these arrangements move towards later stage, it also establishes a confidence in the innovators. This stickiness of the clients is positive for Syngene, as it also helps the company to win more clients. The drugs from these arrangements can become possible candidates for its upcoming CMO (commercial manufacturing) business.

Syngene works at ~20% of the cost of US innovator R&D costs

Rising service offerings is a key to customer stickiness

With 293 clients, Syngene has low client concentration

Exhibit 3: Syngene’s long term relationships

| | Client name | Since | No of scientists | Additional notes |
|-------------------------|--------------------------|-------|------------------|--|
| Dedicated centres | Bristol-Myers Squibb | 2007 | 475 | Produced nine drug candidates, one in clinical trials, contract ends in 2026 |
| | Baxter | 2013 | 150 | R&D of medical products and devices |
| | Amgen | 2016 | 185 | Discovery and development of biotech and small molecule medicines |
| | Herbalife Nutrition | 2016 | Undisclosed | Support product testing, sampling and end-product development |
| Other major engagements | Canadian biotech company | 2017 | Undisclosed | Development and manufacturing of five novel monoclonal antibodies (first in India) |
| | Zoetis | 2017 | Undisclosed | Multi-year agreement to develop animal health medicines and vaccines +commercial manufacturing |

Bristol-Myers Squibb is the most interesting dedicated center which has arrangement until 2026E

Source: Company, IIFL research

\$200mn capex to drive business growth

To put the company in the new growth orbit, Syngene has undertaken a \$200mn capacity expansion plant. This includes following:

- ✧ Oligonucleotides manufacturing facility capable of manufacturing of DNA/RNA, Oligonucleotides, etc (commissioned in FY17).
- ✧ Formulations capacity capable of manufacturing small scale formulations, oral solid dosages (OSD), (commissioned in FY17).
- ✧ Viral Testing facility- Company has commissioned this facility in FY17. Going by the Biosimilars/biologics boom going ahead, viral testing will prove to be a solid opportunity.
- ✧ Company has also commissioned a biologics manufacturing facility in Q3FY18. It has three, 2,000 Liters bio-reactors, which give commercial scale biologics manufacturing capabilities. This capacity will start revenue generation in FY19E. Company is also investing \$100mn to build a commercial API manufacturing facility at Mangalore. This facility is currently under construction and will commence production in FY20E.

\$100mn capex has almost commissioned while rest \$100mn will be commissioned in 2020E

✧ Company added bioinformatics capacities through acquisition of Strand Life Sciences. Bioinformatics is a growing space in the pharma research and the market for the same is expected to grow at a CAGR of 15% to reach \$30bn in 2020E. Bioinformatics is expected to be a good fit for Syngene.

Additionally, the refurbishment of the burnt facility (S2, Bangalore) during fire in Q3FY17 is undergoing and it should commence the operations by Q1FY19E. Syngene, so far has received total ₹81cr, as part of insurance claim and remaining amount of ₹119cr is expected in FY19E.

Syngene has come back on the growth track

Syngene has come out of the facility damage impact which happened in Q3FY17 and has reported sequential improvement in the revenue over the past three quarters. In Q3FY18, company reported constant currency growth of 17% vs. 14% in Q2FY18 and 8% in Q1FY18. In Q3FY17, when its facility was burnt, company's quarterly revenue base was ₹67cr, which the company is expected to achieve in Q4FY18E.

With 17% yoy constant currency growth in Q3FY18, Syngene has returned on growth path

API manufacturing provides revenue visibility beyond FY20E

The commissioning of the Mangalore API facility in 2020E will be a key long term trigger for the company, as it will foray in the lucrative/scalable CMO business. The company has signed commercial contracts for two late stage products with existing clients. These molecules have already been commercialized and the company has started supply of intermediaries for these products from Bangalore facility. CMO is expected to drive the business growth. Assuming 1.5x asset turnover, Mangalore API should be able to generate additional revenues of \$150mn at peak (~₹1,000cr). CMO is a high margins business, and should improve Syngene's margins in the long run.

The API manufacturing facility should lead to generate revenue of ~\$150mn (₹1,000cr) at peak.

Strong financial performance

Syngene's revenue has grown at a CAGR of 17% over FY15-18E. Syngene, historically has grown at a rate of 20%+, however the growth was impacted in FY17 (8.5%) and FY18E (16%) due to the loss of facility in the fire. It has maintained gross margins above 72%+ which shows a strong pricing power. EBITDA margins have also been 30%+ indicating a robust business model. Company has reported 20%+ ROE since FY12-17 owing to the strong growth and margins. We forecast revenue/PAT CAGR 21.5%/22.2% over FY18-20E.

Syngene is expected to deliver PAT CAGR of 22.2% over FY18-20E

Risk factors- (1) slowdown in the global R&D spending, (2) Rupee appreciation, (3) loss of dedicate centers.

Recommendation Parameters for Fundamental/Technical Reports:

Buy – Absolute return of over +10%

Accumulate – Absolute return between 0% to +10%

Reduce – Absolute return between 0% to -10%

Sell – Absolute return below -10%

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India Infoline Limited (Formerly “India Infoline Distribution Company Limited”), CIN No.: U99999MH1996PLC132983, Corporate Office – IIFL Centre, Kamala City, Senapati Bapat Marg, Lower Parel, Mumbai – 400013 Tel: (91-22) 4249 9000 .Fax: (91-22) 40609049, Regd. Office – IIFL House, Sun Infotech Park, Road No. 16V, Plot No. B-23, MIDC, Thane Industrial Area, Wagle Estate, Thane – 400604 Tel: (91-22) 25806650. Fax: (91-22) 25806654 E-mail: mail@indiainfoline.com Website: www.indiainfoline.com, Refer www.indiainfoline.com for detail of Associates.

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For Research related queries, write at research@iifl.com

For Sales and Account related information, write to customer care: cs@iifl.com or call on 91-22 4007 1000