SYSTEMATIX INSTITUTIONAL EQUITIES™

# Indian Pharmaceuticals

## *Back to Basics*

## Contents



## Companies section

# Indian Pharmaceuticals

28 March 2022

## Back to Basics

**The focus is once again on the core business in the Indian Pharmaceuticals industry (IPM) as COVID tailwinds have played out and costs have normalized. A closer look at companies' longer-term strategies reveals that a few of them have developed strong moats in Specialty areas. Besides driving their next leg of growth, we believe the 'Specialty moat' will help these players withstand the pain from price erosions and regulatory challenges. Additionally, the phase of supernormal price declines in the US market seems to be over. This, along with players' increasing focus on Indian formulations and Emerging Markets (EMs), should provide earnings stability. We estimate 8% CAGR in revenues and 14% CAGR in EPS for our coverage universe with a 260bps RoCE improvement (ex-DIVI'S, which saw a boost in FY22 with one-time sales of Molnupiravir) over FY22-24E. Initiating coverage on CIPLA, SUNP, DIVI'S and DRRD with BUY ratings and LPC with a SELL rating.**

**Increasing exposure to India and EMs offers strong earnings support:** The Indian pharma sector has rebounded strongly from the impact of price controls, ban on fixed dose combinations and regulatory hurdles (demonetization/ GST). The USD 22bn domestic pharma market has reverted to double-digit growth (highest in the world). We expect the momentum to continue, led by the increasing exposure to higher-growth Chronic therapies, price hikes in the domestic market and an estimated 3-5% volume growth. Going forward, the focus on Chronic therapies, higher contribution from EMs (branded generics markets mirroring India with out-of-pocket expenses and high profitability), a more sustainable growth profile with limited foreseeable threats and operating leverage should drive profitability higher. We see Cipla, SUNP and DRRD as the key beneficiaries of this theme.

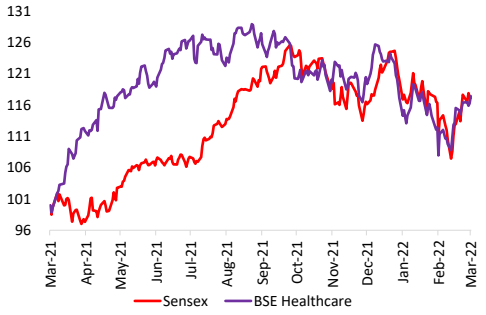
**Price erosion in the US has likely peaked out:** While Indian generics have struggled to maintain their growth momentum in the US owing to hyper-competition, we believe the intensity has likely peaked and expect price erosion to normalize to the 5-7% range from here. This should help protect the base while more sustainable growth will come from complex launches. News-flow on USFDA audits of plants (physical inspections have restarted) would be a key monitorable as these could drive a meaningful upside/ downside to street estimates. We believe Cipla and SUNP are currently the best placed Indian companies in the US.

**Valuations and View:** With leaner cost models and improved leverage positions, we believe Indian companies are well geared to respond to the next set of opportunities. We initiate coverage on the sector with **BUY** recommendations on **CIPLA** (strong India/ EM franchise, growing US respiratory portfolio), **SUNP** (robust traction for its specialty portfolio), **DRRD** (strong cost discipline, increasing focus on branded generics) and **DIVI'S** (high capex intensity, the best placed CRAMS company) while we initiate coverage on **LPC** (weak execution) with a **SELL** rating. Most of our coverage companies (except DIVI'S) currently trade at a discount to their 10-year average valuations on a PE basis. We expect 14% CAGR in earnings and 260bps expansion in RoCE (ex-DIVI'S) over FY22-24E to support our target valuations.

## SECTOR REPORT

| Industry | Pharmaceuticals |
|---|---|

**BSE Healthcare v/s BSE Sensex**




*Source: Bloomberg, Systematix Institutional Research*

**Sector recommendations**

| | CMP (Rs) | TP (Rs) | Upside (%) | Reco |
|---|---|---|---|---|
| SUNP | 902 | 1,068 | 18 | BUY |
| CIPLA | 1,013 | 1,185 | 17 | BUY |
| DRRD | 4,361 | 5,015 | 15 | BUY |
| DIVI | 4,457 | 5,180 | 16 | BUY |
| LPC | 775 | 622 | -18 | SELL |

*Source: Systematix Institutional Research*

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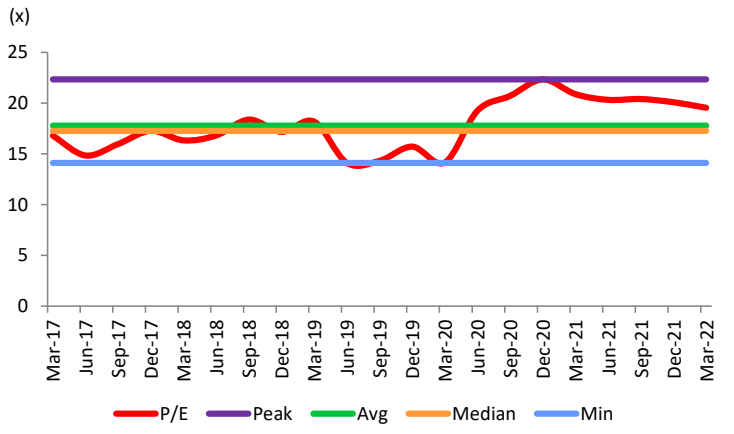
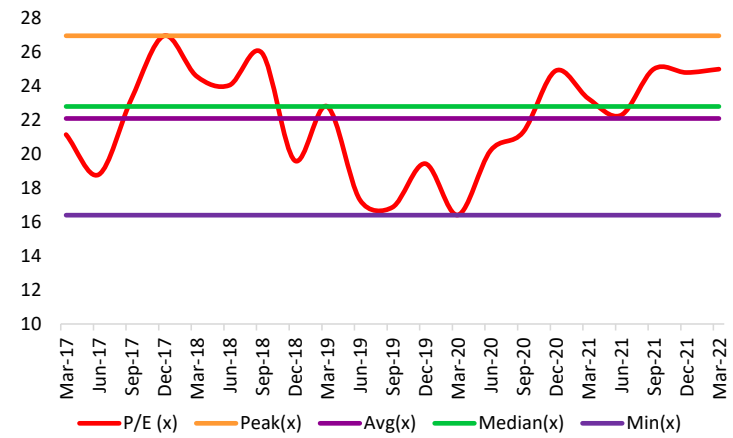
## Valuations for our coverage companies

**Exhibit 1: Nifty Pharma – Valuations came off post Covid**



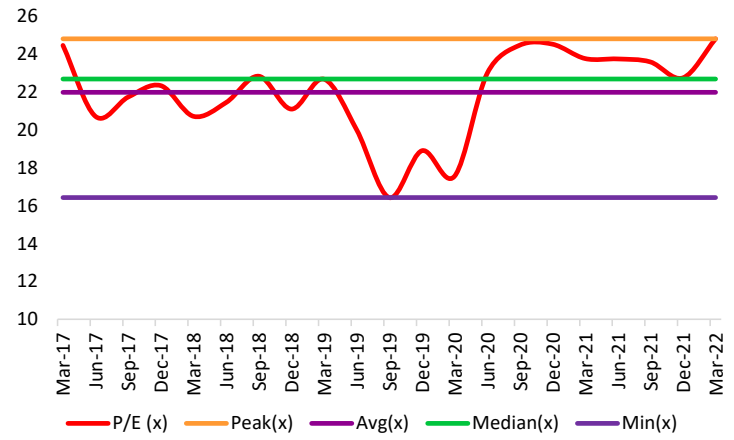

*Source: Company, Systematix Institutional Research*

**Exhibit 2: SUNP – Specialty ramp-up driving recent outperformance**



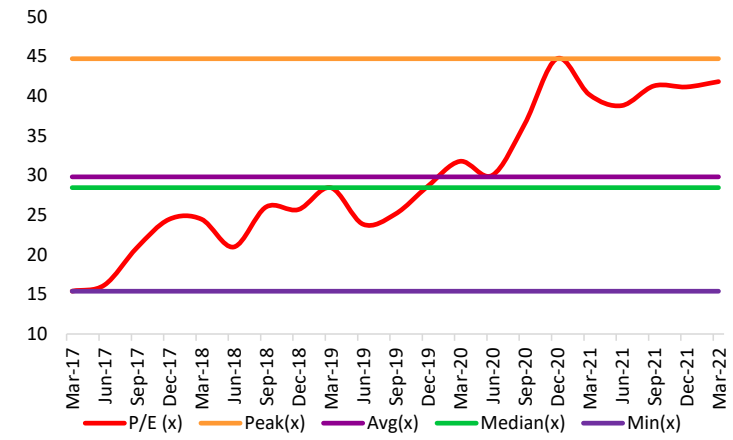

*Source: Company, Systematix Institutional Research*

**Exhibit 3: CIPLA – Consistent outperformer**



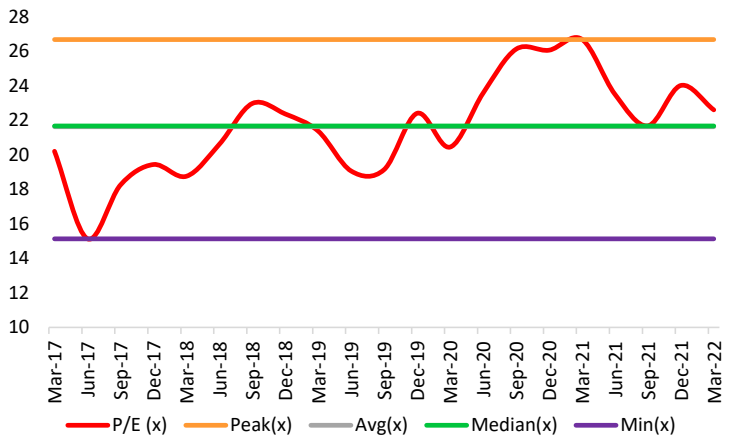

*Source: Company, Systematix Institutional Research*

**Exhibit 4: DIVI – Valuations off from highs as Covid cases declining**



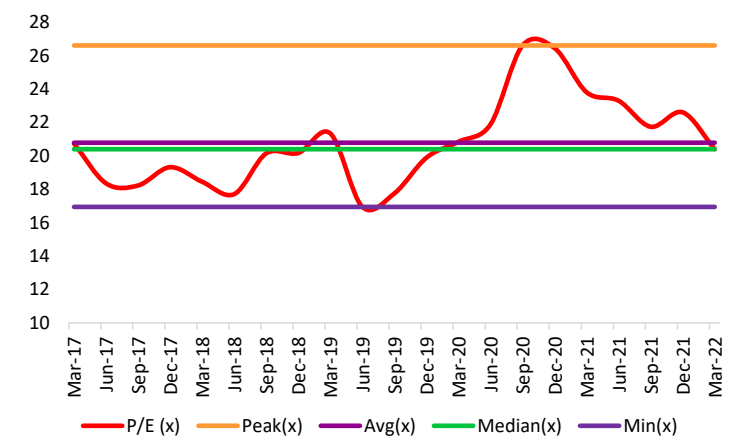

*Source: Company, Systematix Institutional Research*

**Exhibit 5: LPC – Weak execution driving underperformance**




*Source: Company, Systematix Institutional Research*

**Exhibit 6: DRRD – Impacted by the Russia-Ukraine war**




*Source: Company, Systematix Institutional Research*

## Valuation tables

**Exhibit 7: Valuation snapshot**

| Company | Rating | CMP | Target Price | Return (%) | Mkt.Cap (Rs bn) | CAGR over FY22-24E (%) | | | Valuation on FY24E | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | Revenue | EBITDA | EPS | PE (x) | EV/EBITDA (x) | RoCE (%) |
| SUNP | BUY | 902 | 1068 | 18 | 2,164 | 9% | 11% | 12% | 22 | 15 | 18 |
| CIPLA | BUY | 1,013 | 1,185 | 17 | 817 | 9% | 14% | 16% | 20 | 11 | 21 |
| LPC | SELL | 756 | 622 | -18 | 343 | 7% | 26% | 25% | 19 | 10 | 13 |
| DRRD | BUY | 4,361 | 5,015 | 15 | 726 | 7% | 14% | 15% | 19 | 12 | 16 |
| DIVI | BUY | 4,457 | 5,180 | 16 | 1,183 | 10% | 14% | 10% | 35 | 24 | 29 |

| Company | Revenue (Rs bn) | | | EBITDA (Rs bn) | | | EBITDA Margin (%) | | | EPS | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | FY22E | FY23E | FY24E | FY22E | FY23E | FY24E | FY22E | FY23E | FY24E | FY22E | FY23E | FY24E |
| SUNP | 3,89,335 | 4,18,089 | 4,59,301 | 1,04,752 | 1,11,983 | 1,29,747 | 26.9 | 26.8 | 28.2 | 32 | 34 | 40 |
| CIPLA | 2,20,157 | 2,36,767 | 2,62,362 | 50,462 | 55,916 | 65,423 | 22.9 | 23.6 | 24.9 | 38 | 43 | 52 |
| LPC | 1,61,542 | 1,72,939 | 1,86,111 | 20,127 | 25,286 | 32,085 | 12.5 | 14.6 | 17.2 | 25 | 28 | 39 |
| DRRD | 2,10,461 | 2,25,335 | 2,40,178 | 45,007 | 52,471 | 58,221 | 21.4 | 23.3 | 24.2 | 172 | 202 | 228 |
| DIVI | 88,862 | 91,175 | 1,06,736 | 28,599 | 38,393 | 37,176 | 32.2 | 42.1 | 34.8 | 106 | 102 | 127 |

*Source: Company, Systematix Institutional Research*

## Story in Charts

**Exhibit 8: Revenue mix – Domestic formulations and US (Gx) key businesses for Indian pharma players**

| Revenue mix (%; FY21) | Domestic | US | Europe | Africa | EM | API | Others |
|---|---|---|---|---|---|---|---|
| Ajanta | 30 | 22 | - | 24 | 24 | - | - |
| Alembic | 28 | 40 | - | - | 15 | 17 | - |
| Alkem | 66 | 28 | - | - | 7 | - | - |
| Aurobindo | - | 50 | 25 | 8 | 6 | 13 | - |
| Cadila | 44 | 40 | 2 | - | 7 | 4 | 4 |
| **Cipla** | **40** | **21** | **5** | **18** | **10** | **6** | **-** |
| **Dr Reddy's** | **18** | **37** | **8** | **-** | **18** | **17** | **2** |
| Glenmark | 32 | 28 | 12 | - | 16 | 11 | 1 |
| Indoco | 51 | 12 | 20 | - | 8 | 8 | 1 |
| IPCA | 39 | - | 16 | 7 | 9 | 29 | - |
| J.B. Chemicals | 44 | 25 | - | - | 16 | 4 | 11 |
| **Lupin** | **35** | **37** | **9** | **-** | **11** | **8** | **-** |
| Natco | 19 | 50 | - | - | - | 24 | 7 |
| **Sun Pharma** | **31** | **30** | **14** | **-** | **18** | **6** | **-** |
| Torrent | 52 | 16 | 14 | - | 18 | - | - |

*Source: Company, Systematix Institutional Research*

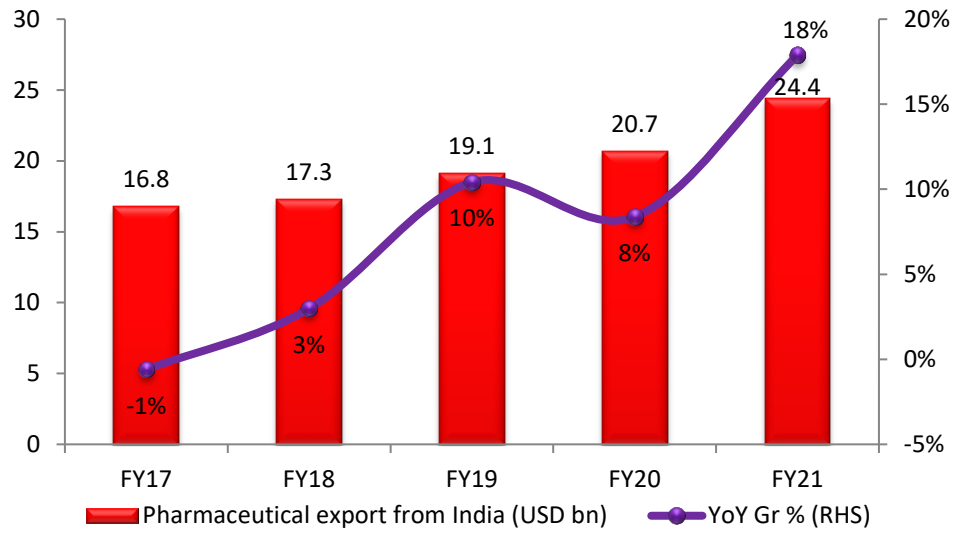
## Indian Pharmaceuticals: A compelling story

The USD 44bn Indian Pharmaceutical industry (IPM) derived ~60% of its revenues from exports with a 6.6% share in India's merchandise exports in FY21. An important player in the global context, India is the world's largest supplier of generic medications, accounting for 20% of the supply by volumes. The country ranks 3rd in terms of pharmaceutical production by volumes and 14th by value with a network of 3,000 drug companies and ~10,500 manufacturing units. Indian drugs are exported to more than 200 countries with USA being the key market.

In FY21, North America was the largest market for India's pharma exports with a 34% share. Exports to the US, Canada and Mexico recorded a YoY increase of 12.6%, 30% and 21.4% respectively. Notably, Indian companies meet ~40% of generics demand in the US and 25% of demand for medicines in the UK.

US is a key market for Indian generics and accounts for 30-35% of revenues for most players. The market opened for Indian generics in 2005/ 2006, post relaxation of the Hatch-Waxman Act which provided marketing exclusivity of products on proving non-infringement/ invalidity of patents. Given that growth remains largely flattish in generics market, cost efficiency has been the key factor defining a successful scale-up for any player. This gives Indian companies a natural advantage in view of their strong reverse engineering skills and low-cost manufacturing base. These factors, along with robust supply chains and good compliance track records, paved the way to success for Indian players in the US generics space.

**Exhibit 9: Pharmaceutical exports from India – 10% CAGR over FY17-21**




*Source: Industry, Systematix Institutional Research*

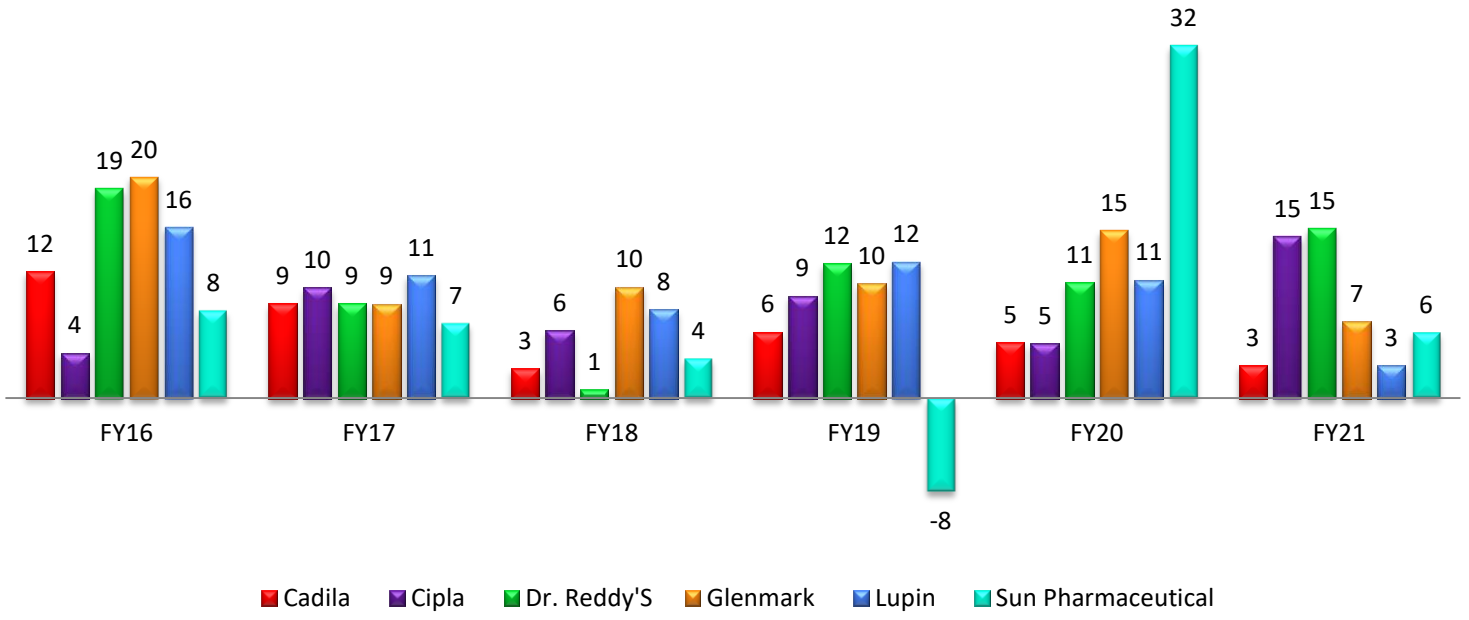
Besides the ~34% contribution from US generics (US Gx), Indian pharma derives ~35% of revenues from the domestic formulations market. Europe, EMs and Africa account for the remaining part of the revenues. In terms of growth, the domestic formulations business has been the key driver over the last few years. US (Gx) business remained flat or declined marginally in low single-digit for most Indian companies over FY18-21 amid price erosions and regulatory issues.

Going forward, increased focus on complex products (injectables, biosimilars, inhalers and specialty) has enabled Indian players to build strong product pipelines for the US market. This, we believe, should reduce the impact of price erosion on their business.

## Domestic formulations: Silver lining in a tough environment

Domestic formulations, valued at USD 22bn (MAT Feb-22) and among the world's fastest growing markets (9-10% per annum), is the backbone of Indian generics. For most Indian companies, a stable domestic business with 35-40% share in revenues has provided a cushion to their earnings as well as supported investments abroad. As the market comprises largely branded generics, it offers higher profitability. With the regulated markets taking a U-turn in terms of growth FY15 onwards, domestic formulations business has been a silver lining for these companies.

**Exhibit 10: Growth (%) in domestic formulations for leading players in IPM**

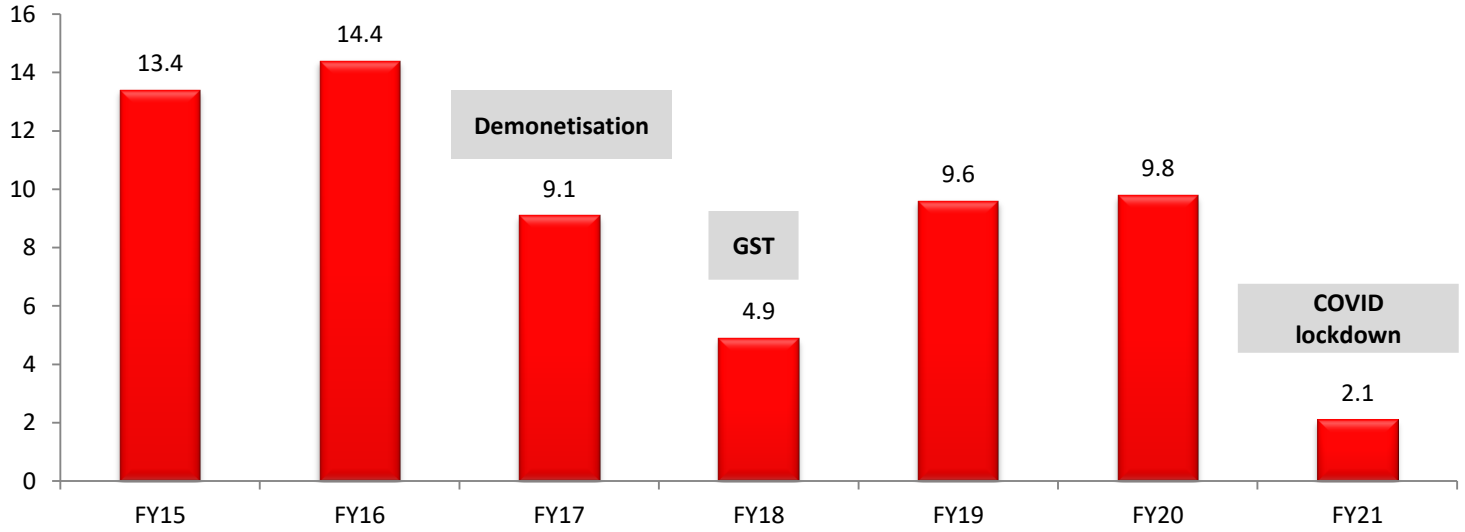



*Source: Company, Systematix Institutional Research*

### India-focused businesses better off in a challenging environment

It is noteworthy that IPM, over FY15-21, grappled with a series of one-off events, including demonetization, GST implementation, price controls and COVID-led lockdowns, that disrupted growth. However, the industry has shown resilience and managed to clock 9% CAGR over the period. Not only that, India-focused companies have outperformed NIFTY as well their pharma peers over the past five years. Especially, companies with a larger share of EBITDA from India business (IPCA and Alkem) have reported better RoCEs as compared to export-oriented companies. India-focused companies have largely outperformed the IPM over FY15-21 which has helped them mitigate the pain encountered in regulated markets.

**Exhibit 11: IPM growth (%) over FY15-21 has been consistent except in years of disruption due to exogenous factors**




*Source: Systematix Institutional Research, AIOCD*

**Exhibit 12: IPM – Therapy-wise breakup of revenues**

| | MAT* Value Mar-21 (Rs bn) | MAT Growth YoY (%) | Market Share (%) |
|---|---|---|---|
| ***IPM*** | ***1,474*** | ***2.0*** | |
| Anti-Infectives | 188 | (4.7) | 13 |
| Cardiac | 204 | 11.2 | 14 |
| Gastro-Intestinal | 167 | 4.6 | 11 |
| Anti-Diabetic | 149 | 5.5 | 10 |
| Vitamins/ Minerals/ Nutrients | 134 | 8.1 | 9 |
| Respiratory | 101 | (8.7) | 7 |
| Pain/ Analgesics | 95 | (2.7) | 6 |
| Derma | 100 | 3.3 | 7 |
| Neuro/ CNS | 91 | 4.8 | 6 |
| Gynaecological | 71 | (1.0) | 5 |
| Anti-Neoplastics | 29 | (2.1) | 2 |
| Ophthal/ Otologicals | 24 | (8.0) | 2 |
| Hormones | 27 | 1.4 | 2 |
| Vaccines | 22 | (2.7) | 1 |
| Urology | 21 | 8.7 | 1 |
| Blood-Related | 17 | (1.4) | 1 |
| Others | 13 | 2.5 | 1 |
| Sex Stimulants/ Rejuvenators | 8 | (5.7) | 1 |
| Stomatologicals | 9 | 11.0 | 1 |
| Anti-Malarials | 5 | (11.2) | 0 |

*Source: AIOCD, Systematix Institutional Research; Note - * MAT – Moving Annual Total*

**Exhibit 13: IPM data for FY21 – MAT (Moving Annual Turnover)**

| Company | MAT-Mar-21 | Market Share (%) | MAT Growth (%) | Volume Growth (%) | Price Growth (%) | NP Gr (%) | Chronic/ Sub-chronic (%) | Contribution from Top-10 Products (%) |
|---|---|---|---|---|---|---|---|---|
| ***IPM*** | ***1,475*** | | ***2.1*** | ***(5.4)*** | ***4.8*** | ***2.6*** | | |
| **SUN PHARMA LABORATORIES** | **120** | **8.2** | **2.7** | **(4.4)** | **5.7** | **1.5** | **62** | **28** |
| ABBOTT HEALTHCARE PVT LTD | 94 | 6.3 | 3.9 | (3.1) | 6.0 | 1.0 | 63 | 50 |
| **CIPLA** | **73** | **4.9** | **7.5** | **(2.8)** | **5.6** | **4.7** | **61** | **28** |
| MANKIND PHARMACEUTICALS | 63 | 4.2 | 2.9 | (5.1) | 4.4 | 3.6 | 50 | 25 |
| ZYDUS CADILA | 63 | 4.2 | 3.7 | (6.1) | 5.0 | 4.9 | 49 | 29 |
| **LUPIN** | **56** | **3.8** | **1.9** | **(5.7)** | **5.6** | **2.1** | **76** | **24** |
| ALKEM LABORATORIES | 51 | 3.5 | 1.5 | (4.6) | 4.0 | 2.1 | 50 | 44 |
| TORRENT PHARMACEUTICALS | 46 | 3.1 | 4.1 | (5.1) | 6.8 | 2.4 | 77 | 27 |
| **DR. REDDYS LABORATORIES** | **43** | **2.9** | **0.1** | **(8.3)** | **5.6** | **2.8** | **49** | **26** |
| MACLEODS PHARMACEUTICALS PVT LTD | 42 | 2.8 | 1.6 | (6.2) | 6.0 | 1.9 | 59 | 24 |
| GLAXOSMITHKLINE PHARMACEUTICALS | 38 | 2.6 | (5.7) | (12.7) | 6.7 | 0.3 | 32 | 58 |
| GLENMARK PHARMACEUTICALS | 37 | 2.5 | 15.2 | (6.1) | 5.2 | 16.1 | 63 | 46 |
| PFIZER | 35 | 2.4 | 4.9 | (1.5) | 5.1 | 1.3 | 46 | 52 |
| SANOFI INDIA | 33 | 2.3 | 2.6 | (5.1) | 6.5 | 1.3 | 58 | 55 |
| IPCA LABORATORIES PVT LTD | 23 | 1.6 | 11.1 | 4.6 | 5.0 | 1.5 | 40 | 43 |
| ALEMBIC | 17 | 1.1 | (1.5) | (8.4) | 5.6 | 1.3 | 45 | 35 |
| ERIS LIFESCIENCES | 14 | 1.0 | 6.3 | (5.6) | 5.5 | 6.3 | 91 | 40 |
| NOVARTIS INDIA | 12 | 0.8 | (9.1) | (9.4) | (0.4) | 0.8 | 72 | 92 |
| FDC | 11 | 0.8 | (1.5) | (6.7) | 2.6 | 2.6 | 22 | 62 |
| NATCO PHARMA | 8 | 0.6 | (23.5) | (20.6) | (4.0) | 1.1 | 3 | 85 |
| AJANTA PHARMA | 10 | 0.7 | 9.6 | 2.2 | 5.4 | 2.0 | 65 | 46 |
| INDOCO REMEDIES | 9 | 0.6 | (5.1) | (11.0) | 4.9 | 1.0 | 21 | 57 |

*Source: AIOCD, Systematix Institutional Research*

**Exhibit 14: Company-wise market share (%) in key therapy segments**

| | ANTI-DIABETIC | INFECTIVES | CARDIAC | DERMA | GASTRO | HORMONES | NEURO / CNS | OPHTHAL | PAIN | RESPIRATORY | UROLOGY | VACCINES | VMN* |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| ABBOTT HEALTHCARE | 1.4 | 3.3 | 3.8 | 5.1 | 3.4 | 3.6 | 3.9 | 0.1 | 3.3 | 4.0 | 0.2 | - | 2.9 |
| ABBOTT INDIA | 0.0 | 0.5 | 0.2 | 0.6 | 7.1 | 13.5 | 4.8 | - | 0.4 | 0.1 | - | 1.8 | **5.4** |
| AJANTA PHARMA | 0.1 | 0.1 | 2.1 | 1.5 | 0.0 | 0.0 | 0.2 | 9.2 | 0.6 | 0.1 | 0.1 | - | 0.2 |
| ALEMBIC | 0.8 | 2.0 | 1.4 | 0.3 | 1.2 | 0.0 | 0.1 | 1.2 | 0.7 | 1.8 | 3.4 | - | 0.9 |
| ALKEM LABORATORIES | 1.6 | 8.4 | 1.1 | 1.8 | 5.5 | 1.0 | 3.0 | 0.0 | 3.3 | 0.9 | 1.0 | - | 4.9 |
| ARISTO | 1.3 | 8.9 | 2.2 | 0.8 | 4.8 | 0.2 | 1.5 | 0.1 | 1.6 | 1.2 | 2.8 | - | 1.0 |
| ASTRAZENECA | 1.5 | 0.0 | 1.5 | - | - | 0.9 | - | - | 0.0 | 0.1 | - | - | 0.0 |
| **CIPLA** | 0.7 | 9.0 | 4.8 | 1.9 | 2.4 | 0.5 | 3.0 | 8.7 | 2.0 | 23.7 | 18.8 | 0.0 | 0.5 |
| **DR. REDDYS** | 1.9 | 1.7 | 2.5 | 4.6 | 4.8 | 0.0 | 2.5 | - | 3.7 | 4.4 | 7.5 | 1.0 | 1.8 |
| ERIS LIFESCIENCES | 3.1 | 0.0 | 1.8 | 0.0 | 0.5 | 0.1 | 1.1 | 0.1 | 0.4 | 0.1 | - | - | 2.2 |
| FDC | 0.1 | 2.3 | 0.4 | 0.5 | 1.9 | - | 0.2 | 3.4 | 0.1 | 0.3 | 0.1 | - | 0.6 |
| GLAXOSMITHKLINE | - | 4.3 | 0.1 | 10.6 | 0.2 | 11.8 | 0.0 | 0.9 | 3.8 | 2.1 | - | 28.9 | 1.9 |
| GLENMARK | 2.2 | 5.9 | 4.8 | 9.2 | 0.1 | 0.0 | 0.1 | 1.7 | 0.1 | 5.6 | - | - | 0.1 |
| INDOCO | 0.3 | 0.7 | 0.0 | 0.4 | 0.7 | 0.0 | - | 1.9 | 0.3 | 1.5 | 2.9 | - | 0.6 |
| IPCA | 0.8 | 0.8 | 1.8 | 1.1 | 0.9 | 0.1 | 1.1 | 0.4 | 7.6 | 0.7 | 2.2 | - | 0.3 |
| **LUPIN** | 9.3 | 3.4 | 7.0 | 0.2 | 2.4 | 0.5 | 3.1 | 1.7 | 2.0 | 6.5 | 2.1 | 0.0 | 1.5 |
| MACLEODS | 1.8 | 6.0 | 3.4 | 3.0 | 1.3 | 14.5 | 1.0 | - | 1.9 | 2.6 | 0.2 | - | 2.7 |
| MANKIND | 3.3 | 6.2 | 3.8 | 3.4 | 3.7 | 0.9 | 2.3 | 2.6 | 2.5 | 4.3 | 2.0 | - | 6.5 |
| MERCK SPECIALITIES PVT LTD | 0.1 | - | 1.0 | 0.0 | - | 0.3 | - | - | - | 0.0 | - | - | - |
| NATCO PHARMA | 0.0 | 1.5 | 0.0 | - | 0.0 | - | 0.0 | - | 0.4 | - | - | - | - |
| NOVARTIS INDIA | 2.8 | 0.1 | 0.7 | 0.0 | 0.0 | - | 0.5 | 5.4 | 2.4 | 0.2 | - | - | 0.5 |
| NOVO NORDISK INDIA | 10.5 | - | - | - | - | 0.0 | - | - | - | - | - | - | - |
| PFIZER | - | 2.7 | 1.9 | 0.2 | 2.6 | 11.8 | 2.7 | 1.2 | 1.9 | 1.8 | 2.8 | 5.9 | 3.8 |
| RANBAXY | 0.9 | 5.5 | 3.6 | 6.6 | 1.1 | 1.0 | 0.0 | 0.0 | 5.6 | 1.2 | 15.2 | 1.2 | 2.6 |
| SANOFI INDIA. | 6.6 | 0.5 | 2.8 | 0.6 | 1.5 | 0.0 | 2.3 | 0.0 | 2.9 | 3.3 | - | 20.0 | 1.0 |
| **SUN PHARMA** | 6.6 | 0.3 | 6.8 | 0.2 | 7.5 | 6.1 | 22.9 | 13.2 | 3.0 | 3.6 | 3.3 | - | 1.5 |
| TORRENT PHARMACEUTICALS. | 2.8 | 0.8 | 7.1 | 1.1 | 4.5 | 0.0 | 7.5 | 0.0 | 2.9 | 0.2 | 0.4 | - | 4.4 |
| ZYDUS CADILA - BIOLOGICS | - | 0.9 | 0.1 | 0.0 | 0.0 | 1.0 | - | 0.4 | 0.3 | - | - | 3.6 | 0.4 |
| ZYDUS CADILA - WELLNESS | - | - | - | 0.0 | 0.0 | - | - | - | - | - | - | - | 0.0 |
| ZYDUS CADILA - ZHL | 0.9 | 4.3 | 4.3 | 3.5 | 3.7 | 10.0 | 0.6 | 0.3 | 5.8 | 5.8 | 0.1 | 0.0 | 1.4 |

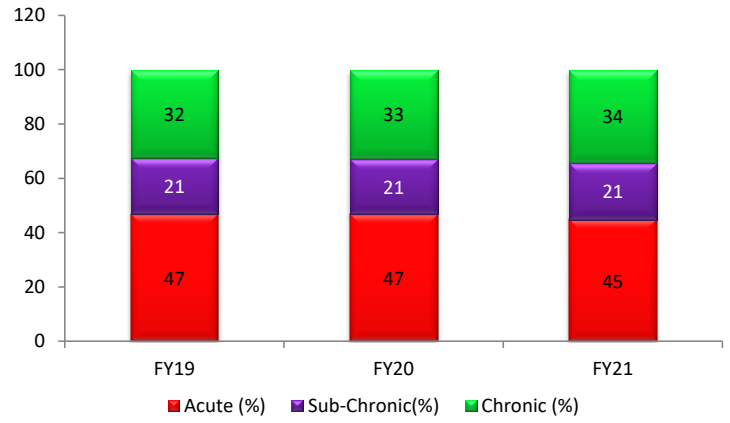
*Source: AIOCD, Systematix Institutional Research; Note: Highlight Rule: Market share above 5%; *VMN - Vitamins/ Minerals/ Nutrients*

## Mix gradually shifting towards Chronic therapies

Chronic therapies have grown faster than the Acute segment in the recent past (200-300bps outperformance vis-à-vis industry) though the gap has been reducing. Acute/ Sub-chronic therapies have consistently maintained their share at 67-68% of IPM sales. Even as the gap is reducing, most product launches are still happening in the Chronic segment. Given that the Acute segment is hyper-competitive and price realizations are usually much lower, companies have an incentive to launch products in the Chronic segment. Chronic segment, on the other hand, has largely been the stronghold of a few strong players like SUNP, TRP, etc.

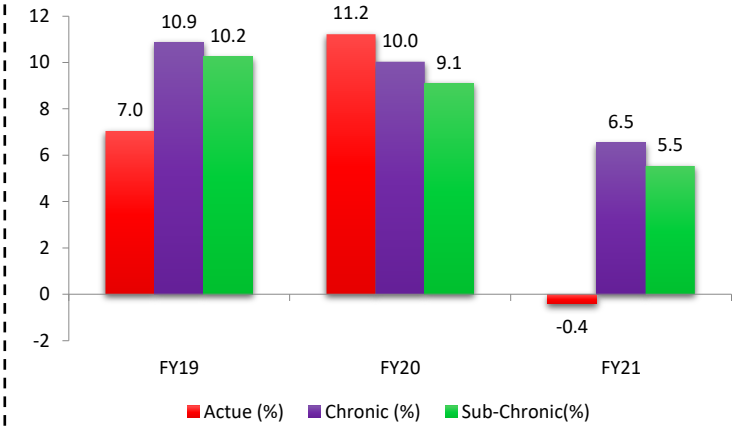
While we acknowledge increasing competition in the Chronic segment from new players as well as e-pharmacies, we believe the segment still has a long growth runway, given lifestyle and demographic changes underway.

**Exhibit 15: Chronic/ Acute mix remains favorable for IPM**




*Source:AIOCD, Systematix Institutional Research*

**Exhibit 16: Chronic products have seen consistent outperformance**




*Source: AIOCD, Systematix Institutional Research*

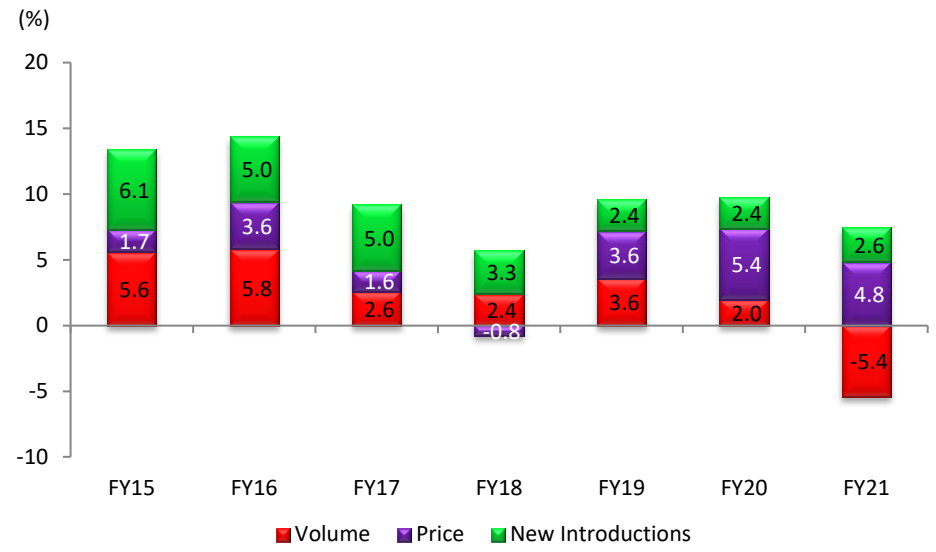
Currently 8,012 Jan Aushadhi Medical Stores operational versus 2,747 in CY17

## A large part of IPM growth attributable to price hikes

Within the three components of growth for pharma companies – volumes, new product launches and prices, price growth has taken over volume growth to become the largest growth driver. Contribution of volume growth in overall IPM has reduced significantly to 20% in Mar-20 versus 34% in Mar-16 while price growth has contributed 55% versus 34% for the same period.

The sharp moderation in volume growth can be attributed to the increasing popularity of trade-generics and Jan Aushadhi medical stores in the recent times. However, price growth has offset the impact of the sedate volume growth. We expect IPM to grow at 9-10% annually for the next few years, mainly led by price growth. With only 18% of the IPM under price control (under the National List of Essential Medicine – NLEM, wherein price hikes are limited to WPI inflation), the remaining can see a maximum hike of 10%.

**Exhibit 17: IPM Growth Split (%) – Price growth a key contributor in recent years**




*Source: AIOCD, Systematix Institutional Research*

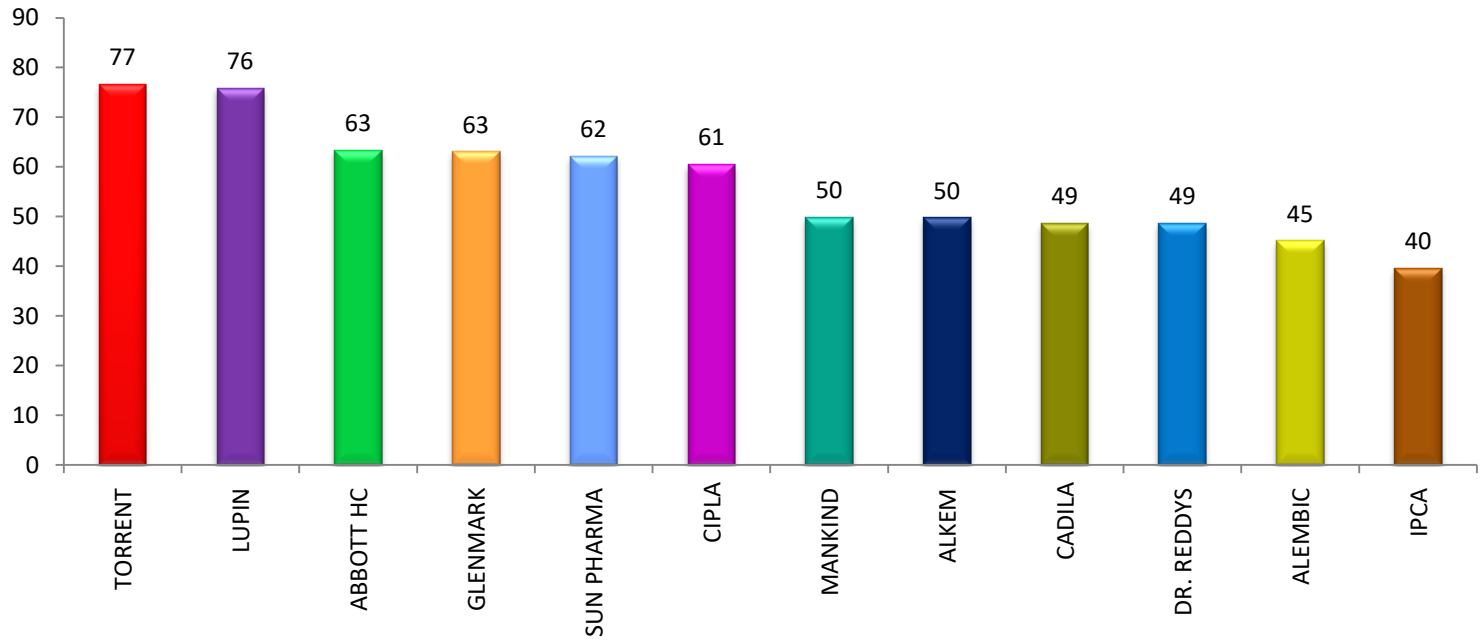
Gross margins of domestic companies with focus on Chronic like Eris Lifescience and Ajanta) are high as 84% and 78%

## Companies striving to improve their Chronic/ Acute mix

Currently, IPM derives ~54% of revenues from Chronic/ Sub-Chronic with top 10 companies supplying 60% of the total demand in these segments. Torrent Pharmaceutical and Lupin are the two leading players in the segments with Chronic/ Sub-chronic products accounting for 75% of their revenues.

With better realizations, higher sales force productivity (most Chronic therapies require a leaner sales force owing to focus mostly on urban cities) and better revenue sustainability, most pharma companies are striving to improve their product mix through in-licensing, acquisitions or in-house product development. Below, we list a few companies with their respective strategy to increase the proportion of Chronic/ Sub-Chronic products in their portfolios (refer to Exhibit 18).

**Exhibit 18: Chronic and Sub-Chronic mix to India in FY21 (%)**




*Source: Source: AIOCD, Systematix Institutional Research*

**Exhibit 19: Companies striving hard to increase their chronic revenues in the domestic market**

| Company | Strategy and key milestone |
|---|---|
| **Lupin** | Explore more in-licensing opportunities in cardio and anti-diabetic segments. Currently, in-licensing contributes 16-18% of domestic sales for Lupin |
| **Cipla** | Breathefree, a public service initiative from Cipla for patients with chronic airway diseases, to improve understanding of respiratory disorders and available treatments among the patients |
| **Glenmark** | Launch of innovated and patent-protected sodium glucose co-transporter-2 (SGLT2) inhibitor, Remogliflozin, in India for type-2 diabetes in Apr-19 |
| **Dr.Reddy's** | Acquisition of 62 brands from Wockhardt to expand its product offerings in Jun-20 |
| **Indoco** | Structuring of Indian business with enhanced focus on chronic products in FY20 |
| **Eris** | Acquisition of Zomelis brand in CY19; share of Chronic/ Sub-chronic products at > 80% of total revenues |
| **Ajanta** | Focus on first-to-launch products |
| **Alkem** | Entered into chronic segments such as cardiology, anti-diabetics and dermatology |

*Source: Company, Systematix Institutional Research*

## Marketing expenses for Acute products are much higher

Acute products are typically more price sensitive compared to Chronic products and volume growth is largely led by new prescriptions. While it is difficult to segregate the marketing expenses for Acute/ Chronic products due to non-disclosure by companies, we have listed below (refer to Exhibit 20) a few companies with focus on the domestic market and a significant share of revenues from Acute or Chronic products to understand the difference between the two product types.

Eris and Abbott India's domestic revenues from Chronic/ Sub-chronic products are 80% and 63% with their marketing cost at 11% and 7% of revenues respectively. On the other hand, Alembic and Indoco – companies with revenue contribution of 55% and 78% respectively from Acute products – have marketing expenses much higher at 37% and 21% of revenues respectively.

**Exhibit 20: Chronic-focused companies have better margins due to lower marketing expenses as % of sales**

| | Chronic/ Sub-Chronic mix (%) of domestic revenues | Marketing expenses as % of domestic revenues | | Acute mix (%) of domestic revenues | Marketing expenses as % of domestic revenues |
|---|---|---|---|---|---|
| Eris | 80 | 11 | Alembic | 55 | 37 |
| Abbott | 63 | 7 | Indoco | 78 | 21 |

*Source: AIOCD, Systematix Institutional Research*

**Exhibit 21: The number of new brand launches by companies has been consistent**

| Company | FY10 | FY11 | FY12 | FY13 | FY14 | FY15 | FY16 | FY17 | FY18 | FY19 | FY20 |
|---|---|---|---|---|---|---|---|---|---|---|---|
| Alembic | 18 | 19 | 20 | 26 | 18 | 9 | 17 | 17 | 18 | 18 | 12 |
| Zydus Cadila | 56 | 63 | 70 | 55 | 57 | 36 | 56 | 77 | 51 | 55 | 64 |
| Cipla | 50 | 53 | 33 | 28 | 39 | 33 | 62 | 34 | 40 | 51 | 44 |
| Dr Reddy's Labs | 33 | 42 | 21 | 24 | 19 | 22 | 31 | 21 | 21 | 19 | 28 |
| Alkem | 52 | 64 | 97 | 61 | 44 | 54 | 61 | 72 | 52 | 59 | 44 |
| IPCA | 9 | 26 | 7 | 20 | 22 | 19 | 10 | 4 | 11 | 12 | 11 |
| Lupin | 58 | 59 | 39 | 60 | 46 | 35 | 49 | 51 | 31 | 44 | 47 |
| Torrent Pharma | 36 | 39 | 43 | 39 | 28 | 36 | 52 | 33 | 22 | 13 | 22 |
| Sun Pharma | 80 | 92 | 55 | 32 | 37 | 40 | 38 | 33 | 22 | 49 | 32 |
| **Total** | **392** | **457** | **385** | **345** | **310** | **284** | **376** | **342** | **268** | **320** | **304** |

*Source: Company, Systematix Institutional Research*

**Exhibit 22: Acquisitions have been one of the key focus areas to achieve faster scale**

| Announce Date | Target Name | Acquirer Name | Deal Value (USD mn) |
|---|---|---|---|
| Jan-15 | Indian brands portfolio | Dr Reddy's Laboratories Ltd | 127 |
| May-15 | Mankind Pharma Ltd | Capital International Inc | 215 |
| Mar-17 | Unichem Business/India & Nepal | Torrent Pharmaceuticals Ltd | 557 |
| Nov-17 | India brand business/Strides Shasun Ltd | Eris Lifesciences Ltd | 77 |
| Feb-18 | Mankind Pharma Ltd | Several PE firms | 350 |
| Jun-18 | Zydus Wellness Ltd | Cadila Healthcare, Amundi SA,True North Managers | 365 |
| Oct-18 | Heinz India Pvt Ltd | Zydus Wellness Ltd,Cadila Healthcare Ltd | 628 |
| Feb-20 | JB Chemicals & Pharmaceuticals Ltd | KKR & Co Inc | 371 |
| May-20 | Intas Pharmaceuticals Ltd | ChrysCapital Management Co | 132 |
| Dec-20 | 62 domestic brands & manufacturing plant | Dr Reddy's Laboratories Ltd | 259 |

*Source: Company, Systematix Institutional Research*

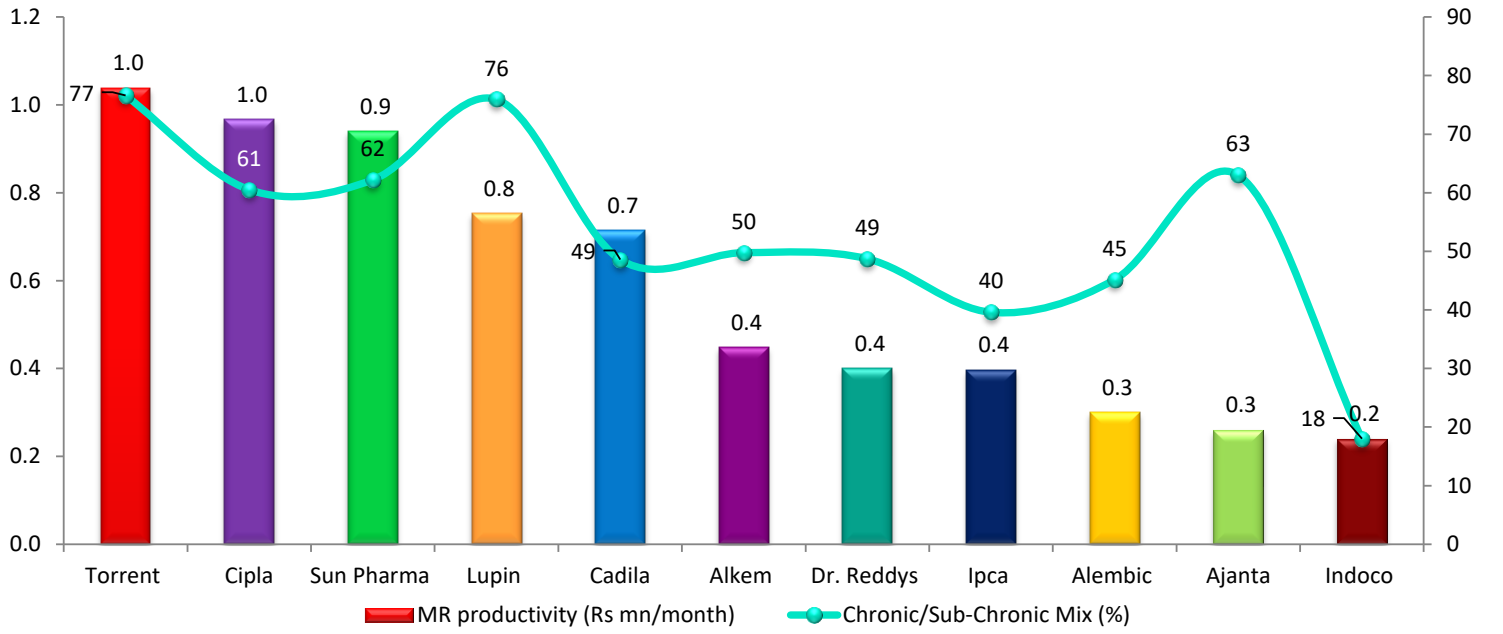
## MR productivity has been improving in recent times

The size of a company's Medical Representatives (MR) team and their productivity are the key factors defining the performance of that company. Sales per MR is the primary measure of productivity, which is further contingent to several factors such as the company's Acute/ Chronic mix, therapy mix of its product offerings, the number of products in a portfolio and the pace of new launches.

While all these factors converge to determine the MR team's productivity for companies, we map the relation with their Chronic/ Acute mix (refer to Exhibit 23). We conclude that companies with higher contribution from Chronic/ Sub-chronic products (at an average 69% of revenues) – Torrent, Cipla, Sun Pharma and Lupin to name a few – have an average MR productivity of Rs 0.92mn per month, the best in the industry.

On the other hand, players with higher contribution from Acute products (an average revenue contribution of 38% from Chronic) – Indoco, Alkem, Ipca and Alembic – have much lower MR productivity of Rs 0.36mn per month. One anomaly is Ajanta Pharma – with 63% of its revenues from Chronic/ Sub-chronic products, the company has MR productivity at Rs 0.26mn per month. This can be assigned to its dominance in ophthalmology, a segment wherein productivity is inherently lower.

**Exhibit 23: MR productivity (Rs mn/month) direct relation with Chronic/Acute mix (%)**




*Source: Company, Systematix Institutional Research*

## Companies focusing on augmenting their field force

Domestic formulations account for 35-40% of revenues for the IPM – the highest share among regions. Companies are keen to grow this share further, either through addition of MRs or via the inorganic route. Two of the largest players in the industry, Sun Pharma and Alkem, have recently announced addition to their existing MR count of >10,000 and we expect other companies to follow suit. We estimate a 15-17% annual increase in the industry's field force (net of attrition) in the coming years.

**Exhibit 24: Field force set to increase with primary focus on improving MR productivity**

| Company | Details and recent update on field force |
|---|---|
| **SUNP** | Expanded its field force in 4QFY20 by 10%; the total count now is 10,900+. The new MRs commenced field work but productivity lower by 6% to Rs0.94mn a month in FY21 from Rs1mn a month in FY20 due to COVID-related disruptions |
| **CIPLA** | Consolidated India branded prescription, trade generics and consumer healthcare businesses as 'One-India' for synergies benefit in distribution and portfolio management |
| **LPC** | MR strength maintained at ~7,000 over FY19-21; focus has increased on Chronic products through in-licensing |
| **TORRENT** | Highest MR productivity in the industry, led by 77% (highest in IPM) of revenues from Chronic/ Sub-chronic products. The company cut its MR count by 400 in FY21 to 3,600 currently with productivity of Rs1.04mn /month |
| **AJP** | MR count trimmed by 200 in 1QFY22 to 2,800. AJP could further reduce the count in FY22 as part of an internal restructuring program. MR productivity at Rs0.26mn/ month; ~Rs0.5mn/ month for the cardiac segment |
| **INDR** | MR productivity among the lowest due to 80% of revenues from Acute therapy products. Restructured the sales force with focus on Chronic/ Sub-Chronic segment and North and East India with same number of MRs |
| **IPCA** | Expanded field force by 200 MRs in 1QFY22 in CNS, derma and ophthalmology segments. MR count stood at 5,000 in FY21. Has guided to increase in field force to 5,800-5,900 with launch of a new division |
| **ALKEM** | Addition of 2,000 MRs in the last 2-3 years, to 10,500 in Q3FY22 |

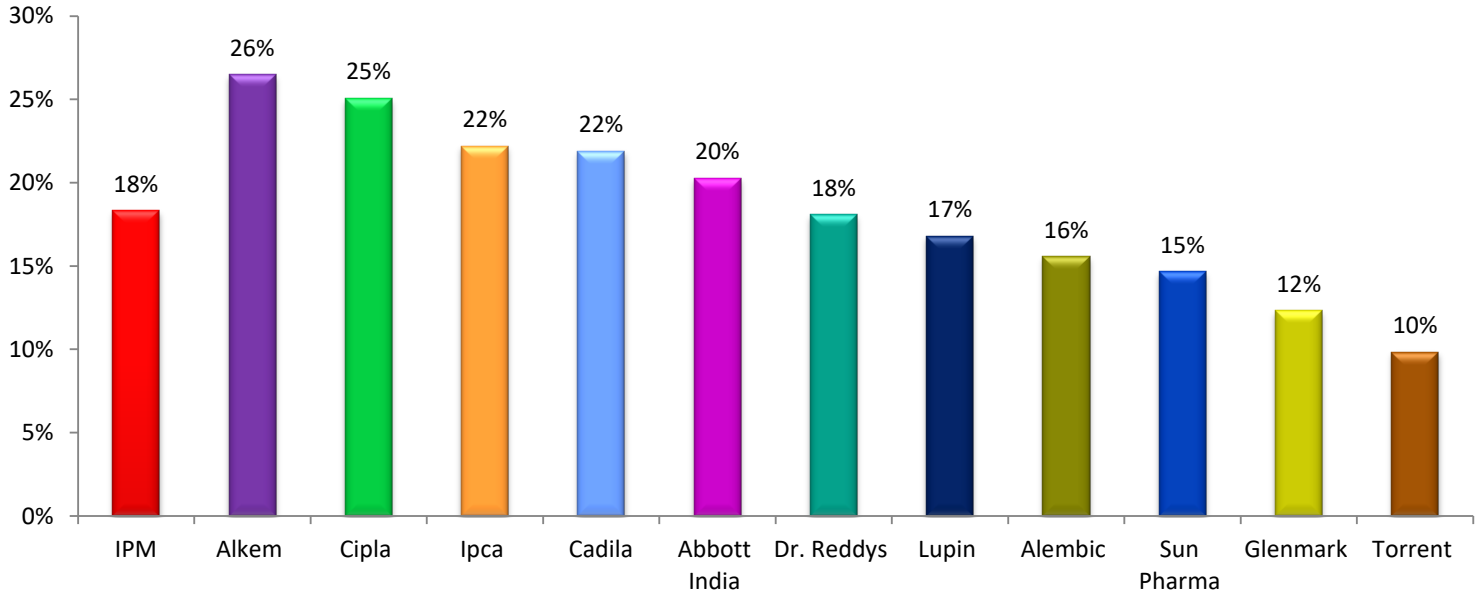
*Source: Company, Systematix Institutional Research*

## Revised NLEM unlikely to have a major impact

The National List of Essential Medicines (NLEM) was revised in Sep-21 to include 39 drugs and exclude 16 from the earlier list prepared in 2015. The NLEM now includes 397 drugs (374 earlier), bringing an incremental 3.4% of IPM's revenues under price control. This implies that per year price hikes in ~21% of IPM's revenues (Rs 52.5bn in MAT value) from 18% earlier will now be linked to the WPI.

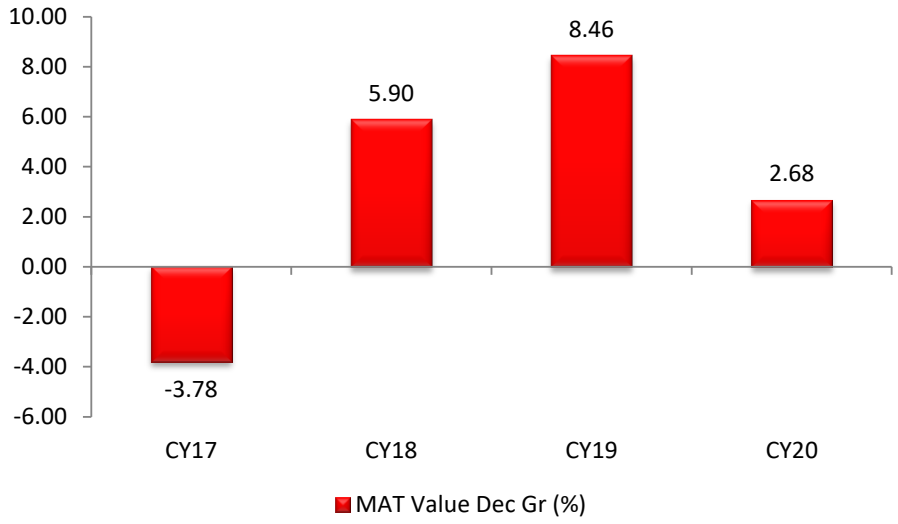
Our rough estimates suggest that the revised NLEM is unlikely to have a noticeable impact on growth for pharma companies. Our view is based on the assumptions that 1) a WPI-linked hike this year will imply an average 9-10% price increase for NLEM portfolio – this is higher than the 3.1% average increase in prices for the last five years, and 2) even if prices of the new drugs included in the NLEM are cut by 10%, the reduction will impact industry growth rates only by 30-40bps.

**Exhibit 25: Domestic sales under NLEM**




*Source: AIOCD, Company, Systematix Institutional Research*

**Exhibit 26: Growth of drugs under NLEM in recent years has been decent**



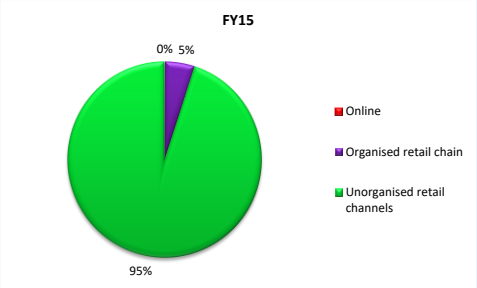

*Source: AIOCD, Systematix Institutional Research*

**Exhibit 27: List of drugs added in NLEM after the latest revision**

| Molecules | IMS MAT Jul-21 sales (Rs mn) | Therapy | Molecules | IMS MAT Jul-21 sales (Rs mn) | Therapy |
|---|---|---|---|---|---|
| Itraconazole | 9,582 | Anti-fungal | Irinotecan HCL Trihydrate | 141 | Oncology |
| Cefuroxime | 8,909 | Anti-infective | Azacitidine | 139 | Oncology |
| Insulin Glargine | 8,334 | Anti-diabetic | Tenofovir+Lamivudine+ Dolutegravir | 134 | Anti-viral |
| Amikacin | 6,152 | Anti-infective | Valganiclovir | 105 | Anti-viral |
| Teneligliptin | 4,066 | Anti-diabetic | Nitazoxanide | 104 | Anti-parasite |
| Mupirocin | 3,358 | Anti-infective | Bendamustine Hydrochloride | 101 | Oncology |
| Ivermectin | 2,420 | Anti-infective | Fludrocortisone | 90 | Hormonal |
| Terbinafine | 2,142 | Anti-fungal | Secnidazole | 82 | Anti-infective |
| Dabigatran | 1,820 | Cardiac | Darunavir+Ritonavir | 71 | Anti-viral |
| Rotavirus vaccine | 1,027 | Vaccine | Fludarabine | 39 | Oncology |
| Montelukast | 822 | Anti-allergy | Lamivudine | 29 | Anti-viral |
| Tenecteplase | 676 | Cardiac | Buprenorphine+Naloxone | 28 | Anti-addiction |
| Tenofovir+Alafenamide Fumarate | 426 | Anti-viral | Procaine Benzylpenicillin | 0 | Anti-infective |
| Latanoprost | 413 | Ophthalmic | Bedaquiline | - | Anti-TB |
| Lenalidomide | 367 | Oncology | Delamanid | - | Anti-TB |
| Buprenorphine | 222 | Pain | Fomepizole | - | Antidote |
| Dolutegravir | 203 | Anti-viral | Leuprolide Acetate | - | Oncology |
| Daclatasvir | 199 | Anti-viral | Nicotine replacement therapy | - | Anti-addiction |
| Ormeloxifene | 152 | Contraceptive | Phenoxymethyl Penicillin | - | Anti-infective |
| Fulvestrant | 152 | Oncology | | | |

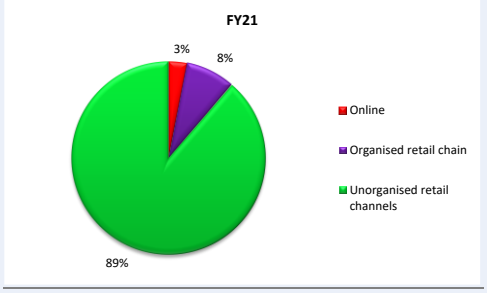
*Source:AIOCD, Systematix Institutional Research*

### e-Pharmacy market share (%) in FY15



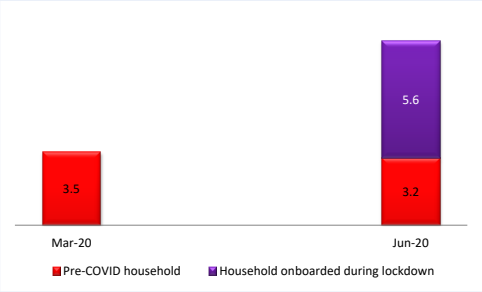

*Source: Technopak Research # Online market share includes sales by pure e-Pharmacy players and through Omnichannels through online mode*

### e-Pharmacy market share (%) in FY21



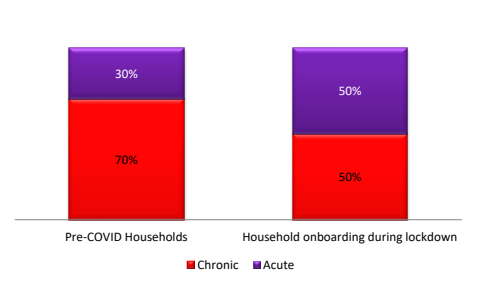

*Source: Technopak Research # Online market share includes sales by pure e-Pharmacy players and through Omnichannels through online mode*

### New HHs opted for online during COVID lockdowns




*Source: RedSeer IP and Analysis*

### Contribution of Acute increased during the lockdowns




*Source: RedSeer IP and Analysis*

## e-Pharmacy: A new contender in the distribution pie

The traditional unorganized retail pharmacy stores/ chains continue to dominate the front-end in IPM with an 89% share of the total sales in India formulations. These retail shops/ chains have largely grown in line with the 8% CAGR registered by IPM over FY15-21. In contrast, organized retail chains, with a share of 8% in India's pharmacy market, have shown 18% CAGR. Notably, FMCG products play an important role in the overall profitability of traditional retail pharmacies, with sales contribution of 15-20% for an unorganized store and as high as 30% for a modern organized pharmacy store.

Over the last few years, ePharmacies have emerged as a new format, including pure e-commerce plays like Pharmeasy, Medlife, 1mg and Netmeds as also omnichannel platforms of brick-and-mortar retailers like Apollo Pharmacy, MedPlus, etc. The online channel has garnered a 3% share of the pharmacy market with a CAGR of 96% in revenues to Rs56bn over FY15-21. Among ePharmacies, 90% of the share is held by pure e-commerce players, fueled by heightened investor interest with larger conglomerates like Reliance Retail and Tata Digital picking up stakes in Netmeds and 1mg respectively.

Assuming that IPM growth rate is maintained at the historical average of 8-9% and the e-Pharmacy segment clocks 25% CAGR over FY21-25E, the e-Pharmacy segment stands to double its market share to 6% and touch Rs138bn in revenues.

### e-Pharmacies during COVID: A big boost

The e-Pharmacy segment achieved a 47% increase in revenues for FY21, spurred by COVID-related lockdowns and buyers' reluctance in stepping out into public places. Despite the initial challenges, ePharmacies stepped up to deliver medicines to 3.5mn households (HHs) across the country during the first wave of the pandemic. Online retailers' customer base expanded to ~8.8mn households by Jun-20 versus 3.5mn in Mar-20. During this period, demand was much higher for COVID-related OTC products like masks, sanitizers, thermometers, steamers, etc. The segment employs 30,000+ skilled professionals.

During the COVID era, adoption of technology by non-metro and first-time buyers has been a key theme across sectors. Within the ePharmacy space, 45% of buyer HHs onboarded are from non-metro regions as against 30% in pre-COVID times.

According to a survey by RedSeer, ~70% of the customers have expressed a proclivity to stick to ePharmacy platforms in a post-COVID world – this emanates from the perceived value proposition offered by these platforms around the higher discounts offered vis-à-vis offline retail stores/ chains, access to hard-to-find medicines, less risk of sub-standard drugs, and integrated service offerings pertaining to doctor consultations and diagnostics. Industry reports indicate that 60-70% medicines in volume terms ordered through these platforms are by Chronic patients.

**Exhibit 28: e-Pharmacy models steadily gaining ground over the last few years**

| Break-up of IPM revenues among formats (Rs bn) | FY15 | FY19 | FY20 | FY21 | FY21 Gr (%) | CAGR FY15-20 (%) |
|---|---|---|---|---|---|---|
| Online players | 1 | 18 | 38 | 56 | 47 | 96 |
| Organized retail chains | 54 | 112 | 135 | 149 | 10 | 18 |
| Unorganized retail channels | 1,045 | 1,434 | 1,553 | 1,607 | 3 | 7 |
| **Total** | **1,100** | **1,564** | **1,726** | **1,812** | **5** | **9** |

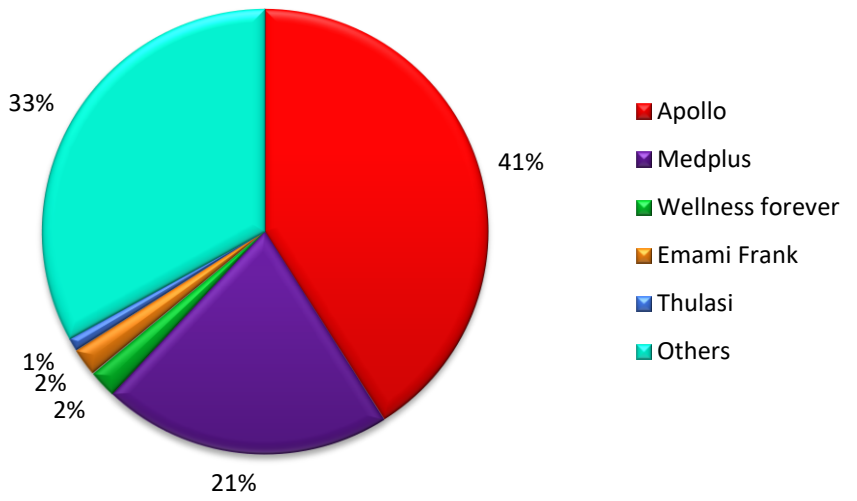
*Source: Technopak Research*

**Exhibit 29: Recent deals and investments in the e-Pharmacy space**

| Company | Investor/ Acquirer | Amount (USD mn) | Deal date | Comments |
|---|---|---|---|---|
| **Netmeds** | Reliance Retail | 85 | Aug-20 | Reliance Retail acquired a 60% stake in online pharmacy retailer Netmeds for Rs 6.2bn. The transaction allows Reliance Retail to increase its stake in Vitalic, the holding company of Netmeds, to 80% by Alr-24 from 60% held currently. Reliance has the option to take 100% control of Vitalic |
| **1mg** | Tata Digital | 250-270 | Jun-21 | The deal was a primary and secondary share sale worth USD 250mn-270mn, with existing investors also infusing capital along with Tata Digital. Of the total deal amount, USD 160 million were as primary infusion into the company with ~60% stake with Tata Digital. |
| **Medlife** | Pharmeasy | 240 | May-21 | PharmEasy's parent company API Holdings acquired a 100% stake in Medlife, whereas Medlife's promoters secured 19.95% stake in the combined entity |
| **Pharmeasy** | Nasper and TPG growth | 323 | Apr-21 | Fresh capital raised to deepen presence in existing markets, in line with Pharmeasy's plan to partner with 100,000+ pharmacies within the next 12 months. Besides, the funds were raised to increase service offerings for both healthcare practitioners and patients |
| **Amazon** | | | Aug-20 | Amazon Pharmacy e-commerce giant Amazon's foray into the online medicine segment. The service launched in select areas in some cities across India with plans for future scale-up; initial focus on OTC products |

*Source: Industry, Systematix Institutional Research*

**Exhibit 30: Market share (%) distribution within organized retail pharmacy**




*Source: Industry, Systematix Institutional Research*

## Trade generics: A potential volume disruptor

Trade generics (Gx) is a cheaper version of branded drugs with the same molecule/s offered under a different or notional brand name. Gx products are directly pushed to distributors/ retailers (and not marketed through a field force) with the retailer pushing it to customers for better margins. This is a volume-focused segment with relatively lower margins for manufacturers as drugs are sold at a steep discount to the branded counterparts.

Sales through the Gx channel are not captured in IPM revenues as the segment is largely focused on tier 3 & 4 cities. As per industry, the Gx channel accounts for 5% of the IPM in value terms but may be 25-30% of industry volumes. A government push via Jan Aushadhi stores is a key growth driver for the segment.

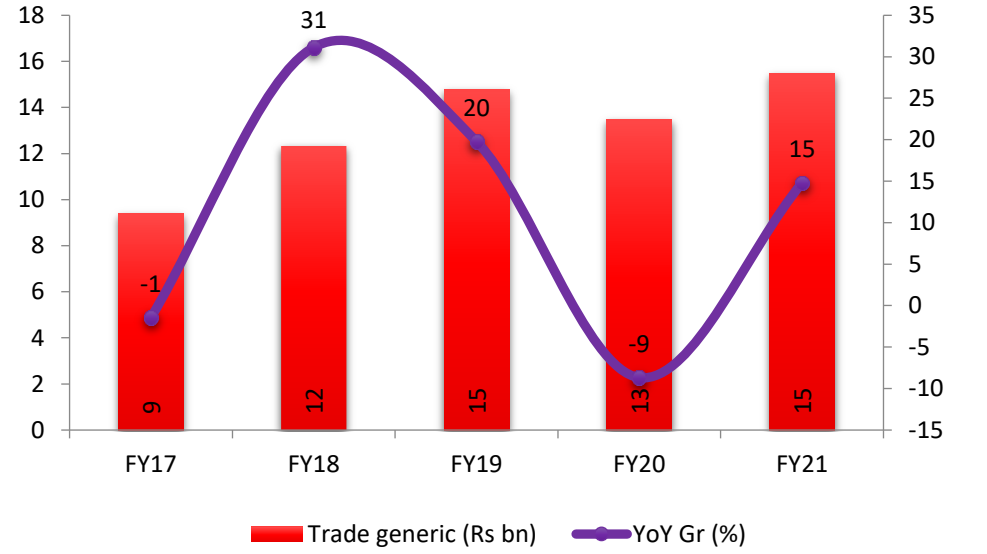
Gx is now a focus area for many companies as the segment has been witnessing robust growth in recent times. Cipla and Alkem are two of the largest players with Gx accounting for 15-20% of their domestic sales. Ajanta, JB Chem and Eris are also present in the segment though with a lower revenue contribution.

**Exhibit 31: Trade generics activity of industry leaders**

| Company | Details |
|---|---|
| **CIPLA** | Largest player in the Gx space with ~18% share in FY21 domestic revenues. Restructured the segment with transfer of products from Gx to CHL |
| **ALKEM** | 15% of the company's domestic business. Growth in higher double digits in FY21 |
| **AJP** | Contributes 10% of the company's domestic business though with reduced focus on the segment over the years |
| **JB Chemicals** | Recently entered the Gx segment |
| **ERIS** | Entered trade segment in FY21 with nominal Capex |
| **TORRENT** | Torrent forayed into Gx business in 1QFY22 with only 20-35 MRs pan-India and without a large capital investment as products will be sourced from contract manufacturers |

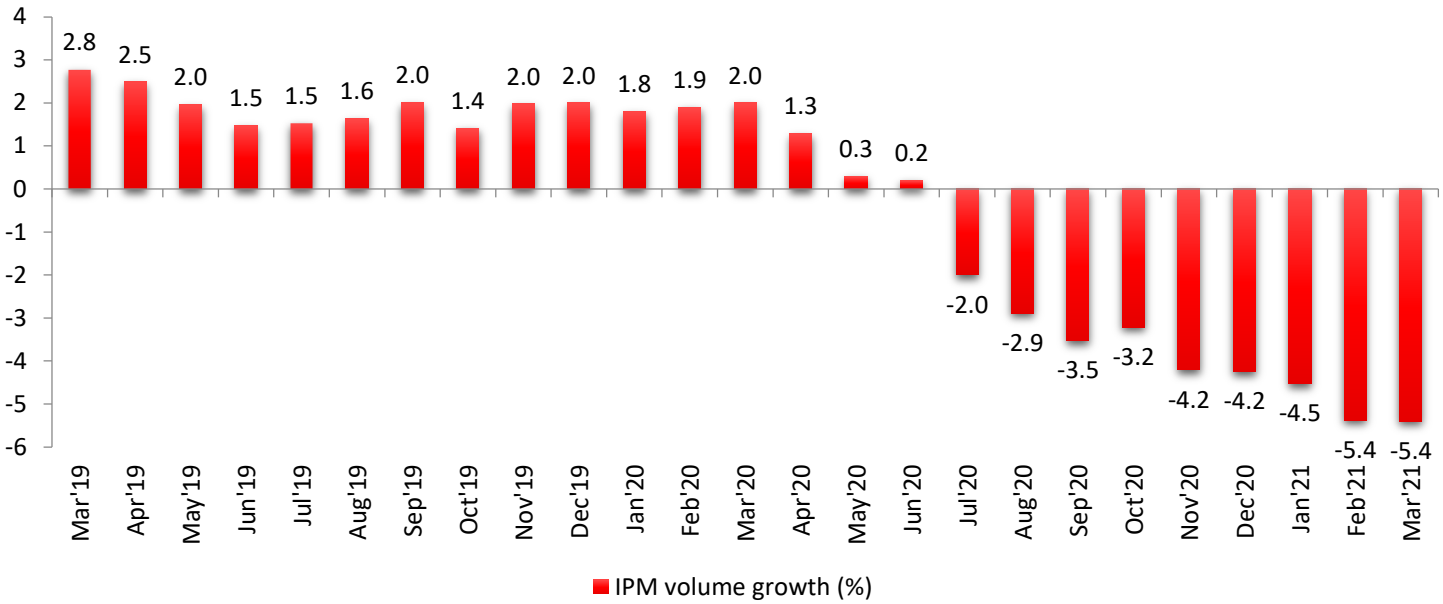
*Source: Company, Systematix Institutional Research*

**Exhibit 32: Cipla – stable performance in Gx over FY16-21**




*Source: Company, Systematix Institutional Research # FY20 decline on account of transfer of some product to CHL*

**Exhibit 33: IPM volume growth (%) – a declining trend in recent years**



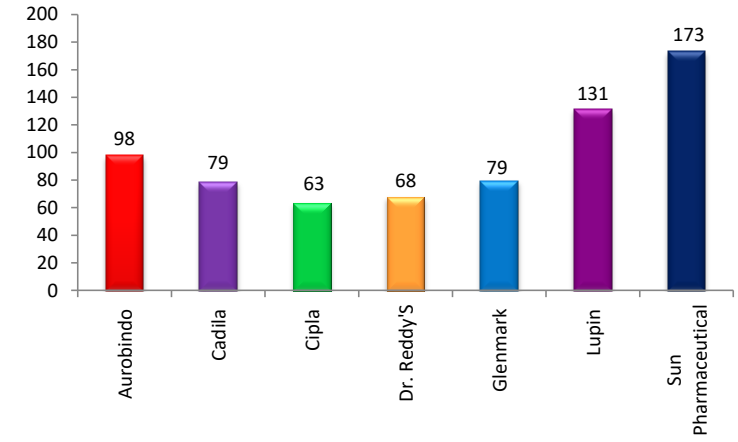

*Source: AIOCD, Systematix Institutional Research*

## Minimal capex, lower risk in domestic business vs generics

Over the last decade, companies had committed a large part of their capex into building the generics business either organically (R&D spends/ front end set-ups/ manufacturing set-ups, etc) or via the inorganic route (acquisition of brands/ portfolios/ companies). Many of these companies, with orientation to exports, targeted their expansion plans mainly towards the US market. However, implementation of GDUFA (Generic Drug User Fee Act) and consolidation at the buyers' end have led to significant price erosion in the US CY15 onwards. In this backdrop, businesses veering towards a higher domestic presence have fared much better and outperformed the peers with focus on US geography.

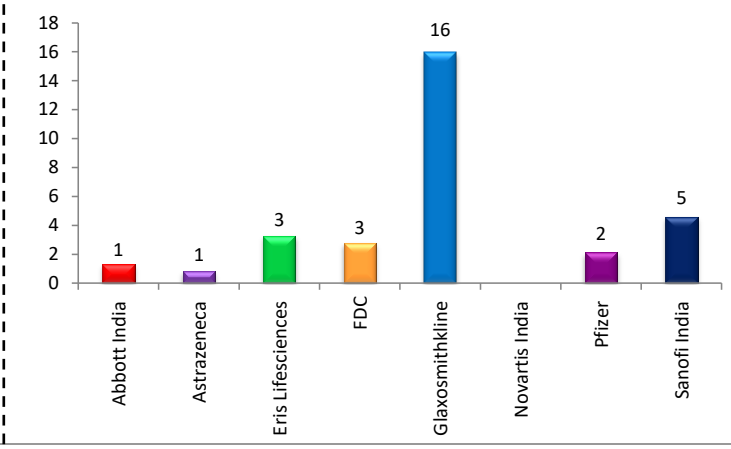
We broadly categorize Indian pharmaceutical companies into two buckets: 1) with average revenue contribution of 35-40% from domestic formulations and remaining largely from export formulations, and 2) pure domestic formulations companies with no export presence.

**Exhibit 34: Cumulative capex (Rs bn; FY15-21) by export focus**




*Source: Company, Systematix Institutional Research*

**Exhibit 35: Cumulative Capex (Rs bn; FY15-21) for domestic focus**




*Source: Company, Systematix Institutional Research*

## Generic players adopted the inorganic route for growth

Generics players' strategy for growth in regulated markets has rested mainly on acquisition of brands/ companies while domestic-focused companies opted for building brands through higher MR productivity.

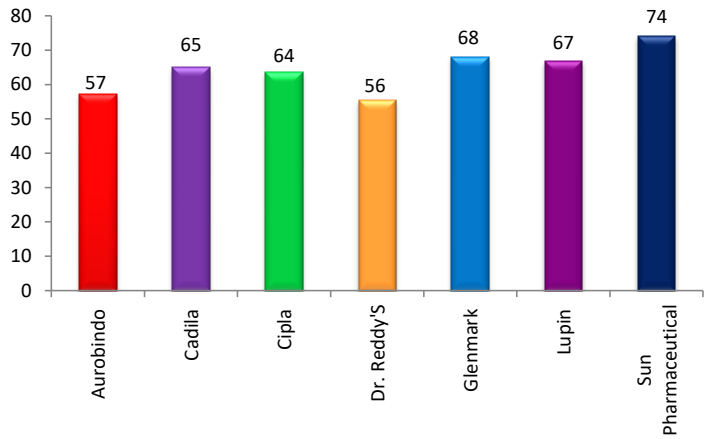
With two different approaches towards growth, companies with focus on domestic market have clearly outperformed export-oriented players over FY16-21 with average Revenue/ EBITDA CAGR of 5%/ 15% (versus export focus 7%/ 4%), EBITDA margin expansion of 632bps (versus a decline of 286bps) and RoNW of 19% (versus 12%). Revenue growth of export-focused companies seems marginally higher due to a stream of acquisitions during the same period. However, domestic formulation companies have seen their profitability and return ratios improving over time.

**Exhibit 36: Growth profile of domestic-focused companies better than generic-focused ones over FY16-21**

| | CAGR over FY16-21 (%) | | EBITDA Margin (%) | | | RoNW (%) | | |
|---|---|---|---|---|---|---|---|---|
| **Export-focused companies** | **Revenue** | **EBITDA** | **FY16** | **FY21** | **Change (bp)** | **FY16** | **FY21** | **Change (bp)** |
| Aurobindo | 12 | 11 | 23.3 | 21.7 | (154) | 12.2 | 12.2 | 0 |
| Cadila | 10 | 7 | 25.7 | 22.6 | (312) | 13.9 | 18.3 | 436 |
| Cipla | 7 | 11 | 18.6 | 22.4 | 375 | 11.7 | 14.1 | 246 |
| Dr. Reddy'S | 4 | (1) | 26.0 | 20.5 | (541) | 9.8 | 11.6 | 183 |
| Glenmark | 8 | 8 | 19.4 | 19.3 | (15) | 11.5 | 14.8 | 324 |
| Lupin | 2 | (7) | 27.0 | 17.2 | (984) | 6.4 | 9.2 | 280 |
| Sun Pharmaceutical | 4 | 1 | 29.3 | 25.6 | (370) | 9.9 | 6.3 | (359) |
| **Average** | **7** | **4** | **24** | **21** | **(286)** | **11** | **12** | **158** |
| **Domestic-focused companies** | | | | | | | | |
| Abbott India | 11 | 20 | 14.1 | 21.4 | 727 | 24.0 | 27.4 | 348 |
| Astrazeneca Pharma | 9 | 52 | 3.2 | 16.8 | 1364 | 20.6 | 22.7 | 211 |
| Eris Lifesciences | 15 | 20 | 28.7 | 36.1 | 737 | 24.7 | 24.7 | 5 |
| FDC | 6 | 8 | 23.2 | 25.1 | 189 | 13.7 | 18.4 | 466 |
| Glaxosmithkline | 2 | 11 | 14.9 | 21.8 | 691 | 23.7 | 21.6 | (211) |
| Novartis India | (12) | (5) | 5.0 | 7.3 | 237 | 1.2 | 2.9 | 174 |
| Pfizer | 2 | 7 | 26.0 | 31.8 | 585 | 14.7 | 17.2 | 246 |
| Sanofi India | 4 | 8 | 22.4 | 27.7 | 527 | 19.1 | 20.9 | 182 |
| **Average** | **5** | **15** | **17** | **23** | **632** | **18** | **19** | **178** |

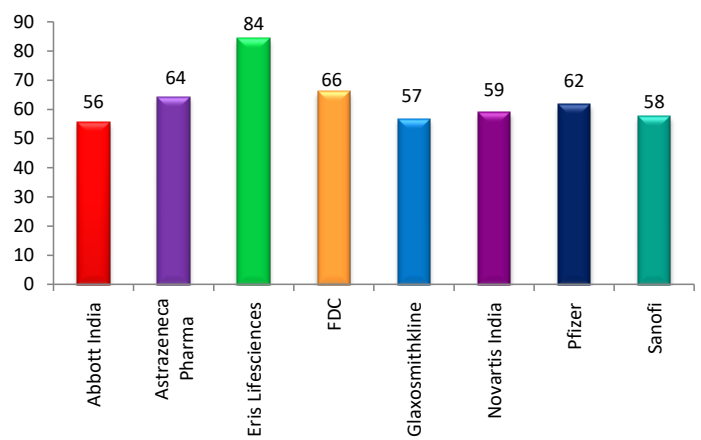
*Source: Company, Systematix Institutional Research, Bloomberg*

**Exhibit 37: Avg. gross margin (%; FY16-21) for export-focused**




*Source: Company, Systematix Institutional Research*

**Exhibit 38: Avg. gross margin (%; FY16-21) for domestic-focused**




*Source: Company, Systematix Institutional Research*

## USA: A low growth market, but still important

**The US journey of Indian players can be divided broadly into four phases:**

**2005-2010:** Large Indian players invested aggressively in US plants and R&D, which impacted return ratios. Large companies invested in front ends and established relationships with distributors during this phase.

**2011-2015:** Indian generic players witnessed strong growth during this phase, with tailwinds from product patent expiries. Margins expanded on operating leverage and return ratios improved with higher capacity utilization/ margin expansion.

**2016-2019:** Intense competition across products, combined with customer consolidation, led to sharp price erosions. Also, USFDA came up with the GDUFA guidelines, which reduced product approval timelines from 35-40 months to 12-15 months. With shorter approval cycles, R&D decisions went haywire for incumbents. During this time, compliance issues also surged materially, which further impacted growth in this market. To counter this, generic players underwent portfolio rationalization and exited products that were economically unviable. Companies also aggressively focused on controlling costs, largely on R&D and Opex side.

**2019-2021:** With large players exiting unviable products, prices started stabilizing and price erosion went down to an average 5-7% from 15-20% earlier. Also, this coincided with COVID-19, and distributor negotiations focused on supply consistency than lower pricing; this provided a further fillip to pricing.

**Outlook on US market:** We believe the heightened price erosion witnessed in FY22 is largely a result of higher channel filling in FY21, as supply consistency was a major worry. As these products approach expiry dates, discounts have gone up commensurately to liquidate the high inventory prevailing in the system. Also, the industry prioritized product procurement over price erosion and thus there was no major price discounts in FY21. In this light, as these contracts came up for renegotiations, customers were demanding much higher discounts to make up for last year's loss. We believe these factors should give way in FY23 and expect a normalized 5-7% price erosions on a broader basis for US portfolios.

Indian generics are gradually scaling up the value chain in terms of product complexity which, combined with leaner cost models, should help improve return ratios. While still early days, there are signs of green shoots with companies seeing initial success in select pockets (Cipla/ Lupin – Respiratory, SUNP – Specialty, and ARBP – Injectables). **We believe the US market will continue to witness moderate growth, but profitability should improve as companies scale up the value chain.**

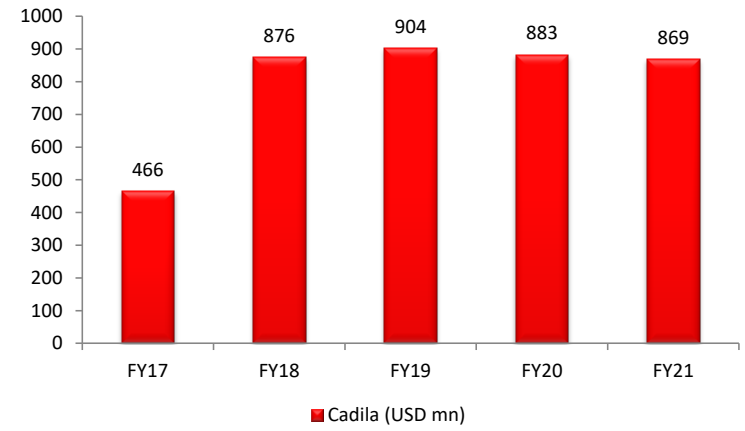
**Exhibit 39: US growth for Indian Pharmaceutical companies has been mixed**

| Revenue (USD mn) | FY17 | FY18 | FY19 | FY20 | FY21 | CAGR (%) FY17-21 |
|---|---|---|---|---|---|---|
| Cadila | 466 | 876 | 904 | 883 | 869 | 17 |
| Aurobindo | 1,019 | 1,145 | 1,292 | 1,621 | 1,668 | 13 |
| Cipla | 392 | 398 | 489 | 547 | 555 | 9 |
| Dr.Reddy's | 949 | 920 | 860 | 911 | 953 | 0 |
| Glenmark | 552 | 493 | 450 | 443 | 416 | (7) |
| Lupin | 1157 | 813 | 778 | 801 | 720 | (11) |
| Sun Pharma | 2,054 | 1,345 | 1,435 | 1,488 | 1,361 | (10) |

*Source: Company, Systematix Institutional Research*

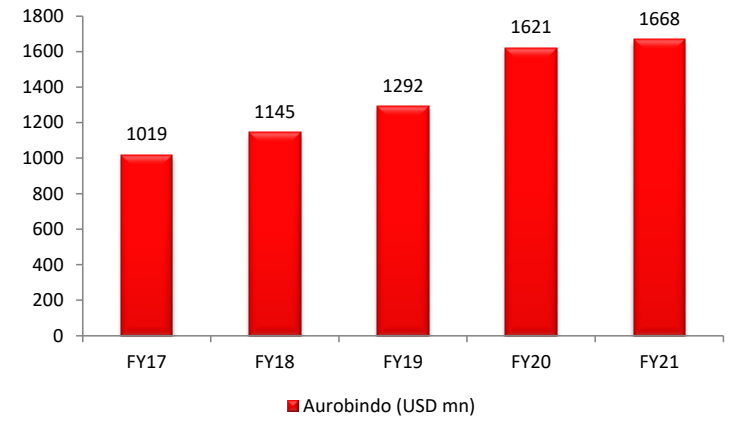
## US growth has been largely flattish to declining over the last five years

**Exhibit 40: CDH – Growth led by Mesalamine franchisee**



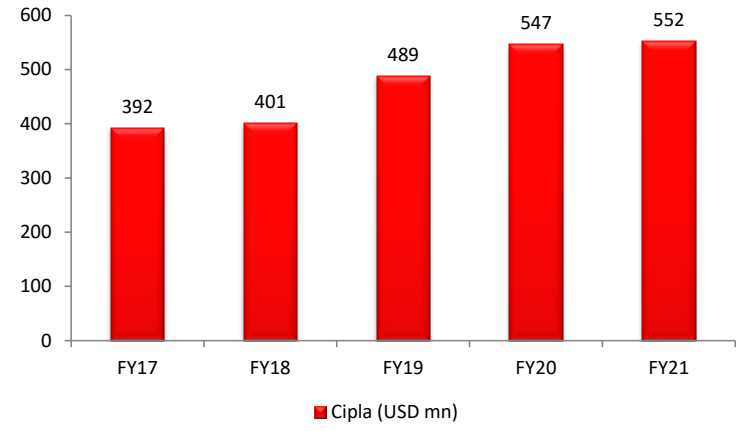

*Source: Company, Systematix Institutional Research*

**Exhibit 41: ARBP – Growth led by higher ANDA filing**



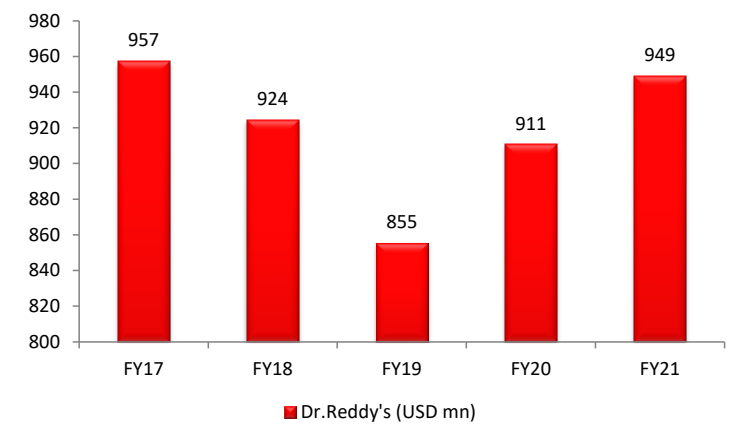

*Source: Company, Systematix Institutional Research*

**Exhibit 42: CIPLA – Respiratory products currently driving growth**



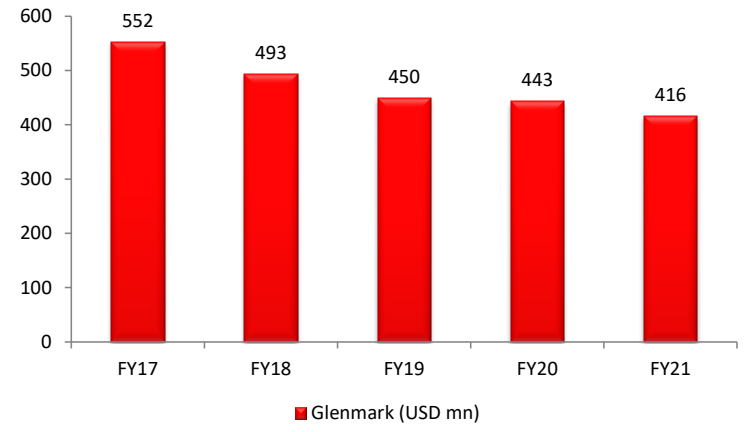

*Source: Company, Systematix Institutional Research*

**Exhibit 43: DRRD – Largely stable**



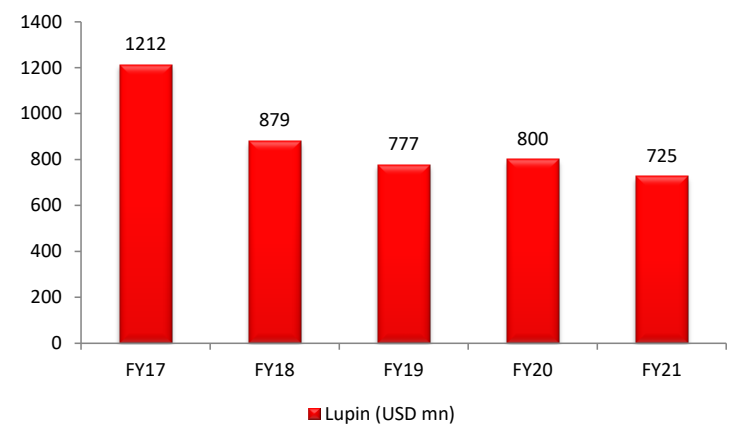

*Source: Company, Systematix Institutional Research*

**Exhibit 44: GNP – Higher price erosion in derma portfolio**



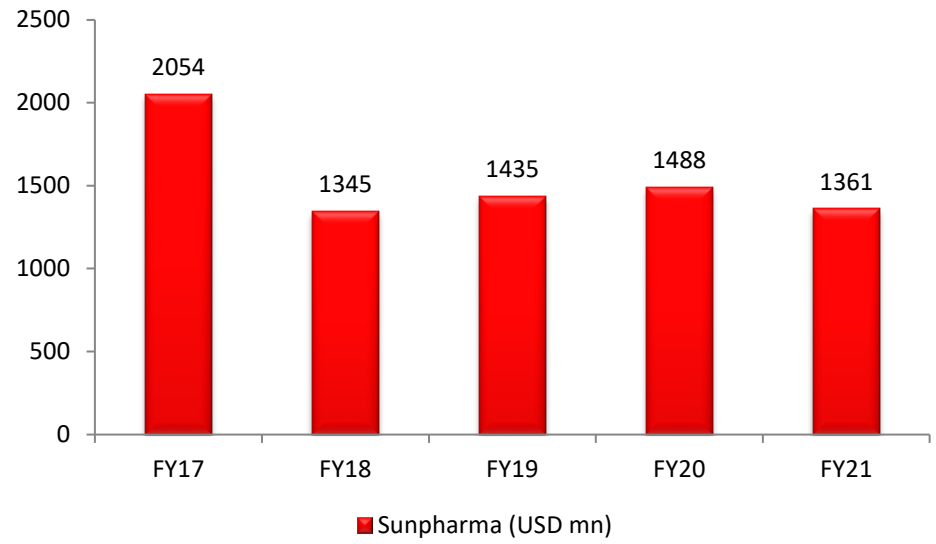

*Source: Company, Systematix Institutional Research*

**Exhibit 45: LPC – Price erosion across products**



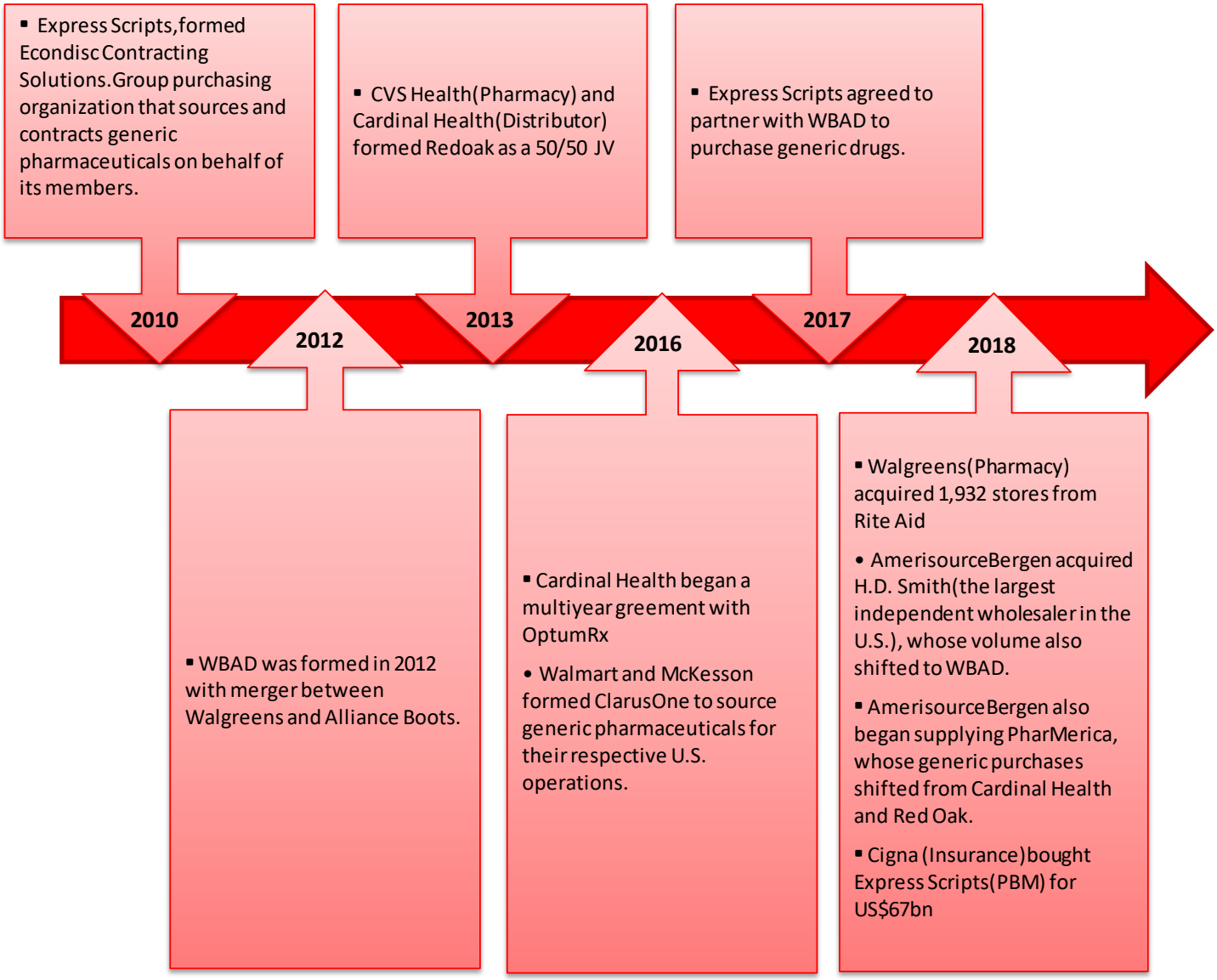

*Source: Company, Systematix Institutional Research*

**Exhibit 46: SUNP-Taro and SUNP's Gx business drag on US business**




*Source: Company, Systematix Institutional Research*

**Exhibit 47: Channel consolidation in the US – a key reason for weak pricing in the US**




*Source: Company, Systematix Institutional Research*

### …and GDUFA has only accentuated the impact

Implementation of GDUFA-1 in 2012 accelerated the approval pace for generics from 2015, which led to deflationary pressure on the segment. In the first five years of the GDUFA program (2013-17), the FDA approved 2,829 new generic drugs – a 21% increase over 2,309 during 2008-12.

The pace of approval was even faster for most subsequent generics, which led to hefty price erosions, especially after the approval of the third and fourth player in a particular generic. On an average, the price of second generic launch has been at a 50% discount to the brand while the third and fourth launches have been at a 75% and 90% discount respectively.

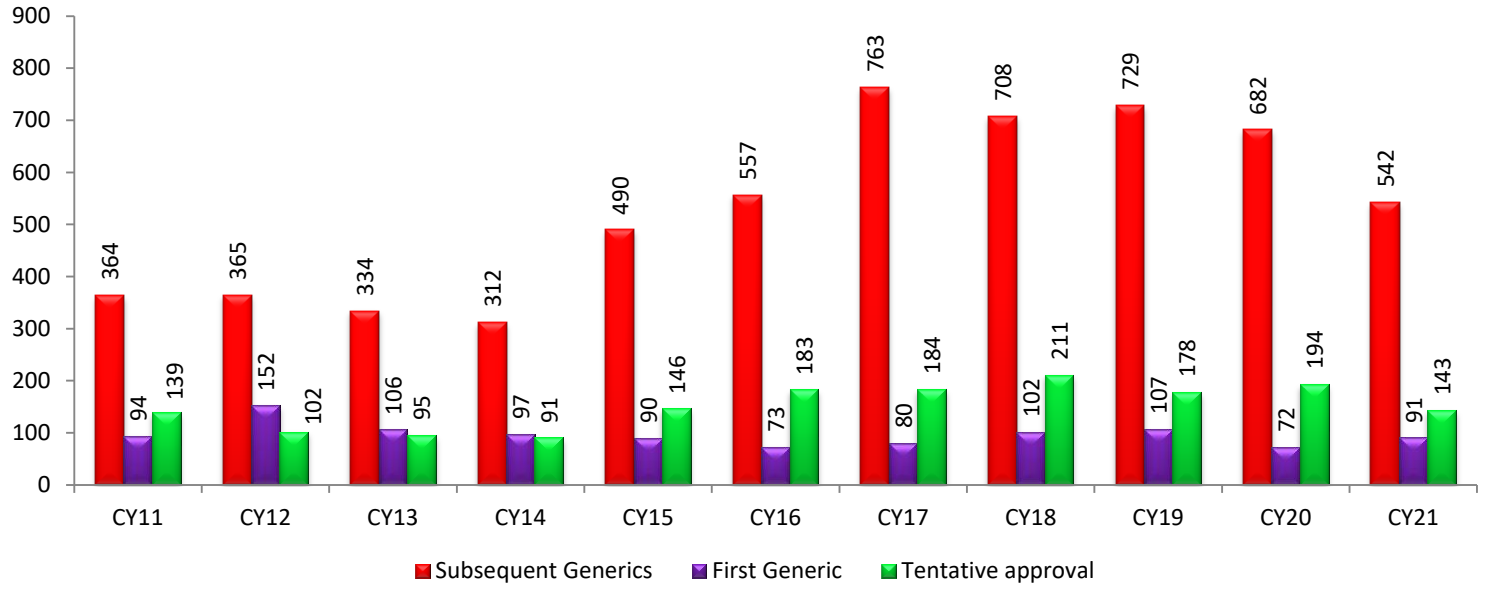
The impact of GDUFA on Indian companies began from 2015, post the clearance of backlogged applications and the FDA's priority review of second and third generics. While older Indian players such as SUNP, LPC, CDH and DRRD have been hit hard by implementation of GDUFA, the situation did not put all the players at a disadvantage.

Players with late entry in the US, like TORRENT, ALKEM, CAPLIN and CIPLA, benefitted from the faster approvals – in turn enabling a faster scale-up for them.

Another point to be noted is that the total number of exclusive first generics, even after the implementation of GDUFA, has been relatively stable with 72-102 ANDAs between 2015-20. What has prevented Indian companies from benefitting from the approvals is deficiencies in their application as also regulatory issues at their plants.

We believe the adverse impact of GDUFA implementation is largely behind for Indian companies and price erosion would be at a more moderate 5-7% from here.

**Exhibit 48: GDUFA implementation in the US market has intensified competition (Nos.)**




*Source: USFDA, Systematix Institutional Research; Note: #Subsequent generics: ANDAs approved after the first generic*

## Regulatory issues have been another drag

Along with sharp price erosions, Indian companies have also been reeling under heightened compliance issues with the USFDA. India has the highest number of USFDA-approved plants outside the US and, therefore, has witnessed more intense scrutiny vis-à-vis other countries. Given the COVID-induced travel restrictions, physical inspections have not been carried out for the last two years and most plants are due for re-inspection.

While the USFDA has resumed selective inspections in the last six months, we expect inspections to resume in full swing in FY23 with priority accorded to plants under compliance issues and ready for re-inspections. This can prove to be either a boon or bane – a successful re-inspection of plants with compliance issues will pave the way for faster approval of stuck product filings; however, plants currently in the clear may draw USFDA observations if compliance is found not up to the mark.

**Exhibit 49: Regulatory status of key plants of Indian companies**

| Company | Facility | Inspection | Current FDA Status | % of US sales in FY21 | Comments |
|---|---|---|---|---|---|
| LUPIN | Goa | Sep-21 | EIR | 20-25% | FDA issued a joint warning letter for Goa and Pithampur Unit 2 on Nov-17. The facility was re-inspected on Feb-19 and Sep-21 (7 observations) and LPC has now received Establishment Inspection Report (EIR) with Voluntary Action Indicated (VAI) |
| | Pithampur Unit 2 | Jan-19 | Warning letter | 15% | Received warning letter in Nov-17 and the plant was re-inspected in Jan-19. LPC has completed Corrective and Preventive Action (CAPA) and is awaiting US FDA inspection |
| | Tarapur | Sep-19 | OAI | <5% | Tarapur plant received Official Action Indicated (OAI) status after FDA inspection in Sep- 19 and the status in maintained |
| | Mandideep Unit 1 | Dec-18 | Warning letter | <5% | Plant received OAI status in Mar-19, and received a warning letter in Sep-19 |
| | Somerset (US) | Nov-20 | Warning letter | <5% | OAI status issued in Mar-19 after facility inspection in Dec-18; FDA re-inspected the plant in Sep-Nov-20 and issued a Form 483 with 13 observations. FDA issued a warning letter in Jun-21 citing repeat violation at multiple sites |
| Aurobindo | Unit 7 | Sep-19 | OAI | 25% | The FDA issued a Form 483 with seven observations in Sep-19; it was escalated to OAI status in Jan-20 |
| | Unit 1 | Aug-21 | OAI | API plant | Under OAI status in Feb-20 inspection |
| | Unit 9 | Feb-19 | OAI | API & intermediate | OAI status since Feb-19 |
| | Unit 11 | Aug-21 | Warning letter | API plant | OAI was issued after 2019 inspection and later escalated to a warning letter in Jun-19. Status remains unchanged even after recent inspection with a warning letter issued in Jan-22 |
| | Unit 16 | Mar-19 | Form 483 | Sterile drugs unit | Form 483 issued in Mar-19 |
| | Dayton, New Jersey (US) | Feb-20 | Warning letter | <5% | The FDA issued a Form 483 with nine observations after plant inspection in Feb-20; it was later escalated to OAI status in Jun-20 and a received a Warning Letter in Oct-20 |
| Cadila | Moraiya | May-19 | Warning letter | 55-60% | OAI status issued in Aug-19, which escalated to a warning letter in Oct-19 |
| Torrent Pharma | Indrad | Apr-19 | Warning letter | 55-60% | OAI status issued in Aug-19, which was later escalated to a warning letter in Oct-19 |
| | Dahej | Mar-19 | OAI | 30-35% | OAI status issued in July-19 |
| | Levittown, PA (US) | Mar-19 | Warning letter | 5% | OAI status issued in July 2019, which escalated to a warning letter in Nov-19 |
| Cipla | Goa | Sep-19 | Warning letter | 25-30% | FDA issued a warning letter in Feb-20 |
| Glenmark Pharma | Baddi | Apr-19 | Warning letter | 7% | OAI status issued in Apr-19, which escalated to a warning letter in Oct-19 |
| Sun Pharma | Halol | Dec-19 | OAI | 25-30% | Halol plant has a pending Form 483 with 12 observations and was classified OAI in Mar-20 |
| Jubilant Pharmova | Roorke | Dec-18 | Import alert | Dosage-4% | Classified the facility as OAI in Dec-18; escalated to warning letter in Mar-19 |
| | Nanjangud | Dec-18 | OAI | API | |
| IPCA | Pithampur | Mar-15 | Import alert | Formulation | Piparia (Silvassa) and SEZ, Indore (Pithampur) use APIs manufactured from the Ratlam facility |
| | Piparia | Mar-15 | Import alert | Formulation | In FY14, the US market contributed 12% of total sales for IPCA Labs |
| | Ratlam | Jan-15 | Import alert | API | Supplies anti-malarial treatment API HCQ sulfate and CQ manufactured from the plant |

*Source : USFDA,Company, Systematix Institutional Research*

## Indian companies responding by moving up the value chain…

With the US base portfolio seeing sharp price declines and further pain on account of regulatory issues, Indian companies are striving to scale up the value chain in terms of product complexity. This is being done by committing higher allocation towards injectables, oncology, hormones, respiratory, etc – areas facing some or the other barriers in terms of product complexity, manufacturing or technology. Initial success has been achieved in certain cases like CIPLA/ LPC in respiratory, DRRD/ ARBP in injectables and SUNP in Specialty portfolio.

While these are still early days, we acknowledge the efforts are in the right direction. To put things in perspective, SUNP aims to significantly strengthen its global Specialty franchise with a bulk of incremental capital allocation in this area. CDH has also guided to increased investments in its innovation franchise. DRRD has reduced its capital allocation on Specialty business and guided to aggressive investments in India and other non-US markets like China. Besides strengthening its injectables/ biosimilars franchise, ARBP has also committed significant capital to the API segment. CIPLA and LPC have been enhancing investments in complex generics.

These products also act as a hedge against margin erosion in the commodity portfolio, given relatively lesser competition and higher profitability.

**Exhibit 50: Indian companies moving towards complex molecules**

| Company | Injectables | Biosimilars | Inhalers | Specialty |
|---|---|---|---|---|
| SUNP | ✓ | ✗ | ✗ | ✓ |
| CIPLA | ✓ | ✓ | ✓ | ✗ |
| DRRD | ✓ | ✓ | ✗ | ✗ |
| LPC | ✓ | ✓ | ✓ | ✓ |
| ARBP | ✓ | ✓ | ✗ | ✗ |
| CDH | ✓ | ✓ | ✗ | ✓ |
| GNP | ✓ | ✗ | ✗ | ✓ |

**Color rule |** **Green:** Significant presence, **Blue:** Minor presence, **Red:** No presence

*Source: Company, Systematix Institutional Research*

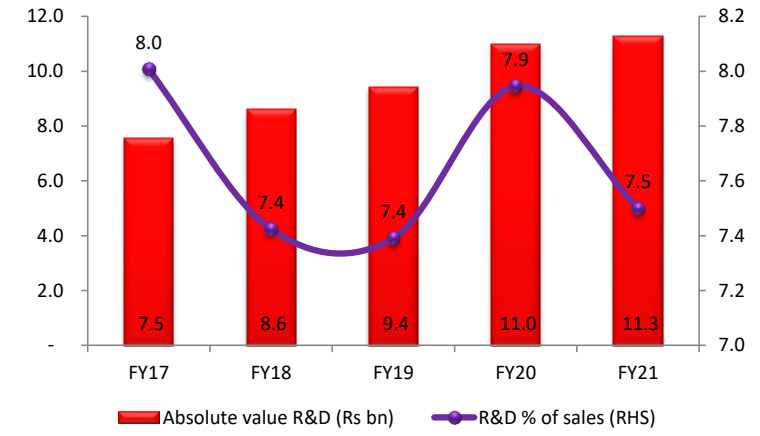
**Exhibit 51: Some of the recent high value products**

| Company | Brand (API) | ANDA filing date | Status | Competitive environment | Remarks | Delay in launch from First Cycle |
|---|---|---|---|---|---|---|
| **Dr.Reddy's/ Biocon** | Copaxone (glatiramer) | CY-14/CY-15 | Yet to launch | Mylan/ Natco launched first generic in Oct-17 at risk. Currently, 3 players approved by the USFDA (including innovator Teva) while Amneal, Synthon and Biocon/ Apotex are also other known filers. Mylan/ Mapi working on once-a-month dosage of glatiramer | Initial guidance was to launch in CY-18 but received CRL several times. Have recently responded to FDA's query and may launch CY22 | 4 years |
| **Dr.Reddy's** | Nuvaring (etonogestrel & ethinyl estradiol) | FY-18 | Received approval from the FDA but yet to launch | Anmeal received approval in Dec-19 and innovator (Merck) launched its own authorized generic soon after Anmeal. Teva received approval recently in Jan-21. gNuraving also has to compete with an a more efficient substitute product, Annovera as it lasts for 12-13 cycles v/s gNuvaring for 1 cycle | Initial guidance was to launch in CY18 and DRRD was expected to be the first generic for gNuvaring. But multiple CRLs delayed the launch. Received approval in Dec-21, but yet to launch as it may be unviable now due to increased competition | 4 years |
| **Cipla** | Proventil HFA (Albuterol) | FY18 | Launched in April-21 | Available with three brands; entry of multiple new players in the last 24 months | Launch was expected in 1HFY20 with a targeted annual sale of USD 100mn but got delayed due to CRL | 2 years |
| **Cipla** | Advair | May-20 | Yet to launch | Mylan launched first generic in May-19 with a 70% discount to brand price while Hikma launched in April-21. The FDA recently accepted Lannett ANDA as a priority filing | Cipla recently received CRL and has guided for a launch in FY23E | 1 year |
| **Lupin** | Proventil HFA (Albuterol) | Jan-17 | Launched in Aug-20 | | Received approval in Aug-20 and enjoys market share of ~15% in the overall albuterol market | 2 years |
| **Biocon** | Glargine | FY-17 | Launched in Aug-20 | Eli Lilly launched Basaglar in Dec-15 and Sanofi launched Toujeo in Mar-15. The API for Innovator Lantus and Toujeu is similar, but Lantus contains 100 units/ milliliter while Toujeo is 3x more concentrated. Basaglar is available in prefilled pen and Launtus in 10ml multi dose vial. Biocon/ Mylan currently hold ~3% market share of Glargine | Biocon received CRL on two occasions for Glargine and also form 483 twice for the manufacturing facility in Malaysia, which delayed the launch | 3 years |

*Source: Company, Systematix Institutional Research*

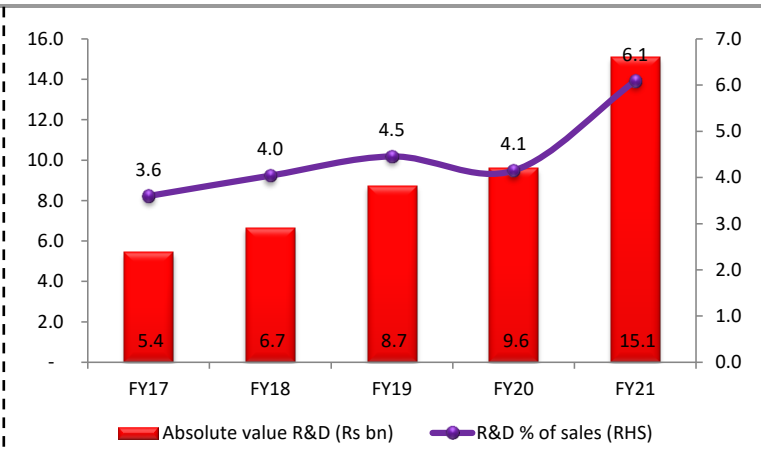
## …and channeling R&D spend into complex, high value assets

**Exhibit 52: CDH – Specialty products yet to be monetized**



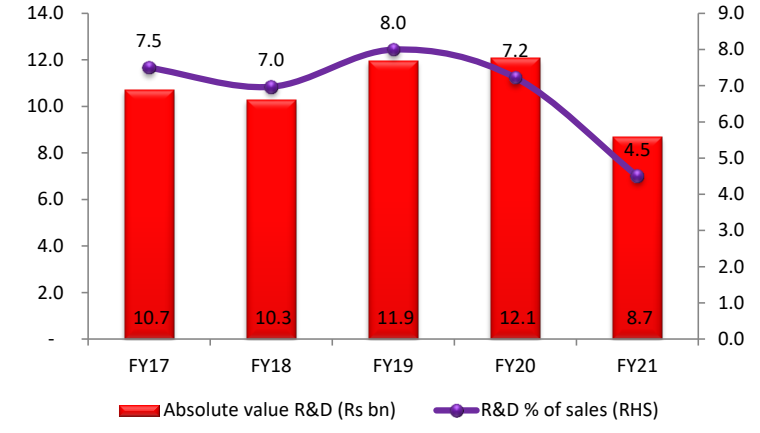

*Source: Company, Systematix Institutional Research*

**Exhibit 53: ARBP – Building injectables and biosimilars pipeline**



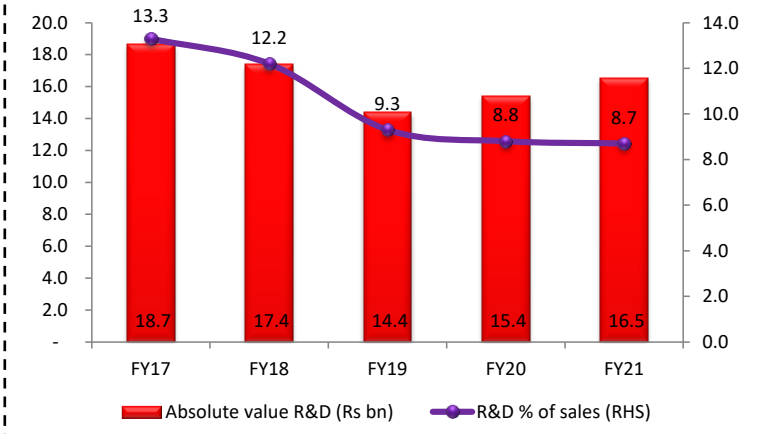

*Source: Company, Systematix Institutional Research*

**Exhibit 54: CIPLA – Focus on respiratory products**



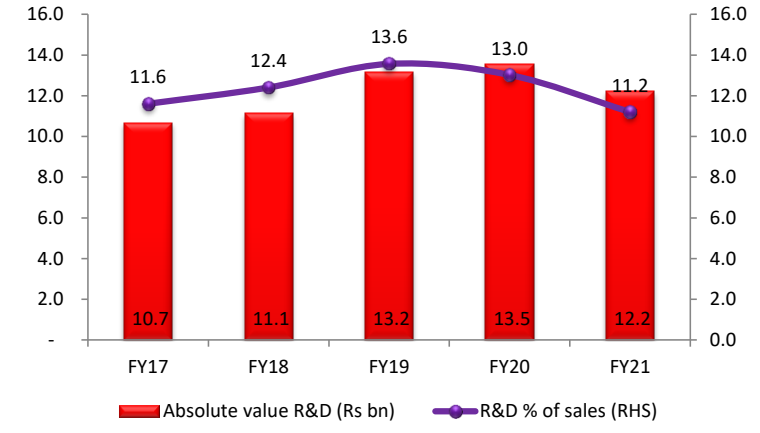

*Source: Company, Systematix Institutional Research*

**Exhibit 55: DRRD – Reduced focus on US-Gx**



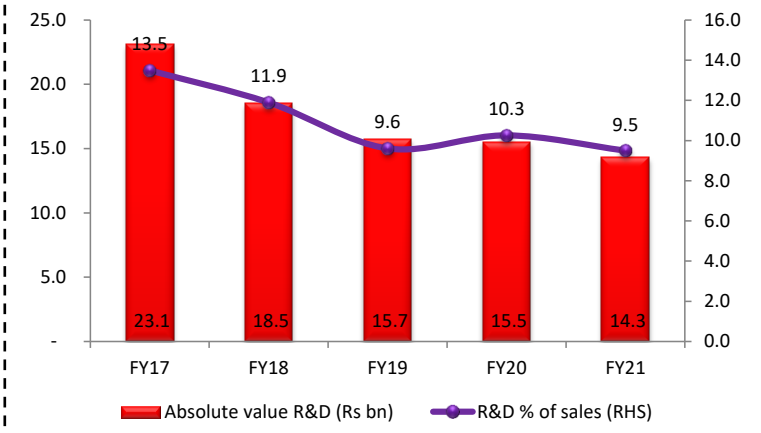

*Source: Company, Systematix Institutional Research*

**Exhibit 56: GNP – Complex products yet to be monetized**



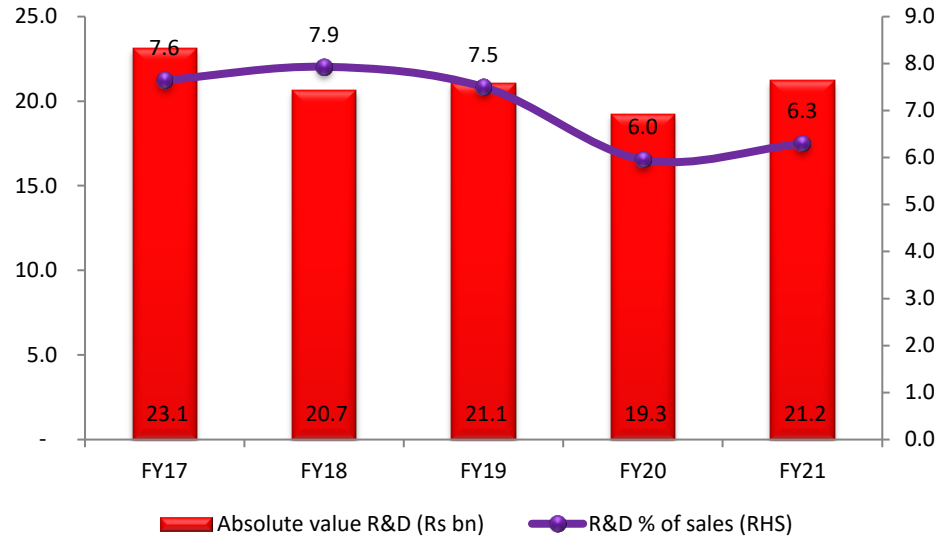

*Source: Company, Systematix Institutional Research*

**Exhibit 57: LPC – Building respiratory and biosimilars portfolio**




*Source: Company, Systematix Institutional Research*

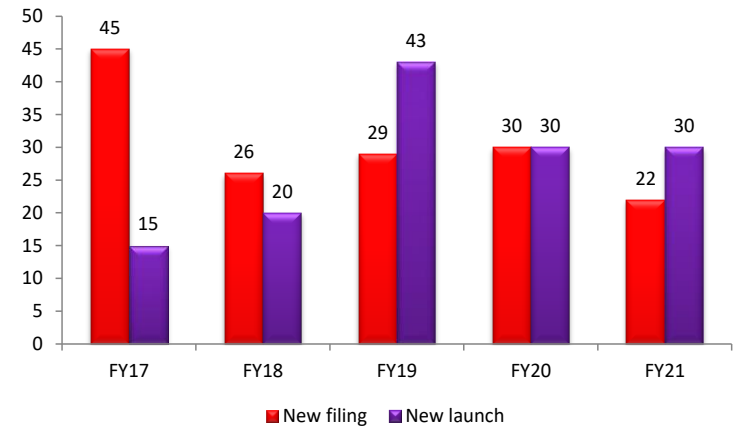
**Exhibit 58: SUNP – Focus on Specialty products**




*Source: Company, Systematix Institutional Research*

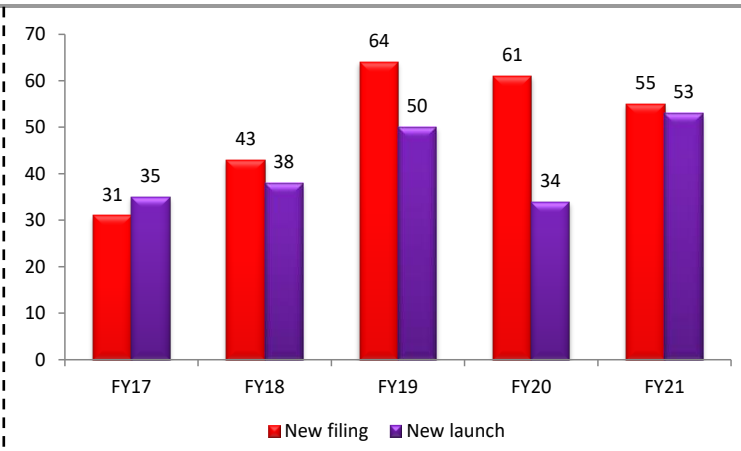
## Lower R&D spends also reflecting in reduced filing intensity

**Exhibit 59: CDH – Focus on increasing filing rate (Nos.)**



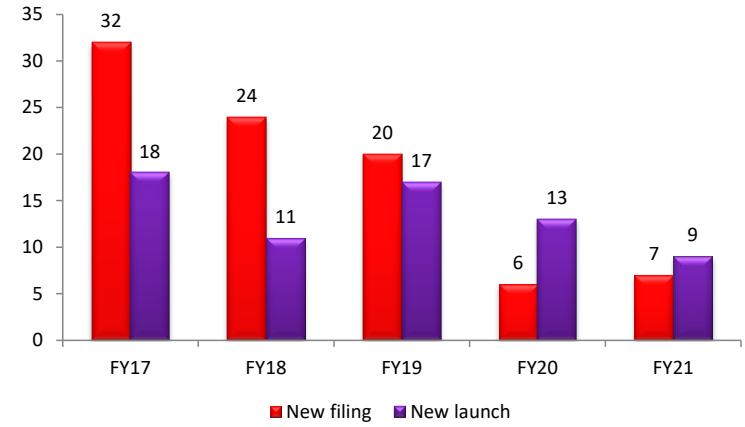

*Source: Company, Systematix Institutional Research*

**Exhibit 60: ARBP – Focus on injectables (Nos.)**



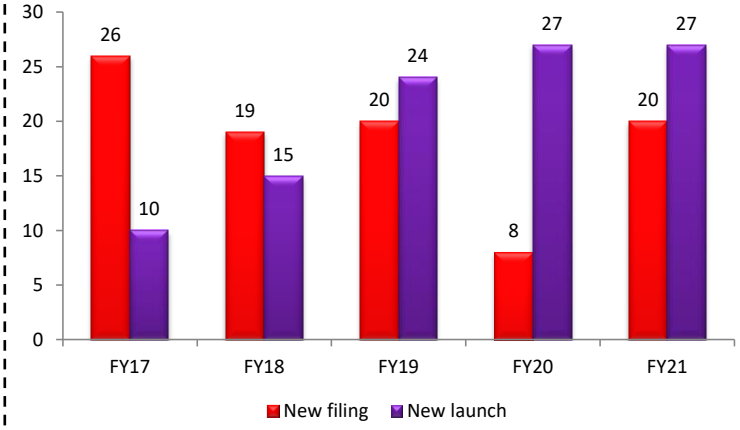

*Source: Company, Systematix Institutional Research*

**Exhibit 61: CIPLA plans to launch one respiratory prod. a year (Nos.)**



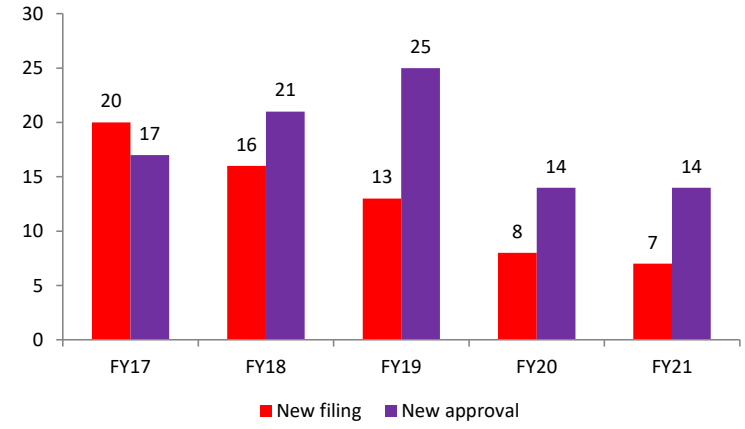

*Source: Company, Systematix Institutional Research*

**Exhibit 62: DRRD – Focus on limited competition products (Nos.)**



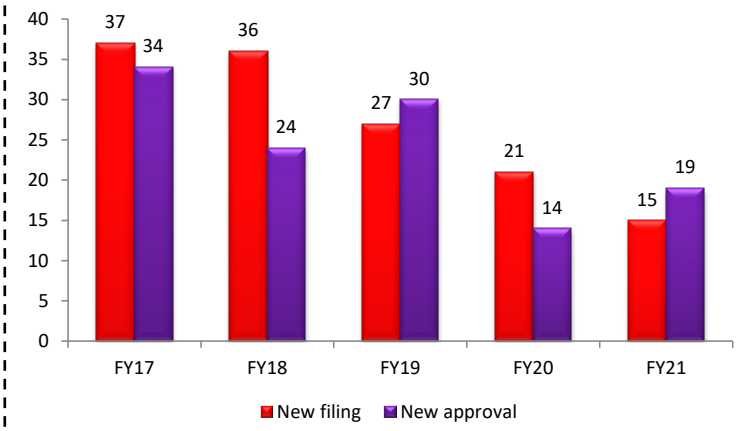

*Source: Company, Systematix Institutional Research*

**Exhibit 63: GNP – A small product pipeline (Nos.)**



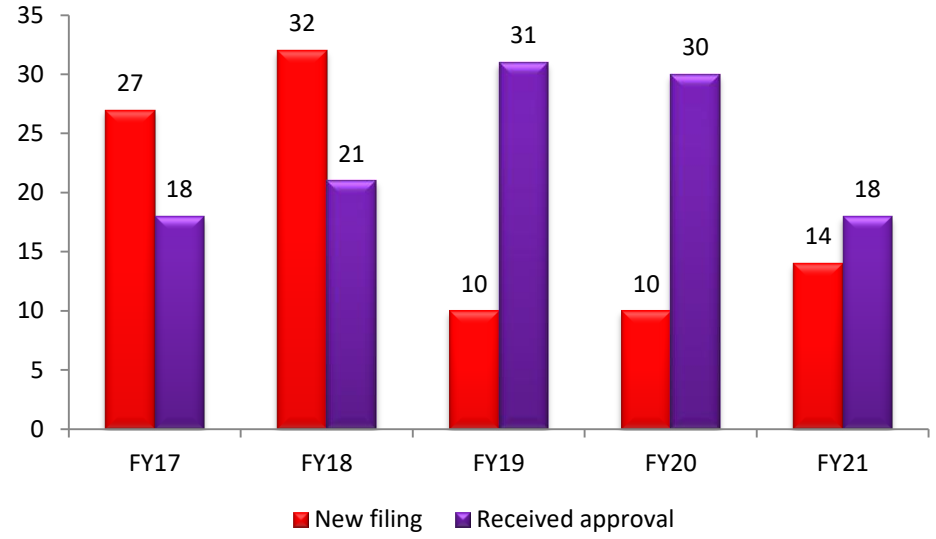

*Source: Company, Systematix Institutional Research*

**Exhibit 64: LPC – gSpiriva, Pegfilgrastim are key launches (Nos.)**




*Source: Company, Systematix Institutional Research*

**Exhibit 65: SUNP - Halol issue has keep the pace of approvals muted (Nos.)**




*Source: Company, Systematix Institutional Research*

## EMs – India-like dynamics, higher profitability

EMs have characteristics quite like the Indian market. Most of these are branded generics markets, require a dedicated field force and are mostly driven by out-of-pocket expenses. Like India, they are highly profitable, require much lower capex and are returns-accretive. Within EMs, Asian countries, LATAM, Africa and Russia/ CIS are the key focus regions for Indian companies.

On an average, Indian companies derived ~15% of their global sales in FY21 from these regions and witnessed 8% CAGR over FY16-21. SUNP and DRRD have the highest (in terms of absolute value) contribution from these markets.

**Exhibit 66: Company-wise contribution from Emerging/ RoW markets**

| (Rs bn) | Revenues in FY21 | CAGR over FY16-21 (%) | % of global revenues FY21 |
|---|---|---|---|
| SUNP | 106 | 13 | 32 |
| CIPLA | 19 | (12) | 10 |
| DRRD | 35 | 30 | 18 |
| LPC | 30 | (1) | 14 |
| GNP | 17 | 0 | 16 |
| ARBP | 14 | 16 | 6 |
| CDH | 10 | 8 | 7 |

*Source: Company, Systematix Institutional Research*

**A customized strategy for each market:** Indian players have increased their exposure in these markets either by setting up own field-force driven front-ends, adopting a distributor-led model, or by participating in institutional tenders. Most of these markets display India-like dynamics (branded generic markets driven by out-of-pocket expenses).

In markets driven by tenders, Indian companies have leveraged their existing product baskets from established markets or through in-license deals. In some instances, companies have also opted for the inorganic route with acquisition of brands or an entire entity. Indian companies have used multiple strategies to scale up in these markets. However, they have tasted success only in one or two large markets at best in view of macro concerns in the form of pricing deflation, increasing coverage of generic drug usage or currency volatility.

**Specialty products:** With increased pricing pressure and higher coverage ratio of generics in select countries, Indian players have also focused on building Specialty baskets through front-end partnerships and in-licensing deals. Cadila, Dr.Reddy's, Lupin and Cipla have built a biosimilars pipeline in EMs while Sun Pharma and Glenmark have out-licensed their specialty products Ilumya and Ryaltris respectively to partners for launch in numerous countries.

## Key markets and areas of focus within RoW and EMs

**Exhibit 67: SUNP – Launch and ramp-up of Ilumya holds the key**

| | |
|---|---|
| **Key regions** | For SUNP, RoW markets include Western Europe, Canada, Japan, Australia, New Zealand (ANZ) and a few other markets. Emerging markets include Romania, Russia, South Africa with Brazil being the largest contributor |
| **Manufacturing capabilities and sales force** | The company has set up local manufacturing units across Bangladesh, South Africa, Malaysia, Romania, Egypt, Nigeria, and Russia to acquire flexibility in servicing these markets. It also has its own front-end in most of the EMs with a total sales representative strength of ~2,200. SUNP follows a mainly distributor-led model in RoW with African countries largely tender-driven |
| **Japanese market** | SUNP's Japanese market portfolio includes differentiated products for hospitals with focus largely on injectables. Also, presence in retail markets with long-listed products including generics for RoW |
| **Growth drivers** | Ramp-up of ILUMYA in Japan and new product launches in other RoW and EMs |

*Source: Company, Systematix Institutional Research*

**Exhibit 68: CIPLA – Unmatached leadership in respiratory products**

| | |
|---|---|
| **Key regions** | CIPLA is the largest player in Sri Lanka, Morocco and Nepal markets with presence also in Malaysia, Colombia, Oman, Australia and New Zealand. Brazilian operations mainly focus on Oncology products while the company remains the leader in respiratory products in Sri Lanka, Nepal and Morocco |
| **New region** | CIPLA forayed into new markets in FY21 with first-time filings and tender bids across Mexico, Saudi Arabia, Indonesia and Argentina |
| **Business strategy** | Operates in EMs with a combination of DTM and B2B strategy; respiratory franchise contributes 55-60% from 10-15 DTM markets. Commenced operations in Malaysia and Columbia through DTM in FY16 |
| **Biosimilars** | Biosimilar products (Adalimumab, Trastuzumab, Etarnercept among others) have been signed in partnership and filed in top DTM markets across EMs to launch in 25 countries |
| **Growth drivers** | Growth in EMs expected to be led by entry in China with focus on respiratory products. CIPLA has an 80:20 JV in China with Jiangsu Acebright and a dedicated factory set up for manufacture of respiratory products |

*Source: Company, Systematix Institutional Research*

**Exhibit 69: DRRD – Launch of injectables in RoW, and biosimilars in Russia and CIS regions**

| | |
|---|---|
| **Key regions** | EMs include Russia, CIS (Romania tender sales, Ukraine, Kazak and Uzbek) and RoW (Brazil, China, South Africa, Vietnam, Myanmar and Jamaica) |
| **China plans** | DRRD the first Indian company to win a tender in 2020; has a list of 80+ products that could be launched in China |
| **Growth drivers** | Scale-up in key markets including Russia, China, Brazil, South Africa and Ukraine by building a healthy pipeline of products including differentiated and oncology products, and expansion of biosimilars |

*Source: Company, Systematix Institutional Research*

**Exhibit 70: LPC – Plans to monetize respiratory products in China**

| | |
|---|---|
| **Key regions** | **EMEA:** Europe contributes 4% of global sales with Germany, UK and France being the key regions. In UK, LPC is the market leader in Anti-Retroviral segment; cardiovascular the largest segment in Africa |
| | **LATAM:** The two biggest markets in the region include Brazil and Mexico, contributing 70% of LATAM revenues. Brazil accounts 45-50% of LATAM revenues. LPC ranks second in ophthalmic products in Mexico and focus is on dermatology in Brazil |
| | **APAC:** LPC present in 10 markets in APAC with Australia, Philippines and Korea being the key markets |
| **China plans** | LPC scouting for a partner having a manufacturing unit in China. Launch of first product in China could take 4-5 years. Has identified products from inhalation portfolio such as generic Luforbec (already approved in the UK) and generic Spiriva (a pipeline product for Europe, Australia, Japan and the US) for entry into China |
| **Growth drivers** | Within EMEA, LPC has a unique range of long-acting injectables, biosimilars and inhalation products. It plans to ramp up the specialty segment with the neurology orphan drug NaMuscla in EMEA, Fostair MDI and expand access to biosimilar Etanercept across EU with its partner Mylan. In APAC, the company plans to launch complex injectable and respiratory products in Australia, and a mix of in-house and in-licensed products in Philippines |

*Source: Company, Systematix Institutional Research*

**Exhibit 71: ARBP – Launch of injectables**

| | |
|---|---|
| **Key regions** | Canada, the largest contributor to EM revenues for ARBP. It is the 8th largest generics company with a 3% market share and contribution of 20-25% in EM revenues. The company also has presence in South Africa, Brazil, Ukraine, Mexico, Columbia and MENA. Products marketed through subsidiaries and local distributors |
| **China plans** | Completed the construction of a manufacturing facility for oral formulations in China. The plant will cater to the Chinese market as well as Europe and Growth markets. Have started filing products from China facility and plans to roll out the first validation batch soon. Also initiated transfer of a few products for Europe to the China facility |
| **Growth drivers** | Intends to launch oncology and general injectables in select key markets post commercialization of injectables facility in Visakhapatnam in 2HFY23E-FY24E |

*Source: Company, Systematix Institutional Research*

**Exhibit 72: GNP – Focus on Ryaltris' ramp-up**

| | |
|---|---|
| **Key regions** | RoW and LATAM are the two key regions for export after the US. Within RoW markets, RCIS (Russia & Ukraine) is the key while also has presence in Asia (Saudi Arabia and Uzbekistan) and Africa (Kenya and Tanzania). In LATAM, Brazil, Mexico and Caribbean are the key markets |
| **Leadership** | Glenmark ranks 11th in the dermatology segment; and 3rd in the expectorants segment in Russia. Has strong position in dermatology and respiratory products in Asian markets |
| **Growth drivers** | Expand presence in key Asian markets through select in-license opportunities with focus on products in respiratory, dermatology and oncology. Focus mainly on oncology and respiratory products in LATAM region |

*Source: Company, Systematix Institutional Research*

**Exhibit 73: CDH – A few biosimilar products in the pipleine for EMs**

| | |
|---|---|
| **Key regions** | EMs include Asia (Myanmar), Africa, Latin America (Brazil and Mexico) and Russia. In Mexico, focus is on branded generics with CNS being the key segment |
| **Growth driver** | CDH plans to expand its footprint in LATAM and Asia regions by launching biosimilar products. Currently, it has a few biosimilar products under different stages of review cycles with the regulatory authorities of Columbia, Mexico Indonesia, Sri Lanka and Thailand |

*Source: Company, Systematix Institutional Research*

## Business models much leaner, balance sheets stronger

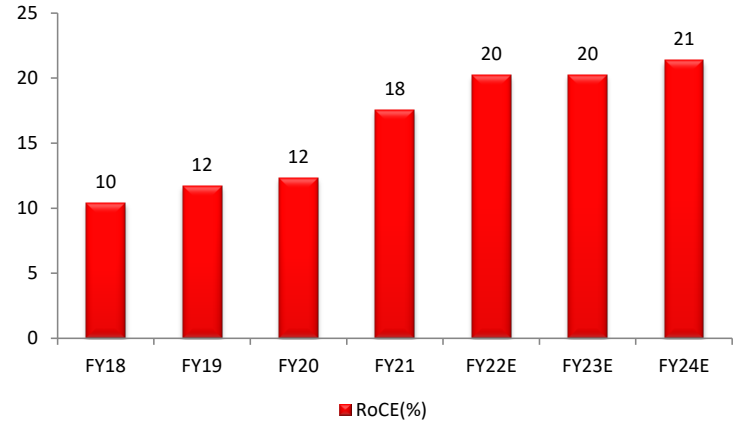
Even before the pandemic began, the Indian pharma industry had started cleaning up balance sheets by reducing leverage, optimizing the cost base and divesting non-core assets/ products. This is a significant move away from the positioning seen a few years ago, when the ability to take business decisions was constrained by leveraged balance sheets and pressure on profitability.

In this cycle, we see a marked shift in capital allocation decisions with companies focusing on their areas of strength in R&D and incrementally investing in assets/ markets offering a longer growth runway. This also provides them higher flexibility to pursue strategic options, both organic and inorganic to drive medium to long term growth.

We believe the pharma sector is in a much better shape today than it was a few years ago, even as strong earnings are crucial to lead the momentum.

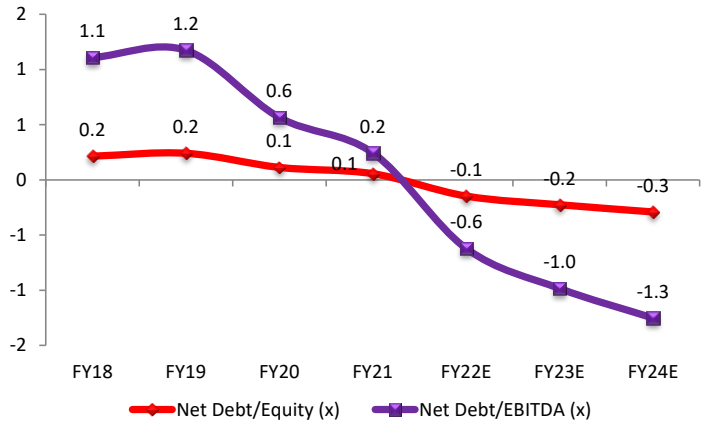
### Balance sheet to remain strong with an expected improvement in RoCE

**Exhibit 74: CIPLA – RoCE profile**



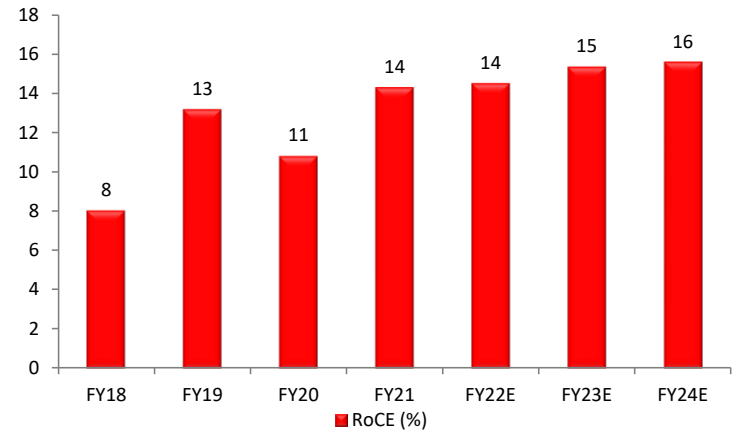

*Source: Company, Systematix Institutional Research*

**Exhibit 75: CIPLA – Leverage trend**



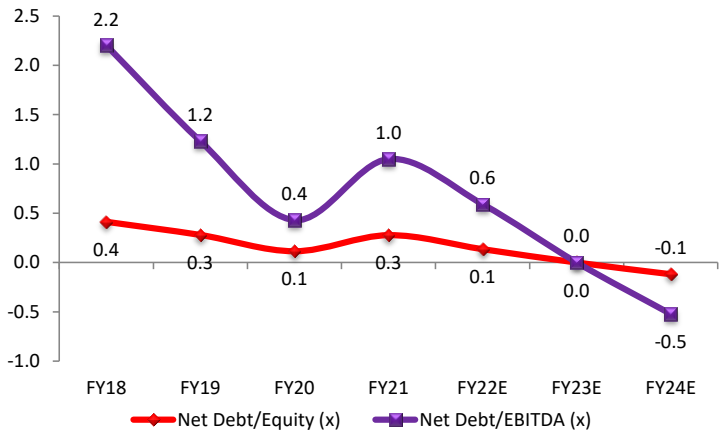

*Source: Company, Systematix Institutional Research*

**Exhibit 76: DRRD – RoCE profile**



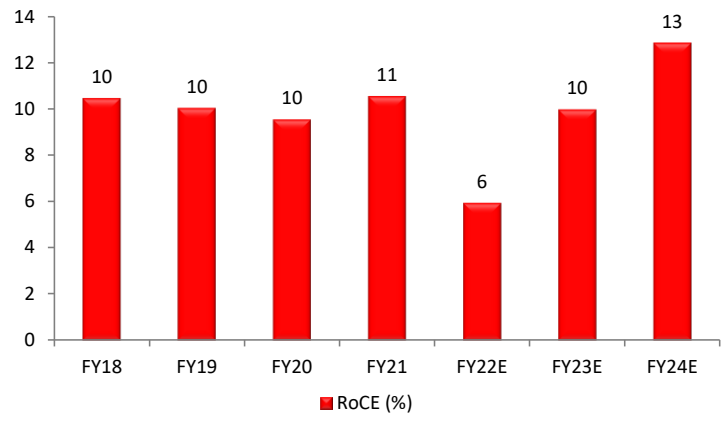

*Source: Company, Systematix Institutional Research*

**Exhibit 77: DRRD – Leverage trend**



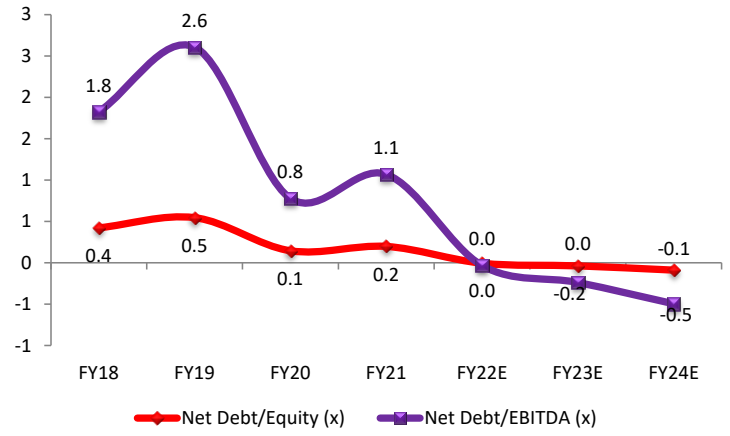

*Source: Company, Systematix Institutional Research*

**Exhibit 78: LPC – RoCE profile**



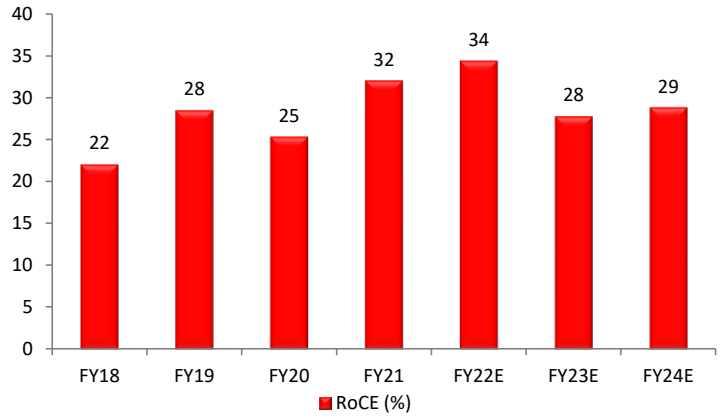

*Source: Company, Systematix Institutional Research*

**Exhibit 79: LPC – Leverage trend**



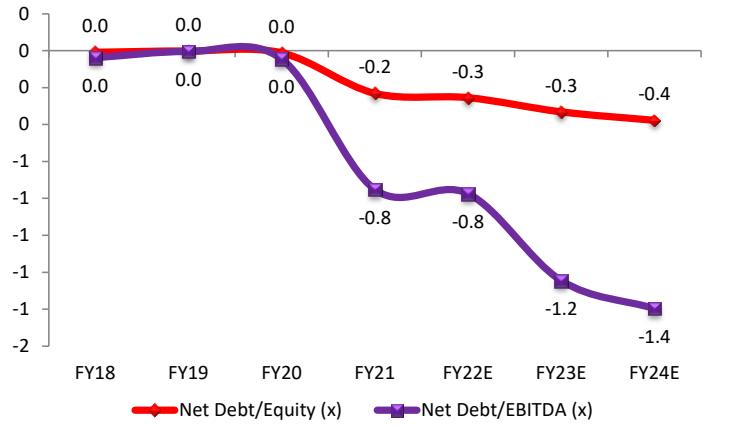

*Source: Company, Systematix Institutional Research*

**Exhibit 80: DIVI – RoCE profile**



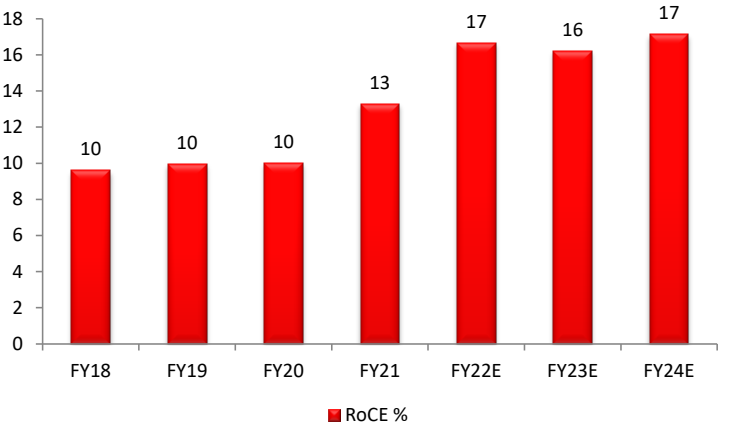

*Source: Company, Systematix Institutional Research*

**Exhibit 81: DIVI – Leverage trend**



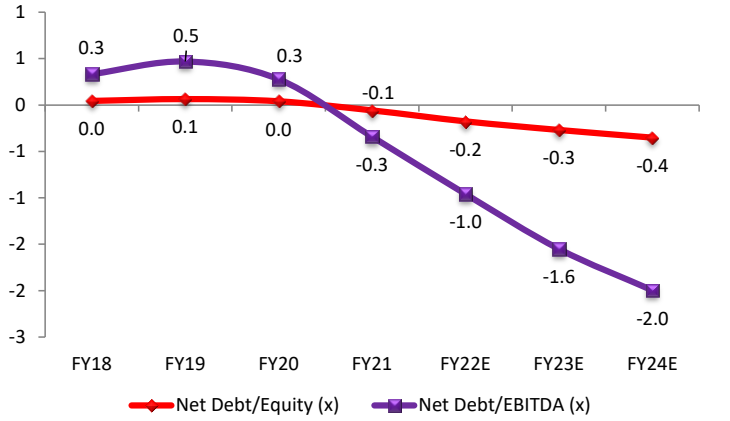

*Source: Company, Systematix Institutional Research*

**Exhibit 82: SUNP – RoCE profile**




*Source: Company, Systematix Institutional Research*

**Exhibit 83: SUNP – Leverage trend**




*Source: Company, Systematix Institutional Research*

## Valuations and Outlook

After two tumultuous years (sharp price erosions in FY22, preceded by a strong FY21 led by Covid tailwinds), we find IPM poised to offer select investment opportunities. The NIFTY Pharma Index has come off by ~8% in the last six months, underperforming NIFTY by ~500bps over this period. We expect the RoCE for our coverage companies to improve by 260bps (ex-DIVI'S) from here in the next two years. Even as these levels will be far lower than returns witnessed at the peak of the cycle in FY14-15, the current RoCE levels are healthy for a mature business model. Companies with a fairly diversified portfolio, balance sheet flexibility, a robust launch pipeline and earnings sustainability will outperform the sector.

### Initiate coverage on CIPLA/ SUNP/ DRRD/ DIVI's with BUY, LPC with SELL

The Indian Pharma market, post a phase of hyper-growth over FY10-15, saw its prospects dampen over FY16-20 on buyer consolidation in the US and an accelerated pace of product approvals. While most companies saw a sharp erosion in their US portfolios in the last five years, the opportunity was used judiciously to rationalize the cost base to achieve a leaner model. Further savings may come in a post-COVID world from a shift from physical events/ conferences to digital marketing events to some extent.

With the cost base reset, the industry is now trying to scale up the value chain in terms of product complexity. In this direction, R&D spends are being rationalized to focus on select high value assets – in contrast to the earlier strategy of filing a higher number of products. Though it is still early days, we believe these efforts are in the right direction.

We are positive on stocks that offer strong earnings visibility and a business moat that can help tide over business cycles. We have a BUY recommendation on CIPLA, SUNP, DRRD and DIVI'S, while we rate LPC as SELL. Below is a brief rationale for each:

**CIPLA (BUY):** A strong domestic business and an improving US business are complemented by a steady pace of launches in respiratory/ injectables segments, a strengthening market presence and improving profitability. BUY with target price of Rs1,185.

**SUNP (BUY):** A scale-up in the Specialty business should drive operating leverage benefits as most costs are front-loaded. Increasing contribution from non-generic markets and a stable US generics portfolio will further aid profitability. BUY with a target price of Rs1,068.

**DRRD (BUY):** The company is a strong play on cost discipline and an improving branded generics presence. Russia-Ukraine concerns, we believe, are overdone and provide a good entry point. BUY with a target price of Rs5,015.

**DIVI'S (BUY):** We believe the company is the best play on India Outsourcing story, complemented by a huge capex drive. Cost discipline, IP adherence and strong execution make it one of our top picks in the sector. BUY with a target price of Rs5,180.

**LPC (SELL):** Poor execution, a weak US franchise with a short product pipeline (only gSpiriva due for launch) in the medium term and sub-industry margins, we believe, will prevent any upside in the stock over our investment horizon. SELL with a target price of Rs622.

# COMPANIES SECTION

# Sun Pharma

28 March 2022

## Specialty business to drive operating leverage

**INITIATING COVERAGE**

**Sector: Pharmaceuticals** **Rating: BUY**

**CMP: Rs 902** **Target Price: Rs 1,068**

**Stock Info**

| | |
|---|---|
| Sensex/Nifty | 57,362/17,153 |
| Bloomberg | SUNP IN |
| Equity shares | 2,399mn |
| 52-wk High/Low | Rs 931/572 |
| Face value | Rs 1 |
| M-Cap | Rs 2164bn/ USD 29 bn |
| 3-m Avg value | USD 44mn |

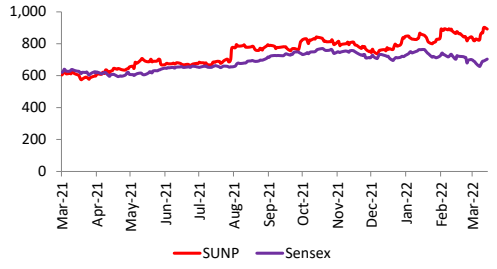
**Financial Snapshot (Rs mn)**

| Y/E March | FY22E | FY23E | FY24E |
|---|---|---|---|
| Sales | 389,335 | 418,089 | 459,301 |
| Gross profit | 284,215 | 303,114 | 332,994 |
| Gross Margin (%) | 73 | 73 | 73 |
| EBITDA | 104,752 | 111,983 | 129,747 |
| Margin (%) | 27 | 27 | 28 |
| PAT | 78,619 | 83,386 | 99,387 |
| EPS | 32 | 34 | 40 |
| DPS (Rs) | 3 | 3 | 3 |
| RoCE | 17 | 17 | 18 |
| P/E (x) | 28 | 27 | 22 |
| EV/EBITDA (x) | 20 | 18 | 15 |

**Shareholding pattern (%)**

| | Jun-21 | Sep-21 | Dec-21 |
|---|---|---|---|
| Promoter | 54.5 | 54.5 | 54.5 |
| –Pledged | 6.3 | 6.5 | 4.8 |
| FII | 11.5 | 12.0 | 13.0 |
| DII | 22.0 | 21.8 | 21.0 |
| Others | 12.0 | 11.7 | 11.5 |

**Stock Performance (1-year)**




**Sun Pharmaceutical's (SUNP) Specialty business has a strong outlook – the heavy upfront investment phase is over, and we expect operating leverage benefits to lead to margin expansion for the company. A higher share of Specialty portfolio in its revenues lends consistency and predictability to earnings. Further, the generics business is expected to remain largely stable with limited downside from the recent lows. A debt-free balance sheet, leadership position in the Indian formulations market, and strong execution history with a rising share of the Branded/ Specialty businesses drive our higher-than-historical-average target multiple for the stock. We initiate coverage on SUNP with a BUY rating and a target price of Rs 1,068. We value the stock at 26x FY24E EPS of Rs 40, a 20% premium to its 5-year historical valuation.**

**Increasing contribution of Specialty/ Branded businesses in revenues:** The share of higher-margin Specialty business has gone up from 8% of SUNP's revenues in 1QFY20 to 12% in 3QFY22. At ~50%, its domestic business (31% of total revenues) has among the best EBITDA margin profiles within the industry. SUNP has been investing heavily in building its Specialty portfolio and we believe that the foundation for growth has been laid. We expect operating leverage benefits to kick in now and drive a further 130bps EBITDA margin expansion to 28.2% over FY22-24E.

**Strong recovery in the Specialty portfolio as COVID concerns recede:** The Specialty business is expected to reach USD 750mn in revenues by FY24E, a 16% CAGR over FY21-24E. Post the decline in Specialty products sales due to the pandemic, the recovery to pre-COVID levels has been faster than expected. Despite higher R&D spends and launch-related expenses of Absorica LD and Winlevi, we believe that a further ramp-up would drive significant operating leverage and margin expansion for the company. The launch of Absorica LD and Winlevi should also, to some extent, mitigate the loss of Absorica revenues due to generic competition.

**Gx and Taro businesses have hit the bottom:** While we do not expect significant growth in Taro/ SUNP's Gx business, we see a material decline unlikely. After a 3,200bps slide in Taro's margins over FY17-21, we believe margins have bottomed out (validated by Taro's Q3FY22 results). On SUNP's Gx business, we expect the price erosion to be offset by a scale-up in gSutent, expected approval of gAsacol HD, and launch of gRevlimid. We are building in a largely flat growth rate for FY22-24E.

**Initiating coverage with BUY and a 12-month price target of Rs 1,068:** SUNP's scale in India, superior margin profile and proven ability to move up the product complexity chain in the US give it a unique advantage among Indian peers. Further, the Specialty business has scaled up rapidly and can potentially drive operating leverage benefits. With Rs 151bn of net cash on books as of 1HFY22, its leadership position in the India formulations market, a strong execution history and the rising share of Branded/ Specialty businesses lead us to assign a higher-than-historical-average target PE of 26x to the stock. We initiate coverage on SUNP with a **BUY** rating and a target price of Rs 1,068. Any slowdown in the specialty portfolio or unexpected penalties in the price-fixing litigation are key risks to our thesis.

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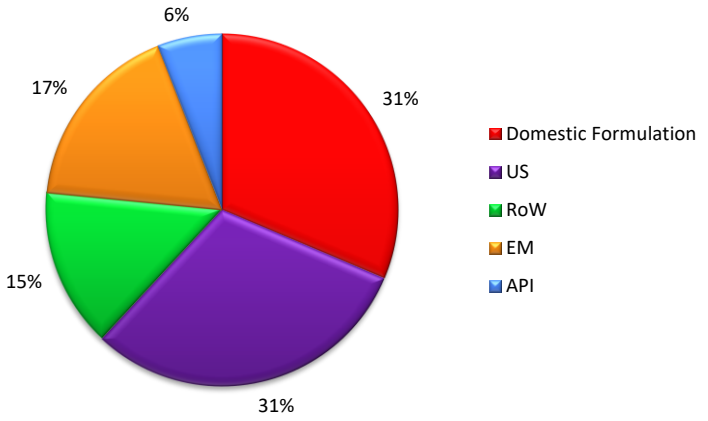
+91 22 6704 8064

**Investors are advised to refer disclosures made at the end of the research report.**

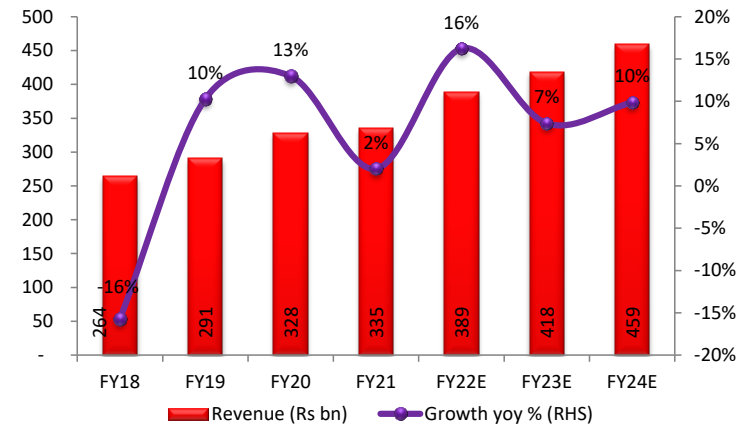
## Story in charts

**Exhibit 1: Business mix (%; FY21)**



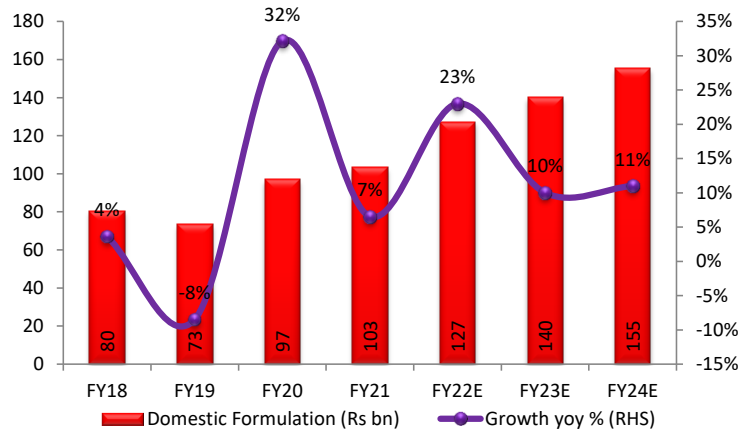

*Source: Company, Systematix Institutional Research*

**Exhibit 2: Domestic/Specialty businesses to be key growth drivers**



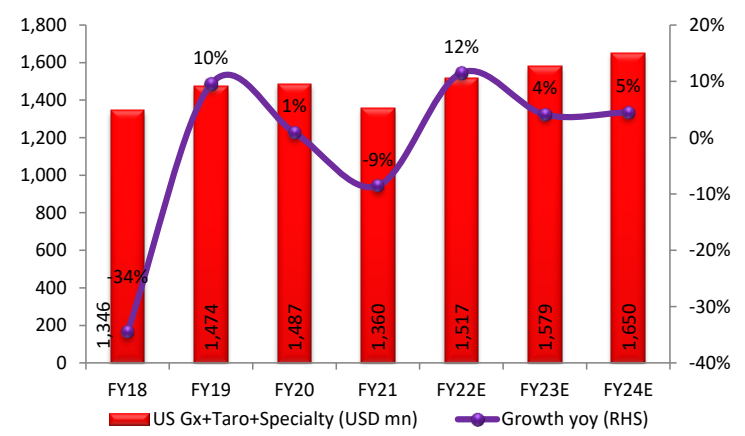

*Source: Company, Systematix Institutional Research*

**Exhibit 3: SUNP to outpace IPM with a beefed up field force**



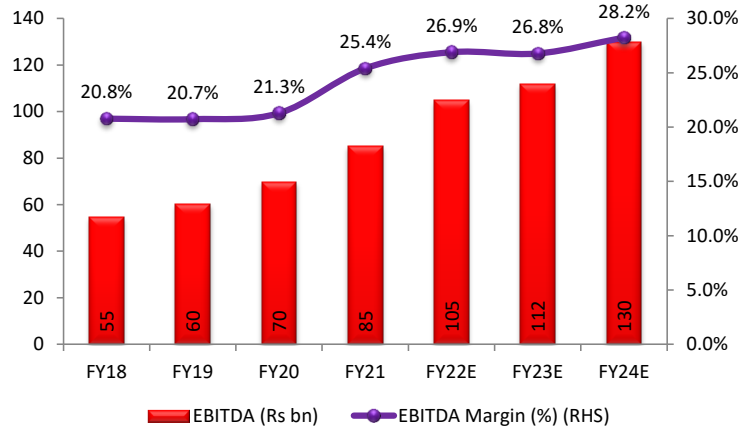

*Source: Company, Systematix Institutional Research*

**Exhibit 4: Specialty products to drive growth in the US**



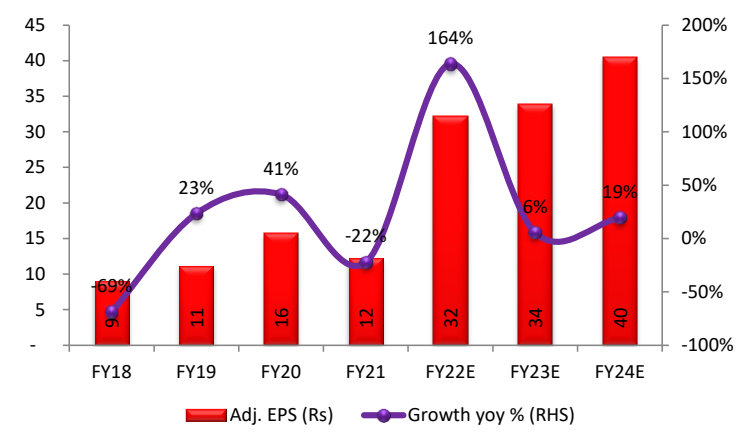

*Source: Company, Systematix Institutional Research*

**Exhibit 5: Margin expansion to be driven by operating leverage**




*Source: Company, Systematix Institutional Research*

**Exhibit 6: Earnings CAGR of 12% over FY22-24E**




*Source: Company, Systematix Institutional Research*

## Executive Summary

SUNP is the largest company in the Indian Pharmaceuticals industry in revenue terms with US formulations and domestic businesses accounting for 62% of its total revenues of Rs 335bn in FY21. The company ranks number one in the domestic formulations market and is the 10th largest in the US generics market. A proactive strategy of acquisitions and in-licensing of Specialty molecules have helped it increase focus on the Specialty portfolio. This, we believe, will lead to a healthy earnings growth for the company in the coming years.

SUNP has an 8.1% share of IPM, with anti-diabetic (6.6% share), cardiology (6.8%), ophthalmology (13.2%) and neurology (23%) being the key therapies. To garner a still higher share of the market, it has recently added 1,000 Medical Representatives (MRs) to its field force and launched 96 products (including COVID-related) in the domestic market in FY21.

**Leadership position in India**

The company is the leader in the domestic formulations market with an 8%+ share and strong presence across key segments. Despite its large base, it has kept pace with industry growth rates on the back of a strong brand portfolio and large field force (>10,900 MRs). SUNP has recently augmented its MR strength by 10% to sharpen its focus on key therapies and increase doctor coverage. In this backdrop, we expect the company to sustain 10% revenue CAGR over FY22-24E in India, that too with improved margins (~50% EBITDA margins in India business).

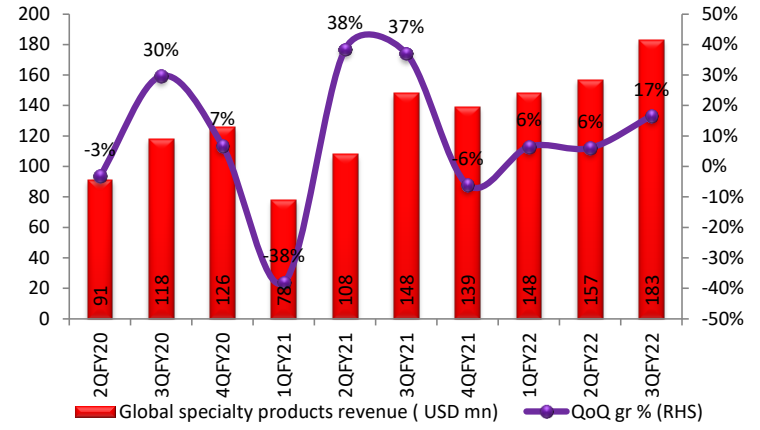
**Largest Indian company in the US Specialty market**

In the US market, SUNP derives 30% of its revenues from Specialty products (Ilumya being a key driver among others). This makes it the largest Indian company in the Specialty segment in this market. It has a basket of other products (Winlevi, Cequa, Odomzo, Levulan, Absorica etc) and has built a large base of ~USD 475mn of Specialty revenues in FY21. These products are scaling up well and have already crossed FY21 revenues in 9MFY22. We expect a 10% CAGR in Specialty products for the company over FY22-24E, driven by market share gains. Along with reduced Opex led by a decline in DTC spends, we expect a breakeven in the segment by FY23E.

**Ilumya emerging as a star product for SUNP in US Specialty**

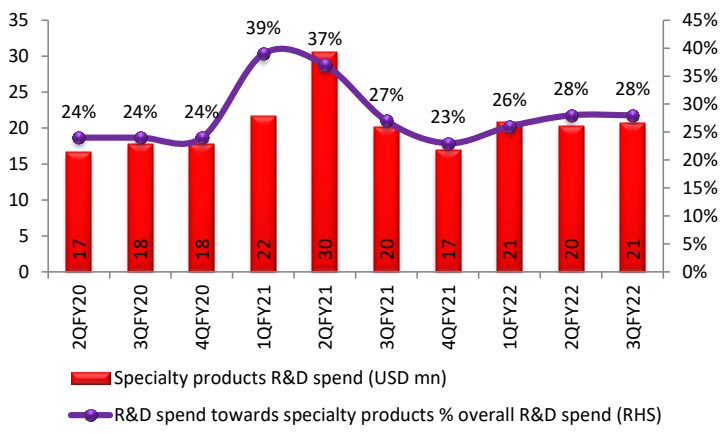
Ilumya, the latest antagonist indicated for treatment of moderate-to-severe Plaque Psoriasis in adults, is a key product for SUNP with global sales of USD 143mn in FY21 (USD 90mn in FY20) and ~5% share in its total revenues. Within the IL-23 category, where it faces competition from Skyrizi (Abbvie) and Tremfya (J&J), Ilumya and Skyrizi command a dominant market share and have grown at a fast clip in recent times. While Levulan and Ilumya bore the brunt of COVID in FY21, a sharp pick-up has been seen in 9MFY22 with sales of Ilumya already crossing FY21 levels. Notably, the drug's approval for Psoriatic Arthritis indication will potentially expand Ilumya's addressable market size to USD 5bn only in the US, which can be an upside to our estimates. We expect 10% CAGR in Specialty products for SUNP over FY22-24E, driven by market share gains.

**Exhibit 7: Global Specialty products witness uptick post COVID**




*Source: Company, Systematix Institutional Research*

**Exhibit 8: R&D spend on specialty products remains stable**




*Source: Company, Systematix Institutional Research*

### We expect Taro margins to have hit a trough

While Taro's product pipeline continues to be thin (17 pending ANDAs), we believe its US business has hit a trough. Post a sharp decline that was further accentuated by COVID, margins have bounced back in 9MFY22. Additionally, visible signs of stability in pricing in the derma segment should support profitability hereon. Note that Taro's derma business has outperformed the US derma market in terms of prescriptions in FY21. While the US derma category (in Rx terms) slid ~30% in FY21, Taro saw a modest decline of 15%. We expect Taro's business to stabilize from here, registering an organic 3% CAGR over FY22-24E.

**Exhibit 9: Key catalysts and product pipeline**

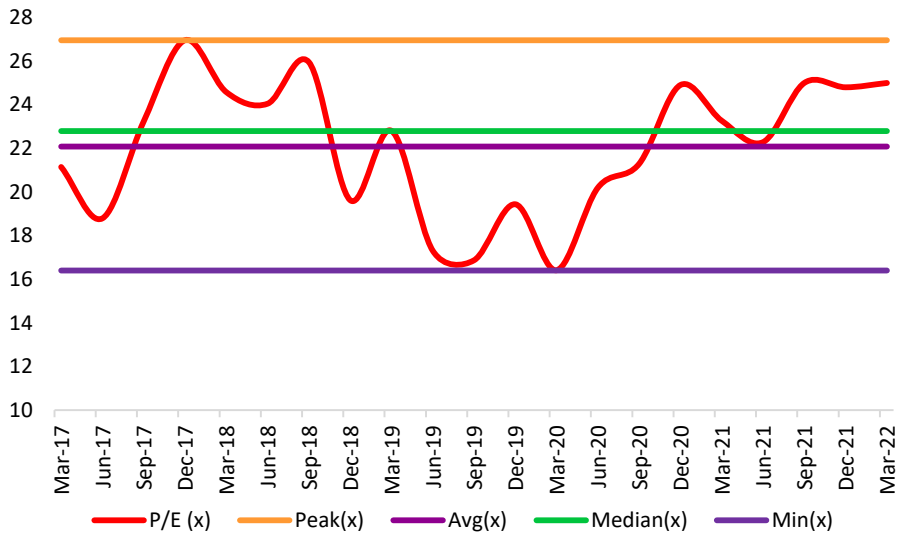
| | |
|---|---|
| Ilumya - Japan | Ramp-up of Ilumya in Japan; launched in the region in Sep-20 |
| | |
| Ilumya - MENA | Performance of Ilumya in MENA region to be closely monitored as SUNP has entered into an exclusive licensing and distribution agreement for ILUMYA™ with Hikma in FY21 |
| | |
| Ilumya – US Clinical Trials | Commenced Phase-3 clinical trials for Psoriatic Arthritis and currently approved for Plaque Psoriasis indication |
| | |
| SCD-044 – US Clinical Trials | Initiated Phase-2 clinical trials for potential oral treatment for Atopic Dermatitis and moderate to severe Plaque Psoriasis |
| | |
| MM-II - US | Commenced Phase-2 trials for potential treatment for knee pain in patients with symptomatic knee osteoarthritis |
| | |
| GLP-1R- US | Glucagon-Like Peptide-1 Receptor) agonist – Initiated Phase-1 clinical trials for treating diabetes |

*Source: Company, Systematix Institutional Research*

**Valuations & View: Initiating coverage with BUY rating**

SUNP's scale in India, superior margin profile and proven ability to move up the product complexity chain in the US give it a unique advantage among Indian peers. Further, the Specialty business has seen an impressive scale-up and can potentially drive operating leverage benefits. The Rs 151bn of net cash on books as of 1HFY22, its leadership position in the India formulations market, and a strong execution history along with the rising share of the Branded/ Specialty businesses lead us to assign a higher-than-historical average target PE of 26x. We estimate Revenue/ EPS CAGR of 9%/ 12% for SUNP over FY22-24E and EBITDA margin expansion of 130bps. The stock trades at around its 5-year average valuation of 22x earnings. Assigning a 20% valuation premium, we arrive at a target price of Rs 1,068 for the stock based on 26x FY24E EPS of Rs 40. We initiate coverage on the company with a **BUY** rating.

**Exhibit 10: P/E**




*Source: Company, Systematix Institutional Research*

## Key Risks

**Delay in resolution for the Halol manufacturing plant**

SUNP has filed 30-35% of its pending ANDAs from the Halol facility, which has been under OAI (Official Action Indicated) status since Nov-19. While physical USFDA inspections have resumed and we expect Halol to be in the queue, its US generics business recovery process could face delays if the plant fails to secure clearance in the re-inspection.

**Increase in COVID cases**

The company's Specialty products are primarily in the derma and ophthalmic segments. These products usually require patients to visit hospitals/ clinics for administration as also follow-ups with doctors. Any increase in COVID cases could result in a restriction on the movements of patients and MRs, leading to an impact on the ramp-up of SUNP's Specialty products and, hence, our earnings estimates.

**A steep price erosion in US base business**

SUNP's generics business has a large base in the US and contributes 30% of its overall revenues in the region with Taro contributing 40%. With price erosions in the US being an industry-wide concern for large pharmaceutical players, any significant price erosion over and above the normalized range of 5-7% could lead to a downward revision in our earnings estimates for FY23 and FY24E.

## Milestones

**Exhibit 11: SUNP - Key milestones and events**

| |
|---|
| **2010-2016 – a phase of inorganic growth** |
| 2010 - Acquired Taro Pharmaceutical for access to dermatology segment in USA and Canada |
| 2012 - Acquired Dusa to expand the dermatology portfolio |
| 2014 - Acquired Pharmalucence for access to sterile injectables capacity in the US |
| 2015 - Ranbaxy merger which led to SUNP becoming the largest player in the domestic market |
| 2016 - Forayed into Japan by acquiring 14 brands from Novartis |
| **2017-2020 – launch of specialty products** |
| 2018 - Launched Ilumya, Yonsa and Kapspargo Sprinkle in the US |
| 2019 - Launched Bromsite, Xelpros, Infugem/ InfuSMART, Cequa and Drizalma Sprinkle in the US |
| 2020 - Launched Absorica LD in USA and Ilumya in Japan |
| **Upcoming key news and events – 2022-2024E** |
| Resolution of Halol facility, which is currently under OAI status |
| Approval of Ilumya for Psoriatic Arthritis indication and other products (SCD-044, MM-II, GLP-1R) which are under clinical trials |
| Ramp-up of Specialty products |

*Source: Company, Systematix Institutional Research*

# Investment Analysis

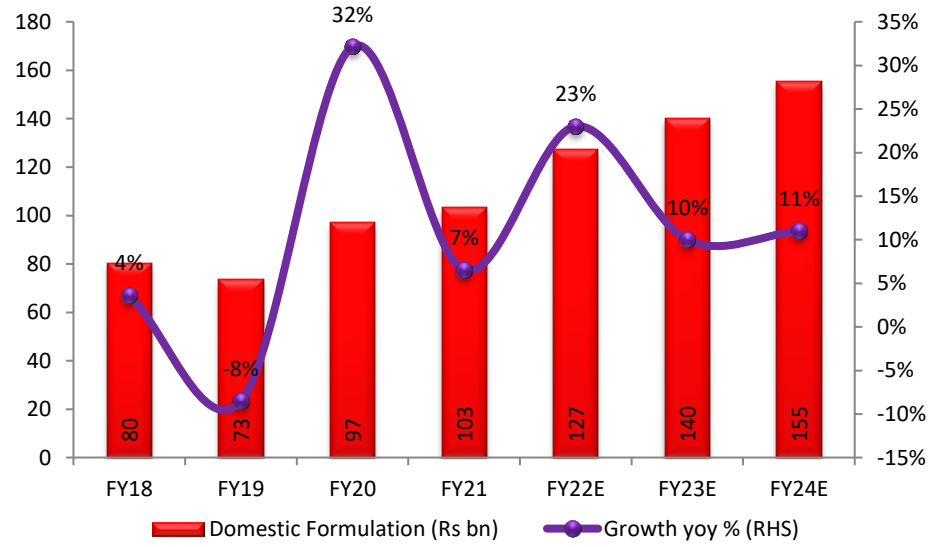
**Leadership position in India**

SUNP is the leader in the domestic formulations market with an 8%+ share and strong presence across key segments. Despite its large base, SUNP has kept pace with industry growth rates with a strong brand portfolio and large field force (>10,900 MRs). Even as FY17-20 proved to be a period of setbacks for SUNP due to business restructuring post Ranbaxy acquisition, planned inventory reduction in 2QFY19 and distribution changes in 4QFY19, the company has managed to revert to its strong growth trajectory in the last two years.

According to IQVIA, SUNP has gained market share in neurosciences segment (+14bps; ranked first), gastro (+27bps; ranked first) and pain management (+33bps; ranked second) over the last two years. With intense competition in cardiac and anti-diabetic segments, SUNP has conceded 80bps and 27bps market share but still ranks first and fourth respectively.

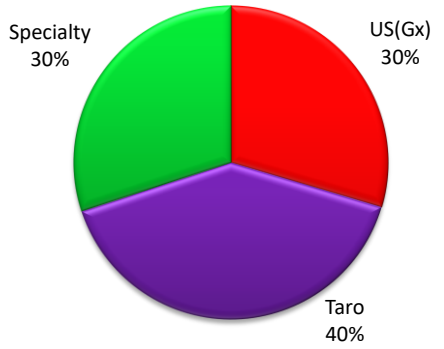
SUNP has recently augmented its MR strength by 10% to sharpen its focus on key therapies and increase doctor coverage. In this backdrop, we expect it to sustain a 10% revenue CAGR over FY22-24E in India, that too with improved margins (~50% EBITDA margins in India business).

**Exhibit 12: Increased field force to drive outperformance in IPM**




*Source: Company, Systematix Institutional Research*

**US formulations– Revenue break-up (FY21)**




*Source: Systematix Institutional Research*

## US Formulations: Specialty growing faster than Generics

SUNP marked its presence in the US market in 1997, much ahead of its peers, and managed to capitalize on the entire patent expiry curve of 2000-2010. The company is now gradually transitioning into a Specialty business to create long-term sustainable growth levers, as the US generics story has lost its step.

**Short-term blip on revenues/ margins, Specialty offers growth visibility**

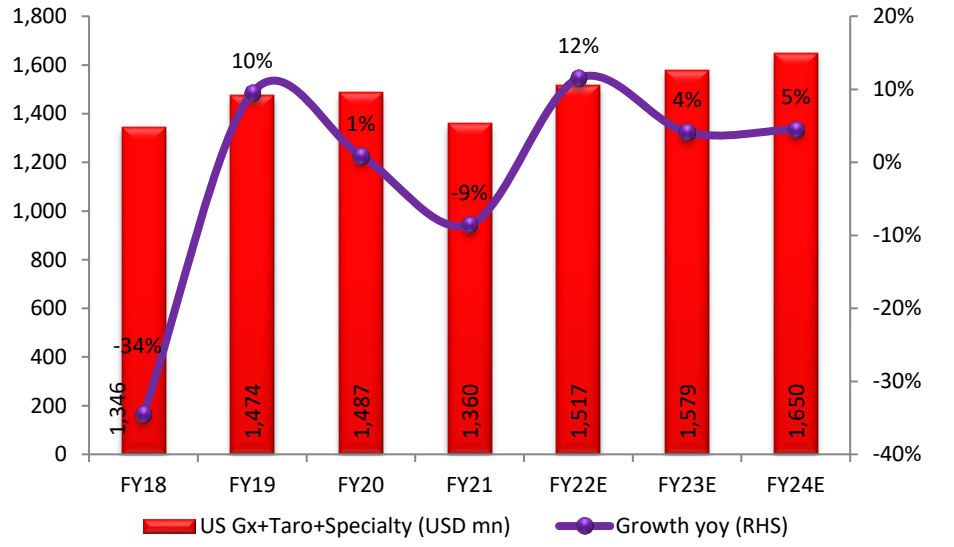
With peak sales of USD 2.2bn in FY15 post the merger of Ranbaxy, SUNP's US formulations revenues have declined 8% compounded annually over FY15-21. This can be attributed to pricing pressure in Taro's portfolio and Gx products, ongoing regulatory issues around the Halol facility and a COVID-induced disruption in ramp-up in Specialty products.

Along with this, heavy investments in R&D at an average 7% of sales (Rs 146.2bn cumulative over FY15-21) to build a niche Specialty portfolio dented its EBITDA margins, which declined from 29.4% in FY15 to 21% in FY20. However, the Specialty portfolio has reduced SUNP's dependence on the highly competitive generics products and will work to provide revenue stability from the US operations in the longer term. Excluding the hit from COVID, it has recently made good progress on the Specialty side.

**Growth rebound expected in the US business**

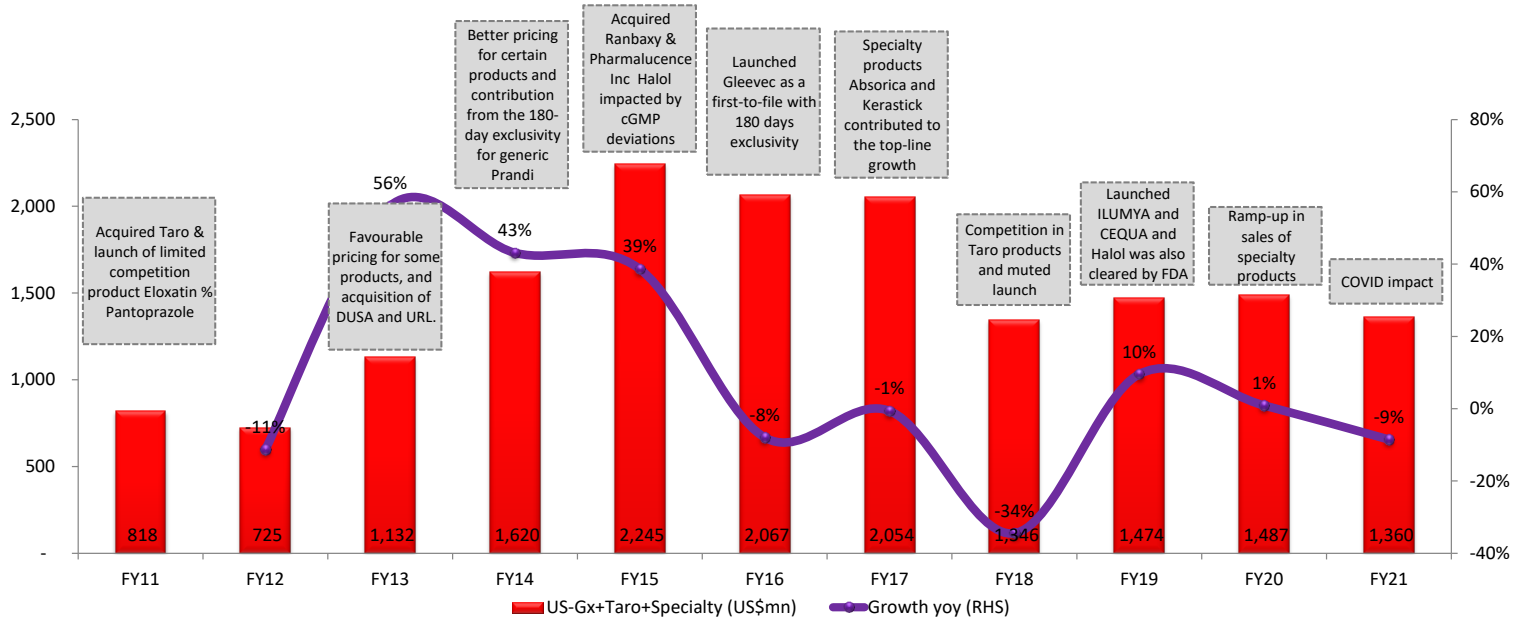
We believe SUNP has hit a trough in its generics business (including Taro). While we do not expect any meaningful growth in this business from here, a substantial fall is also unlikely. We forecast revenue CAGR of 4% for the company's US formulations business over FY22-24E with 10% CAGR in its Specialty portfolio. This should also reflect favorably on margins as a major part of the costs is front-loaded and Specialty products offer higher profitability. We expect SUNP's EBITDA margins to expand from 26.9% in FY22E to 28.2% in FY24E (up 130bps), driving sustainable RoCE levels of 18% in FY24E from a low of 10% in FY18.

**Exhibit 13: SUNP – Specialty products to drive growth in the US**



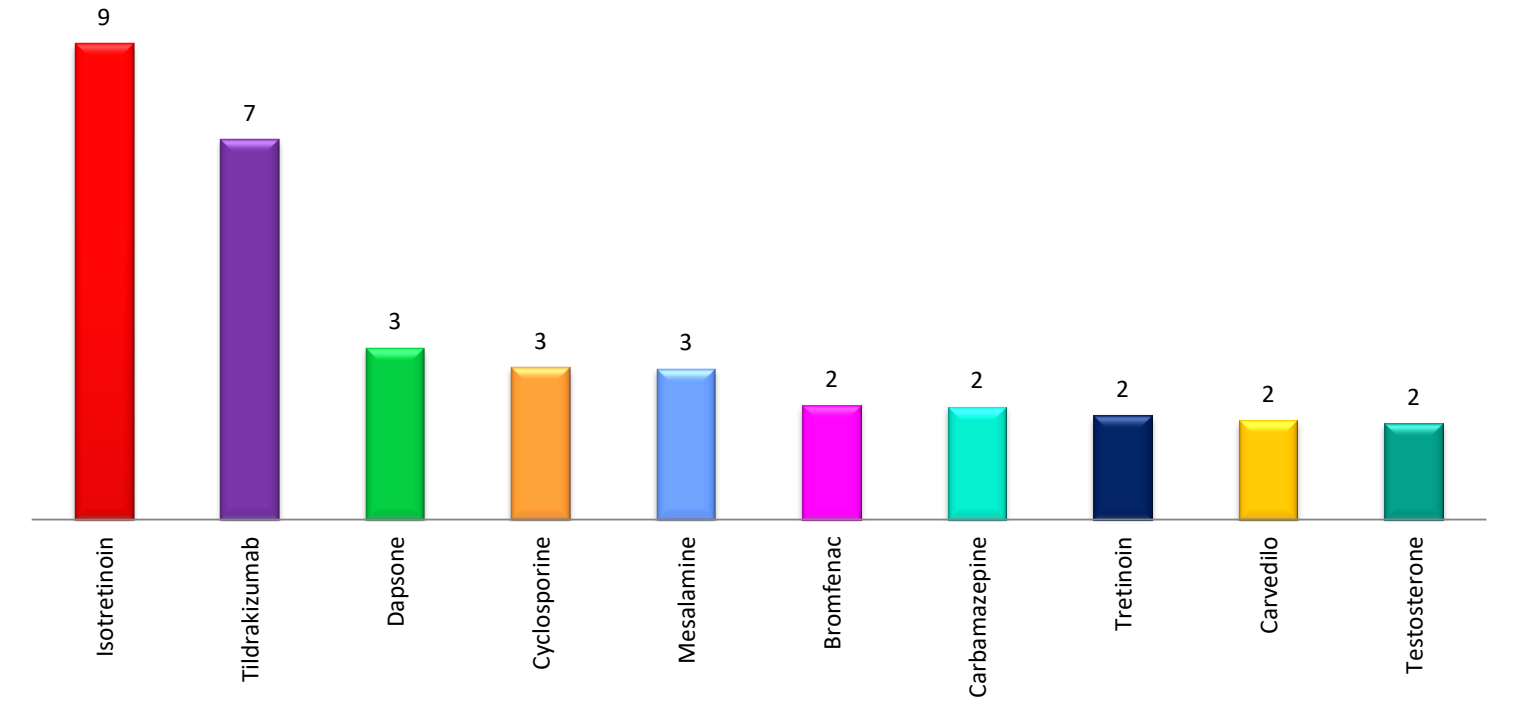

*Source: Company, Systematix Institutional Research*

**Exhibit 14: Track record of SUNP's US business**



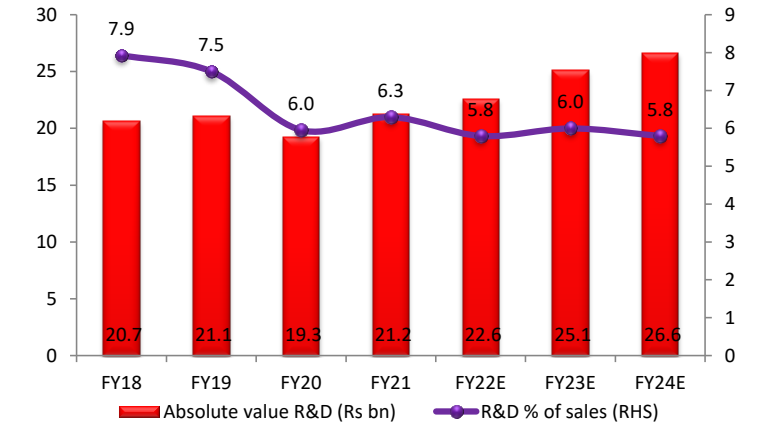

*Source: Company, Systematix Institutional Research*

**Exhibit 15: Top 10 products' contribution to US revenues (%)**



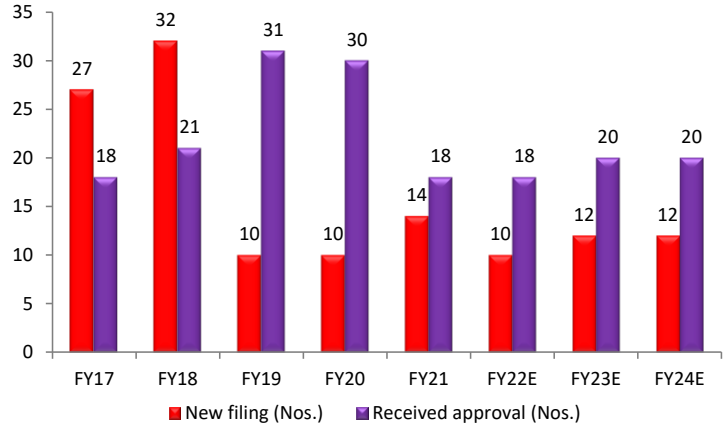

*Source: Company, Systematix Institutional Research*

**Exhibit 16: R&D spend expected to remain flat going forward**




*Source: Company, Systematix Institutional Research*

**Exhibit 17: New approvals and ANDA filing trend**



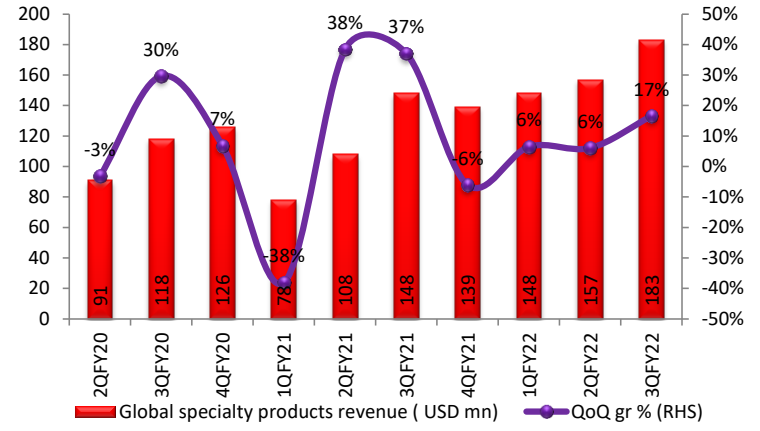

*Source: Company, Systematix Institutional Research*

## Specialty portfolio to drive operative leverage benefits

SUNP has been the front runner among Indian companies in Specialty products and is currently the largest Indian pharmaceuticals player with Specialty revenues of USD 475mn in FY21. Of this, we believe 80-85% comes from the US market and the remaining from Japan, MENA and a few other regions. In the Specialty segment, SUNP focuses mainly on dermatology, ophthalmology and oncology therapies. Isotretinoin (Absorica) and Tildrakizumab (Ilumya) are the largest products with a 6-7% and 9-10% share respectively in its US revenues in FY21, followed by Levulan (~5%).

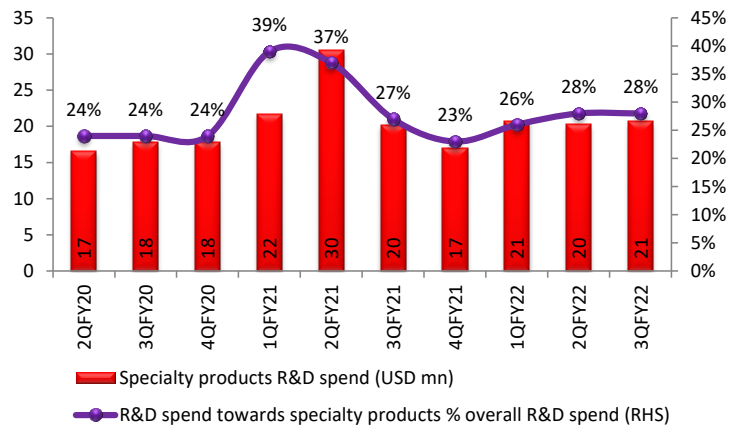
SUNP, over FY20 and FY21, channeled ~27% (average) of its R&D spend into Specialty products. While Levulan and Ilumya bore the brunt of COVID in FY21, there has been a sharp pick-up in 9MFY22 with sales of Ilumya already crossing FY21 levels. Given that Levulan is a clinically administered product in hospital settings, its sales too have started picking up with easing lockdown restrictions. We expect 10% CAGR in Specialty products for SUNP over FY22-24E, driven by market share gains.

**Exhibit 18: Global Specialty products witness uptick post COVID**




*Source: Company, Systematix Institutional Research*

**Exhibit 19: R&D spend on Specialty products remains stable**

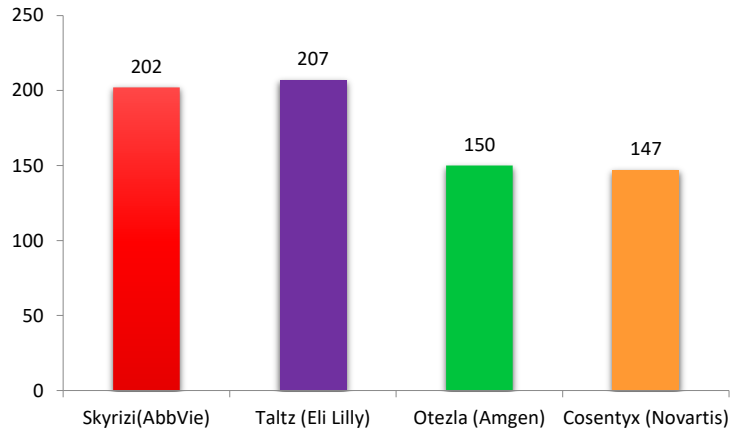



*Source: Company, Systematix Institutional Research*

## Lower DTC spend on Specialty products to aid margins

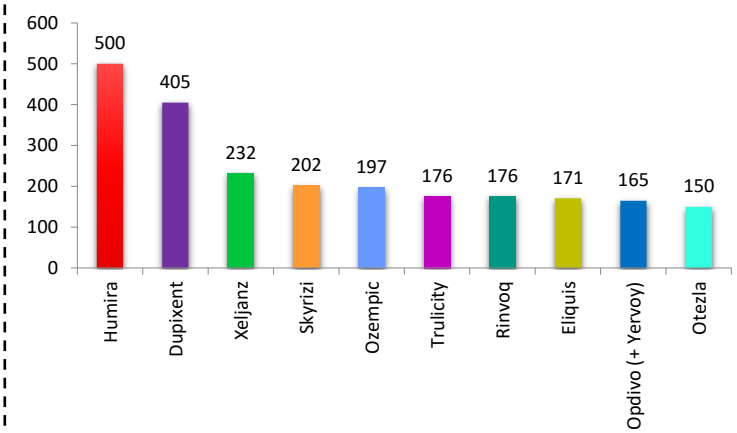
Direct-to-Consumer (DTC) advertising, mainly via television, accounts for majority of the pharmaceutical industry's total marketing spend. DTC spends have higher significance in categories like derma and anti-diabetic, which are typically characterized by product complexity and a large addressable market. While companies incur heavy spends initially, advertising on TV has proved to be the most effective medium to create consumer awareness for such products. DTC spends on a product are the highest in the initial 1-2 years of launch and tend to get rationalized once the product starts to scale up.

**Exhibit 20: DTC spend on psoriasis drugs post launch (USD mn)**




*Source: Company, Systematix Institutional Research*

**Exhibit 21: Top 10 DTC spends in 2020 (USD mn)**




*Source: Company, Systematix Institutional Research*

## Ilumya emerging as a star product

Initiated in Mar-19, SUNP's estimated DTC spend of USD 70mn-80mn on Ilumya has been lower than that by competitors. The drug is administered in a hospital/ clinic set-up and COVID restrictions curtailed movement of patients for therapy within a few months of its launch. Now that the high upfront investment phase for product development and marketing is behind, SUNP has guided to lower Opex in the Specialty segment. Ilumya is ramping up well and we expect this would help margin expansion and breakeven in the Specialty business in coming years.

**Sales set to pick up pace:** Ilumya is an IL-23 interleukin-23, the latest antagonist indicated for the treatment of moderate-to-severe Plaque Psoriasis in adults. It is a key product for SUNP with global sales of USD 143mn in FY21 (USD 90mn in FY20) and contributes ~5% to overall revenues. Within the IL-23 category, where SUNP faces competition from Skyrizi (Abbvie) and Tremfya (J&J), Ilumya and Skyrizi command a dominant market share and have grown at a fast clip in recent times.

However, since its launch three years ago in the US market, Ilumya revenues have been below expectations due to COVID-induced disruptions. Ilumya is invariably administered in hospital settings, where operations were curtailed in view of the lockdown restrictions. With COVID concerns largely behind and green shoots visible in recent performance, we expect Ilumya global sales to scale up to USD 225mn-240mn annually in FY23 and FY24E from USD 143mn in FY21. Our assumptions do not factor in the drug's approval for Psoriatic Arthritis indication – a consideration that will expand Ilumya's addressable market size to USD 5bn only in the US.

**Exhibit 22: Psoriasis treatment drugs – competition landscape**

| Treatment type dosage | Dosage and frequency | PASI (Psoriasis Area Severity Index) |
|---|---|---|
| **IL-23 Newest Biological treatment** | | |
| Skyrizi-Risankizymab-(Abbvie) | Week 0, 4, then every 12 weeks | After 16 weeks PASI score 90 |
| Ilumya Tildrakizumab-(Sunpharma) | Week 0 and 4, then every 12 weeks | At week 28, 74% of the patients achieved a PASI- 75 response, and at week 64, 84% of the patients sustained a PASI-75 response. |
| Tremfya-Guselkumab(J&J) | Week 0 and 4, then every 8 weeks | PASI 90 in week 16 |
| **IL-12/23 Older Interleukin molecule** | | |
| Stelara-Ustekinumab (J&J) | Week 0 and 4, then every 12 weeks | PASI 75 attained in 28 weeks |
| **IL-17 Previous generation approved Interleukin Molecules** | | |
| Taltz Ixekizumab (Lily) | Week 0 and every 2 weeks for 3 months, then every 4 weeks | After 24 weeks PASI score 90 |
| Siliq-Brodalumab (Amgen) | Week 0, 1, 2, then every 2 weeks | PASI 75 after 12 weeks of treatment |
| Cosentyx-Secukinumab-(Novartis) | Week 0, 1, 2, 3 and 4, then every four weeks | PASI 75 at week 16, and 90 at 52 weeks. |
| **TNF (Tumor Necrosis Factor) Alpha Oldest Biological treatment** | | |
| Cimzia-Certolizumab (UCB) | Week 0, 2 and 4, then every other week | 79% after 48 weeks of treatment and PASI 90 after 48 weeks of treatment |
| Enbrel-Etanercept-(Amgen) | Twice weekly for 3 months, then once weekly | PASI score of 75 by week 12. |
| Humira-Adalimumab (AbbVie) | Once every other week | After 24 weeks, patients achieved 75% PASI |
| Remicade-Infliximab(J&J) | Week 0, 2, and 6, then every 8 weeks | Patients Achieved PASI score of 75 by 10 Week |
| Simponi-Golimumab (J&J) | Once every month | PASI 75 after 14 weeks of treatment |

*Source: Company, Systematix Institutional Research*

**Exhibit 23: Lower dosage and higher PASI score of IL-23 molecules give them an edge over older generation drugs**

| | IL-23 | IL-17 | TNF inhibitors |
|---|---|---|---|
| **Drugs** | Stelara (ustekinumab) Tremfya (guselkumab), Ilumya (tildrakizumab-asmn) and Skyrizi (risankizumab-rzaa) | Cosentyx (secukinumab), Taltz (ixekizumab) and Siliq (brodalumab) | Humira (adalimumab), Enbrel (etanercept), and Remicade (infliximab) |
| | | | |
| **IL-23 v/s TNF** | **Ilumya v/s Enbrel:** 61% of Ilumya patients achieved a PASI 75 score at Week 12 compared with 48% of Enbrel patients | **Tremfa v/s Humira:** At the end of 48 weeks, 76.3% of Tremfya patients achieved PASI 90 score compared to 47.9% for Humira | Majority of patients say the drugs do not provide complete skin clearance. In addition, it is common for patients to discontinue anti-TNF treatment due to loss of response and adverse effects |
| | | | |
| **IL-23 V/s IL-17** | **Tremfya v/s Cosentyx:** At 48 weeks, 85% of Tremfya patients achieved PASI 90 score vs 70 of those administered Cosentyx | | |
| | | | |
| **Key advantage of IL-23** | IL-23 inhibitors require less frequent dosing compared with targeting of downstream cytokines such as IL-17 and TNF-α | | |

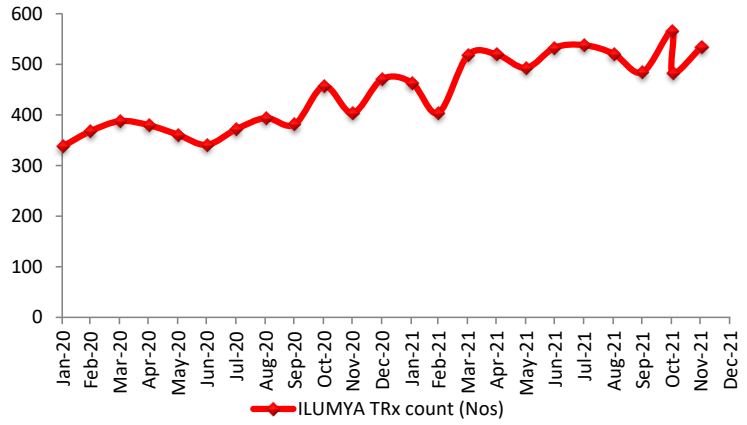
*Source: Company, Systematix Institutional Research*

**Exhibit 24: SUNP's Ilumya (Tildrakizumab) journey so far and future outlook**

| Brand (Molecule) and launch date | Ilumya (Tildrakizumab) – USA, Europe and Australia (2018), Japan (2019), Out-licenced to CMS for Greater China in 2019 |
|---|---|
| Indication | Currently approved by FDA to treat moderate-to-severe Plaque Psoriasis; in clinical trials (Phase 3) for Psoriatic Arthritis |
| Revenue details | Global sales of USD 143mn in FY21 with 90% from the US. Second largest product in the US with contribution of 8-10% to overall US revenues |
| Background | SUNP acquired L-23p19 inhibitor novel biologic asset called tildrakizumab (earlier MK-3222) from Merck in Sept-2014, for an upfront payment of USD 80mn; another USD 250mn spent for developing the drug. Market size for Plaque Psoriasis in the US is ~USD 7bn, of which the addressable market for Ilumya (Interleukin-based) is ~USD 2.5bn |
| Competitive scenario | IL-23 inhibitors are the latest molecules in the segment and have emerged as a safer and more effective option for the treatment of moderate-to-severe Plaque Psoriasis compared to oldest inhibitors like IL-17 and TNF. In the IL-23 category, Skyrizi-Risankizymab-(Abbvie) and Tremfya-Guselkumab (J&J) are Ilumya's key competitors. Lilly's Mirikizumab for Psoriasis treatment scrapped despite phase 3 success due to the intense competition from existing molecules |
| Outlook | While lockdown restrictions delayed ramp-up of Ilumya in FY20 and 1HFY21, SUNP registered 51% increase in Ilumya sales in FY21 led by bounce-back in 2HFY21. Ilumya failed to break even in FY22 in the wake of COVID restrictions, high upfront marketing costs, trials for Psoriasis Arthritis and early access program. With tapering Opex, Ilumya is likely to break even by FY23E, driven by margin expansion. Interestingly, Ilumya has so far been the only IL-23 inhibitor for Psoriasis treatment having a 5-year safety and efficacy data – this should translate into higher confidence among physicians for usage over a longer time horizon and create revenue sustainability for SUNP |

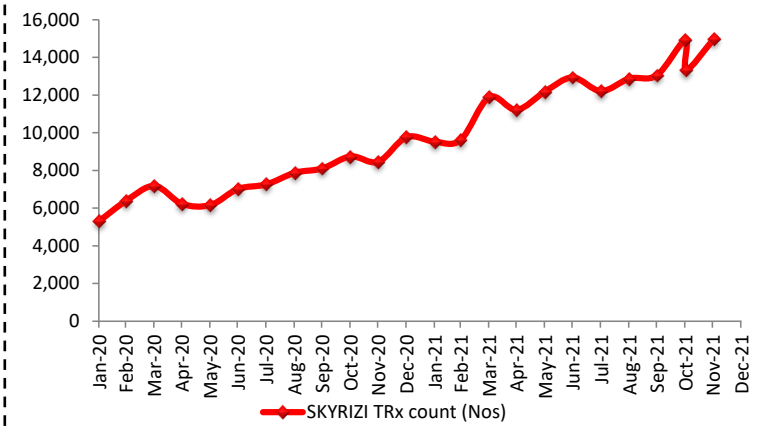
*Source: Company, Systematix Institutional Research*

**Exhibit 25: Ilumya – number of monthly prescriptions**




*Source: Company, Systematix Institutional Research*

**Exhibit 26: Skyrizi – number of monthly prescriptions**



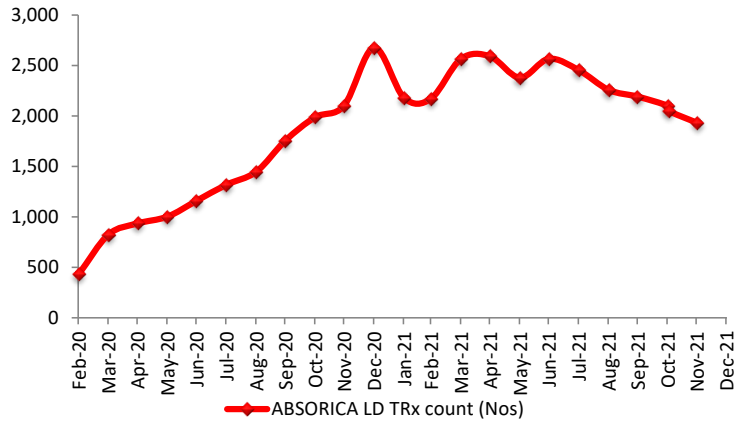

*Source: Company, Systematix Institutional Research*

**Exhibit 27: SUNP's Absorica (Isotretinoin) journey so far and future outlook**

| Brand (Molecule) and launch date | Absorica (Isotretinoin) - Became part of SUNP post Ranbaxy merger in CY15 |
|---|---|
| Indication | Treatment of severe nodular acne that cannot be cleared up by any other acne treatments, including antibiotics |
| Revenue details | Largest product in SUNP's portfolio with contribution of 9-12% in its overall US revenues with IQVIA annual sales of USD 158mn |
| Background | First marketed by Roche under the brand name Accutane for the treatment of severe recalcitrant nodular acne (SRNA). The product was discontinued due to adverse side effects like depression. Cipher reformulated the molecule, received approval from the US FDA in May 2012 and outlicensed to Ranbaxy |
| Competitive scenario | Teva launched first generic in Apr-21 and SUNP launched Absorica LD (lower dosage) in Feb-20 to compensate for the loss of revenue from Absorica. Alternate products for treating severe acne are Solodyn, Ziana, Doryx, Duac and BenzaClin while Absorica is also available under different brand names like Zenatane (Dr.Reddy's), Claravis (Teva), Myorisan (Douglas) and Amnesteem (Mylan) which are AB rated to isotretinoins |
| Outlook | Absorica LD 32 mg, bioequivalent to 40 mg Absorica capsule, enhances absorption at a 20% lower dose and launched with micronization technology. SUNP had launched Absorica LD 15-18 months before the launch of first Absorica generic to convert existing patients to the lower dosage regime. While COVID lockdown slowed down the conversion rate, SUNP plans to ramp up Absorica LD in FY23E. SUNP has also launched its Absorica authorized generic |

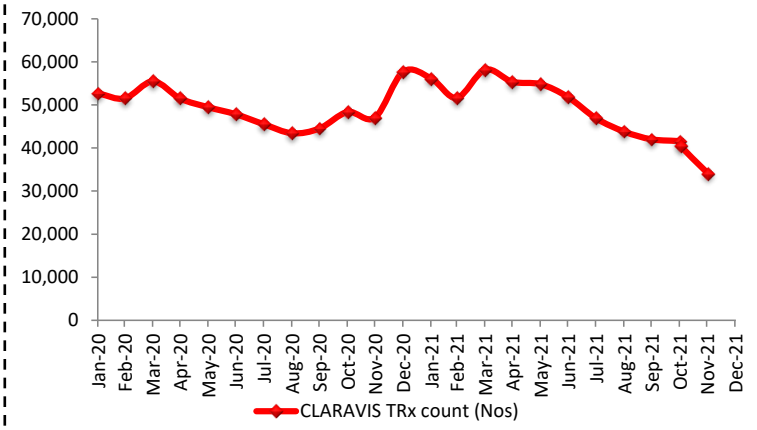
*Source: Company, Systematix Institutional Research*

**Exhibit 28: Absorica LD – number of monthly prescriptions**




*Source: Company, Systematix Institutional Research*

**Exhibit 29: Claravis – number of monthly prescriptions**



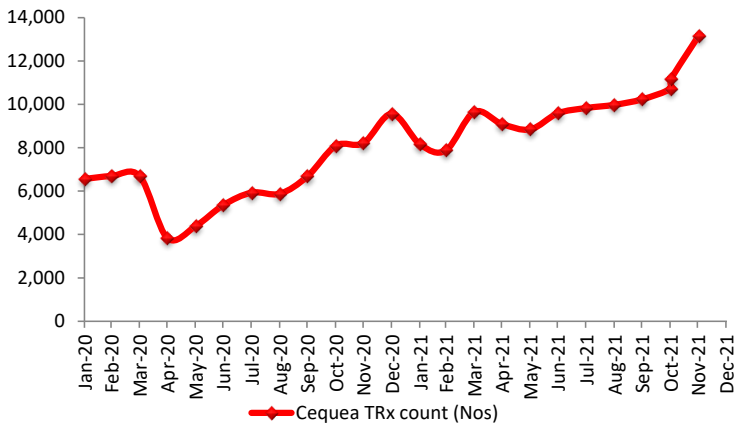

*Source: Company, Systematix Institutional Research*

**Exhibit 30: SUNP's Cequa journey so far and future outlook**

| Brand (Molecule) and launch date | Cequa (cyclosporine ophthalmic solution 0.09%) - Launched in Oct-19 |
|---|---|
| Indication | Calcineurin inhibitor immunosuppressant indicated to increase tear production in patients with keratoconjunctivitis sicca (dry eye) |
| Revenue details | Cequa is one of the top 10 products for SUNP with contribution of 3-5% to its overall US revenues |
| Background | SUNP acquired Cequa from Auven Therapeutics in 2016 by paying an upfront amount of USD 40mn besides substantial contingent development and commercial milestone payments, and royalties. Cequa provides the highest FDA-approved concentration of cyclosporine A (CsA) and is the first and only approved CsA product that incorporates nanomicellar technology |
| Competitive scenario | Allergan's Restasis (cyclosporine ophthalmic emulsion) and Novartis' Xiidra (lifitegrast) are other alternatives for dry eye with US sales of USD 755mn and USD 400mn-500mn respectively. Novartis acquired Xiidra from Takeda in Jul-19 at an upfront cost of USD 3.4bn and an additional USD 1.9bn in potential milestone payments. Xiidra was the first treatment approved by the USFDA for both signs and symptoms of dry eye disease, with a mechanism of action that targets inflammation while Restasis decreases inflammatory processes in the eye that can affect tear production |
| Outlook | Restasis and Cequa are similar drugs but with different concentrations of cyclosporine (0.05% and 0.09% respectively). Cequa has the highest USFDA approved concentration of cyclosporine and is the only USFDA-approved cyclosporine treatment delivered with nanomicellar (NCELL™) technology, which helps to improve the bioavailability and physicochemical stability of cyclosporine, resulting in improved ocular tissue penetration. Post COVID, MRs have started visiting physicians leading to the successful ramp-up of Cequa in FY22 |

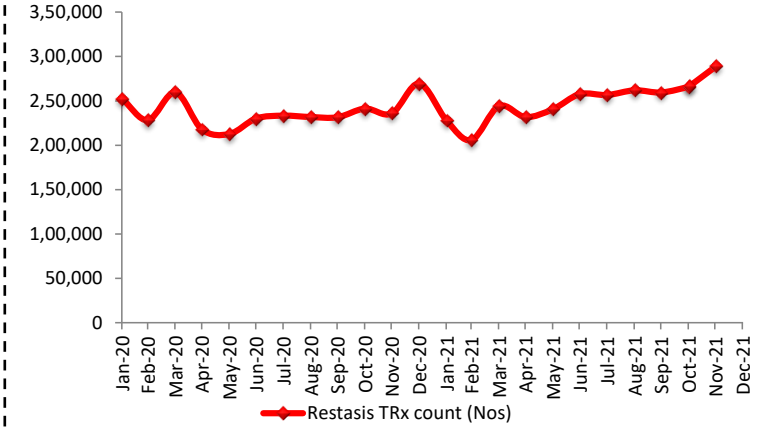
*Source: Company, Systematix Institutional Research*

**Exhibit 31: Cequa – number of monthly prescriptions**




*Source: Company, Systematix Institutional Research*

**Exhibit 32: Restasis – number of monthly prescriptions**



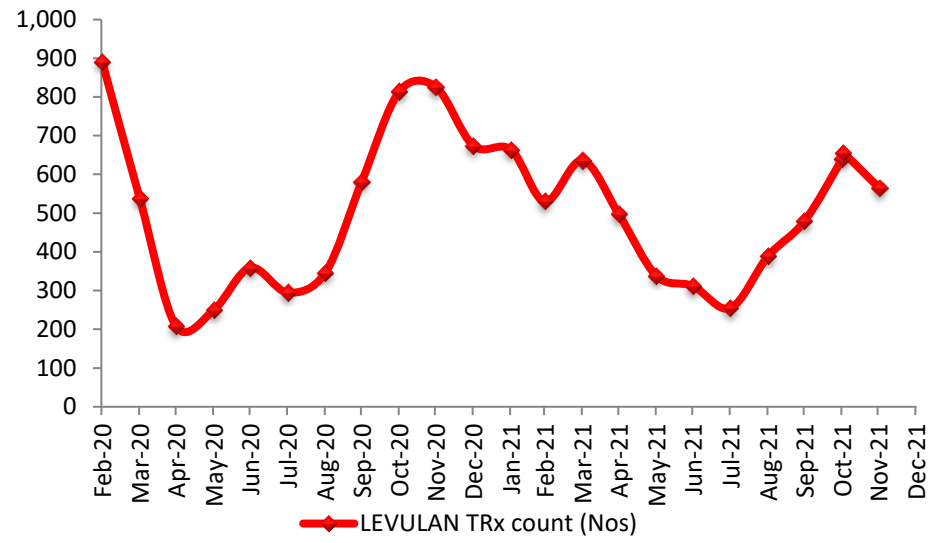

*Source: Company, Systematix Institutional Research*

**Exhibit 33: SUNP's Levulan Kerastick journey so far and future outlook**

| Brand (Molecule) and launch date | Levulan Kerastick (aminolevulinic acid HCl topical solution) + BLU-U (Blue Light Photodynamic Therapy). Launched in the year 2000 by Dusa Partner Schering |
|---|---|
| **Indication** | Treatment of minimally-to-moderately thick actinic keratosis (AC) of the face or scalp |
| **Revenue details** | Revenue of USD 62mn FY21 (vs USD 105mn in FY20) with a 5% contribution to SUNP's US revenues |
| **Background** | Part of Dusa Pharma, acquired in 2012 and no generic approved currently. Levulan-Kerastick is a single-use, disposable applicator that allows for uniform application of Levulan topical solution in standardized doses. The 20% topical solution is prepared just prior to the time of use by breaking the ampules and mixing the contents by shaking the applicator |
| **Competitive scenario** | Biofrontera's Ameluz (Gel Tube) was launched in CY18 and offers superior clinical benefits of scalp clearance (Ameluz 65-82% vs Levulan 50%) and a shorter incubation period (three hours for Ameluz and 14-18 for Levulan) than Levulan (Liquid Stick) with 30-35% lower pricing than Levulan. This has led to the loss of market share for SUNP with its revenue declining to less than half from a peak of USD 138mn in FY17 |
| **Outlook** | Biofrontera submitted for approval of a larger red-light source for photodynamic therapy (PDT) to be used in combination with Ameluz®, the BF-RhodoLED® XL in Mar-21, which will broaden the label to include additional indications in the future and compete with Levulan Kerastick and BLU-U. Although there are many treatment options available for AC, Ameluz and Levlan are the most effective treatments. We expect Levlan to maintain its market share at current levels. Data from Phase 3 trials supports the efficacy and safety benefits of the product, with photodynamic therapy (PDT) in treating minimally-to-moderately thick actinic keratoses on the upper extremities |

*Source: Company, Systematix Institutional Research*

**Exhibit 34: Levulan – number of monthly prescriptions**



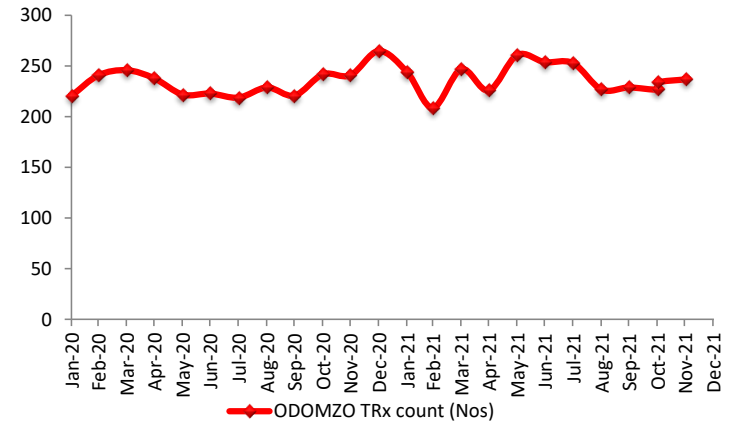

*Source: Company, Systematix Institutional Research*

**Exhibit 35: SUNP's Odomzo journey so far and future outlook**

| Brand (Molecule) and launch date | Odomzo (Sonidegib) - CY18 |
|---|---|
| Indication | Locally Advanced Basal Cell Carcinoma (LABCC) - Skin Cancer |
| Revenue details | Contribution of 1-2% of SUNP's US sales with 15% growth witnessed in FY21 |
| Background | Odomzo the first branded oncology product for SUNP, acquired from Novartis in 2016 for USD 175mn. It is a hedgehog pathway inhibitor indicated for the treatment of LABCC in adult patients that has recurred following surgery or radiation therapy, or those who are not candidates for surgery or radiation therapy |
| Competitive scenario | Around 70% of the drug's volumes are prescribed by dermatologists, and the remaining by oncologists. Competitive landscape: Odomzo is a direct competitor to Erivedge (Roche) which has the first mover advantage with its launch in 2012. Erivedge is approved for metastatic basal cell carcinoma (mBCC) and LABCC while Odomzo is approved only for LABCC. Cemiplimab (Libtayo) by Regeneron Pharmaceuticals is a new product for LABCC treatment (received approval in Feb-21) |
| Outlook | Basal Cell Carcinoma (BCC) accounts for almost 80% of skin cancers and the first line of treatment for LABCC is Hedgehog-GLI (HH) pathway inhibitors. Of these, only three have been approved by the USFDA with Erivedge controlling most of the market owing to its first-mover advantage while Odomzo is ramping up gradually. Erivedge's US revenues stood at ~USD 200mn in CY20 with growth of 6% YoY while Odomzo grew 15% YoY indicating that it is gaining market share. We believe LABCC is a limited competition space and Odomzo peak sales could touch USD 70mn-80mn by FY24E |

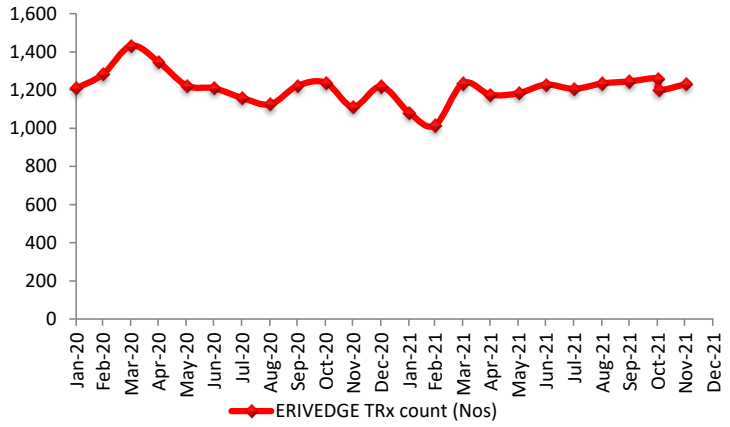
*Source: Company, Systematix Institutional Research*

**Exhibit 36: Odomzo – number of monthly prescriptions**




*Source: Company, Systematix Institutional Research*

**Exhibit 37: Erivedge – number of monthly prescriptions**



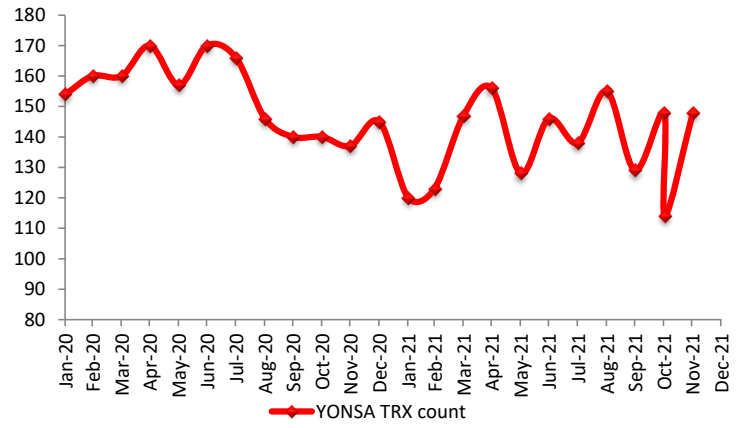

*Source: Company, Systematix Institutional Research*

**Exhibit 38: SUNP's Yonsa journey so far and future outlook**

| Brand (Molecule) and launch date | Yonsa (Abiraterone acetate) - CY18 |
|---|---|
| Indication | Combination with methylprednisolone indicated for the treatment of patients with metastatic castration-resistant prostate cancer (CRPC) |
| Revenue details | 1-2% contribution to SUNP's US revenues |
| Background | Acquired from Churchill Pharma. Yonsa taken in combination with methylprednisolone is the only abiraterone acetate with no food restrictions, thereby giving patients the flexibility to take it with or without food |
| Competitive scenario | Yonsa has the same API (abiraterone acetate) as Zytiga but is a different formulation. It is a novel molecule as it is approved in combination with methylprednisolone and can be taken with or without food while Zytiga has to be taken with only food. Multiple generics for Zytiga have now entered the market |
| Outlook | Post the entry of generic players in FY20/21, market size for abiraterone acetate has been stable at USD 400mn. We expect gZytiga to limit Yonsa's market share gains |

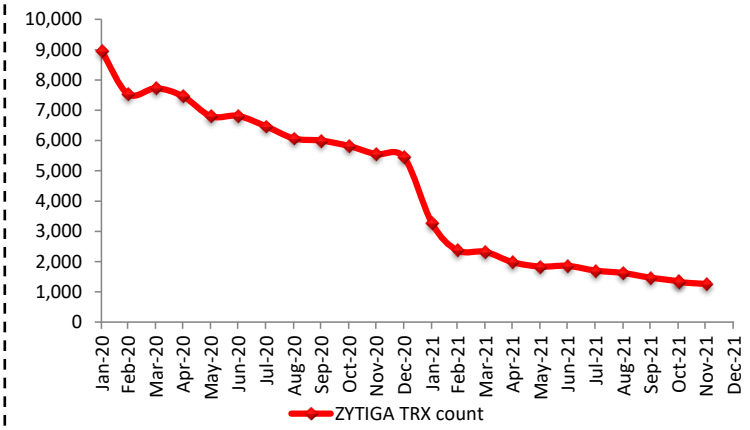
*Source: Company, Systematix Institutional Research*

**Exhibit 39: Yonsa – number of monthly prescriptions**




*Source: Company, Systematix Institutional Research*

**Exhibit 40: Zytiga – number of monthly prescriptions**



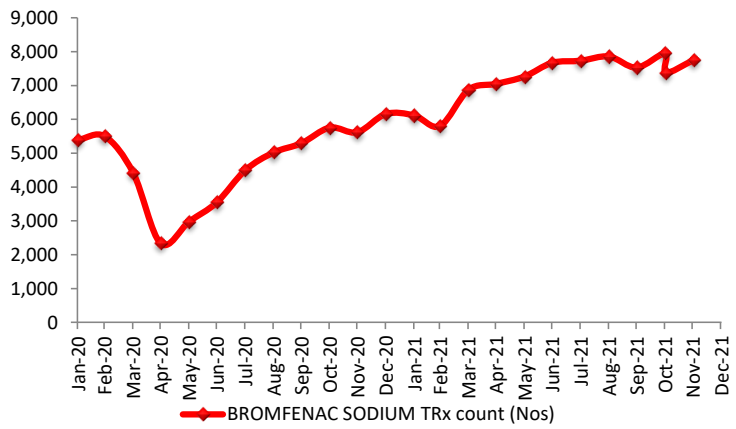

*Source: Company, Systematix Institutional Research*

**Exhibit 41: SUNP's Bromsite journey so far and future outlook**

| Brand (Molecule) and launch date | Bromsite (bromfenac ophthalmic solution 0.075%) - CY16 |
|---|---|
| Indication | Treatment of post-operative inflammation and prevention of ocular pain in patients undergoing cataract surgery |
| Revenue details | Contribution of 2-3% to SUNP's US revenues and among its top 10 products |
| Background | Developed by California-based InSite Vision, which was acquired by SUNP in CY15. It was the first branded ophthalmic product for the company. API bromfenac was first approved in March 2005 with the brand name Xibrom (ISTA Pharma) for treatment of inflammation following cataract surgery with twice daily use and 0.09% concentration. Bromday a Bausch & Lomb product was approved in Oct-2010 with one drop with 0.09% concentration. |
| Competitive scenario | The size of the Bromfenac ophthalmic solution 0.09% market is USD 10mn-20mn. Prolensa and Ilevro are alternate products used for the same indication. With Bromsite using DuraSite technology, it enhances the ocular bioavailability of bromfenac, leading to significantly higher NSAID concentrations throughout both the anterior and posterior segment ocular tissues as compared to Prolensa or Ilevro. Some studies indicate that BromSite prevents pain whereas Prolensa helps in the reduction of pain |
| Outlook | The NSAID ophthalmic market size is ~USD 400mn and the latest treatments include Dextenza, Inveltys and Lotemax SM while older treatment are Prolensa, Durezol and Ilevro. The market has heated up with the new approvals and with SUNP receiving an unfavourable court ruling against Lupin for Bromsite, it has further weakened the company's prospects in this drug.SUNP has settled the litigation with Lupin with details undisclosed |

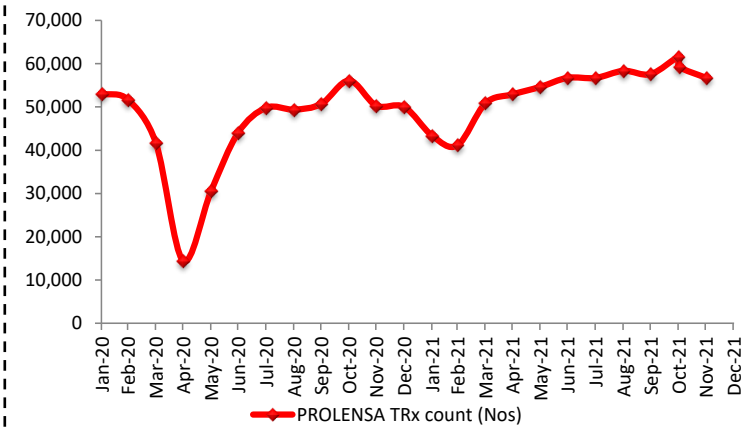
*Source: Company, Systematix Institutional Research*

**Exhibit 42: Bromfenac Sodium – number of monthly prescriptions**




*Source: Company, Systematix Institutional Research*

**Exhibit 43: Prolensa – number of monthly prescriptions**



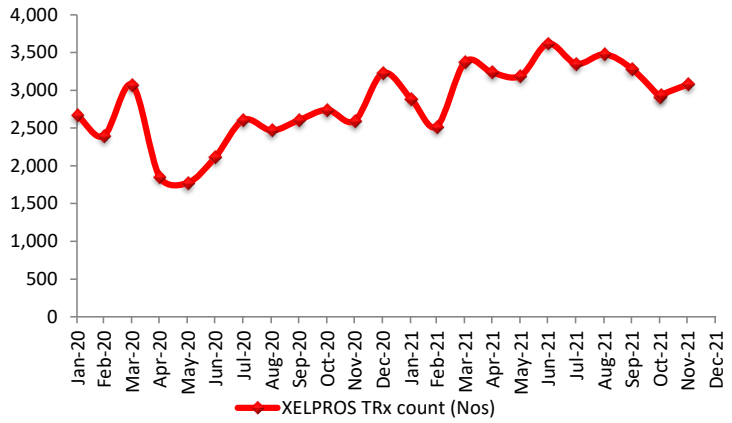

*Source: Company, Systematix Institutional Research*

**Exhibit 44: SUNP's Xelpros journey so far and future outlook**

| Brand (Molecule) and launch date | Xelpros (latanoprost Ophthalmic Emulsion 0.005%) - CY19 |
|---|---|
| Indication | Reduction of elevated IOP in patients with open-angle glaucoma or ocular hypertension |
| Revenue details | NA |
| Background | Xelpros® offers a novel and Benzalkonium Chloride (BAK)-free treatment option for patients with open-angle glaucoma or ocular hypertension. The currently marketed Latanoprost Eye Drops contain BAK, which is a common preservative in topical ocular preparations; however, its prolonged use may lead to adverse effects on the ocular surface, affecting quality of life and reducing adherence to treatment and overall outcomes. Use of BAK has been associated with increased risk of developing OSD. Patients with OSD experience symptoms of ocular discomfort like dryness, burning or stinging, itching, irritation, tearing, etc. |
| Competitive scenario | The main competing product is Xalatan (Pfizer). In a head-to-head comparative study in Glaucoma patients, Xelpros® was found to be as effective and safe as Xalatan and it is the first and only form of latanoprost that is not formulated with BAK. XELPROSTM is developed using SPARC's proprietary Swollen Micelle Microemulsion (SMM) technology. |
| Outlook | The lockdown restrictions impacted revenues from Xelrpos as it was launched just before COVID. With COVID fears now behind, it is expected to scale up in FY23/24E. |

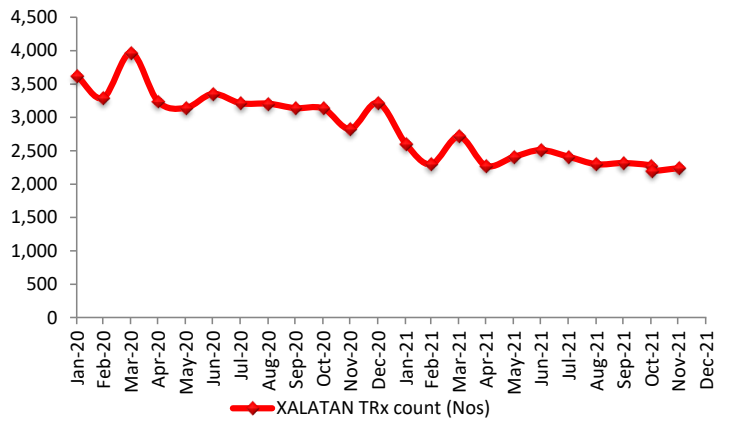
*Source: Company, Systematix Institutional Research*

**Exhibit 45: Xelpros – number of monthly prescriptions**




*Source: Company, Systematix Institutional Research*

**Exhibit 46: Xalatan – number of monthly prescriptions**



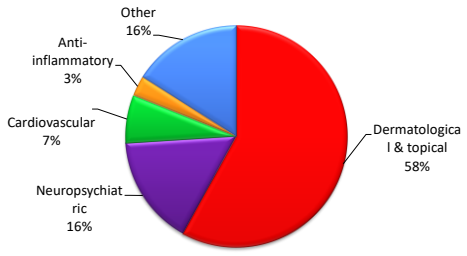

*Source: Company, Systematix Institutional Research*

**Exhibit 47: SUNP's Infugem/ InfuSMART journey so far and future outlook**

| Brand (Molecule) and launch date | Infugem/ InfuSMART (gemcitabine in 0.9% sodium chloride injection) - CY19 |
|---|---|
| Indication | Gemcitabine (chemotherapy product) in premixed, ready-to-use bags |
| Revenue details | NA |
| Background | Infugem is an intravenous use, ready-to-administer (RTA) bag and uses a proprietary technology which allows cytotoxic oncology products to be premixed in a sterile environment and supplied to prescribers in RTA infusion bags. It involves dose banding practice whereby standardized doses of intravenous cytotoxic drugs are used for ranges (or 'bands') of doses calculated for individual patients |
| Competitive scenario | Gemcitabine was first approved by the USFDA in 1996 under the trade name Gemzar, and then in 2010 as a generic drug. Gemcitabine HCL is used as a first-line treatment for Breast, Non-Small Cell Lung and Pancreatic Cancer with a combination of paclitaxel, cisplatin and fluorouracil. It is also used for ovarian cancer. Several generic players have launched gemcitabine though Infugem is the only one with RTA |
| Outlook | Infugem is the first USFDA approved formulation of gemcitabine that is packaged in a ready-to-administer, premixed bag to help prevent overdosing or underdosing of gemcitabine. It improves clinical outcomes, overcomes barriers to the use of cytotoxic chemotherapies and reduces the risk for contamination for healthcare providers. The product commands a premium pricing compared to generics and SUNP is ramping the product well post COVID |

*Source: Company, Systematix Institutional Research*

**Taro: Category-wise sales breakup (FY21)**




*Source: Systematix Institutional Research*

## Taro: Limited downside risk; may opt for inorganic growth

Taro has been the biggest disappointment for SUNP in recent times. After touching a peak of USD 951mn in FY16, Taro revenues have declined at 10% compounded annually over FY16-21. Gross and EBITDA margins have also dropped sharply to decade lows of 54% and 26% respectively in FY21, led by competition in its key molecules and muted new launches. Currently, Taro accounts for 12% of SUNP's total revenues and 40% of US revenues, 13% of EBITDA and 18% of profits.

**After a spell of intense competition and COVID-disruptions…**

Notably, the top-10 products accounting for 20-25% of Taro's total revenues saw a steep decline of 25% compounded annually over FY16-21. This can be largely attributed to increased competitive intensity in the derma portfolio (60-65% of revenues). COVID-19 lockdown restrictions added to the pressure on performance as the number of in-person consultations and procedures declined sharply, leading to a revenue decline of 15% for Taro in FY21.

**…derma business has been doing well for Taro**

While the product pipeline continues to be thin with only 17 pending ANDAs, we believe Taro's US business has hit a trough. Post the sharp correction, margins have bounced back in 9MFY22. Also, visible signs of stability in pricing in the derma segment should support profitability hereon. Note that Taro's derma business outperformed the US derma market (in Rx terms) FY21 – while the US derma category slid ~30% in the year, Taro registered a modest decline of 15%.

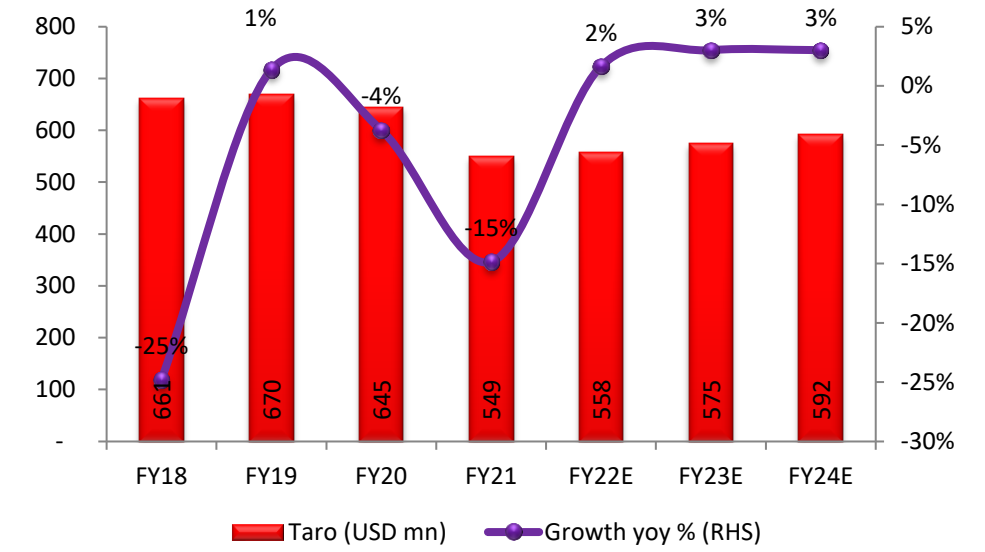
**Ongoing acquisition in derma; limited earnings potential in near term**

With a large cash balance of USD 1.3bn as of CY21, we believe Taro may scout for inorganic opportunities to bolster growth. While we expect a 3% CAGR in Taro's topline over FY22-24E (not factoring in any inorganic growth), EBITDA margins are likely to sustain at 25% levels.

Taro has recently announced acquisition of a 100% stake in Alchemee for a cash consideration of USD 90mn. Proactiv, Alchemee's flagship brand, is an anti-acne solution (currently marketed in the US, Japan and Canada) with sales of USD 166mn in CY21. While the acquisition looks cheap at 0.6x sales, it is noteworthy that the brand has consistently been declining since CY19 and revenues in CY21 were 20% lower YoY – ~1/6$^{th}$ of its CY15 sales.

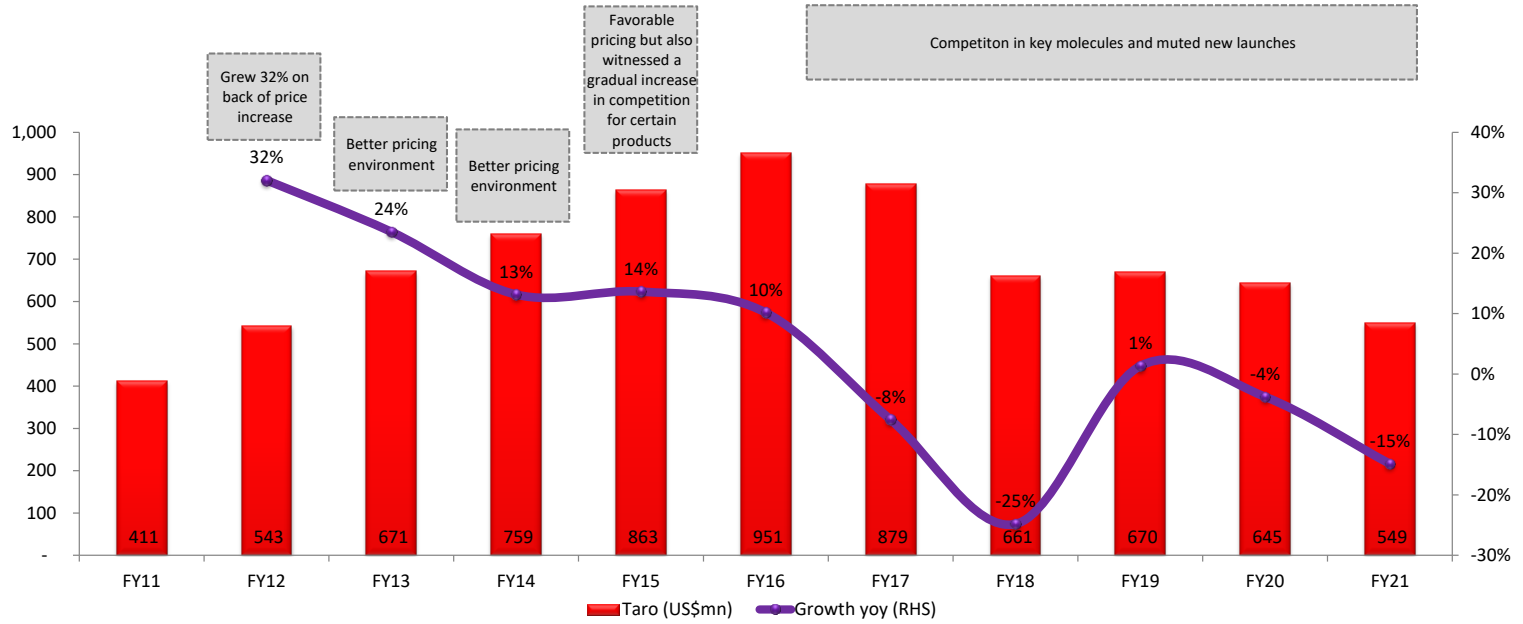
Taro's ability to turn around the acquired asset and portfolio expansion would be the key monitorables in the near term. Pending closure of the acquisition and lack of clarity on the current revenue run-rate, we do not factor in this acquisition in our estimates. In any case, we see the acquisition offering limited accretion to earnings (less than 5%) in the near term given that the portfolio will require considerable investments to grow.

**Exhibit 48: Taro – we estimate 3% revenue CAGR over FY22-24E**



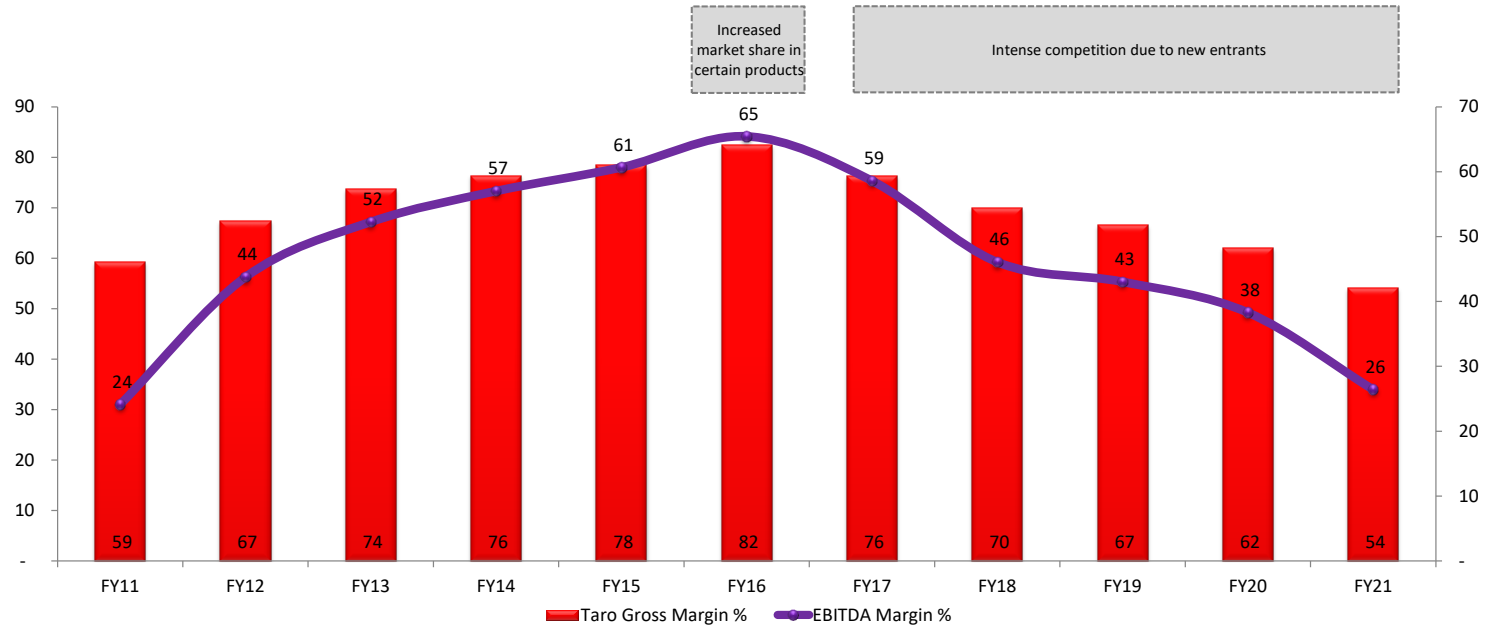

*Source: Company, Systematix Institutional Research*

**Exhibit 49:Taro – Pricing pressure derailed growth from FY18 onwards**



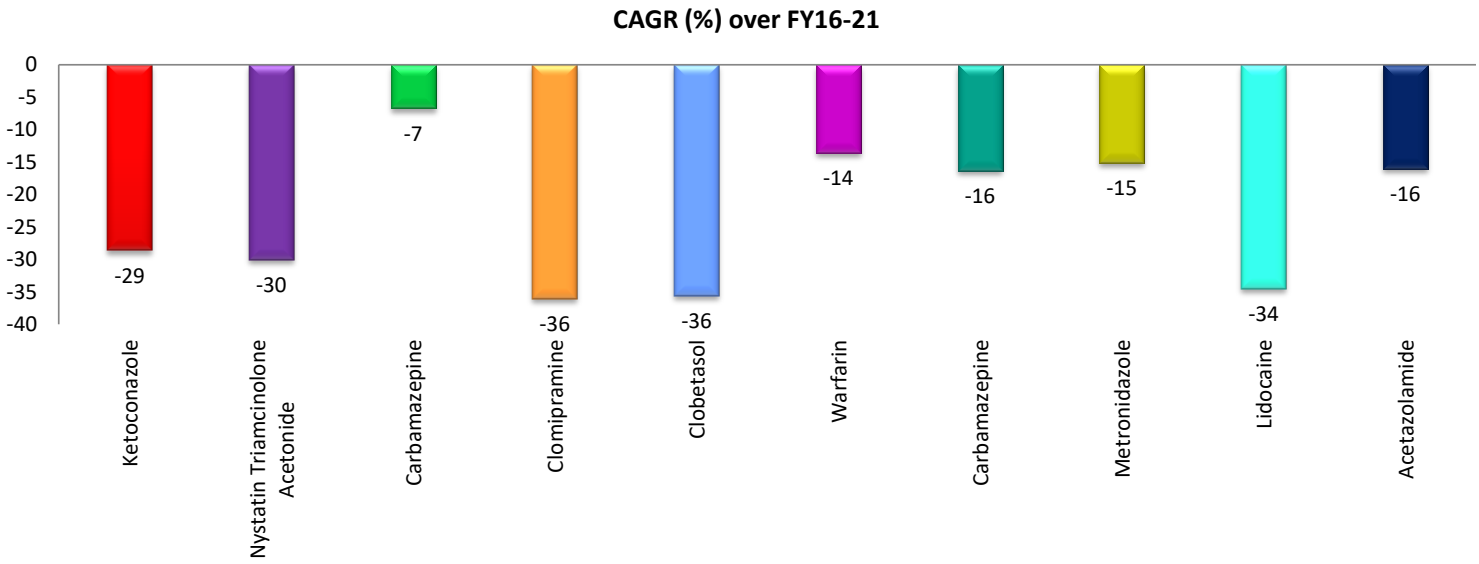

*Source: Company, Systematix Institutional Research*

**Exhibit 50: Taro - Margins near a decade-low**




*Source: Company, Systematix Institutional Research*

**Exhibit 51: Taro top-10 products revenue trend**




*Source: Company, Systematix Institutional Research*

**Exhibit 52: SUNP's Para IV filings**

| Brand | Molecule | Market Size (USD) | Innovator | Litigation filed | Status of litigation | Patent expiry | Comments |
|---|---|---|---|---|---|---|---|
| Forteo | Teriparatide Injection | USD 510mn (CY20) | Eli Lilly | Jul/2021 | Open | Mar/2025 | Teva, Apotex, AMPHASTAR Pharma and SUNP are the only filers |
| Viberzi | eluxadoline tablets | NA | Allergan | Aug/2021 | Open | Mar/2033 | Alkem, Hetero, MSN Labs, Aurobindo, Zydus Cadila other known filers |
| Xarelto | Rivaroxaban | USD 4.1bn (CY19) | Bayer | Jul/2021 | Open | Nov/2024 | 10+ players have filed Para-IV for the product |
| Ibrance | palbociclib | USD 5.3bn (CY20) | Pfizer | Feb-21 | Open | Feb/2034 | Aizant, Alembic, Apotex, Aurobindo, Cipla, Hetero, Mylan, Natco, Qilu Pharma, Dr.Reddy's, Teva, Zydus Cadila and MSN Labs other known filers |
| Synjardy XR | Empagliflozin/ Metformin | USD 374mn (IQVIA MAT Nov-20) | Boehringer Ingelheim | Mar/2021 | Open | Apr/2027 | MSN Labs, Aurobindo, Cipla and Lupin other known filers |
| Zubsolv | Buprenorphine HCL & naloxone HCL sublingual | USD 77mn (CY20) | Orexo | Jul/2021 | Open | May/2030 | SUNP and Actavis two filers for the drug |
| Trijardy | Empagliflozin-Linagliptin-Metformin HCL XR | NA (launched in Jan-20) | Boehringer | Nov/2020 | Open | May/2030 | SUNP and Lupin the only filers |
| Kalydeco | Ivacaftor | USD 800mn (CY20) | Vertex pharma | Jul/2020 | Open | Aug/2029 | SUNP and Lupin the only filers till date |
| Vraylar | Cariprazine | USD 951mn (CY20) | Allergan | May-21 | Open | Jul-29 | SUNP, Aurobindo and Zydus Cadila known filers |
| Lexiscan | Regadenoson | NA | Gilead | Oct/2018 | Open | Feb/2027 | Apotex, Sandoz, SUNP, Wockhardt, Dr Reddy's, Accord (Intas), International Medication, Gland, Glenmark, USV, Hospira Inc, Meitheal, Mylan, American Regent known filers |
| Gilenya | Fingolimod | USD 3bn(CY20) | Novartis | Jul/2018 | Open | Mar-26 | 15+ generic players filed ANDA for the drug. Settlement with a few generic players with undisclosed launch date |
| Bridion | sugammadex-Inj | USD 1.1bn (CY20) | Merck | Mar/2020 | Open | Jan-26 | 15+ known Para-IV filers till date |
| Jublia | Efinaconazole topical solution | USD 222mn (CY20) | Bausch Pharma | Dec-18 | Closed | Oct/2034 | 15+ players submitted ANDAs for the drug. Acrux has settlement with the innovator which includes the launch date for the product to remain confidential |
| Rhofade | Oxymetazoline HCl | ~USD 25-30mn(CY19) | Allergan | Oct-20 | Closed | Jun-35 | Sun (Taro) and Perrigo the only two filers |
| Korlym | Mifepristone | USD 354mn (CY20) | Corcept Therapeutics | May-21 | Closed | Nov-32 | Teva, SUNP and Hikma known filers |
| Xifaxan | Rifaximin | USD 1.5bn(CY20) | Salix Pharmaceuticals | Apr-19 | Closed | Jun-29 | SUNP the sole filer for 200mg tablet while Actavis, Sandoz and Alvogen filers for 500mg |
| Finacea | Azelaic acid-Foam | ~USD 60-80mn (MAT-Jan-19) | Leo Pharma | Feb-19 | Closed | Feb-29 | Teva, Perrigo, Menlo and Sun (Taro). Menlo entered into a settlement and license agreement to resolve the remaining pending patent litigation involving Finacea® Foam |

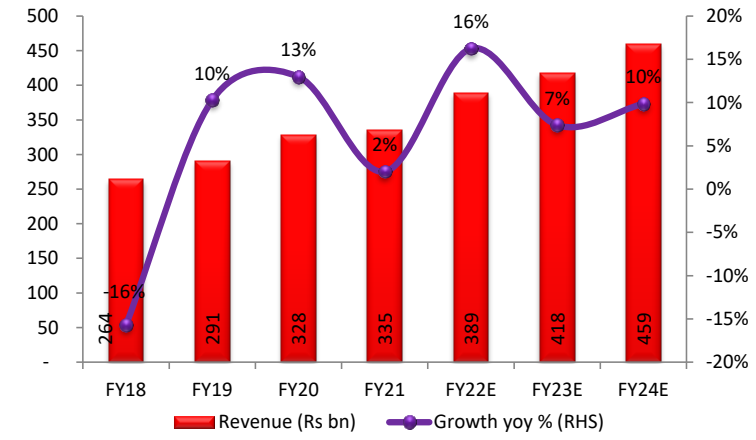
*Source: RPX Insight, USFDA, Systematix Institutional Research*

## Financial Analysis

### US Specialty – the key growth driver

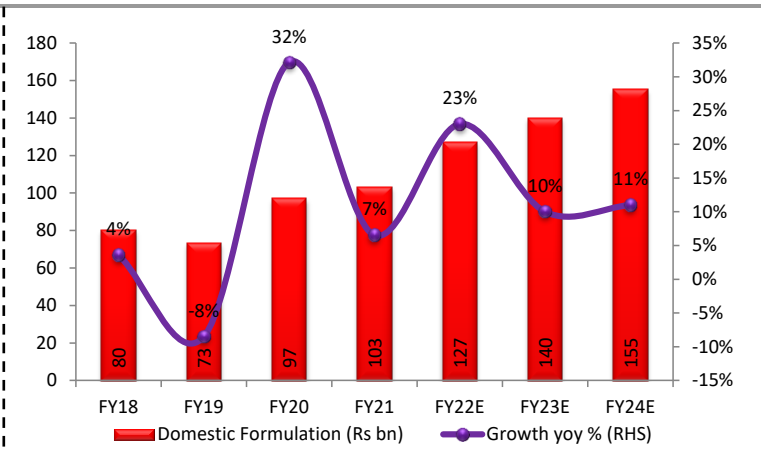
We expect revenue CAGR of 9% for SUNP over FY22-24E, driven by 1) ramp-up of Specialty products in the US led by Ilumya; 2) a higher MR count in IPM driving a 100-200bps outperformance in formulations vis-à-vis the industry; and 3) Specialty product launches in RoW markets. We expect Taro's business to stabilize from here, registering an organic 3% CAGR over FY22-24E. Given Taro's USD 1.3bn cash on books, we expect it to utilize the cash to acquire portfolios/ companies.

**Exhibit 53: Branded formulations and Specialty key growth drivers**



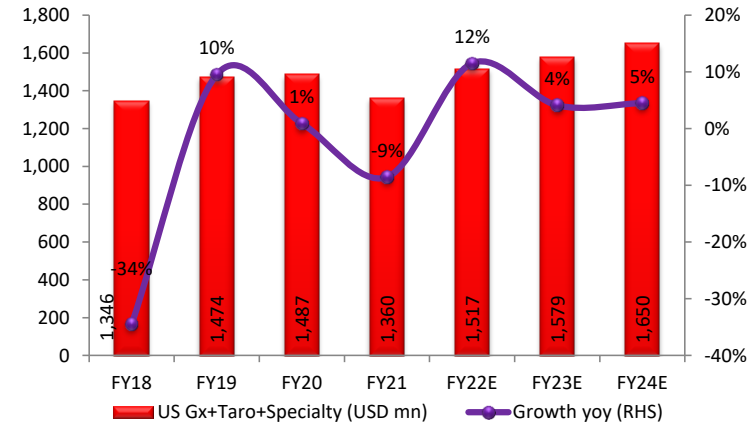

*Source: Company, Systematix Institutional Research*

**Exhibit 54: India business could outperform IPM by 100-200bps**



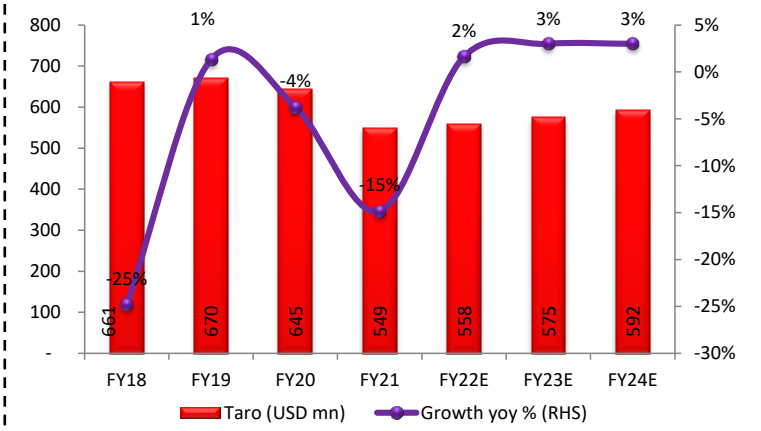

*Source: Company, Systematix Institutional Research*

**Exhibit 55: Specialty business to drive growth in US formulations**




*Source: Company, Systematix Institutional Research*

**Exhibit 56: Limited downside for Taro with 3% expected CAGR**

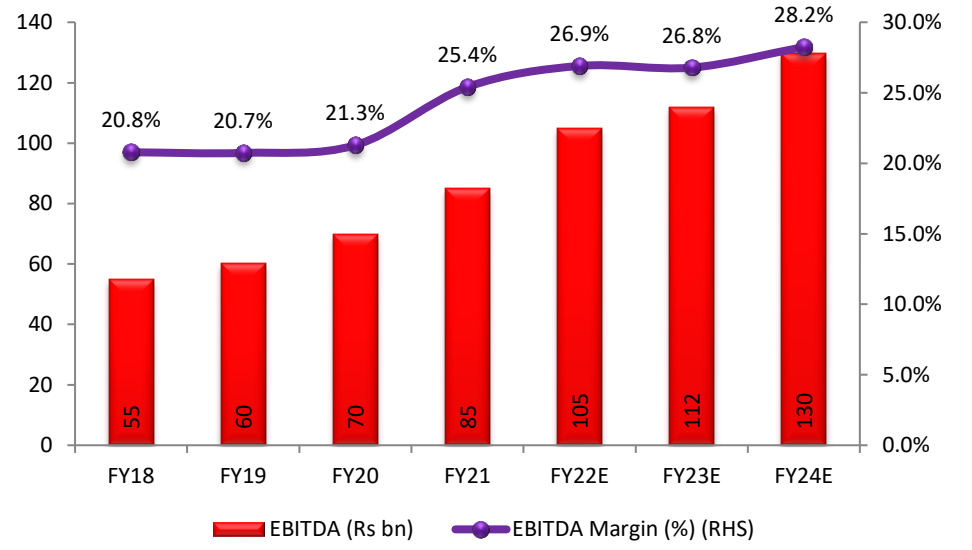



*Source: Company, Systematix Institutional Research*

**Margin expansion ahead, led by ramp-up of Specialty products**

SUNP was in an investment phase during FY18-20 for building its Specialty portfolio in the US market. This resulted in higher R&D and marketing expenses. A large part of the investment was aimed at acquiring front-end capabilities (field force) for Specialty products and DTC spends to engage and educate patients about the innovative products and new treatments at SUNP. The Specialty business has been scaling up gradually and the investment phase is now over for the company. With the benefits of its past investments starting to accrue, we expect EBITDA margins to sustain at 25%+ levels for SUNP, at least for the next couple of years.

**Exhibit 57: Expect breakeven in US specialty business in FY23 with margin expansion**



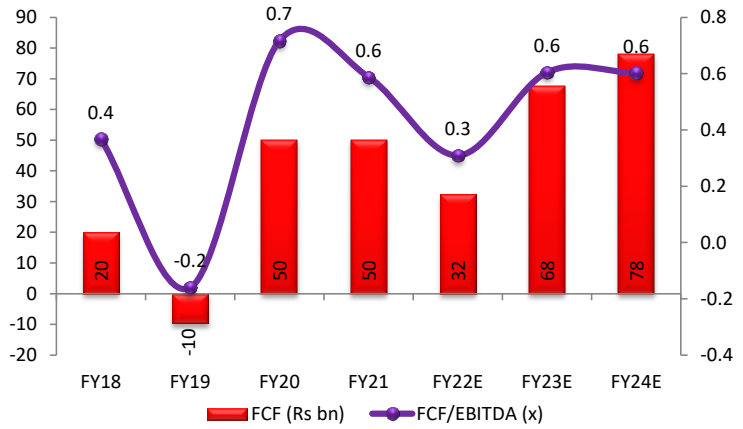

*Source: Company, Systematix Institutional Research*

**Prudent investment decisions in the recent times**

Post Ranbaxy-acquisition in FY15, SUNP has stayed away from large acquisitions and kept its focus on building a niche Specialty portfolio for long-term gains. The strategy has worked towards its vision of reducing dependence on generic molecules, which are prone to steep price erosions. Notably, SUNP's cumulative capex of Rs 78.8bn over FY18-21 (Rs 103bn over FY14-17) was spent mainly on acquiring Specialty brands besides some routine capex.

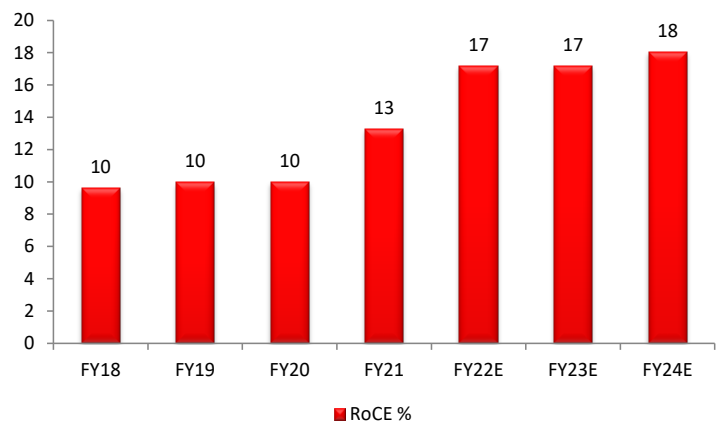
Going forward, while we expect SUNP to retain focus on US Specialty products, any large acquisition in the domestic formulations market can be ruled out. Being a leader in the IPM, the company already has a dominant share in the large therapy areas. Led by healthy growth in the US business, we expect RoCE to reach 18% in FY24E after being at around 10% over FY18-20.

**Exhibit 58: Cumulative FCF of Rs 178bn over FY22-24E**



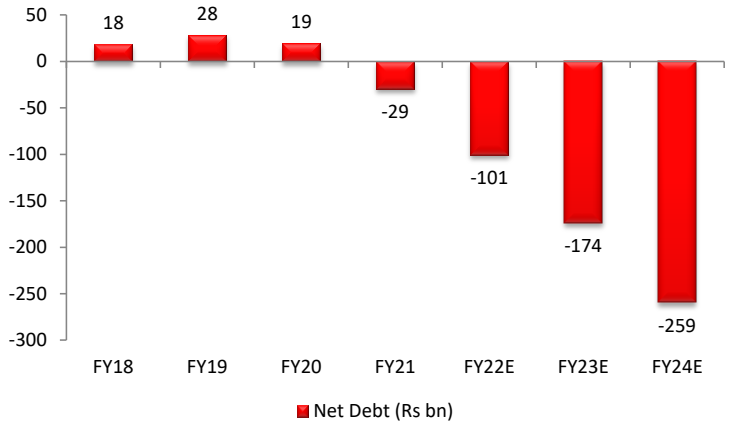

*Source: Company, Systematix Institutional Research*

**Exhibit 59: RoCE to improve with the uptick in US formulations**



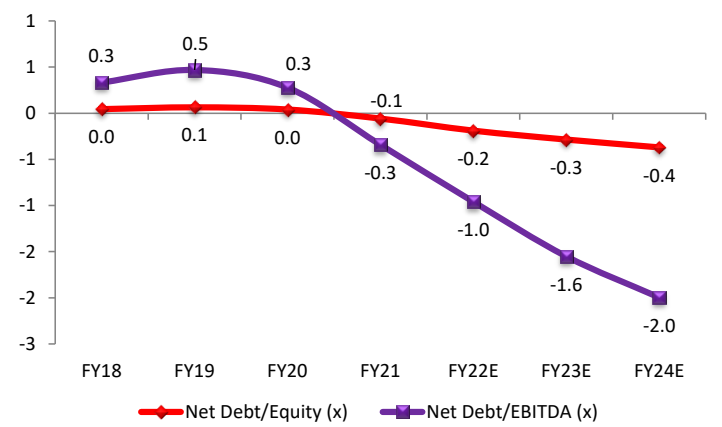

*Source: Company, Systematix Institutional Research*

**Exhibit 60: SUNP to remain cash positive**



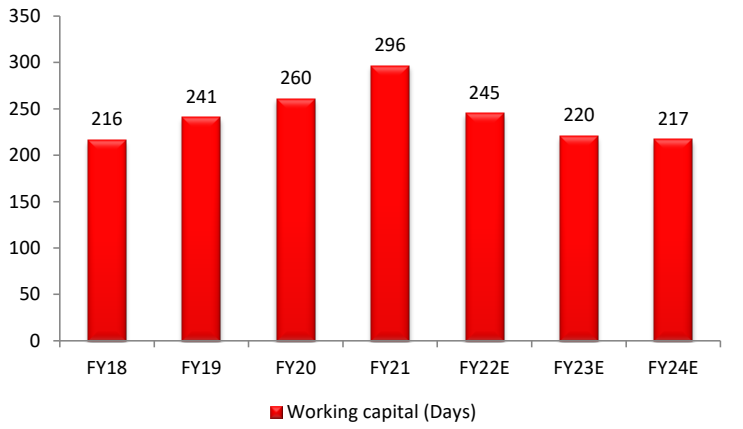

*Source: Company, Systematix Institutional Research*

**Exhibit 61: Leverage ratio to get better**



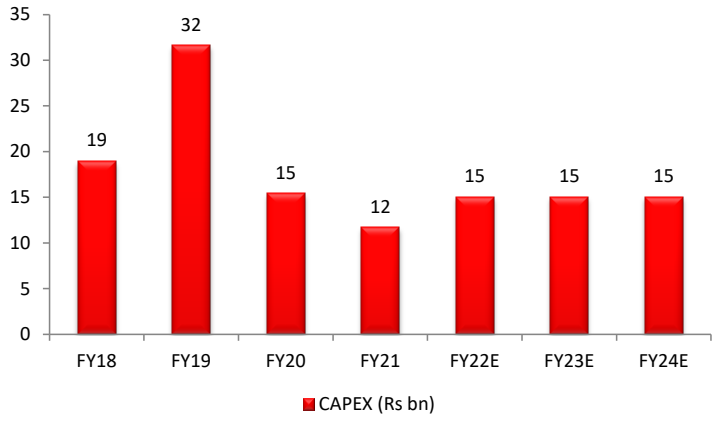

*Source: Company, Systematix Institutional Research*

**Exhibit 62: Reduction in Working Capital days**




*Source: Company, Systematix Institutional Research*

**Exhibit 63: Capex to remain in the range of Rs 15bn**




*Source: Company, Systematix Institutional Research*

## Valuations & View

SUNP's scale in India, superior margin profile and proven ability to move up the product complexity chain in the US give it a unique position among Indian pharma players. Further, the impressive scale-up in the Specialty business in recent quarters has the potential to drive operating leverage benefits. A net cash balance sheet, leadership position in the India formulations market, a strong execution history and a rising share of the Branded/ Specialty businesses in overall revenues drive our higher than historical average target multiple.

At 22x FY24E EPS of Rs 40, SUNP currently trades largely in line with its 5-year average valuation. We believe the stock deserves to trade at a higher multiple vis-à-vis the historical average on account of its improving business fundamentals, led by:

a) Higher contribution from Specialty products (45% of US revenues in FY24E)

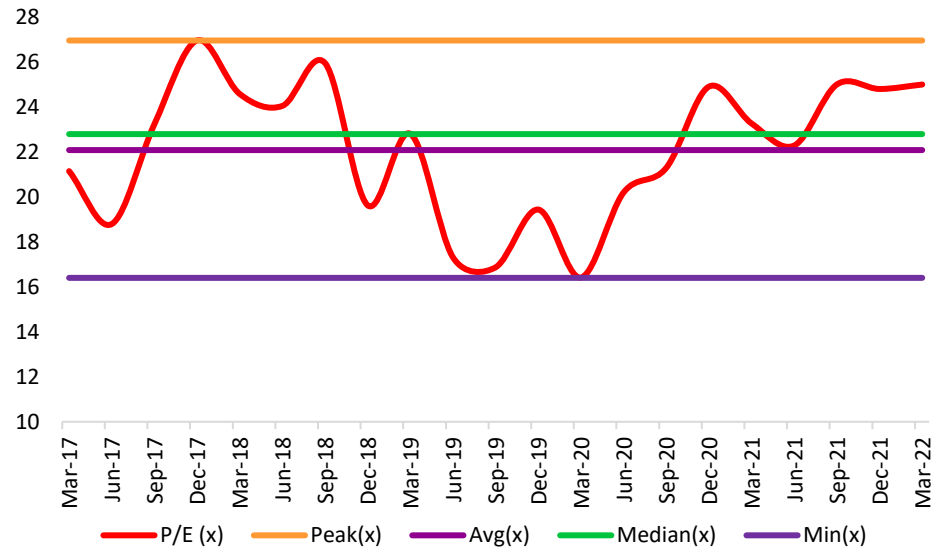
b) Outperformance in the domestic formulations market led by a larger field force

c) Expected improvement in EBITDA margins to >30% in FY24E, and

d) Cumulative FCF of Rs 178bn over FY22-24E with RoCE improving to 18% by FY24E

We initiate coverage on the stock with a **BUY** rating and assign a PE of 26x on FY24E EPS of Rs 40 to arrive at a target price of Rs 1,068.

**Exhibit 64: P/E**




*Source: Company, Systematix Institutional Research*

# Annexures

## Company Background

**SUNP the 4th largest in global specialty generic pharma, largest in IPM**

SUNP was founded by Mr Dilip Shantilal Shanghvi in 1983 with five psychiatry products and a manufacturing facility for tablets and capsules at Vapi, Gujarat. It was only in the early 1990s that SUNP commenced its first R&D facility and added manufacturing facilities as also product lines in the fields of cardiology and gastroenterology.

**Establishing presence in US markets key focus in the 90s decade…**

SUNP acquired a host of brands/ companies/ manufacturing facilities and set up its formulations and API units in the 1990s. Caraco Pharmaceutical Laboratories, USA was its first international acquisition in 2007, followed by several others including Chattem Chemicals, Taro, Dusa and Ranbaxy in the subsequent years to strengthen its presence in the US market. SUNP acquired its capabilities in the Specialty segment mainly through acquisitions with focus on derma and ophthalmic products.

**…emerged as a dominant player in the US and India across segments**

SUNP is the 2nd largest Indian company in the US, among the top 10 in generic pharmaceuticals and the largest Indian company in Specialty products in this market, besides ranking 2nd by prescriptions in the generic dermatology market. The US business consists of Taro (40% of US revenues), Specialty products (~30%) and Gx (30%). In the domestic formulations space, SUNP ranks number one with a market share of 8.2% in IPM with the Ranbaxy portfolio contributing 30-35% to its overall domestic formulation revenues. US and India formulations are the two key contributors to its business with a 62% share in overall revenues. The company has an MR count of 10,900+. It is a leading player in several therapies like anti-diabetic (6.6% share), cardiology (6.8%), ophthalmology (13.2%) and neurology (23%).

**Sizeable footprint across EMs**

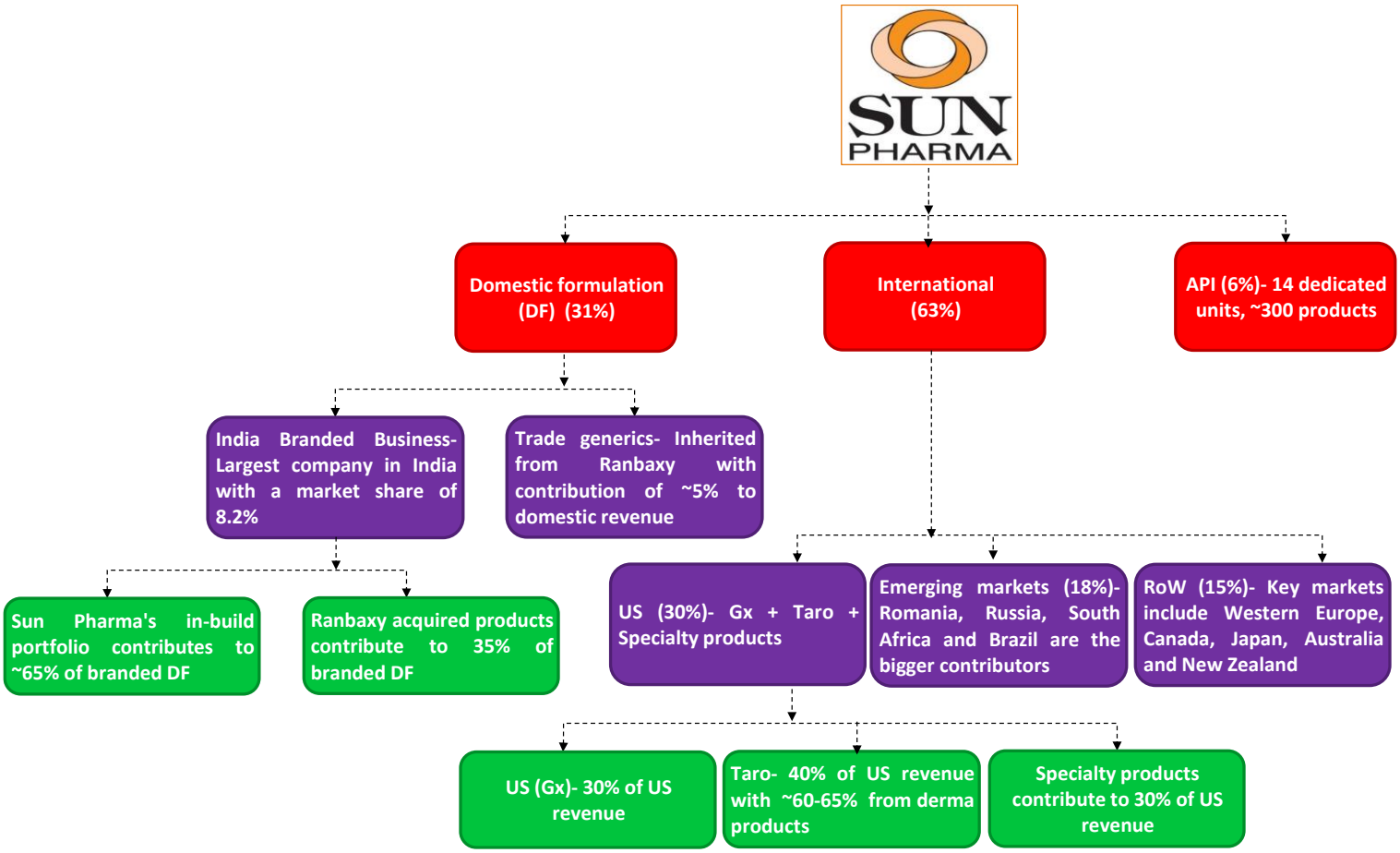
In emerging markets, SUNP is the largest Indian pharmaceuticals company and sells products in ~80 markets with focus on Romania, Russia, South Africa, Brazil and Mexico among others. It has local manufacturing units across Bangladesh, South Africa, Malaysia, Romania, Egypt, Nigeria and Russia. The company has a strength of ~2,200 MRs in emerging markets.

**Exhibit 65: Key management personnel**

| Name | Designation | Education | Roles and achievements |
|---|---|---|---|
| Dilip S. Shanghvi | Managing Director | Graduate in Commerce from Kolkata University | Mr Shanghvi has been the driving force behind SUNP ever since it became operational and is involved in strategic decisions. A visionary who was among the early identifiers of the opportunity offered by rising life expectancy, especially in North America and Europe, he has been instrumental in scaling up the business first in India and then in the US through a string of acquisitions. He was awarded the Padma Shri in 2016 |
| Abhay Gandhi | CEO - North America | Bachelor of Science and a Master's in Marketing Management from University of Mumbai; Diploma in Business Management from The Institute of Chartered Financial Analysts of India (ICFAI University) | Prior to joining SUNP, Mr Gandhi held positions at Boehringer and Nestle India Ltd. He has been with SUNP for over 20 years now in various roles |

*Source: Company, Systematix Institutional Research*

**Exhibit 66: Business segments**




*Source: Company, Systematix Institutional Research*

## Annual Report Analysis

**Exhibit 67: FY21 Annual Report Takeaways**

| | | | | |
|---|---|---|---|---|
| **Domestic formulations** | Field force expanded in Q4FY20 to 10,900+ MRs. Launched 96 products including anti-epileptic Brevipil (Brivaracetam) and FluGuard (Favipiravir) | Supplied drugs like Remdesivir, Itolizumab, Hydroxychloroquine (HCQS), Favipiravir and Liposomal Amphotericin B in the Indian market for treatment of COVID-19 and associated ailments | In May 2021, entered into a licensing agreement with Eli Lilly for Baricitinib | Lockdown resulted in temporary closure of doctor clinics, reduction in patient consultations, postponement of non-critical treatments and restricted movement of MRs |
| | | | | |
| **US market** | US market contributed 30% to overall revenues in FY21 and witnessed a decline of 8% YoY to USD 1360mn | US(Gx) continued to register Y-o-Y price erosion, driven by higher competitive intensity on faster pace of generic approvals and customer consolidation | Completed corrective actions for Halol facility, which was classified as an "Official Action Indicated (OAI)" in March-2020. Awaiting re-inspection from the USFDA | Taro recorded ~15% decline in overall revenues to USD 549mn for FY21 |
| | | | | |
| **Specialty products** | Global specialty business grew 11% to USD 475mn in FY21 despite pandemic-related challenges. Global Ilumya sales up 51% to USD 143mn in FY21 | Temporary closure of doctor clinics in the US in 1HFY21 led to lower patient footfalls and postponement of certain treatments. This impacted specialty sales in the first half, including sales of Ilumya, Cequa and Levulan | Launched Ilumya in Japan and entered into an exclusive licensing and distribution agreement for Ilumya with Hikma for Middle East & North Africa (MENA) region | First generic for Absorica launched In April 2021 and Absorica LD launched in Feb-20 to mitigate the impact. But lockdown restrictions prevented ramp-up |
| | | | | |
| **RoW and API** | Leading Indian pharmaceuticals companies operating in Western Europe, Canada, Japan as well as Australia & New Zealand (ANZ) | RoW markets characterized by an ageing population and increasing incidence of chronic ailments and lifestyle diseases as also government efforts to tighten healthcare budgets | API business important for SUNP as it provides opportunities for strong backward integration and speed-to-market. With 300 offerings in the product portfolio, it caters to large generic manufacturers and innovator companies, after meeting captive consumption | SUNP has 14 API manufacturing units across various countries and develops 20-30 APIs annually |
| | | | | |
| **Emerging Markets** | MR count of ~2,200 for the region. Sells its products in ~80 markets with focus on Romania, Russia, South Africa, Brazil, Mexico among other markets | Established local manufacturing footprint in Canada, Japan, Australia, Israel and Hungary | Follows a distribution-led growth model focused on development and commercialization of complex generics and differentiated products to drive sustainable and profitable progress | Local manufacturing units in Bangladesh, South Africa, Malaysia, Romania, Egypt, Nigeria and Russia provide flexibility in servicing these markets |

*Source: Company Annual Report, Systematix Institutional Research*

## Plant details

**Exhibit 68: Halol facility**

*Source: Company, Systematix Institutional Research*

**Exhibit 69: Dadra facility**

*Source: Company, Systematix Institutional Research*

**Exhibit 70: Plant details**

| Plant locations | Plant locations |
|---|---|
| Survey No.214 and 20, Govt. Industrial Area, Phase-II, Piparia, Silvassa - 396 230, U.T. of D&NH | Plot No. B-2 Madkaim Industrial Estate, Ponda, Goa |
| | |
| Survey no. 259/15, Dadra - 396191, U.T. of D. & NH | Village & PO Ganguwala, Tehsil Paonta Sahib-173025, Distt. Sirmour, Himachal Pradesh |
| | |
| Plot No.24/2 and No.25, GIDC, Phase- IV, Panoli - 395 116, Dist. Bharuch, Gujarat | Village Toansa, P.O. Railmajra Distt. Nawansahar-144533 (Punjab) |
| | |
| Plot No. 4708, GIDC, Ankleshwar - 393 002, Gujarat. | A-41, Industrial Area, Phase VIII-A, Sahibzada Ajit Singh Nagar, Mohali-160071 (Punjab) |
| | |
| Halol-Baroda Highway, Near Anand Kendra, Halol, Dist. Panchmahal- 389350 Gujarat | Plot No. K - 5,6,7, Ghirongi Industrial Area, Malanpur, Dist. Bhind, Madhya Pradesh |
| | |
| Plot No. 817/A, Karkhadi - 391 450, Taluka: Padra, Dis5. Vadodara, Gujarat | Pharma Manufacturing Industrial Area 3 A.B. Road, Dewas-455001, Madhya Pradesh |
| | |
| Plot No. Z/15, Sez-1, Po. Dahej, Taluko vagra, Dist. Bharuch, Gujarat | Sathammai Village, Karunkuzhi Post, Maduranthakam T.K. Kanchipuram Dist. Tamil Nadu - 603 303 |
| | |
| A-7 & A-8, MIDC Industrial Area, Ahmednagar - 414 111, Maharashtra | Khasra No. – 1335-1340, Near Epip Phase-1, Hill Top Industrial Area, Vill.-Bhatolikalan,Barotiwala, Distt-Solan, Himachal Pradesh, – 174103 |

*Source: Company, Systematix Institutional Research*

# FINANCIALS

### Profit & Loss Statement

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **Net Revenues** | **3,28,375** | **3,34,981** | **3,89,335** | **4,18,089** | **4,59,301** |
| YoY gr. (%) | 13 | 2 | 16 | 7 | 10 |
| Cost of Goods Sold | 92,305 | 86,901 | 1,05,121 | 1,14,974 | 1,26,308 |
| Gross Profit | 2,36,071 | 2,48,081 | 2,84,215 | 3,03,114 | 3,32,994 |
| Margin (%) | 72 | 74 | 73 | 73 | 73 |
| Employee Cost | 63,624 | 68,622 | 72,740 | 76,377 | 80,195 |
| Other Expenses | 1,02,549 | 94,331 | 1,06,723 | 1,14,755 | 1,23,051 |
| **EBITDA** | **69,898** | **85,127** | **1,04,752** | **1,11,983** | **1,29,747** |
| YoY gr. (%) | 16 | 22 | 23 | 7 | 16 |
| Margin (%) | 21 | 25 | 26.9 | 26.8 | 28.2 |
| Depn and Amort. | 20,528 | 20,800 | 21,223 | 22,498 | 23,773 |
| **EBIT** | **49,370** | **64,328** | **83,529** | **89,485** | **1,05,974** |
| Margin (%) | 15 | 19 | 21 | 21 | 23 |
| Net Interest | 3,027 | 1,414 | 1,074 | 709 | 559 |
| Other Income | 6,360 | 8,355 | 10,037 | 12,914 | 15,789 |
| **Profit Before Tax** | **52,702** | **71,269** | **92,492** | **1,01,690** | **1,21,204** |
| Margin (%) | 2.7 | 2.7 | 2.7 | 2.7 | 2.7 |
| Total Tax | 8,228 | 5,147 | 13,874 | 18,304 | 21,817 |
| Effective tax rate (%) | 16 | 7 | 15 | 18 | 18 |
| **Profit after tax** | **44,474** | **66,122** | **78,619** | **83,386** | **99,387** |
| EPS | 16 | 12 | 32 | 34 | 40 |
| YoY gr. (%) | 41 | -22 | 164 | 6 | 19 |

*Source: Company, Systematix Institutional Research*

### Balance Sheet

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| Equity Share Capital | 2,399 | 2,399 | 2,399 | 2,399 | 2,399 |
| Res. & Surp. (Ex OCI) | 4,88,847 | 4,92,399 | 5,28,353 | 6,05,068 | 6,96,504 |
| **Net Worth** | **4,91,247** | **4,94,798** | **5,30,752** | **6,07,467** | **6,98,903** |
| Short term debt | 55,494 | 24,449 | 21,449 | 18,449 | 15,449 |
| Long term debt | 20,713 | 9,177 | 7,177 | 5,177 | 3,177 |
| Trade payables | 35,836 | 39,737 | 55,056 | 59,220 | 63,756 |
| Other Provisions | 43,474 | 49,098 | 49,098 | 49,098 | 49,098 |
| Other liabilities | 35,761 | 59,408 | 59,408 | 59,408 | 59,408 |
| **Total Liabilities** | **6,82,524** | **6,76,667** | **7,22,940** | **7,98,819** | **8,89,791** |
| | | | | | |
| Net block | 1,05,675 | 1,02,349 | 96,126 | 88,629 | 79,856 |
| CWIP | 6,589 | 9,365 | 9,365 | 9,365 | 9,365 |
| Oth. Non-current asset | 1,28,409 | 1,19,483 | 1,19,483 | 1,19,483 | 1,19,483 |
| Investments | 1,02,488 | 97,089 | 60,714 | 60,714 | 60,714 |
| Cash & Cash Equivalents | 56,766 | 62,730 | 1,29,138 | 1,97,357 | 2,77,749 |
| Debtors | 94,212 | 90,614 | 1,11,844 | 1,20,104 | 1,31,943 |
| Inventories | 78,750 | 89,970 | 91,203 | 98,101 | 1,05,616 |
| Other current asset | 44,040 | 35,173 | 35,173 | 35,173 | 35,173 |
| Deferred Tax Assets | 65,595 | 69,893 | 69,893 | 69,893 | 69,893 |
| **Total Assets** | **6,82,525** | **6,76,667** | **7,22,941** | **7,98,819** | **8,89,792** |

*Source: Company, Systematix Institutional Research*

### Cash Flow

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| PBT | 50,096 | 27,994 | 92,492 | 1,01,690 | 1,21,204 |
| Depreciation | 20,528 | 20,800 | 21,223 | 22,498 | 23,773 |
| Others | -602 | -2,701 | -45,338 | -12,205 | -15,230 |
| Working capital | 8,986 | 25,641 | -7,144 | -10,994 | -14,818 |
| Direct tax | -13,459 | -10,029 | -13,874 | -18,304 | -21,817 |
| Net cash from Op. | 65,548 | 61,704 | 47,359 | 82,685 | 93,113 |
| Net Capital exp. | -15,420 | -11,701 | -15,000 | -15,000 | -15,000 |
| Others | -10,469 | 17,063 | 46,412 | 12,914 | 15,789 |
| Net Cash from Invst. | -25,889 | 5,362 | 31,412 | -2,086 | 789 |
| Debt changes | -33,419 | -43,170 | -5,000 | -5,000 | -5,000 |
| Dividend paid | -13,792 | -15,595 | -6,289 | -6,671 | -7,951 |
| Others | -6,305 | -2,337 | -1,074 | -709 | -559 |
| Net cash from Fin. | -53515 | -61101 | -12363 | -12380 | -13510 |
| Net change in cash | -13,856 | 5,964 | 66,408 | 68,219 | 80,391 |
| Closing cash | 56,767 | 62,730 | 1,29,138 | 1,97,357 | 2,77,749 |

### Ratios

| YE: Mar | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **Per Share (Rs)** | | | | | |
| EPS | 16 | 12 | 32 | 34 | 40 |
| CEPS | 24 | 21 | 41 | 43 | 50 |
| BVPS | 189 | 194 | 208 | 239 | 276 |
| DPS | 1 | 1 | 3 | 3 | 3 |
| **Return Ratio(%)** | | | | | |
| RoCE | 10 | 13 | 17 | 17 | 18 |
| RoE | 9 | 6 | 16 | 15 | 16 |
| **Balance Sheet** | | | | | |
| Net Debt : Equity (x) | 0.0 | -0.1 | -0.2 | -0.3 | -0.4 |
| Net Working Capital (Days) | 153 | 138 | 126 | 127 | 127 |
| **Valuation(x)** | | | | | |
| PER | 57 | 74 | 28 | 27 | 22 |
| EV/EBITDA | 12 | 17 | 20 | 18 | 15 |
| EV/Sales | 3 | 4 | 5 | 5 | 4 |

*Source: Company, Systematix Institutional Research*

| Revenue details (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| Domestic Formulation | 97,102 | 1,03,432 | 1,27,221 | 1,39,944 | 1,55,337 |
| US | 1,05,425 | 1,00,839 | 1,13,744 | 1,13,675 | 1,18,800 |
| RoW | 45,210 | 48,191 | 54,455 | 60,990 | 68,309 |
| EM | 55,044 | 57,834 | 69,401 | 79,811 | 91,783 |
| API | 19,159 | 19,503 | 19,113 | 20,069 | 21,072 |
| US (US$mn) | 1,487 | 1,360 | 1,517 | 1,579 | 1,650 |
| Taro(US$mn) | 645 | 549 | 558 | 575 | 592 |

*Source: Company, Systematix Institutional Research*

# Cipla

28 March 2022

## Diversified branded generics play; US region to drive operating leverage

**INITIATING COVERAGE**

**Sector: Pharmaceuticals** **Rating: BUY**

**CMP: Rs 1,013** **Target Price: Rs 1,185**

**Stock Info**

| | |
|---|---|
| Sensex/Nifty | 57,362/17,153 |
| Bloomberg | CIPLA IN |
| Equity shares | 807mn |
| 52-wk High/Low | Rs 1,083/782 |
| Face value | Rs 2 |
| M-Cap | Rs 818bn/ USD 10.9bn |
| 3-m Avg value | USD 33mn |

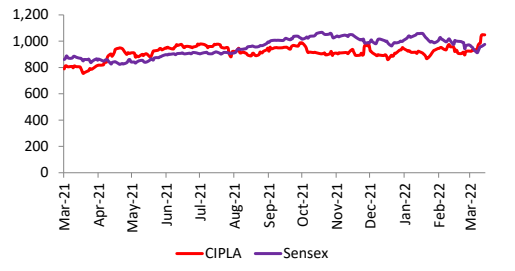
**Financial Snapshot (Rs mn)**

| Y/E March | FY22E | FY23E | FY24E |
|---|---|---|---|
| Revenue | 220,157 | 236,767 | 262,362 |
| Gross profit | 135,397 | 146,796 | 162,665 |
| Gross Margin (%) | 62 | 62 | 62 |
| EBITDA | 50,462 | 55,916 | 65,423 |
| Margin (%) | 23 | 24 | 25 |
| PAT | 30,955 | 34,887 | 41,695 |
| EPS | 38 | 43 | 52 |
| DPS (Rs) | 5 | 5 | 5 |
| ROCE (%) | 20 | 20 | 21 |
| P/E (x) | 27 | 24 | 20 |
| EV/EBITDA (x) | 16 | 14 | 11 |

**Shareholding pattern (%)**

| | Jun-21 | Sep-21 | Dec-21 |
|---|---|---|---|
| Promoter | 36.7 | 36.1 | 36.1 |
| –Pledged | | | |
| FII | 24.8 | 24.8 | 24.3 |
| DII | 16.4 | 21.1 | 21.6 |
| Others | 22.1 | 18.0 | 18.0 |

**Stock Performance (1-year)**




**CIPLA offers a strong mix of formidable presence in branded markets like India/ South Africa and a fast-growing US business led by respiratory and complex products. The company already has a leadership position in India, while its regulated market business (especially the US) is at an inflexion point with the respiratory/ injectables portfolio at the cusp of monetization. Based on these factors, we estimate 16% earnings CAGR for CIPLA over FY22-24E. Given its debt-free balance sheet, strong FCF generation and improving return ratios, the stock should re-rate from the current valuation of 20x FY24E EPS of Rs52 and move towards a premium valuation. We initiate coverage on Cipla with a BUY rating and target price of Rs 1,185 based on 23x FY24E earnings.**

**Sustainable growth in branded markets:** CIPLA derives ~59% of its revenues from the Indian and South African branded markets. This provides consistency and visibility of strong profitability and returns. In India, it ranks first in the respiratory and urology therapies, is the largest player in the fast-growing Gx segment and is present in the consumer health segment. In South Africa, it is among the top-10 generic players and has a strong position in the respiratory, HIV and CVS segments. CIPLA has been growing ahead of the industry in these markets with 8-10% annual growth; we expect the outperformance to continue given its strong positioning.

**US business – at an inflexion point:** CIPLA has built a promising respiratory product pipeline for the US market by leveraging its domestic market leadership. It has validated its capabilities by getting approvals for complex products like Albuterol and Lanreotide injections. The pipeline looks strong with potential launches of gRevlimid, gAdvair, gAbraxane, gQvar, gSomatuline depot, etc. The management expects incremental sales of USD 300mn-500mn by FY25E, implying double-digit growth in the US. We expect it to register an 10% CAGR in its US business over FY22-24E to USD 712mn.

**A strong balance sheet:** CIPLA's debt-free balance sheet offers it the flexibility to pursue inorganic opportunities as well as complex R&D projects. It has demonstrated superior execution capabilities with the launch of complex products. Led by an estimated 16% CAGR in earnings over FY22-24E, we expect the company to generate FCF of Rs 96bn and have higher return ratios over the next two years. This, we believe, will drive a re-rating in the stock.

**Initiating coverage with a BUY rating and 12-month price target of Rs 1,185:** At Rs 1,013, the stock trades at 20x its FY24E EPS – a 9% discount to its 5-year historical average valuation. We believe the strong earnings outlook, FCF generation of Rs 96bn over FY22-24E and improving return ratios should support its premium valuation. With high visibility on key launches and a sizeable contribution from branded markets, the risk to earnings seems relatively lower. Our target price is based on 23x FY24E EPS of Rs 52, a 5% premium to its 5-year average valuation.

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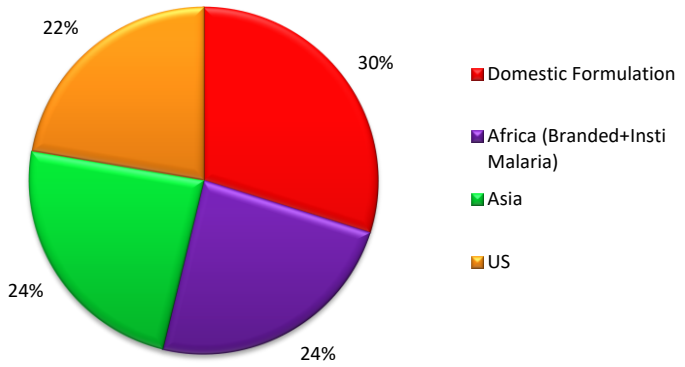
**Investors are advised to refer disclosures made at the end of the research report.**

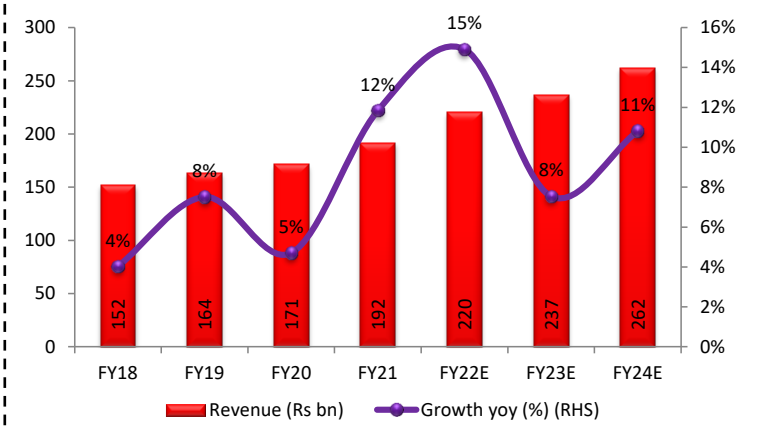
## Story in charts

**Exhibit 1: Business mix (%; FY21)**



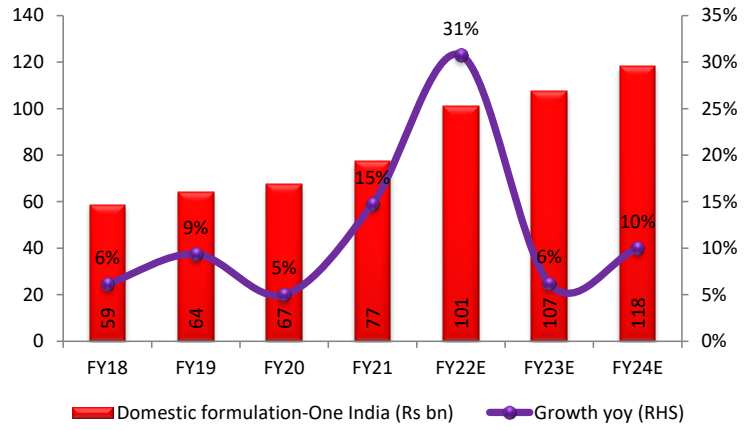

*Source: Company, Systematix Institutional Research*

**Exhibit 2: Revenue CAGR of 9% over FY22-24E**



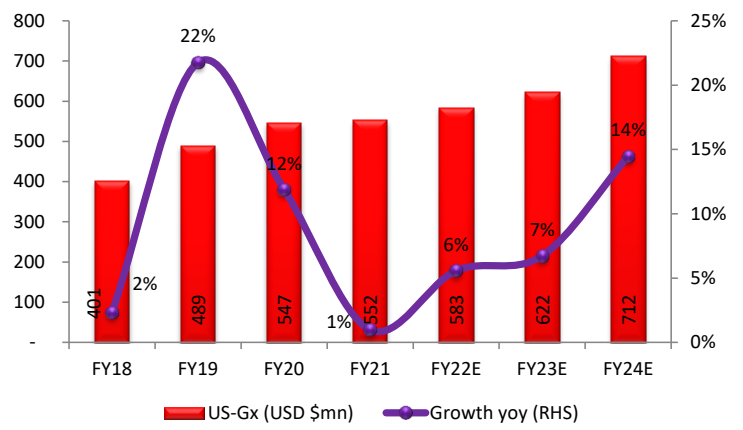

*Source: Company, Systematix Institutional Research*

**Exhibit 3: Domestic formulations business to outpace IPM**



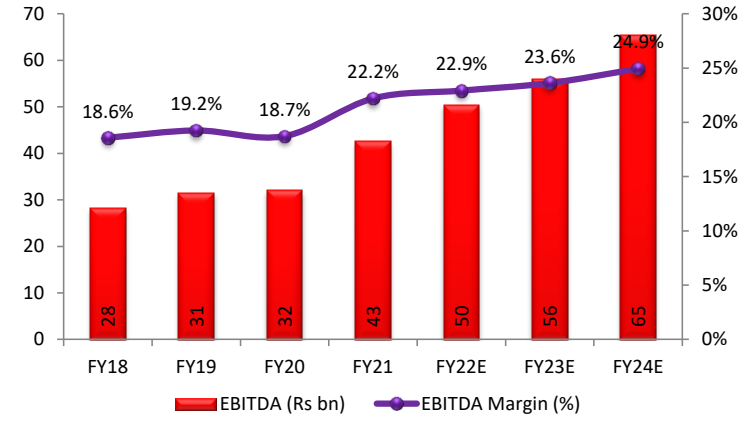

*Source: Company, Systematix Institutional Research*

**Exhibit 4: Launch of respiratory products to drive growth in US (Gx)**



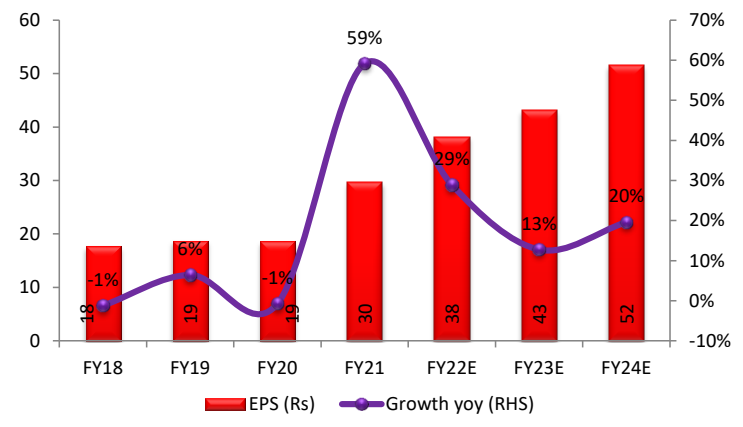

*Source: Company, Systematix Institutional Research*

**Exhibit 5: EBITDA margin to touch 25% levels in FY24E**



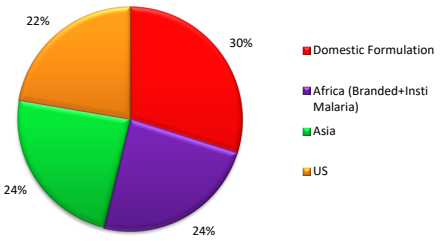

*Source: Company, Systematix Institutional Research*

**Exhibit 6: EPS CAGR of 16% over FY22-24E**




*Source: Company, Systematix Institutional Research*

**Business mix (%; FY21)**




*Source: Company, Systematix Institutional Research*

## Executive Summary

CIPLA is the second-largest inhaler selling company (MDI and DPI inhaler devices) globally, with a market share of 24.6% in the domestic respiratory segment and seven of its brands featuring in top-10 respiratory brands by value. Within IPM, the company ranks third with a market share of 5% and is the second-largest player in the Chronic ailments segment. It is also the market leader in respiratory and urology therapies with a share of 24.6% and 14.8% respectively, and fourth in cardiac therapy with a share of 5.4%. CIPLA's domestic business comprises trade (Gx) and consumer health (CHL), accounting for 20% and 5% of the overall domestic formulations revenues respectively. Over FY17-21, CIPLA's domestic formulations business grew at a CAGR of 9%, in line with IPM.

The company has registered revenue CAGR of 9%, EBITDA CAGR of 15% and EPS CAGR of 19% with a 360bps expansion in EBITDA margins backed by a strong balance sheet over FY18-21.

**More than half of business from branded exports, US and SA key markets**

Export formulations account for 55% of the company's revenues, with US and South Africa being the key markets. In the US, CIPLA has altered its strategy to build a front-end presence organically and through the acquisition of Hetero's US subsidiaries (InvaGen and Exelan in Sep-2015). Over the years, growth in the US has been led by its own filings, while Invagen revenues have been in the same range.

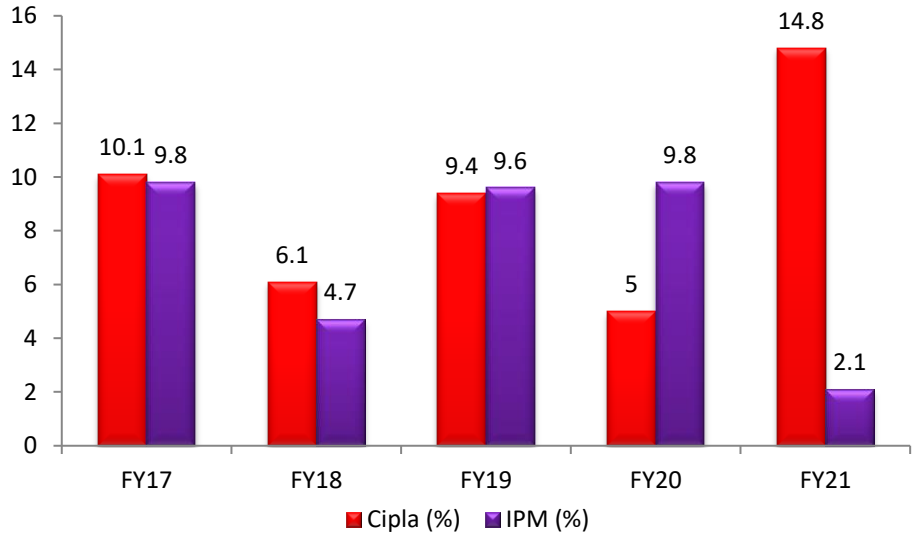
CIPLA plans to introduce new products in the US based on its own ANDAs every year while the focus will remain on unlocking value from respiratory products. The African private market constitutes 68% of the overall African market and accounts for 7% of the market share with top therapies, namely CNS, respiratory and gastrointestinal. The remaining part of revenues comes from HIV and anti-malaria tender businesses.

**Domestic inhaler franchisee to remain the backbone of India business**

CIPLA generates 30-35% of its overall domestic revenues (ex-COVID drugs) from inhalation products – this provides an inherent advantage vis-à-vis peers as: 1) inhalers are chronic products and usage is usually for a longer tenure, 2) barriers to entry are high due to complexity of drug-device combinations and stricter regulatory norms, and 3) lower Opex (mainly marketing costs) compared to Acute-focused companies due to stickiness of brands. The growth opportunity is large, given an estimated 90mn patients with respiratory illnesses in India with less than 10mn getting proper treatment. Further, only 30% of the patients in India use inhalers compared to 70% globally.

We expect CIPLA to maintain its leadership in the domestic inhalation segment and believe that there is a long runway for growth.

**Exhibit 7: CIPLA consistently outperforming IPM**




*Source: Company, Systematix Institutional Research*

**'One-India' strategy to strengthen consumer health business**

CIPLA consolidated its three domestic business segments – branded (Rx), trade (Gx) and consumer health (CHL) – under the 'One-India' model in FY20 to strengthen its domestic formulations business. The objective was to deepen and leverage the channel partnerships in tier 3 & 4 cities, expand product offerings and develop consumer connect. We believe the CHL segment would be the biggest beneficiary under the 'One-India' model as select consumer-oriented brands have been transferred from trade (Gx) to CHL. This would help CIPLA expand its consumer reach via distribution through OTC and FMCG channels like groceries, modern trade outlets and leading e-commerce platforms. We expect CIPLA's Indian formulations business to register 8% CAGR over FY22-24E.

**Launch of limited competition products in the US – future growth driver**

CIPLA has been working to build a promising respiratory product pipeline for the US market by leveraging its domestic market leadership. The company has already launched four respiratory products in the US, including high-value launches like gAlbuterol. It has guided for one respiratory product launch every year from FY23E, starting with gAdvair, possibly followed by gQvar and a partnered product in the subsequent years.

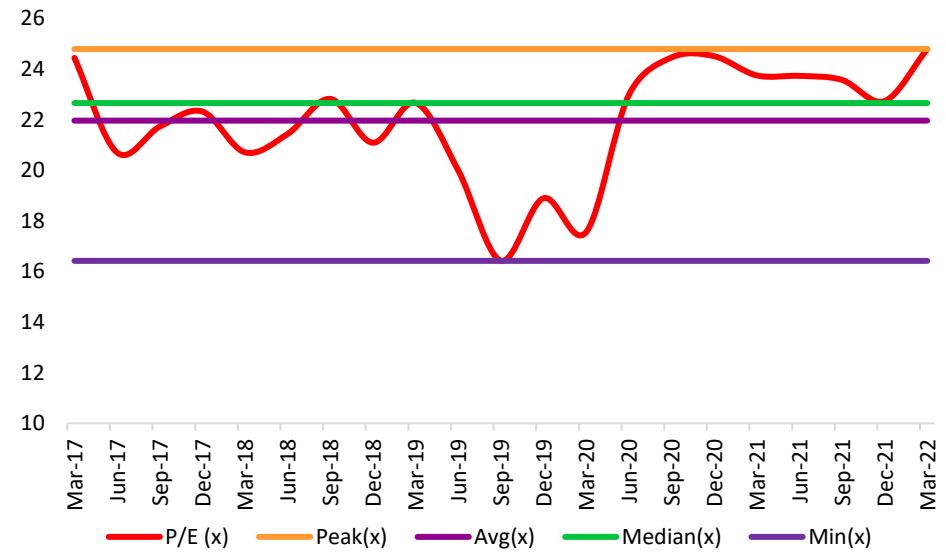
In addition to respiratory, CIPLA expects injectables to be a value driver going forward. The current US injectables base is small (estimated at <5% of US sales), but the recent approval of Lanreotide injection (a partnered product) should beef up the injectables portfolio. With a likely launch in Sep-22, gAbraxane is another product to watch out for in the near term. Overall, ~15% of CIPLA's pending pipeline is in the injectables space.

CIPLA expects the US business to add USD 300mn-500mn to its sales by FY25 driven by launch of limited competition and high-value products such as respiratory and injectables. We expect an 10% CAGR in CIPLA's US revenues over FY22-24E to USD 712mn, led by its pipeline of respiratory products and other limited competition products.

**Valuations and Outlook**

The stock currently trades at 20x its FY24E EPS – a 9% discount to its 5-year historical average of 22x earnings. With high visibility on key launches and a large contribution from branded markets, the risk to earnings seems muted. We assign a target price of Rs 1,185 to the stock, based on 23x FY24E EPS of Rs 52 – a 5% premium to its 5-year average valuation. We believe the outlook of 16% EPS growth, FCF generation of Rs 96bn and higher return ratios over FY22-24E should support premium valuations.

**Exhibit 8: P/E**




*Source: Systematix Institutional Research*

## Key Risks

**Delay in the launch of gAdvair**

CIPLA filed gAdvair with the regulator in May-20 and received CRL (Complete Response Letter) for the product. It has already replied to the CRL queries and is awaiting the regulator's response. Inhaler products usually go through multiple cycle reviews and final approval takes 18-24 months from the date of filing. Our base case scenario assumes the product to be launched in 1HFY23E. Any further delay would defer market share gains for the company and impact our estimates.

**Market share loss in gAlbuterol**

CIPLA has scaled up gAlbuterol since its launch in Apr-20 and currently has a 16% share in the overall Albuterol market (likely same as LPC's share). The gAlbuterol market has largely stabilized after the entry of Sandoz with no price erosion seen since then. However, the presence of several generic players does pose the possibility of a fight for market share turning into a price war and impacting CIPLA's profitability.

## Milestones

**Exhibit 9: Key milestones and events**

| 2010-2015 – A transformation journey with new management and their ideology of inorganic growth |
|---|
| 2013 – Dr YK Hamied stepped down as MD in Mar-13 and Mr Subhanu Saxena was appointed as CEO |
| 2013 – Acquired a 100% stake in CIPLA Medro |
| 2014 – CIPLA Medpro entered a sales and distribution arrangement with Teva to market its product portfolio in South Africa |
| 2015 – Acquired US-based companies InvaGen and Exelan Pharmaceuticals for USD 550mn |
| **2016-2020 – Focus on building respiratory product pipeline for the US and restructuring of India market** |
| 2016 – Mr Umang Vohra appointed as CEO after Mr Subhanu Saxena's exit |
| 2017 – Filed ProAir HFA (albuterol pMDI) in the US |
| 2020 – Filed Advair ANDA and consolidated India branded prescription, trade generics and consumer healthcare business as 'One-India' strategy |
| 2020 – Received approval for ProAir for the US market and settlement for Revlimid for launch in CY22 |
| **Three-year strategy over 2022-2024** |
| India to deliver above-market growth through focused execution of the 'One-India' strategy and enhanced patient connection through respiratory awareness campaigns |
| US market – launch of 4-5 limited competition products, including one inhalation each fiscal |
| South Africa – Launch of product backlogs and branded OTC expansion through partnerships |
| Emerging markets – Focus on DTMs and new frontier markets (China and Brazil) for organic growth; expansion of biosimilar partnerships in key markets |

*Source: Company, Systematix Institutional Research*

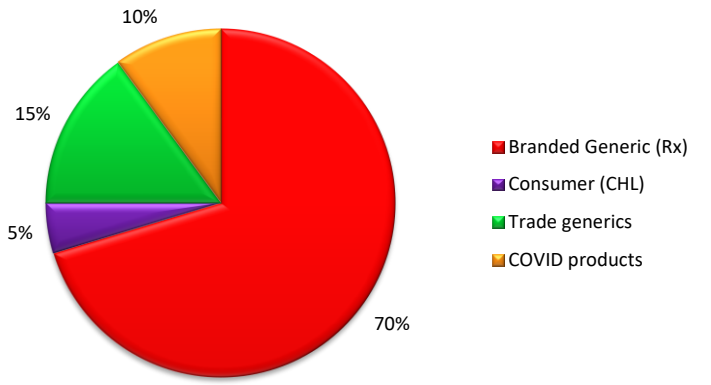
## Investment Analysis

**Domestic formulations remain the mainstay**

Within the domestic formulations business, CIPLA has three sub-segments – branded generics, trade generics and Consumer (CHL). In the branded generics segment, it has a dominant 3rd position with a share of 5.3% (Source: IMS) and the segment accounts for ~43% of revenues (contribution higher in FY22E due to COVID-19, ~40% normalized contribution). Of this, 55-60% of the business is from Chronic segments with a significant share of therapies like respiratory, cardiology and gynecological.

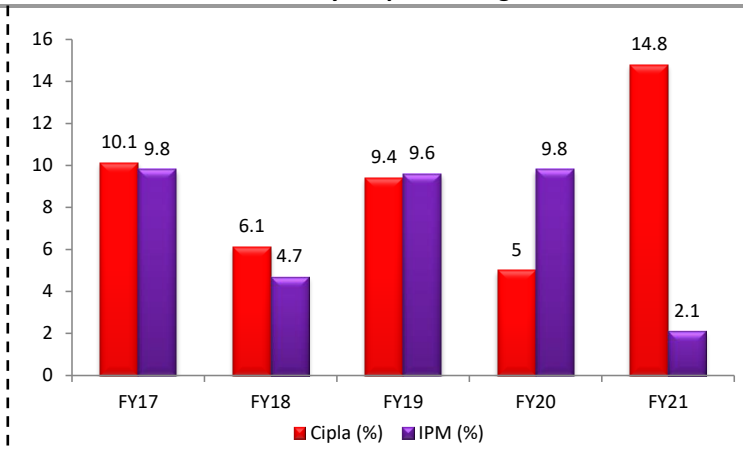
CIPLA has a leadership position in India's respiratory and urology segments with a market share of 24.6% and 14.8% respectively. While the company's performance lagged the industry average till FY18, the trajectory has changed in the last 3-4 years, aided by a strong product portfolio in cardiology and diabetes, sales force productivity and healthy volume growth (including generic-generic). It has a large sales force in the domestic market (7,000-8,000 MRs).

**Exhibit 10: Revenue mix for domestic formulations (%; FY21)**




*Source: Company, Systematix Institutional Research*

**Exhibit 11: CIPLA consistently outperforming IPM**




*Source: Company, Systematix Institutional Research*

**Key strategies to build the domestic business:**

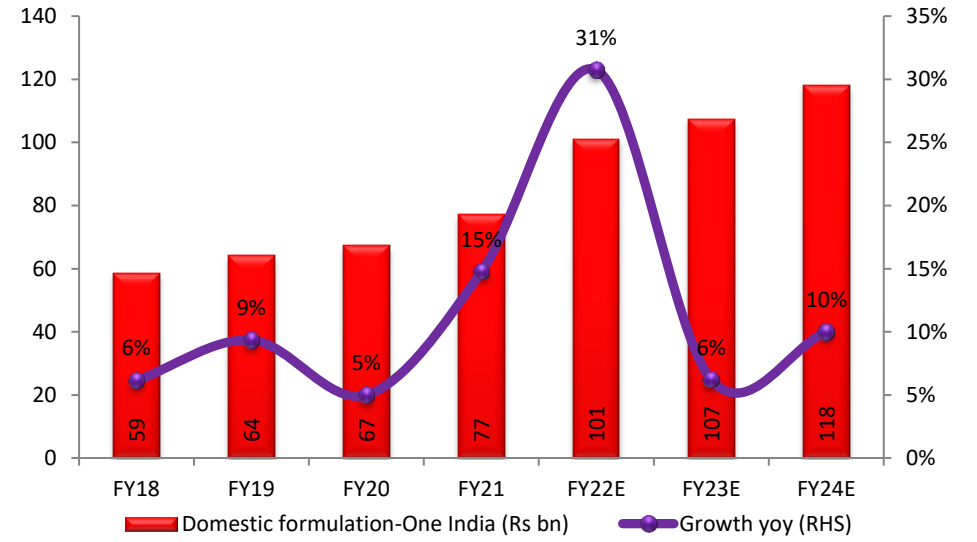
a) **Bolstering its geographical presence:** Over the last few years, CIPLA has centralized its model in India to create a team that addresses competition and speeds up the implementation of strategies. This should help improve the penetration of CIPLA's portfolio in tier 2 & 3 cities.

b) **Strengthening therapy leadership:** CIPLA is restructuring the field force to bring in more focus. The therapy-wise divisions will have key account managers focused on large specialists and hospitals rather than all MRs focusing on relevant doctors and GPs.

c) **Building a broader pipeline of products:** The company has increased focus on in-licensing (high-value segments like dermatology), which should support new product introductions in the market.

While the India business has benefited meaningfully from the sale of COVID-19 related drugs in FY22, the segment could see rationalization in FY23 with lower COVID cases. The key growth catalyst for domestic formulations would be: 1) outperformance in branded (Rx) led by strong inhalation franchises, and 2) increased coverage with deeper penetration in tier 3 & 4 cities through the 'One-India' strategy leading to growth in the trade generics and consumer (CHL) segments. We expect the Indian formulations business to register 8% CAGR over FY22-24E.

**Exhibit 12: 'One-India' growth trend over FY22-24E**



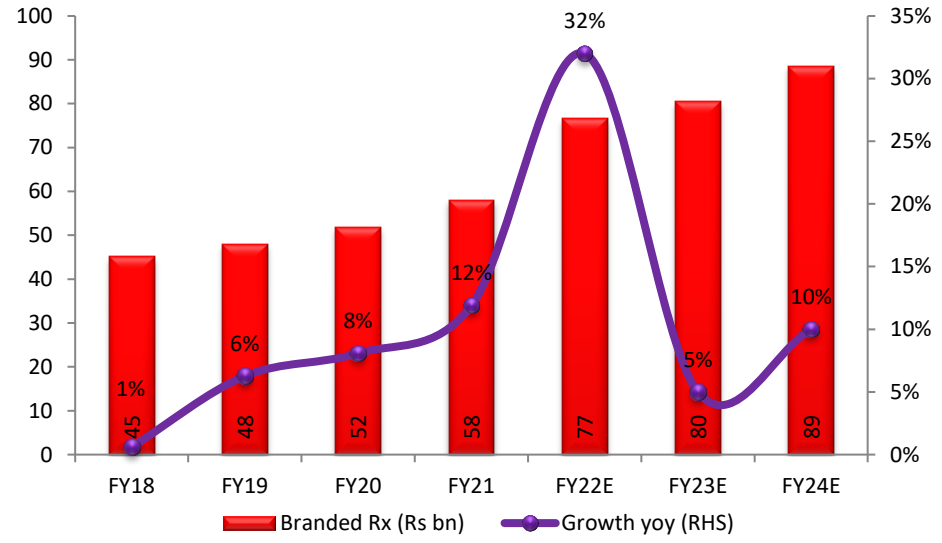

*Source: Company, Systematix Institutional Research*

## Strong domestic inhaler franchise offers sustainable growth

CIPLA has built a strong franchise in the domestic inhalation market, with a share of 24.6% in the respiratory segment (Lupin, the 2nd largest player, has a 6.5% share). While the respiratory market in India declined 8.4% in FY21 due to COVID-19, CIPLA's respiratory business grew 4.1%. The company generates 30-35% of its overall domestic revenues (ex-COVID drugs) from inhalation products – this provides an inherent advantage vis-à-vis peers as: 1) inhalers are chronic products and usage is usually for a longer tenure, 2) barriers to entry are high due to complexity of drug-device combinations and stricter regulatory norms, and 3) lower Opex (mainly marketing costs) compared to acute-focused companies due to stickiness of brands.

The growth opportunity is large, given an estimated 90mn patients with respiratory illnesses in India with less than 10mn getting proper treatment. Further, only 30% of the patients in India use inhalers compared to 70% globally. We expect CIPLA to maintain its leadership in the domestic inhalation segment and believe that there is a long runway for growth.

**Exhibit 13: CIPLA's branded (Gx) growth to be led by respiratory products**




*Source: Company, Systematix Institutional Research*

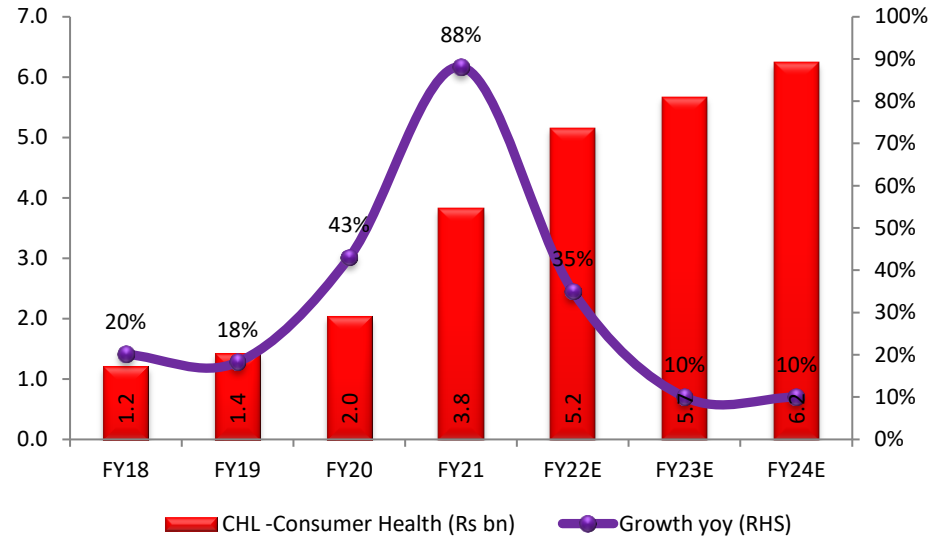
## 'One-India' strategy to strengthen CHL

CIPLA consolidated its three domestic businesses – branded (Rx), trade generics (Gx) and consumer health (CHL) – under the 'One-India' model in FY20 to strengthen its domestic formulations business. The objective was to deepen and leverage the channel partnerships in tier 3 & 4 cities, expand product offerings and develop consumer connect. We believe the CHL segment would be the biggest beneficiary under the 'One-India' model as select consumer-oriented brands are transferred from trade (Gx) to CHL. This would help CIPLA expand its consumer reach via distribution through OTC and FMCG channels like groceries, modern trade outlets and leading e-commerce platforms.

Over FY20-21, six brands with high consumer demand have been transferred from trade (Gx) to CHL, enabling the launch of these products' line extensions and, in turn, portfolio expansion. *Nicotex* and *Cofsils* are the key brands in the segment – the products have maintained their market position in the respective categories and reported strong revenue growth. *CIPLA ORS* and *Pregtest* have also been gaining momentum.

The CHL business achieved break-even in 1HFY22 and is now positively contributing to profitability. While adjusted growth for CHL's transfer products stood at 18% in FY21 (88% reported growth), we expect growth to normalize to 10% for the consumer segment over FY22-24E.

**Exhibit 14: CIPLA's CHL segment expected to continue growing in double digits**




*Source: Company, Systematix Institutional Research*

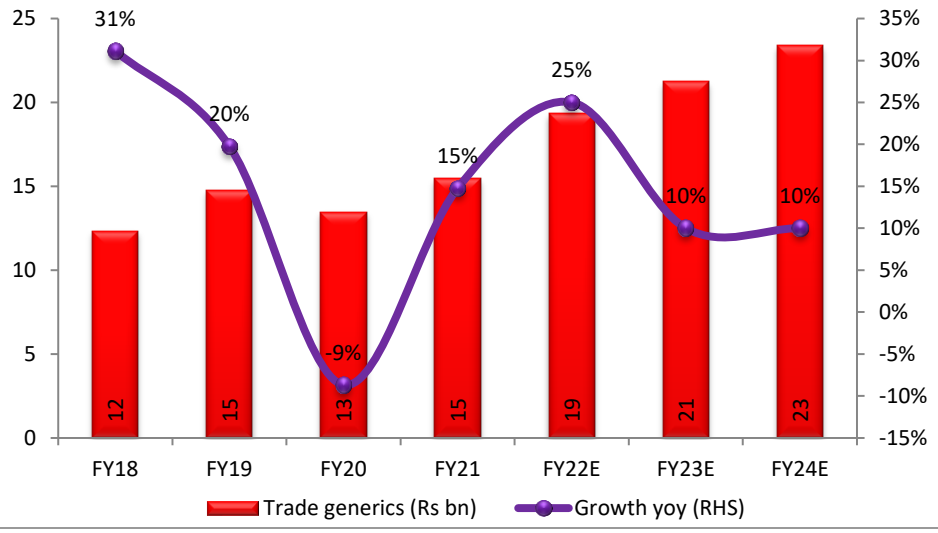
## Awareness program to drive Trade (Gx) demand

CIPLA is one of the oldest players (since FY16-17) in the trade generics segment, where products are pushed through channel partners and marketing efforts directed through higher margins rather than the ethical marketing route (i.e., doctors). Gx is one of the largest and fastest growing segments in India and contributes 18-20% to CIPLA's domestic revenues. The company remains a leader in this space, with the segment witnessing strong volume growth in tier 3 & 4 cities.

CIPLA has a wide reach of 15,000+ pin codes through a robust supply chain that includes ~5,500 stockists. The Gx business caters to 26 Acute and Chronic therapy categories, including 150+ brands and 11+ dosage forms. At least five brands in this segment are clocking sales in excess of Rs 1bn while another four earn sales of Rs 500mn-1bn.

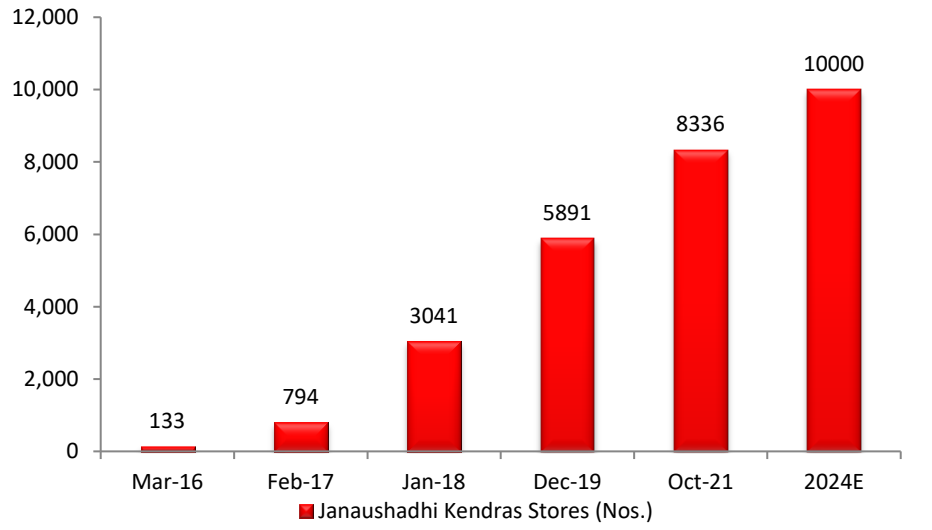
Despite a decline in FY20 as CIPLA undertook restructuring of its channel partners, it reported 13% revenue CAGR over FY17-21 in Gx. The company could be a key beneficiary of the increasing awareness about the Gx segment and the government's focus on *Jan Aushadhi scheme*, given it wide range of products and network reach compared to peers. We expect 10% revenue CAGR in Gx for CIPLA over FY22-24E.

**Exhibit 15: Growing awareness and adoption of cheaper drugs to benefit CIPLA**




*Source: Company, Systematix Institutional Research*

**Exhibit 16: *Jan Aushadhi* stores gaining momentum**




*Source: Systematix Institutional Research*

**Exhibit 17: Key players in trade generics segment**

| Company | Comments and details |
|---|---|
| **CIPLA** | Largest player in the Gx space with a contribution of 18-20% to domestic revenues |
| | |
| Alkem | 15% of domestic business from Gx |
| | |
| Ajanta | 10% contribution of Gx to domestic business; focus on the segment has declined over the years |
| | |
| JB Chemicals | Recent entry in the Gx segment |
| | |
| Eris | Entered the segment in FY21 with nominal capex |
| | |
| Torrent Pharma | Entered the space in 1QFY22; Gx currently contributes to 2% of domestic revenue |
| | |
| Fredun Pharma | Plans to enter 18 states by end-FY22 |

*Source: Company, Systematix Institutional Research*

## Respiratory product pipeline key catalyst for the US market

CIPLA initially adopted the more conservative partnership route in the US rather than establishing its front-end presence. However, the partnership model offered limited control on end-execution and resulted in CIPLA lagging peers in the region despite its early presence. Subsequently, in FY12/ 13, the company announced a major strategic shift by establishing a US front-end. It set up a team under the leadership of Mr Tim Crew (ex-Teva) and started filing ANDAs under its own label. The first products from its stable were launched in FY15.

In 2016, CIPLA acquired Invagen and Exelan Pharma for USD 230mn to bolster its US presence. This provided a portfolio of ~40 ANDAs (including 5 FTFs), 32 marketed products, a pipeline of 30 products and a manufacturing base in the US. Meanwhile, it also reclaimed products from its partners. Over FY20-22, its US business has been flattish (up ~6% CAGR), albeit on a high base of FY20 (given the limited-time opportunity of gSensipar). This can be assigned to a shift from B2B to DTC leading to a decline in the B2B segment and super-normal industry-wide price erosions in the US market.

**Respiratory and Injectables – the primary value drivers going forward**

CIPLA has been working on building a promising respiratory product pipeline for the US market by leveraging its domestic market leadership. It has already launched four respiratory products in the US, including high-value launches like gAlbuterol. It has guided for one respiratory product launch every year from FY23E, starting with gAdvair, possibly followed by gQvar and a partnered product in the ensuing years.

The company is also conducting phase 2 trials on a couple of complex inhalation products which, if successful, will add to the medium-term pipeline. Successful commercialization of respiratory products in the US will be the key growth driver for CIPLA, given the higher margins in the segment and lower pricing pressure and competition for inhaler products vis-à-vis oral solids.

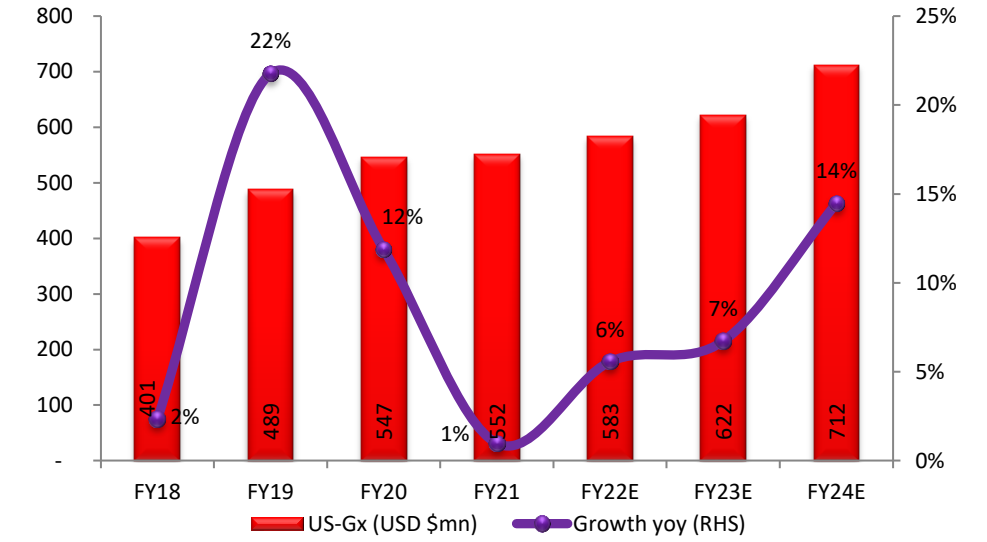
In addition to respiratory, the company expects injectables to be a value driver going forward. The current US injectables base is small (estimated at <5% of US sales), but the recent approval of Lanreotide injection (a partnered product) should beef up the injectables portfolio. Lanreotide is a highly complex depot injection with supportive competitive dynamics. Patents for the product have expired and there has been no other generic approval for this drug so far in the US.

The market size for Lanreotide is large (USD 867mn as per IQVIA). However, note that CIPLA's product is approved under the 505(B2) route and, hence, not interchangeable. We, therefore, see gradual market share gains and expect USD 80mn in revenues from the product in FY24E. The company has filed for two more peptide injectables. With a likely launch in Sep-2022, gAbraxane is another product to watch out for in the near term. Overall, ~15% of its pending pipeline is in the injectables space.

**Expect mid-teens growth in US business over FY22-25E**

CIPLA expects the US business to add USD 300mn-500mn to its sales by FY25, implying a double-digit CAGR (mid-teens) in the US. We believe a large part of this incremental growth will be driven by the respiratory portfolio and high-value injectable launches like gAbraxane. We expect a 10% CAGR in its US revenues over FY22-24E to USD 712mn, led by the pipeline of respiratory products and other limited competition products. Our base case scenario assumes gAdvair launch in 1HFY23E and a market share of ~15% by end-FY24E.

**Exhibit 18: US growth to be led by new respiratory launches**



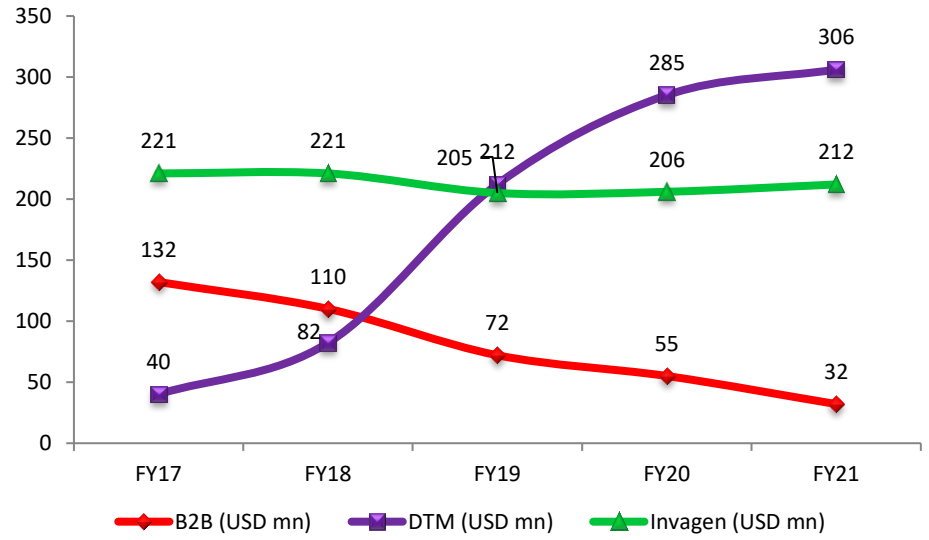

*Source: Company, Systematix Institutional Research*

**Exhibit 19: Product pipeline for the US**

| Brand (API) | Market size | Details | Current status | Potential launch date |
|---|---|---|---|---|
| **Advair HFA (fluticasone and salmeterol)** | USD 600mn-700mn | GSK was the product innovator and its last patent expired in 2016. Mylan (first generic Jan-CY19) and Hikma launched the generic while Lannett's application was accepted by the FDA. Lupin and Sandoz discontinued a trial while the latter took a USD 442mn impairment in CY-19 | Filed in May-20 with FDA and received CRL | 2HFY23 |
| | | | | |
| **Injectables** | - | Filed two partnered peptide injectables, one of which in an NDA application | Pending approval | FY23 |
| | | | | |
| **Inhaler** | - | CIPLA to launch one inhaler every fiscal starting with Advair in FY23E. Two inhaler products about to enter clinical trials | | FY24 |
| | | | | |
| **Tramadol IV** | ~USD 500mn | CIPLA invested USD 35mn post closure of stage 1 (Feb FY19). It acquired 5.8mn shares at USD 6 each for a 33.3% stake in Avenue Therapeutics on a fully diluted basis. Post the closure of stage-2, CIPLA will invest USD 180m to acquire remaining shares in Avenue Therapeutics | Received CRL for the same second time in Aug-21, stating concerns related to insignificant information if used against other pain killers | - |
| | | | | |
| **QVAR (beclomethasone dipropionate)** | ~USD 200mn | Teva received approval in Aug-17. CIPLA and Aurobindo are known filers for the product. Device patent is protected till 2031 | Innovator has sued generic filers and the launched is blocked | - |
| | | | | |
| **Abraxane** | ~USD 1.25bn | The patent expires in 2024 but CIPLA has guided for a launch in FY23E. BMS (Innovator) has also entered settlement with Teva for launch in 2022 | CIPLA is in the process of sharing more data with the USFDA | 2HFY23 |

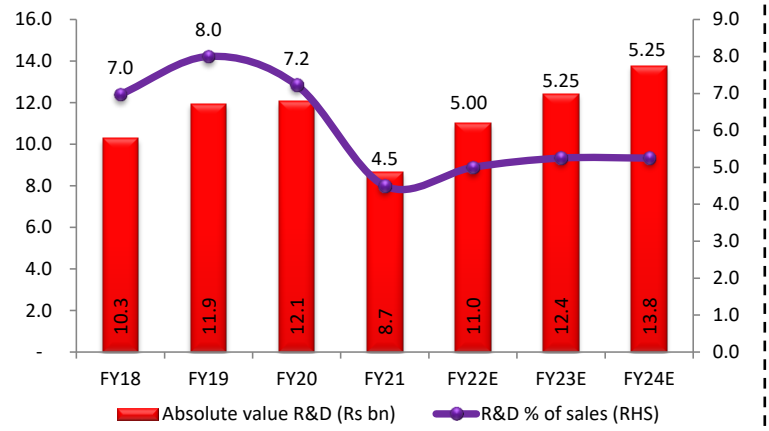
*Source: Company, Systematix Institutional Research*

**Exhibit 20: US formulations – CIPLA's business mix**



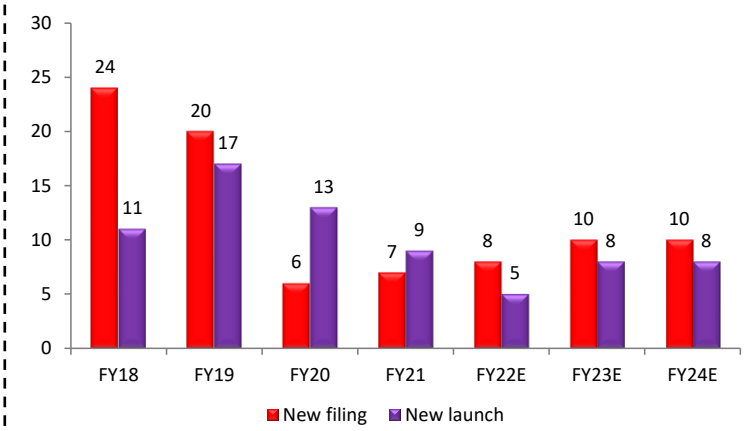

*Source: Company, Systematix Institutional Research*

**Exhibit 21: R&D spend trend**



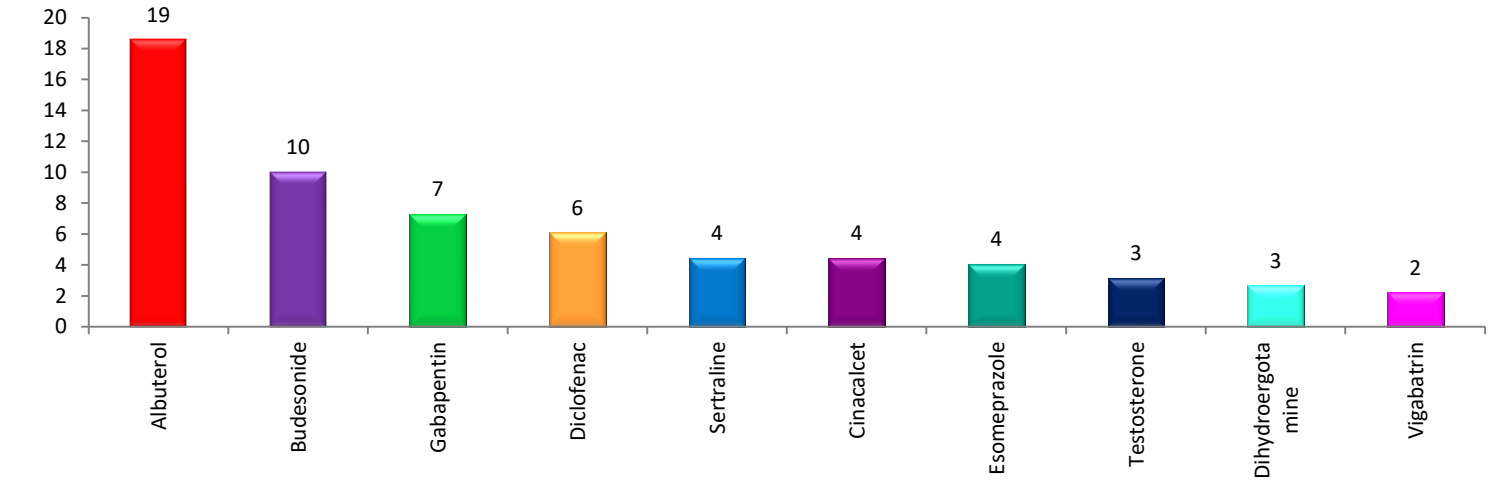

*Source: Company, Systematix Institutional Research*

**Exhibit 22: ANDA filing trend (nos.)**




*Source: Company, Systematix Institutional Research*

**Exhibit 23: Top-10 products in the US as % of US revenues in FY21**




*Source: Industry, Systematix Institutional Research*

**Exhibit 24: CIPLA's Para-IV filings**

| Brand | Molecule | Market Size (USD) | Innovator | Litigation filed | Patent expiry | Comments |
|---|---|---|---|---|---|---|
| Juluca | Dolutegravir Sodium/ Rilpivirine Hydrochloride (50mg and 25mg) | USD 335mn (9M-CY20) | ViiV Healthcare (GSK) | Jul-2020 | Oct-2027 | CIPLA and LPC the only two known filers for Juluca |
| Descovy | Emtricitabine / Tenofovir | USD 639mn (6M-CY21) | Gilead | Dec-2019 | Feb-2022 | LPC, Apotex, Shilpa Medicare, Sunshine Lake, Laurus, Natco, Macleods and Hetero are also known filers |
| Dovato | Dolutegravir and Lamivudine | USD 374mn (CY20) | ViiV Healthcare (GSK) | Nov-2019 | Oct-2027 | CIPLA the only ANDA filer for the drug till date |
| Synjardy XR | Empagliflozin/ Metformin | USD 374mn (IQVIA MAT Nov-20) | Boehringer Ingelheim | May-2019 | Apr-2027 | MSN Labs, Aurobindo, SUNP and LPC other known filers |
| Otezla | Apremilast | USD 2.2bn (CY20) | Celgene | Jun-2018 | Dec-2028 | Total 19 Para-IV filers. Amgen acquired Otezla from Celgene for USD 13.4bn deal from Celgene in Aug-19 |
| Trintellix | Vortioxetine | USD 270mn (CY20) | Takeda | Oct-2017 | Jun-2027 | 16 known Para-IV filers with Alkem, Amneal, CIPLA and Sandoz with tentative approvals |
| Kyprolis | Carfilzomib (Injection) | USD 710mn (CY20) | Onyx | 2016 | Dec-2027 | Court issued the decision by upholding validity of patent claims which would prevent CIPLA from selling generic until patent expiry |
| Qvar | Beclomethasone dipropionate-Inhalation | USD 250mn (CY20) | Teva | Oct-20 | May-31 | CIPLA and ARBP the only two filers |

*Source: USFDA, Industry, Company, Systematix Institutional Research*

## South Africa: A steady market for CIPLA

South Africa is CIPLA's third largest market. The company has strong presence in the branded (private market constitutes ~68% of its Africa revenues) and tender businesses. CIPLA has been present in this market for over two decades through its supply agreement with Medpro. CIPLA was the largest supplier of drugs to CIPLA Medpro, and later acquired Medpro in 2013 for USD 512mn. The acquisition has strengthened CIPLA's position in the South African branded market by establishing its front-end presence in pharma, OTC and animal healthcare. CIPLA is the third-largest OTC player in the private South Africa market with ~USD 90mn revenues currently.

**Making inroads in African markets through acquisition and JV route**

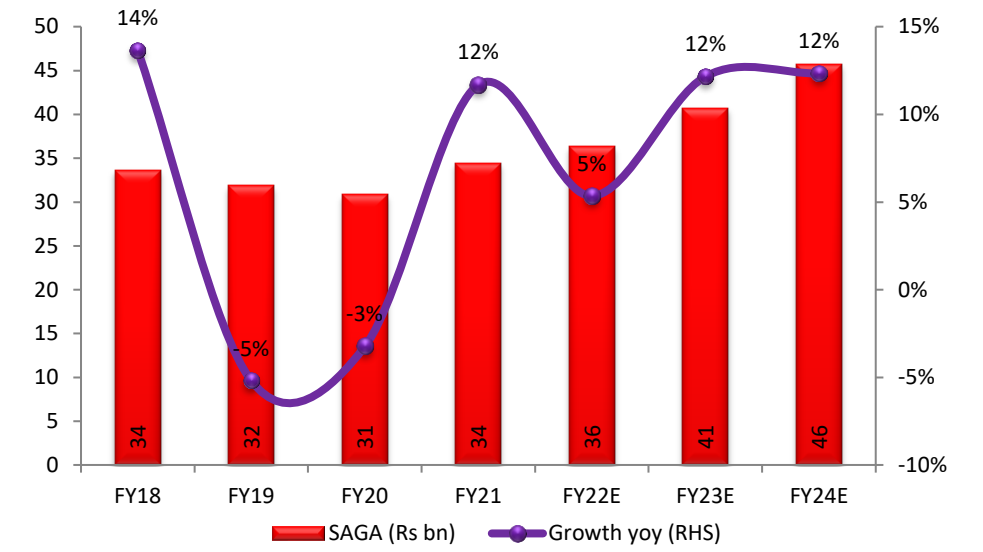
The acquisition has helped CIPLA strengthen its presence in other African markets (like North Africa, Uganda and other adjacent areas) by leveraging the existing product portfolio. CIPLA Medpro is among the Top-10 South African pharmaceutical companies focusing on chronic segments (generics and OTC). Further, CIPLA entered into a JV with Teva in South Africa, adding ~65 approved products in therapies like oncology, CNS, women's health, CVS and ophthalmology.

**Consistent pace of launches to support growth momentum**

Tenders, particularly ARV tenders, have been a crucial component of CIPLA's African business as also a growth driver. The company has, however, recently altered its strategy given increased pricing pressure in ARV tenders. To improve profitability, it is shifting away from the low-margin business to participate in HIV tenders on a case-to-case basis. The company is currently the largest ARV supplier by volumes in South Africa's private market, where it has consistently outpaced the market growth. We expect the momentum to continue given its strong positioning and consistent launches (38 in 9MFY22). We see limited growth in the tender business (in South Africa, other sub-Saharan Africa and global access business), as it bids only for higher-margin tenders.

CIPLA expects 10% CAGR in the global consumer health portfolio (India + South Africa) over FY22-24E. We factor in a 12% CAGR in Africa market for the company.

**Exhibit 25: Private market to drive Africa growth**



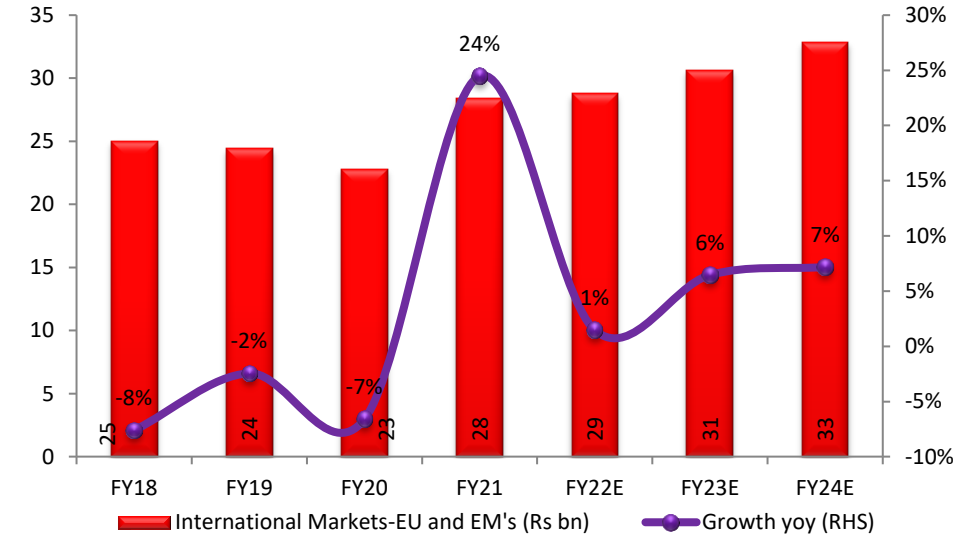

*Source: Company, Systematix Institutional Research*

## Respiratory and biosimilars to drive international business

CIPLA operates in EMs with a combination of DTM and B2B strategy, with respiratory products contributing 55-60% of EM revenues. It has been the leader in respiratory products in 10-15 DTM countries like Sri Lanka, Nepal and Morocco. The company is also present in Brazil, Malaysia, Colombia, Oman, Australia and New Zealand, with Brazilian operations focused on oncology products.

We believe the next leg of growth for CIPLA will come from value unlocking by launching respiratory products in China and biosimilars in EMs. It has entered into a JV with Jiangsu Acebright to set up a dedicated factory for respiratory products in China, which could begin commercialization from FY24E. Meanwhile, the launch of biosimilar products in new markets like Mexico, Saudi Arabia, Indonesia and Argentina should drive growth in FY23E. We estimate a 7% CAGR for CIPLA's International business over FY22-24E.

**Exhibit 26: International markets – expect 7% CAGR over FY22-24E**



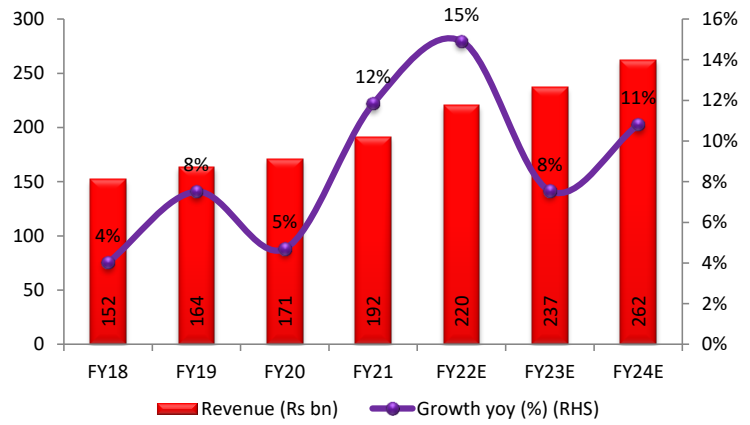

*Source: Company, Systematix Institutional Research*

## Financial Analysis

### Sustained growth momentum

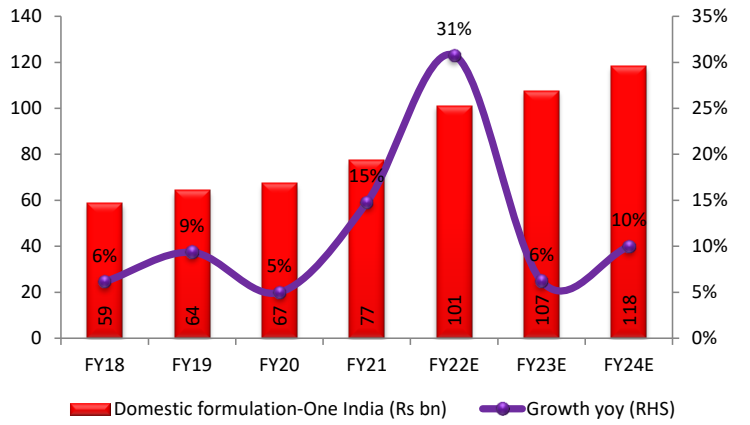
We expect 9% CAGR in CIPLA's revenues over FY22-24E, led by: a) 8% CAGR in 'One-India' with branded formulations outperforming the IPM, b) 10% CAGR in US (Gx) with the monetization of respiratory and complex products driving revenues of USD 712mn in FY24E, and c) sustained growth in international markets led by respiratory products in DTM and foray into China.

**Exhibit 27: Revenue CAGR of 9% expected over FY22-24E**



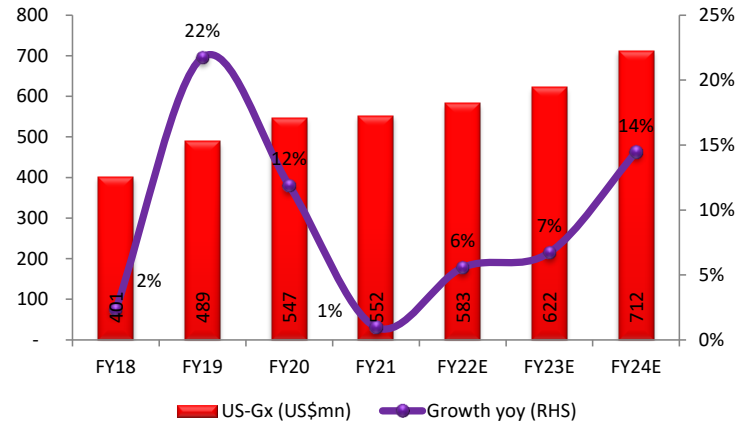

*Source: Company, Systematix Institutional Research*

**Exhibit 28: One-India growth led by branded generics**



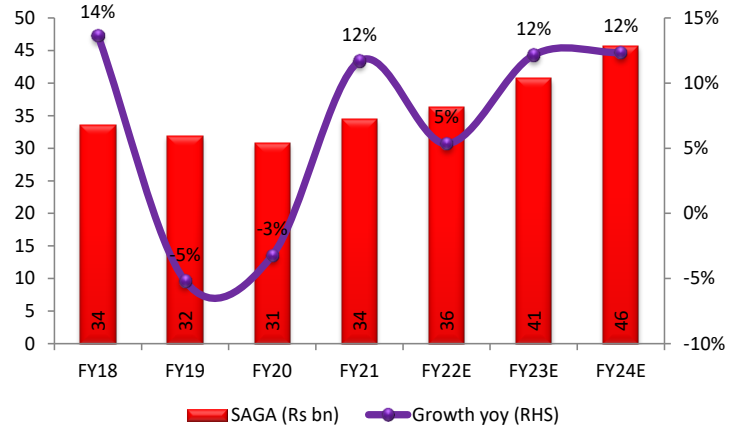

*Source: Company, Systematix Institutional Research*

**Exhibit 29: US (Gx) growth through launch of respiratory products**




*Source: Company, Systematix Institutional Research*

**Exhibit 30: South Africa growth to be driven by private market**

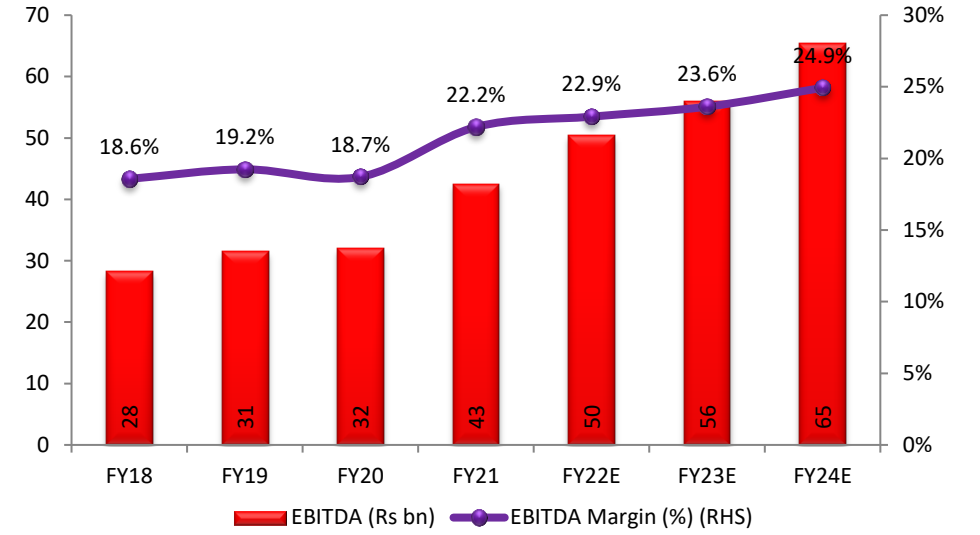



*Source: Company, Systematix Institutional Research*

## US growth to drive margin expansion, return ratios

We expect a large part of CIPLA's EBITDA margin expansion over FY22-24E to be led by sustainable growth in the US market on the back of launch of respiratory and limited competition products. R&D spending is also expected to be lower as clinical trials of most of its inhaler products have been completed. Integrating different business segments into the 'One-India' program would rationalize field force productivity and deepen its reach in lower-tier cities. We expect these factors to drive EBITDA margin expansion of 200bps to 25% over FY22-24E for CIPLA.

**Exhibit 31: Margin expansion on course with US (Gx) growth**

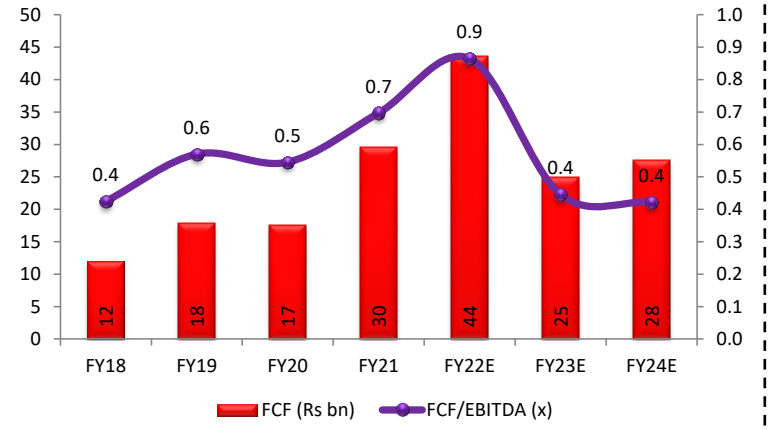



*Source: Company, Systematix Institutional Research*

### Lower capex with a track record of prudent capital allocation

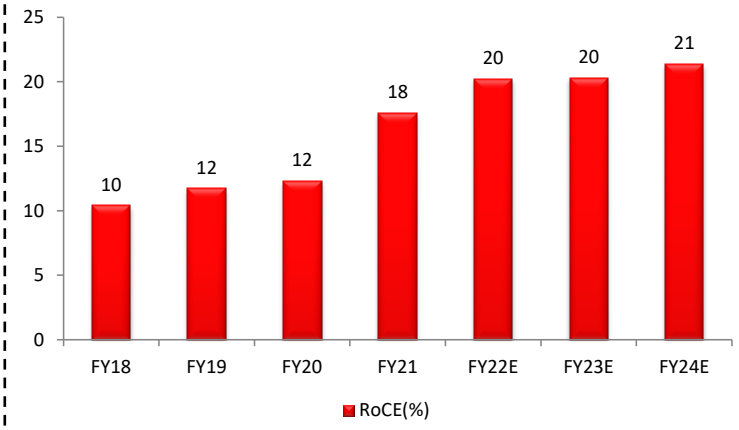
CIPLA has stayed away from large acquisitions in recent years, even as peers aggressively seeking inorganic growth. CIPLA's growth has primarily been driven by in-house developed products for the US market, tie-ups with global players for biosimilars in emerging markets and market share gains in existing products in the domestic market. Also, the company had lower capex needs given a sufficient capacity to meet the demand for growing products. We expect CIPLA to continue with its lower capex program, generating cumulative FCF of Rs 96bn over FY22-24E; with an improving US business, RoCE should increase to 21% in FY24E.

**Exhibit 32: Cumulative FCF of Rs 96bn over FY22-24E on lower capex**



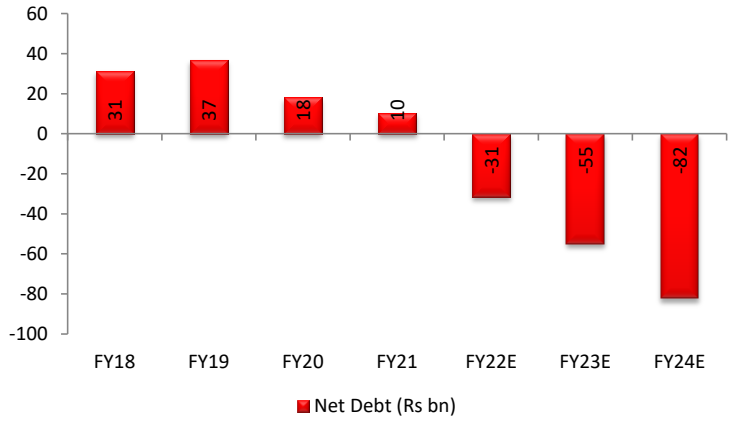

*Source: Company, Systematix Institutional Research*

**Exhibit 33: RoCE (%) to expand with improvement in US business**



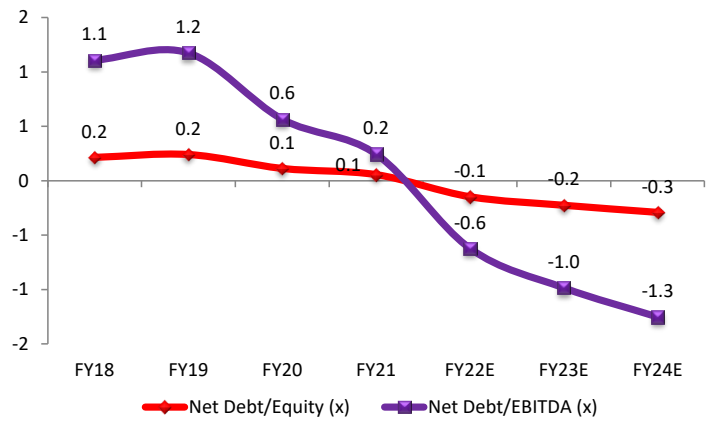

*Source: Company, Systematix Institutional Research*

**Exhibit 34: CIPLA to remain net cash positive**



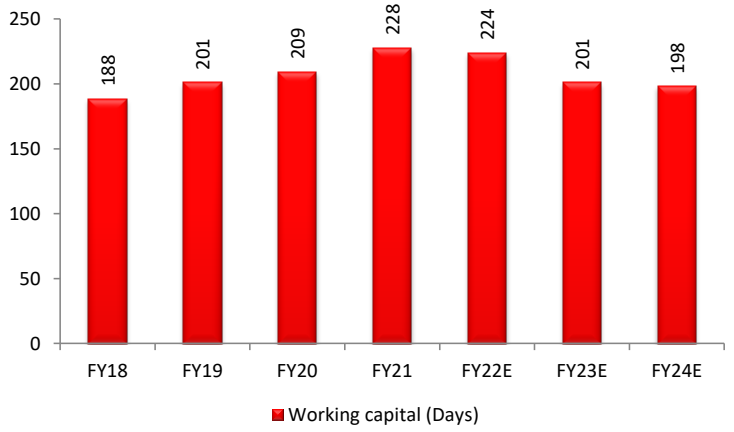

*Source: Company, Systematix Institutional Research*

**Exhibit 35: Consistent improvement in leverage ratio**



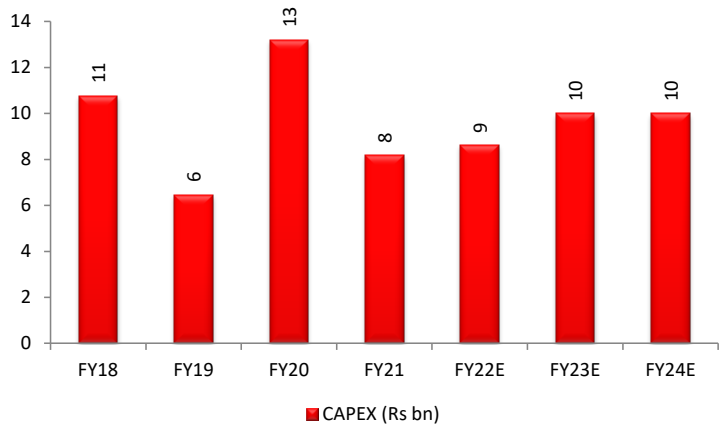

*Source: Company, Systematix Institutional Research*

**Exhibit 36: A shrinking Working Capital cycle**




*Source: Company, Systematix Institutional Research*

**Exhibit 37: Focus on organic growth to keep capex low**




*Source: Company, Systematix Institutional Research*

## Valuations & View

Given CIPLA's strong track record of US regulatory compliance, focus on organic growth and lower capex, its business model has always had a superior risk profile vis-à-vis peers. The company's growth has been driven by domestic formulations, while the US performance has lagged its own expectations due to delayed launch of complex and limited competition products. However, based on higher visibility on US business led by the guidance for launch of one respiratory product every fiscal and other limited competition products, we envisage a revenue CAGR of 9%, EBITDA CAGR of 14% and EPS CAGR of 16% over FY22-24E with EBITDA margin expansion of 200bps to 25% by FY24E.

The stock currently trades at 20x FY24E EPS of Rs 52, a discount of 9% to its 5-year average of 22x. We believe CIPLA deserves to trade at a higher multiple vs its historical average based on the improving business fundamentals:

a) Launch of one respiratory product every year in the US along with other complex products

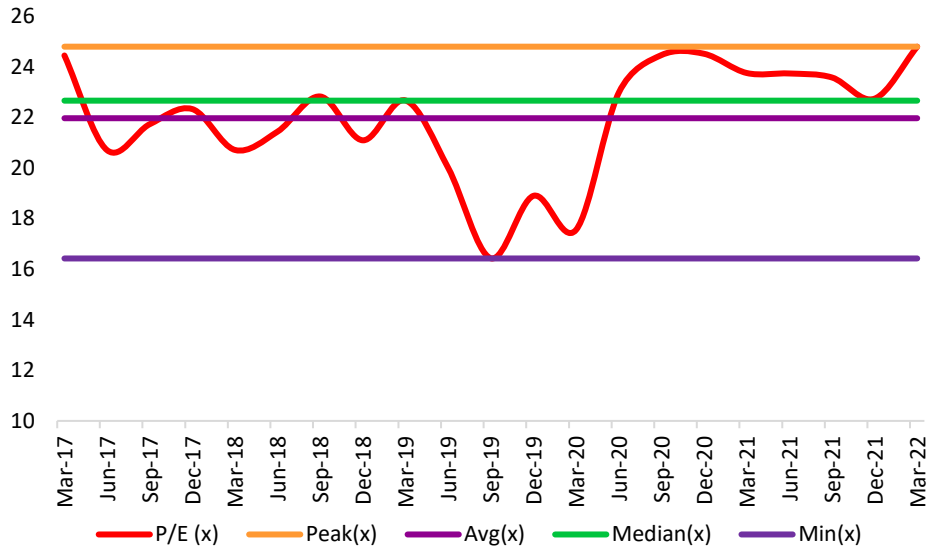
b) 'One-India' program driving growth in all Indian formulation business segments

c) EBITDA margin improvement of 200bps between FY22-24E, and

d) Cumulative FCF of Rs 96bn over FY22-24E and an improvement in RoCE to 21%

We initiate coverage on the stock with a **BUY** rating and assign a 23x multiple on FY24E EPS of Rs 52 to arrive at a target price of Rs 1,185.

**Exhibit 38: P/E**




*Source: Systematix Institutional Research*

# Annexures

## Company Background

CIPLA was incorporated in 1935 as Chemical Industrial & Pharmaceutical Laboratories Ltd by Mr Khwaja Abdul Hamied. In 1952, the company set up its first research division. In 1960, CIPLA's second plant in Vikhroli, Mumbai commenced operations to produce fine chemicals with particular emphasis on natural products. During the 1960s, multinational companies dominated the industry and monopolized the domestic market, controlling 80% of the sales volume.

Dr YK Hamied took control of CIPLA after his father Mr Khwaja Abdul Hamied's death in 1972. The enactment of the Indian Patent Act, 1970 in Sep-1972 was a major reform for the industry, giving domestic companies legal rights and freedom to manufacture and market within India almost any drug available internationally. This led CIPLA to launch 30 important drugs for the first time in India, including its first respiratory product Salbutamol and beta blocker Propranolol.

CIPLA was the first Indian company to get USFDA approval for its bulk drugs facility at Vikhroli, Mumbai in 1985. It was also the first to market the first anti-retroviral drug, Zidovudine, in India in early-1990s. Dr Hamied was enormously influential in pioneering the development of multi-drug combination pills, notably for HIV/ AIDS. CIPLA slashed the prices of HIV/ AIDS drugs in Africa (2001) to less than a dollar a day, breaking a Big Pharma stranglehold.

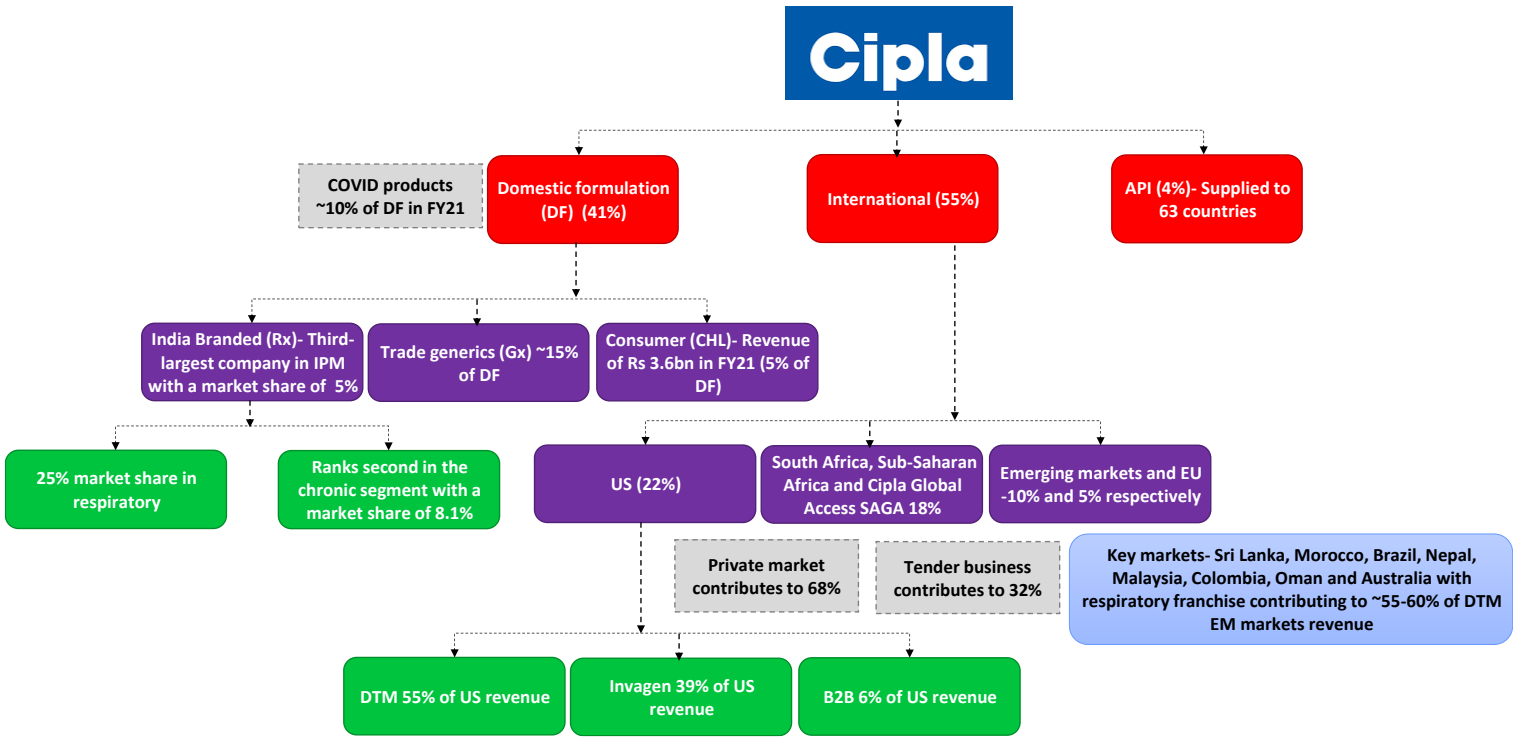
Dr YK Hamied stepped down as MD of CIPLA in Mar-13 (currently Chairman) and handed over the responsibility to the new CEO, Mr Subhanu Saxena, with a stated aim to increase CIPLA's international presence. Mr Saxena took the inorganic route towards the objective – and CIPLA acquired South-African distributor Medpro and two US-based companies, InvaGen Pharmaceuticals Inc and Exelan Pharmaceuticals, during his short tenure. He stepped down as CEO in Aug-16, citing personal reasons. CIPLA elevated Mr Umang Vohra (Ex Dr. Reddy's) as its CEO and MD – the first-ever executive outside CIPLA's promoter family to head the company. His focus has since been on scaling up investments to expand the product portfolio across regions.

**Exhibit 39: Key management personnel**

| Name of Person | Designation | Education | Roles and achievements |
|---|---|---|---|
| Mr Umang Vohra | Managing Director and Global CEO | Bachelor of Engineering in Computer Science from M.S. Ramaiah Institute of Technology. Master of Business Administration from TAPMI in 1996 | Appointed as a Global Chief Financial and Strategy Officer in Sep-2015; was elevated to CEO and MD in Aug-2015 post Mr Subhanu Saxena's exit His focus has primarily been on growth in the US and domestic market, with strict cost controls. Post his appointment as CEO, CIPLA exited ~30 low profitable regions and divested the animal business.<br><br>Previously, Mr Vohra has worked with Eicher Motors and PepsiCo before joining Dr Reddy's, where he headed its North American business |

*Source: Company, Systematix Institutional Research*

**Exhibit 40: Business segments**




*Source: Company, Systematix Institutional Research*

## Annual Report Analysis

**Exhibit 41: FY21 Annual Report Takeaways**

| | | | | |
|---|---|---|---|---|
| **Domestic Formulation** | Branded prescription business delivered above-market growth of 14%. Respiratory market in India declined 8.4%, while CIPLA's respiratory business grew 4.1%. Maintained leadership in urology and gained market share in dermatology, ophthalmology and oncology segments | Witnessed strong demand for organic products; traction in consumer brands continued post transfer from trade generics business; three brands transferred in FY21 | Entered an agreement with Roche for marketing and distribution of Oncology drugs – Herclon (Trastuzumab), Avastin (Bevacizumab) and Ristova (Rituximab); partnered with Boehringer Ingelheim to co-market three new oral anti-diabetics drugs | Over the past two years, six brands have been transferred to CIPLA Health (CHL - Consumer arm) including *Clocip, Naselin* and *CIPLAdine* in FY21 and *Prolyte ORS, Maxirich* and *Mamaxpert* in FY20. Adjusted for these, CHL's revenues grew 18% with annual revenues exceeding Rs2.25bn |
| | | | | |
| **US (Gx)** | CIPLA gained market share of 87% in gProventil, 16.5% in generic Albuterol HFA and 13.2% in overall Albuterol HFA | Institutional business under Exelan Pharmaceuticals scaled-up to over USD 100mn in FY21 and 13 new products launched by CIPLA | 7 ANDAs filed, including two peptide injectables through external partnerships of which, one is a new drug application. | Settled ongoing litigation for the launch of generic Revlimid while launch of IV Tramadol and Pulmazole was delayed due to regulatory issues |
| | | | | |
| **EMs and EU** | Largest player in Sri Lanka, Morocco and Nepal. Maintained top-3 position in other focus markets in volume and value terms. CIPLA forayed into new markets with first-time filings and tender bids across Mexico, Saudi Arabia, Indonesia and Argentina in FY21 | Expanded biosimilar partnerships with global pharmaceutical companies for platform play across key geographies like Australia, New Zealand and Algeria. Plans to enter two new front-end markets – Brazil and Spain | CIPLA's growth plans in China remained on track with manpower addition and equipment being installed at the construction site | Fluticasone Propionate Salmaterol (FPSM) pMDI market share is 20.8% and Beclomethasone 14% in UK. Also deepened presence in respiratory, oncology, complex injectables and ARVs segments |
| | | | | |
| **SAGA** | Sub-Saharan Africa business grew 13% YoY in USD terms, driven by strong commercial execution. CIPLA Global Access businesses grew by 38% YoY in USD terms on the back of higher orders | Largest OTC player in SA private market with market share of 7%. Top three therapies and market share in SA private market – Respiratory (12.2%), CVS (7.1%) and CNS (10.4%) | Partnered with Alvotech for marketing and distributing oncology products in South Africa. Rolled out 31 new products, including CNS and oncology products | The 3rd largest pharmaceutical corporation (Rx + OTC) within South Africa's (SA) private market with 7% market share; The 3rd largest ARV player in the private market with an 18.2% share |

*Source: Company Annual Report, Systematix Institutional Research*

## Plants details

**Exhibit 42: Goa facility**

*Source: Company, Systematix Institutional Research*

**Exhibit 43: Indore facility**


*Source: Company, Systematix Institutional Research*

**Exhibit 44: Plant details**

| Plant type | Location |
|---|---|
| API | Virgonagar, Old Madras Road, Bengaluru |
| | Bommasandra-Jigani Link Road, Industrial Area, KIADB 4th Phase, Bengaluru |
| | |
| API and formulations | MIDC, Patalganga |
| | MIDC Industrial Area, Kurkumbh |
| | |
| Formulations | Verna Industrial Estate-Goa |
| | Village Malpur Upper, P.O. Bhud, Nalagarh, Baddi |
| | Village Kumrek, Rangpo |
| | Indore SEZ, Phase II, Sector III, Pharma Zone, P.O. Pithampur |
| | Taza Block, Amba Tareythang Illaka, Rorathang |

*Source: Company, Systematix Institutional Research*

# FINANCIALS

### Profit & Loss Statement

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **Net Revenues** | **171,320** | **191,596** | **220,157** | **236,767** | **262,362** |
| YoY gr. (%) | 5 | 12 | 15 | 8 | 11 |
| Cost of Goods Sold | 59,914 | 73,519 | 84,761 | 89,971 | 99,698 |
| Gross Profit | 111,406 | 118,077 | 135,397 | 146,796 | 162,665 |
| Margin (%) | 65 | 62 | 62 | 62 | 62 |
| Employee Cost | 30,270 | 32,518 | 35,445 | 37,926 | 40,581 |
| Other Expenses | 49,076 | 43,034 | 49,490 | 52,954 | 56,661 |
| **EBITDA** | **32,060** | **42,524** | **50,462** | **55,916** | **65,423** |
| YoY gr. (%) | 2 | 33 | 19 | 11 | 17 |
| Margin (%) | 19 | 22 | 23 | 24 | 25 |
| Depn. and Amort. | 11,747 | 10,677 | 10,074 | 10,774 | 11,474 |
| **EBIT** | **20,314** | **31,848** | **40,389** | **45,142** | **53,950** |
| Margin (%) | 12 | 17 | 18 | 19 | 21 |
| Net Interest | 1,974 | 1,607 | 1,066 | 666 | 506 |
| Other Income | 3,442 | 2,660 | 3,082 | 3,315 | 3,673 |
| **Profit Before Tax** | **21,782** | **32,901** | **42,404** | **47,790** | **57,116** |
| Total Tax | 6,312 | 8,888 | 11,449 | 12,903 | 15,421 |
| Effective tax rate (%) | 29 | 27 | 27 | 27 | 27 |
| **Profit after tax** | **15,470** | **24,013** | **30,955** | **34,887** | **41,695** |
| EPS | 19 | 30 | 38 | 43 | 52 |
| YoY gr. (%) | -1 | 59 | 29 | 13 | 20 |

*Source: Company, Systematix Institutional Research*

### Balance Sheet

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| Equity Share Capital | 1,613 | 1,613 | 1,613 | 1,613 | 1,613 |
| Res. & Surp. (Ex OCI) | 158,960 | 184,243 | 211,167 | 242,022 | 279,685 |
| **Net Worth** | **160,573** | **185,856** | **212,780** | **243,635** | **281,298** |
| Short term debt | 4,472 | 3,347 | 3,347 | 3,347 | 3,347 |
| Long term debt | 23,693 | 14,984 | 9,984 | 4,984 | 2,984 |
| Trade payables | 22,818 | 4,041 | 29,555 | 31,785 | 35,221 |
| Other Provisions | 12,578 | 22,877 | 21,747 | 21,747 | 21,747 |
| Other liabilities | 5,409 | 4,066 | 4,066 | 4,066 | 4,066 |
| **Total Liabilities** | **229,542** | **235,170** | **281,478** | **309,563** | **348,663** |
| | | | | | |
| Net block | 96,829 | 81,138 | 79,682 | 78,909 | 77,435 |
| CWIP | 8,245 | 9,689 | 9,689 | 9,689 | 9,689 |
| Other Non-current asset | 0 | 0 | 0 | 0 | 0 |
| Investments | 17,047 | 12,534 | 12,534 | 12,534 | 12,534 |
| Cash and Cash Equi. | 10,039 | 7,933 | 44,710 | 63,394 | 88,287 |
| Debtors | 38,913 | 34,457 | 55,848 | 60,062 | 66,555 |
| Inventories | 43,776 | 46,692 | 56,095 | 60,327 | 66,849 |
| Other current asset | 14,692 | 42,729 | 22,920 | 24,650 | 27,314 |
| **Total Assets** | **229,542** | **235,171** | **281,478** | **309,563** | **348,663** |

*Source: Company, Systematix Institutional Research*

### Cash Flow

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| PBT | 21,782 | 32,901 | 42,404 | 47,790 | 57,116 |
| Depreciation | 11,747 | 10,677 | 10,074 | 10,774 | 11,474 |
| Interest | -1,468 | 1,607 | -2,016 | -2,648 | -3,167 |
| Others | 2,663 | -977 | -1,280 | -150 | -150 |
| Working capital | 2,274 | 3,717 | 14,529 | -7,945 | -12,243 |
| Direct tax | -6,312 | -10,374 | -11,449 | -12,903 | -15,421 |
| **Net cash from Op.** | **30,685** | **37,550** | **52,261** | **34,917** | **37,609** |
| Net Capital exp. | -13,203 | -7,914 | -8,619 | -10,000 | -10,000 |
| Others | 14,242 | -15,958 | 3,082 | 3,315 | 3,673 |
| **Net Cash from Invt.** | **1,040** | **-23,872** | **-5,536** | **-6,685** | **-6,327** |
| Issue of share cap. | 1 | 1 | 0 | 0 | 0 |
| Debt changes | -14,998 | -10,835 | -5,000 | -5,000 | -2,000 |
| Dividend paid | -4,292 | -3,882 | -3,882 | -3,882 | -3,882 |
| Others | -10,096 | 1,548 | -1,066 | -666 | -506 |
| **Net cash from Fin.** | **-29,385** | **-13,169** | **-9,948** | **-9,548** | **-6,388** |
| **Net change in cash** | **2,340** | **509** | **36,777** | **18,684** | **24,894** |

### Ratios

| YE: Mar | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **Per Share (Rs)** | | | | | |
| EPS | 19 | 30 | 38 | 43 | 52 |
| CEPS | 33 | 43 | 51 | 56 | 66 |
| BVPS | 196 | 227 | 261 | 299 | 346 |
| DPS | 5 | 5 | 5 | 5 | 5 |
| **Return Ratio (%)** | | | | | |
| RoCE | 12 | 18 | 20 | 20 | 21 |
| RoE | 10 | 14 | 16 | 15 | 16 |
| **Balance Sheet** | | | | | |
| Net Debt: Equity (x) | 0.1 | 0.1 | -0.1 | -0.2 | -0.3 |
| Net Working Capital (Days) | 209 | 228 | 224 | 201 | 198 |
| **Valuation(x)** | | | | | |
| PER | 54 | 34 | 27 | 24 | 20 |
| EV/EBITDA | 0.6 | 17.3 | 15.6 | 13.6 | 11.2 |
| EV/Sales | 0.1 | 3.8 | 3.6 | 3.2 | 2.8 |

*Source: Company, Systematix Institutional Research*

| Revenue details (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **India formulations** | **67,410** | **77,360** | **101,147** | **107,429** | **118,172** |
| **US** | **38,740** | **41,090** | **43,900** | **46,654** | **53,400** |
| SAGA | 30,870 | 34,480 | 36,327 | 40,744 | 45,773 |
| International Markets | 22,810 | 28,390 | 28,804 | 30,663 | 32,862 |
| API | 7,520 | 7,980 | 7,980 | 8,778 | 9,656 |
| **Total** | **167,350** | **189,300** | **218,157** | **234,267** | **259,862** |

*Source: Company, Systematix Institutional Research*

# Dr. Reddy's Laboratories

28 March 2022

## Increased focus on branded generics

**INITIATING COVERAGE**

**Sector: Pharmaceuticals** **Rating: BUY**

**CMP: Rs 4,361** **Target Price: Rs 5,015**

**Stock Info**

| | |
|---|---|
| Sensex/ Nifty | 57,362/17,153 |
| Bloomberg | DRRD IN |
| Equity shares | 166mn |
| 52-wk High/ Low | Rs 5,614/ 3,655 |
| Face value | Rs 5 |
| M-Cap | Rs 725bn/ USD 9.7bn |
| 3-m Avg value | USD 24mn |

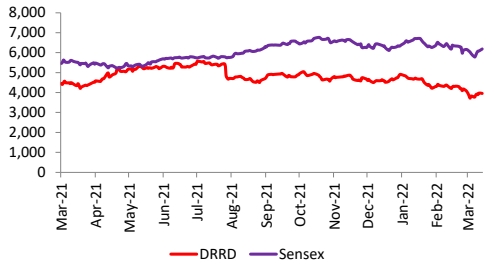
**Financial Snapshot (Rs mn)**

| Y/E March | FY22E | FY23E | FY24E |
|---|---|---|---|
| Revenue | 210,461 | 225,335 | 240,178 |
| Gross profit | 111,965 | 122,807 | 132,098 |
| Gross Margin (%) | 53 | 55 | 55 |
| EBITDA | 45,007 | 52,471 | 58,221 |
| Margin (%) | 21 | 23 | 24 |
| PAT | 28,042 | 33,136 | 37,311 |
| EPS | 172 | 202 | 228 |
| DPS (Rs) | 25 | 30 | 35 |
| RoCE (%) | 14 | 15 | 16 |
| P/E (x) | 25 | 22 | 19 |
| EV/EBITDA (x) | 17 | 14 | 12 |

**Shareholding pattern (%)**

| | Jun-21 | Sep-21 | Dec-21 |
|---|---|---|---|
| Promoter | 26.7 | 26.7 | 26.7 |
| –Pledged | - | - | - |
| FII | 29.0 | 27.7 | 27.4 |
| DII | 16.2 | 21.8 | 22.3 |
| Others | 28.1 | 23.8 | 23.6 |

**Stock Performance (1-year)**

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**Increased focus on branded generics**

**Dr. Reddy's (DRRD) has, in the last few years, shifted its focus to productivity improvement, implementation of strict cost control measures and increasing exposure to markets like India and China. We believe that price erosion in the US market should abate from FY23E onwards as channel inventory rationalizes. The US business is set to grow on the back of 25+ launches including high-value products like gRevlimid and possibly gCopaxone. We expect the sustained focus on improving efficiencies to drive a 15% earnings CAGR for DRRD over FY22-24E. We initiate coverage on the stock with a BUY rating and arrive at an SOTP-based price target of Rs 5,015 – valuing the core business at a 5-year average valuation of 21x FY24E EPS of Rs 228 and adding Rs 200 as NPV for the gRevlimid launch.**

**Out with the old, in with the new:** Under the leadership of Mr Erez Israeli, DRRD has changed its strategy to a razor-sharp focus on capital productivity and emphasis on branded businesses. India has become a more important market due to the steep price erosions in the US and delay in launch of key products on account of regulatory issues. Over the last few years, DRRD has replaced 18 of its top 25 personnel, mostly with internal candidates. The CEO is now involved in product selection and appraisals are more stringent with a steeper risk-reward. This has led to a much leaner organizational structure amid divestment of non-core facilities/ products.

**Changing business mix in favor of select emerging markets:** DRRD is gradually shifting its focus away from the US generics business to emerging markets like India and China. As a result, incremental capital allocation is largely to these markets for both organic and inorganic initiatives. With an early mover advantage in China and 80+ products eligible for fast-track approval, DRRD is set to be the biggest beneficiary of the relaxation in clinical trial norms set by the Chinese regulator. The share of India formulations in revenues remains much lower vis-à-vis large comparable peers. The company plans to grow this business through higher MR productivity, new launches and acquisition of promising brands. Russia, with ~8% share of revenues in FY21, is also an important market where it has strong presence in branded formulations and institutional biosimilars. However, the ongoing geopolitical concerns may hit near-term growth with no expected timeline for business to return to normal.

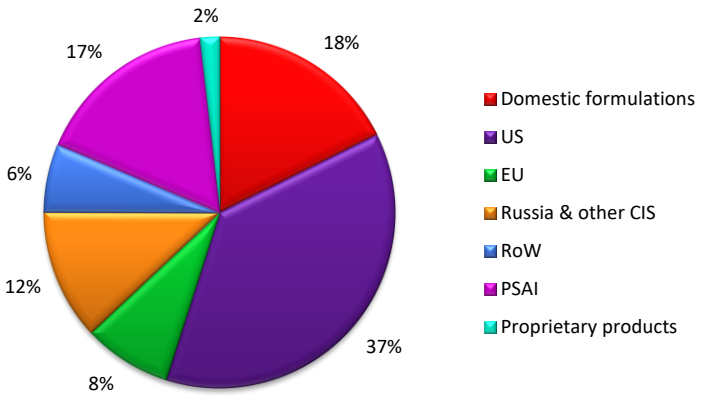
**Retained focus on cost control:** As seen for peers, DRRD too witnessed an erosion in its US business but managed to arrest the fall in margins by narrowing its focus on cost containment and rationalization of products/ facilities. Improving productivity at the organization level has been at the forefront in areas like procurement, R&D, sales force efficiencies, etc. Over FY17-21, a 3% compounded annual decline in SG&A expenses helped DRRD achieve close to its guided EBITDA margin of 25% even as peers struggled to sustain margins. Over FY22-24E, we expect a 15% earnings CAGR for the company, led by the sustained focus on efficiency.

**Initiating coverage with BUY:** At CMP, DRRD trades at 18x FY24E EPS of Rs 228 (ex-gRevlimid), a 14% discount to its 5-year average valuation of 21x. We value the stock on an SOTP basis by assigning a multiple of 21x core earnings of Rs 228 in FY24E and add Rs 200 as NPV from its gRevlimid launch (which has exclusivity on select dosages). We arrive at a 12-month target price of Rs 5,015 and initiate coverage on the stock with a BUY rating (no value assigned to its Sputnik vaccine agreement).

**Investors are advised to refer disclosures made at the end of the research report.**

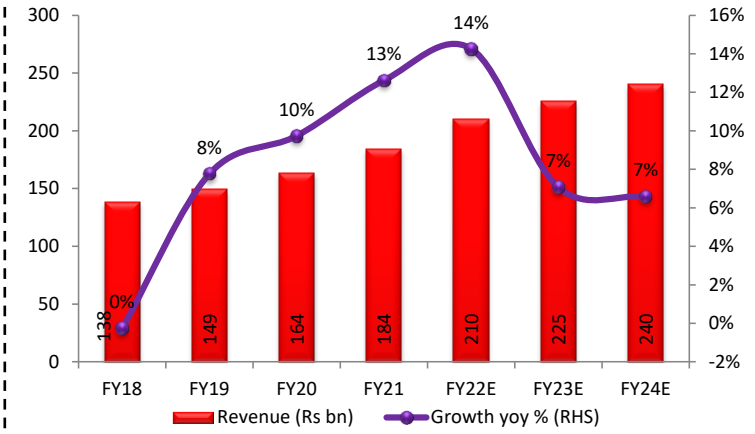
## Story in charts

**Exhibit 1: Business mix (%; FY21)**



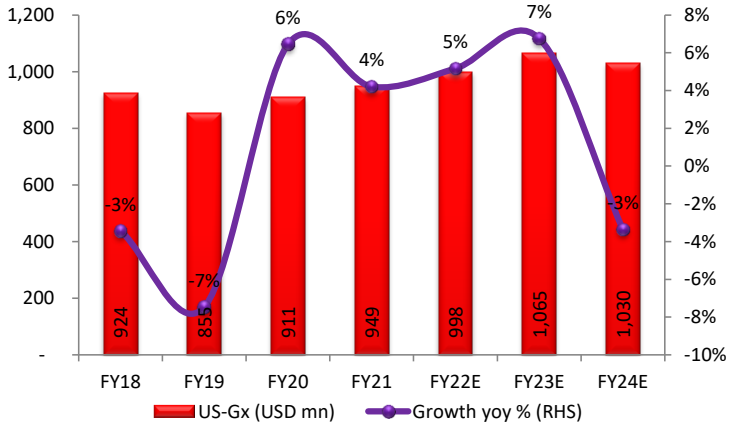

*Source: Company, Systematix Institutional Research*

**Exhibit 2 Revenue CAGR of 7% over FY22-24E**



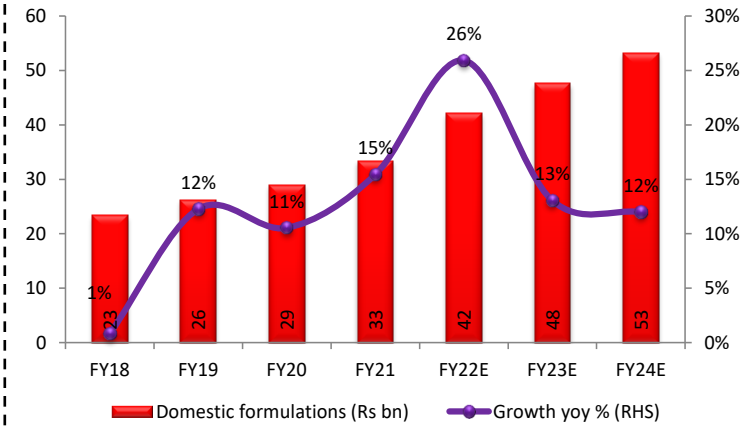

*Source: Company, Systematix Institutional Research*

**Exhibit 3: US growth to be led by high-value launches (ex-Revlimid)**



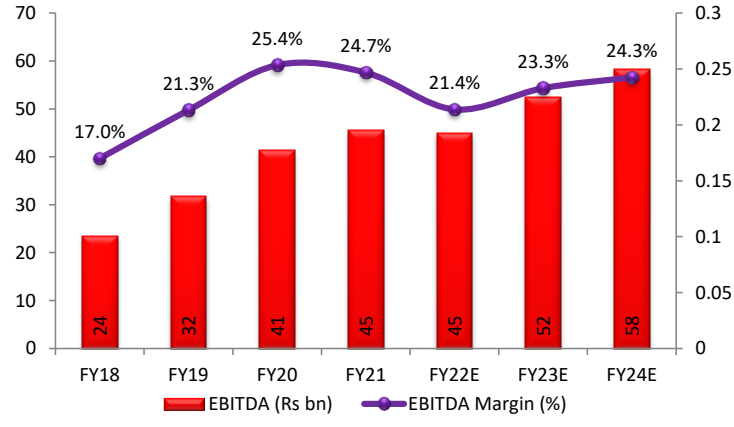

*Source: Company, Systematix Institutional Research*

**Exhibit 4: Increased focused on domestic formulations**



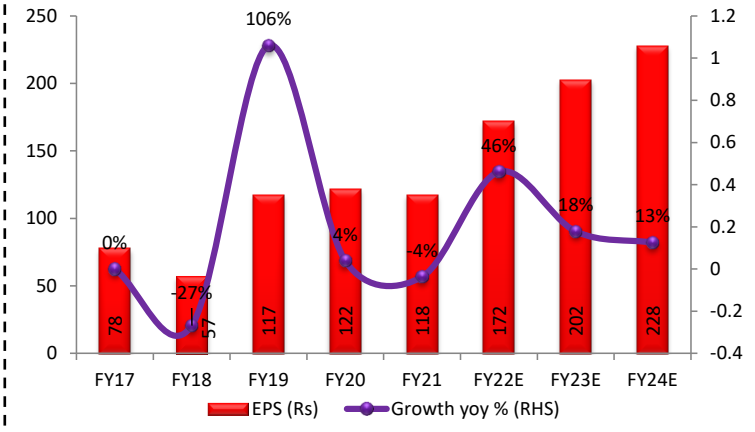

*Source: Company, Systematix Institutional Research*

**Exhibit 5: Cost control initatives to help margin expansion**




*Source: Company, Systematix Institutional Research*

**Exhibit 6: EPS CAGR of 15% over FY22-24E**




*Source: Company, Systematix Institutional Research*

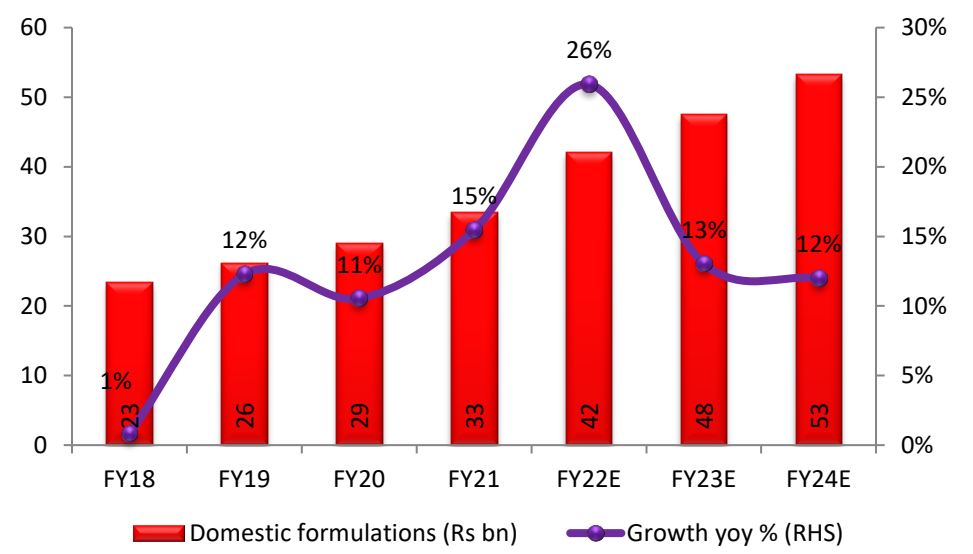
## Executive Summary

We believe DRRD is gradually transforming into a more efficient organization with a keen focus on capital productivity. The company has undergone a seismic change in the last few years with 18 of its 25 key managers replaced. The new management views the businesses from a different perspective. While earnings contribution from the US business remains significant, India, Russia, and China are now equally important markets; the company aspires to grow these businesses aggressively over the next five years and enter the league of top companies in the domestic market. It is well positioned in emerging markets such as China, CIS and Brazil to capture low-to mid-teens growth.

**Renewed focus on India market**

DRRD, while among the oldest players in India, has the lowest share of the industry vis-à-vis comparable peers (19% of its revenues in FY21 against 35-40% for the latter). We expect the company to take the inorganic as well as organic route to scale up its domestic formulations business, to ~25% share of total revenues by FY25E. With an estimated cumulative FCF of Rs 81bn over FY22-24E and its unleveraged balance sheet, we believe DRRD will actively scout for promising brands that can fill the gaps in its product portfolio. We expect its domestic formulations business to outperform IPM by 300-400bps and clock revenue CAGR of 13% over FY22-24E.

**Exhibit 7: DRRD – Domestic formulations to outperform IPM**




*Source: Company, Systematix Institutional Research*

**US Business – Concentration risk reducing**

The existing US portfolio seems largely stable with a lower concentration risk (top-10 products contribute 42% of US revenues). In terms of pipeline, we believe the recent, relatively stronger launches (gKuvan, gCiprodex, gVascepa and AG launch of gVasostrict) and 25+ guided launches including high potential gRevlimid and gCopaxone should support growth in the medium term. Over the last two years, new launches have contributed to an estimated USD 100mn of incremental sales every year for DRRD. FY22 has been an anomaly and recorded much higher price erosion than normal as channel partners focused on reducing inventory post the stocking up in FY21 due to COVID. We expect price erosion to revert to the normal 5-7% range in FY23 and expect a 2% revenue CAGR in DRRD's US business over FY22-24E.

**New management remains focused on profitable growth**

Over the last few years, 18 of the top 25 personnel at DRRD have been replaced mostly with internal candidates. The CEO is now involved in product selection and appraisals are more stringent with a steeper risk-reward. The new order at the company has led to a much leaner organizational structure amid divestment of non-core facilities/ products and, hence, a 3% compounded annually decline in Opex over FY17-21. Another big shift in strategy has been on the Specialty side, wherein DRRD is now limiting itself only to developing a molecule and then monetizing it.

The company has guided to sustaining margins at ~25%; based on the recent progress, we believe this will be achieved easily.

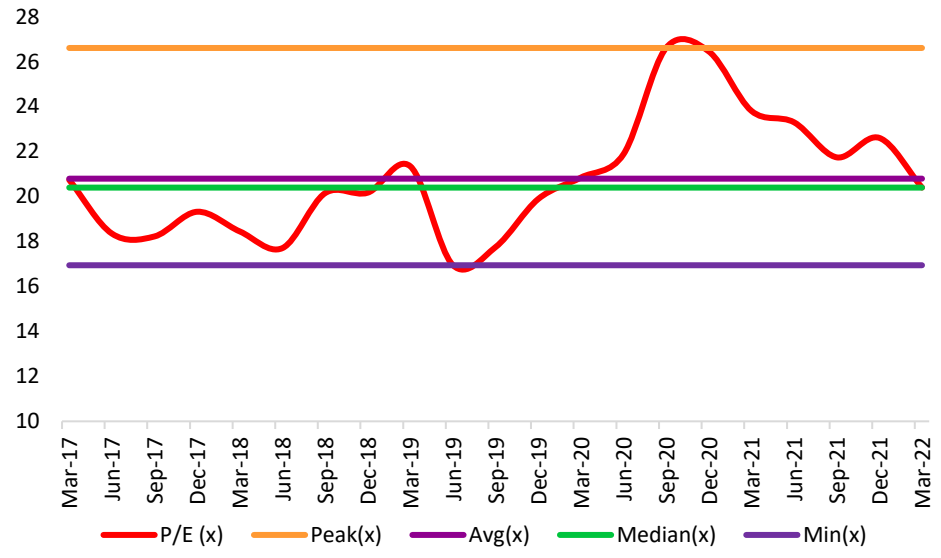
**Russia-Ukraine conflict – We build in a revenue decline of mid-single digit in FY23E**

The ongoing strife between Russia and Ukraine has prompted multiple sanctions against Russia. These, in turn, have led to RUB depreciation, restrictions in shipment of containers and a weak outlook for orders from Russia. These factors can potentially have an adverse impact on DRRD's performance in these markets. We estimate a 6-7% hit on this count to its earnings for FY23/ 24E. We build in a revenue decline of mid-single digit for the Russia and CIS regions business in FY23E and a normalization in FY24E.

**Valuations and outlook**

We initiate coverage on the stock with a **BUY** rating and arrive at an SOTP-based price target of Rs 5,015 by valuing the core business at 21x FY24E earnings of Rs 228 and adding Rs 200 as NPV for its gRevlimid launch (which has exclusivity on select dosages). The valuation is also supported by prospects of its value-accretive acquisitions in India and emerging markets. We do not assign any value to its Sputnik vaccine agreement.

**Exhibit 8: P/E**




*Source: Company, Systematix Institutional Research*

## Key Risks

**Further delay in launch of gCopaxone**

DRRD was the first player to file gCopaxone 40mg in CY14 but has been unable to secure final approval for the product as it has received multiple CRLs (Complete Response Letters) for it. With Copaxone currently a 3-player market, we believe it can potentially drive growth in DRRD's US business over FY23-25E. We assume an FY23 launch of gCopaxone with EPS contribution of Rs 10 in FY23E and Rs 20 in FY24E (included in our core earnings) for the company. Any delay in launch of the product would lead to a downward revision in our earnings estimates.

**Expensive acquisition of brands in domestic formulations**

With the increased focus on domestic formulations, we believe that DRRD would scout for acquisition of brands/ companies to expand its product offerings for the domestic market. Historically, acquisition of brands in the Indian market have been valued in the range of 4-5x EV/Sales. With other larger peers also looking to expand their product offerings, this valuation range may trend upwards, and the realized synergies could be lower due to the expensive acquisitions.

**Escalation of the Russia-Ukraine crisis**

DRRD generated 8% of its total revenues from Russia in FY21 with a large chunk of it coming from OTC and institutional biosimilars. The recent sharp depreciation in the RUB and the extent of the sanctions imposed on Russia have led to a price correction in the stock. While we have already built in a worst-case scenario in our assumptions, a further escalation of the issue could be a trigger for further earnings cut for FY23/ 24E.

## Milestones

**Exhibit 9: Dr. Reddy's – Key milestones and events**

| |
|---|
| **2015-2017 – Multiple issues hamper growth** |
| 2015 – Warning letter for three facilities |
| 2016 – Acquisition of eight ANDAs from Teva |
| 2016 – Write-down of outstanding receivables from Venezuela |
| **2018-2021 – Focus on cost control, resolution of regulatory issues and emphasis on non-US markets** |
| 2018 – Sale of API manufacturing business unit located in Jeedimetla (Hyderabad) and antibiotics facility in the US |
| 2019 – Divested three Proprietary products – Zembrace, Symtouch and Tosymra to Upsher |
| 2020 – Acquisition of 62 brands from Wockhardt |
| 2020 – Closure of warning letter of three sites (API-Srikakulum, Miryalguda, and Oncology-Duvadda) received since 2015 |
| 2021 – Enters into a definitive agreement with Citius Pharmaceuticals to sell its rights to anti-cancer agent E7777 (Denileukin Diftitox) |
| **Three-year strategy – 2022-2024** |
| Renewed focus on domestic formulations market with the objective to increase share in overall revenues |
| Launch of biosimilar products in Emerging Markets |
| Launch of the long-awaited Nuvaring and Copaxone in US market |
| EMs - Focus on DTMs and new frontier markets (China and Brazil) for organic growth and expansion of biosimilar partnerships in key markets |

*Source: Company, Systematix Institutional Research*

## Investment Analysis

**Out with the old, in with the new**

Under the leadership of Mr Erez Israeli, DRRD has seen a change in strategy with a razor-sharp focus on capital productivity and higher focus on branded businesses. India is now a more important market than the US due to steep price erosions there and delays in launch of key products arising from regulatory issues. Over the last few years, 18 of the top 25 personnel have been replaced – mostly with internal candidates. The CEO is now involved in product selection and appraisals are more stringent with a steeper risk-reward.

The new order at DRRD has led to a much leaner organizational structure amid divestment of non-core facilities/ products and, hence, a 3% compounded annually decline in Opex over FY17-21. Another big shift in strategy has been on the Specialty side, wherein it is now limiting itself only to developing a molecule and then monetizing it. The company has consciously refrained from commercial selling to save on upfront costs. Thus, while peers struggled to sustain margins over the last few years, DRRD has fared much better. The company has managed to broadly remain in the 25% margin range – in line with its internal target.

**Exhibit 10: Sweeping management changes at DRRD**

| Name | Current designation | Joined DRRD in | Experience (years) | Previous organization | Incumbent | Incumbent's designation |
|---|---|---|---|---|---|---|
| Erez Israeli | Chief Executive officer | Apr-18 | 25 | Executive Officer - Enzymotec | G.V. Prasad | Chief Executive Officer |
| Marc Kikuchi | CEO, North America Generics | Feb-19 | 25 | CEO - Zydus Pharmaceutical (America) | Alok Sonig | EVP and Head - North America Generics |
| Deepak Sapra | SVP and Head, PSAI | Jan-03 | 44 | Asst. Divisional Engineer - India Railways | Dr. K.V.S Ram Rao | SVP and Head - PSAI Commercial Organization |
| Sauri Gudlavalleti | SVP and Head - Integrated Product Development Organization | Mar-15 | 15 | Associate Partner - Mckinsey and Co. | Dr. Amit Biswas | EVP and Head - Integrated Product Development Organization |
| Dr Raymond de Vre | SVP and Head of Biologics | Jul-12 | 23 | Partner - Mckinsey and Co. | Dr. Cartikeya Reddy | EVP and Head - Biologics |
| Archana Bhaskar | Chief Human Resources Officer | Jun-17 | 30 | VP Human Resources for Royal Dutch Shell | Dr. S. Chandrasekhar | President and Global Head - Human Resources |
| Sanjay Sharma | Global Head of Manufacturing | Aug-17 | 29 | Integrated Supply Chain Operations for Coca Cola (India and South Asia | Samiran Das | EVP and Head of Global manufacturing Practices |
| Patrick Aghanian | CEO - European Generics | Oct-19 | 55 | Global Head of Zentiva | - | - |

*Source: Company, Systematix Institutional Research*

## Renewed focus on domestic formulations

DRRD, while among the oldest players in Indian pharma market, has the lowest share of the industry vis-à-vis comparable peers (19% of its revenues in FY21 against 35-40% for the latter). Till recently, the company has had its focus on building complex products for the US markets (Proprietary products). Further, the India portfolio is largely dominated by Acute therapies, wherein DRRD largely lacks leading market share except in Stomatologicals and GI. It also does not have any meaningful presence in high-growth therapies like cardiology and diabetology. With the new CEO Mr Erez Israeli at the helm, DRRD has shifted its focus to India and other EMs.

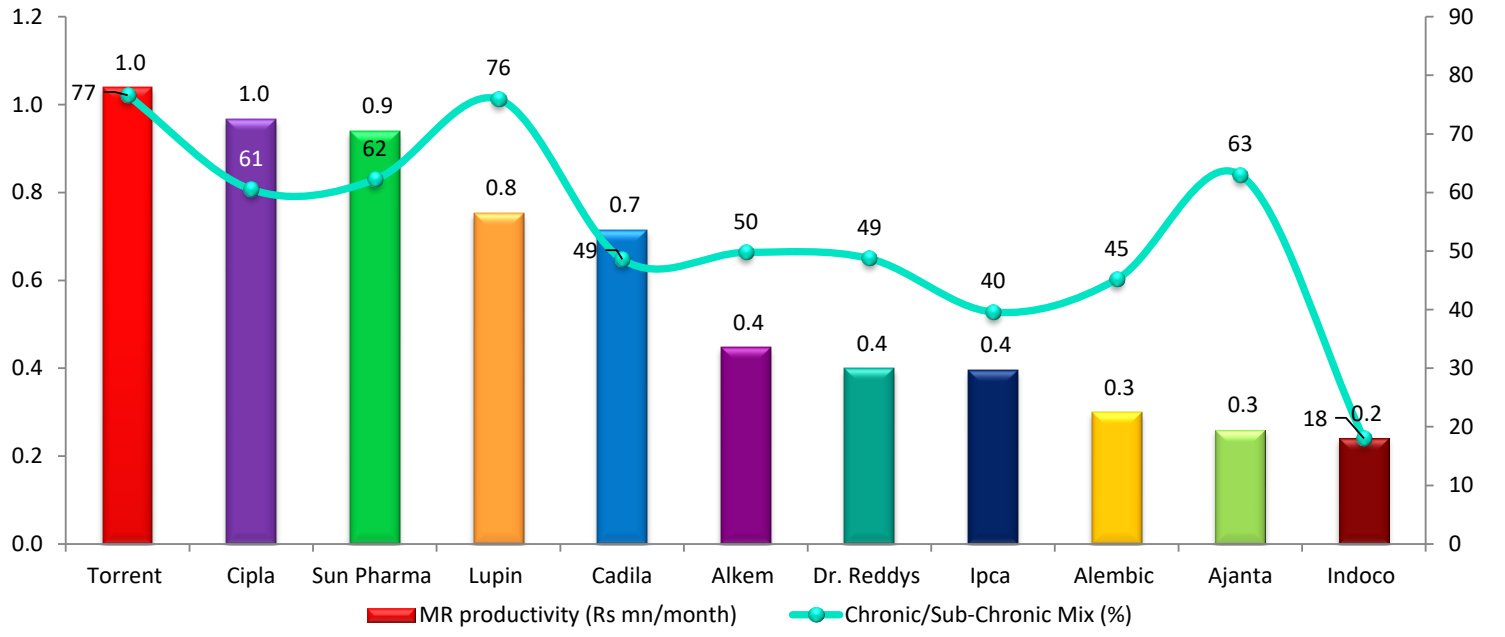
**Key focus areas for DRRD include**:

1) Improving MR productivity through deeper penetration in tier 2 & 3 cities – historically low-focus areas for the company
2) Expanding the product basket across therapies through new launches and acquisition of select promising brands, and
3) Launch of COVID-related products

DRRD has recently recorded strong growth in India and EMs, partially led by demand for COVID products. The company expects to sustain growth in these markets beyond the COVID-related demand through new product introductions as well as partnerships. The strategy entails focus on strengthening its presence in tier 4 cities with a dedicated field force, improved sales effectiveness, investments in R&D for new products, and building an OTC business.

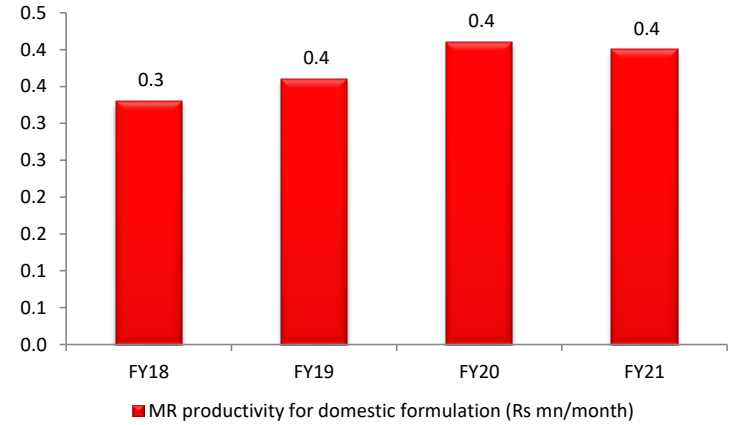
Growth in India and EMs is a top priority for DRRD. To this effect, it has undertaken leadership changes in these markets and expects to sustain above-market growth in India. Recent acquisition of Wockhardt's India portfolio adds to the scale, though it does not really swing the needle towards Chronic therapies.

**Exhibit 11: MR productivity – DRRD has a long way to go…**



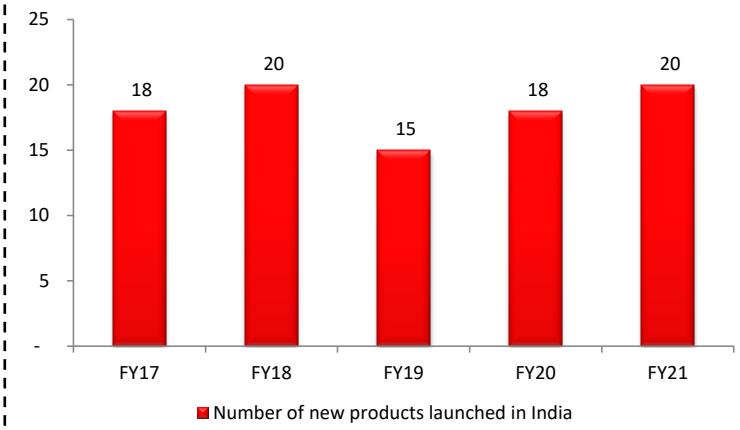

*Source: Company, Systematix Institutional Research*

**Exhibit 12: …despite improvement in the last four years**



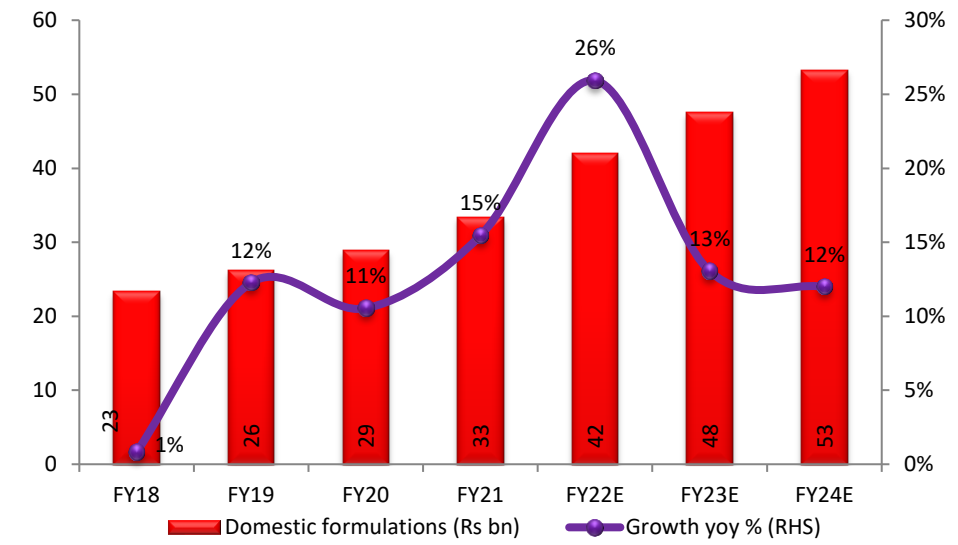

*Source: Company, Systematix Institutional Research*

**Exhibit 13: New launches in India market to pick up pace**




*Source: Company, Systematix Institutional Research*

**Exhibit 14: DRRD – Domestic formulations to outperform IPM**




*Source: Company, Systematix Institutional Research*

We expect DRRD to take the inorganic as well as organic route to scale up its domestic formulations business, to a much higher ~25% share in total revenues by FY25E. With an estimated cumulative FCF of Rs 81bn over FY22-24E and its unleveraged balance sheet, we believe the company will actively scout for promising brands that can fill the gaps in its product portfolio. We expect DRRD's domestic formulations business to outperform IPM by 300-400bps and clock revenue CAGR of 13% over FY22-24E.

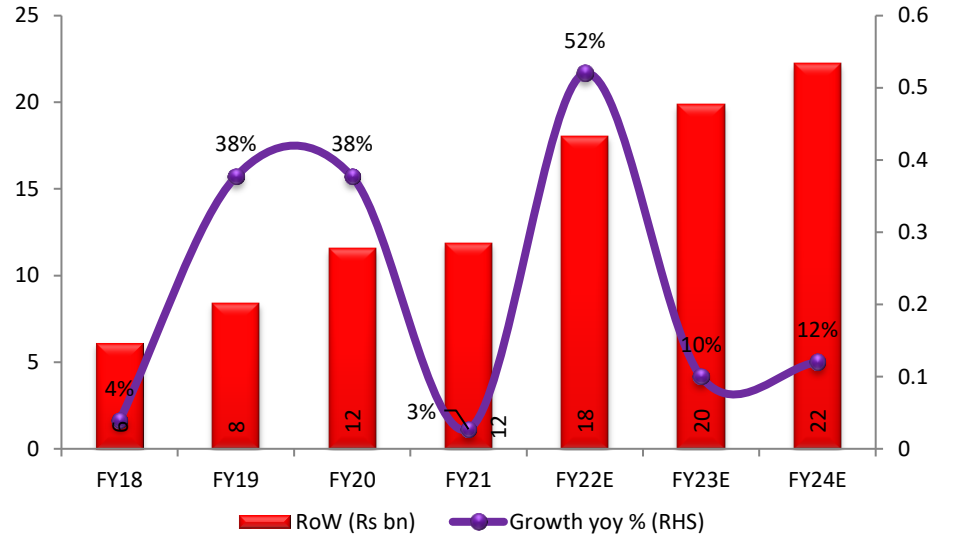
## Best positioned Indian player to capture China opportunity

Indian pharmaceutical companies have, of late, shown immense interest in China post relaxation of the country's drug approval process (clinical trial waiver for drugs already approved in the US, EU or Japan). DRRD is arguably the only Indian generics company with sizeable presence in two emerging markets – Russia and China – outside of India. We expect China to be a key growth driver for DRRD going forward.

While peers have recently laid down the roadmap to capitalize on the opportunity through JVs and tie-ups, DRRD already has revenues of ~USD 130mn in China. The company has a manufacturing facility in China for sale through Kunshan Reddy Pharmaceuticals (a JV). Besides, it is scaling up production at in-house India facilities to sell in China. To avail of the exemptions for conducting biostudies, DRRD is moving production of some of its products to contract manufacturers based in China.

DRRD, after winning a 2-year supply tender for Olanzapine, has become the first Indian company to win a tender in China for supply of drugs to public hospitals as also the first Indian company to launch an anti-cancer drug, Abiraterone, in China.

**Exhibit 15: China an important part of DRRD's growth strategy for RoW regions**




*Source: Company, Systematix Institutional Research*

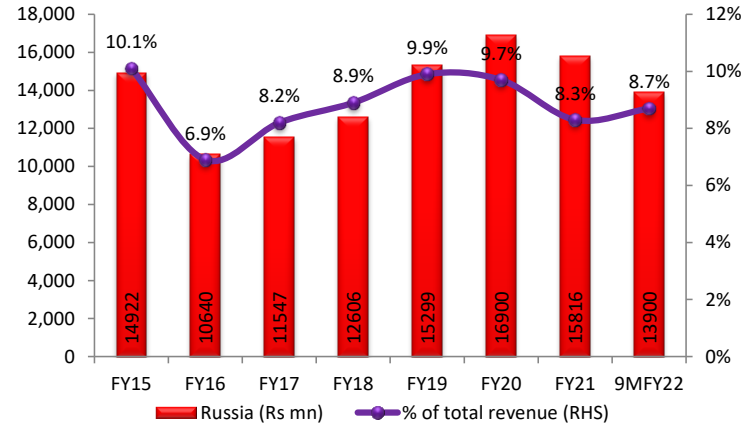
With various decisive reforms introduced by China to promote generic drugs and lower their prices, Indian players are looking to repeat the success achieved in the US market over the last decade. We believe DRRD is well placed to capitalize on this opportunity. The company has already identified 80+ products from its US portfolio that are eligible for launch in China with 10-15 already filed with the regulator and awaiting approval. China remains a large opportunity for the company, with a minimum 3-year time horizon for capturing any meaningful contribution. We are not building in any significant upside from China in our FY23/24E assumptions as filings from Indian facilities could take 3-4 years to launch.

## Impact of Russia-Ukraine conflict may last longer than expected

While the contribution of Ukraine (2% of FY21 revenues) in DRRD's total earnings and future growth remains insignificant, Russia (8% of FY21 revenues) is a key market for the company. Notably, 60-65% of its Russia revenues are derived from branded products, where growth has been steady on the back of price hikes every year and accelerated new product launches.

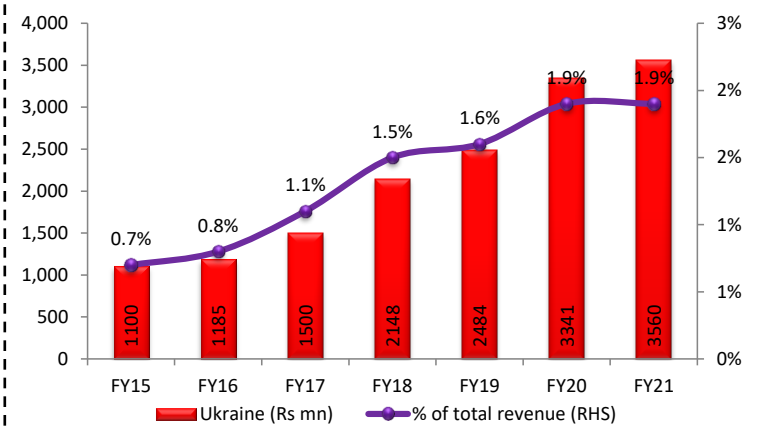
As per IQVIA, DRRD ranks 16th in terms of revenues in Russia with a market share of 1.7%, and the top-5 brands (Nise, Omez, Nasivin, Cetrine and Ibuclin) accounted for 62% of its retail sales in FY21. Its strategy in Russia is to focus on the gastro-intestinal, pain management, cough & cold, allergy and oncology therapies. The company has also built a strong presence in biosimilars (tender-driven) in EMs with four products already launched and three in different stages of clinical trials.

**Exhibit 16: Russia contribution to total revenues at ~9% in 9MFY22**




*Source: Company, Systematix Institutional Research*

**Exhibit 17: Ukraine contribution to total revenues at 2% in FY21**




*Source: Company, Systematix Institutional Research*

The ongoing strife between Russia and Ukraine has prompted multiple sanctions against Russia. These, in turn, have led to RUB depreciation, restrictions in the shipment of containers and a weak outlook for orders from the region. These factors, we believe, can potentially have an adverse impact on the company's performance in these markets.

**Below, we give DRRD's financial exposure to Russia and Ukraine:**

- Russia and Ukraine contributed 8% and 2% of total revenues respectively in FY21
- Overhead costs account for 25-30% of Russia revenues (RUB terms)
- EBITDA margins for the region are below corporate level
- Russian subsidiaries account for 1.5% of DRRD's total assets
- Cash flow hedge of RUB 5,875mn (35-40% of Russia revenues) as of Dec-22
- Net assets of foreign subsidiaries are completely hedged

**Impact of Russia-Ukraine conflict in the worst-case scenario**

We believe DRRD's earnings would take a hit from the Russia-Ukraine conflict given: 1) the recent 30-35% depreciation of RUB leading to a 20-25% lower repatriation value of revenues for the next 12 months – this is assuming DRRD maintains a hedge for 35-40% of its forecast revenues through forward contracts, 2) a complete loss of business from Ukraine in FY23/ 24E (2% share in total revenues in FY21), 3) lower shipments to Russia for at least the next two quarters resulting in a 30-35% drop in revenues, and 4) negative operating leverage weighing on EBITDA margin.

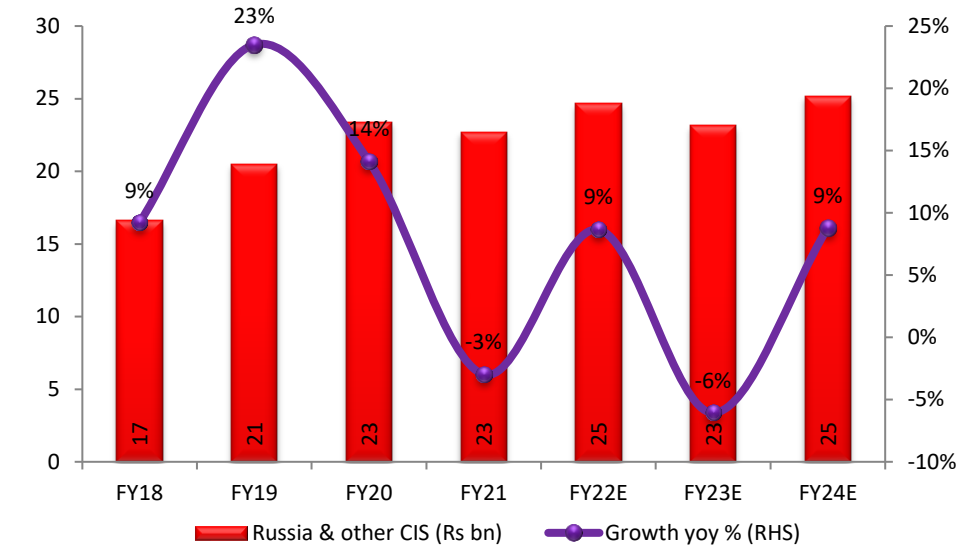
Building in the above assumptions, we expect DRRD's Russia and other CIS regions revenues to grow by merely 1% over FY22-24E with a decline of 6% in FY23E on account of a muted 1HFY23E and 9% growth in FY24E. We have assumed the worst-case scenario for its Russia/ Ukraine business in our estimates. Overall, we expect a 6-7% hit on DRRD's earnings for FY23/ 24E.

**Exhibit 18: Impact of Russia-Ukraine conflict – scenario analysis**

| | Assumptions | DRRD's total EPS (Rs) | | | Russia's contribution to EPS (Rs) | | |
|---|---|---|---|---|---|---|---|
| | | FY22E | FY23E | FY24E | FY22E | FY23E | FY24E |
| Best case | Russia growth story remains intact without any business impact | 175 | 210 | 236 | 15 | 16 | 18 |
| Base case | 4QFY22/ 1QFY23E growth declines by 30% YoY due to shipment issues; growth back on track from 2QFY23E with revenue increase of 15% in FY24E | 172 | 202 | 228 | 10 | 8 | 12 |
| Worst case | 4QFY22 and 1HFY23E growth lower by 30% YoY with a flattish; ~10% revenue growth in FY24E on a low base | 167 | 199 | 226 | 7 | 5 | 8 |

*Source: Company, Systematix Institutional Research*

**Exhibit 19: Russia-Ukraine conflict to weigh on growth**




*Source: Company, Systematix Institutional Research*

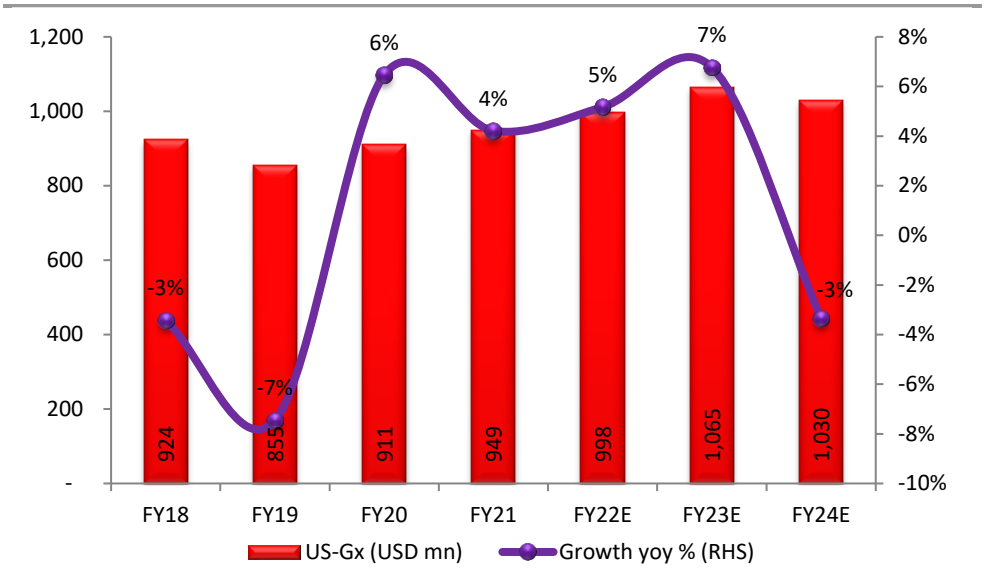
## US portfolio: Low risk of price erosion

US has been an important market for DRRD with the company focusing on creating a pipeline of difficult-to-make products (gFondaparinux, gAzacitidine, etc) in the past. While it saw good initial success with product exclusivities, channel consolidation and accelerated approval timelines resulted in an industry-wide price erosion emanating from higher competition.

DRRD reacted to the events by diversifying its pipeline with a larger number of lower-risk molecules. Significant emphasis is now being laid on R&D productivity under the stewardship of Mr Israeli, and unviable projects have been abandoned. In FY21, DRRD launched 27 products – in line with its new US portfolio strategy, with a target to launch 25+ products per year.

The existing US portfolio seems largely stable with lesser concentration (top-10 products contribute 42% of US revenues). In terms of pipeline, we believe the recent, relatively stronger launches (gKucan, gCiprodex, gVascepa and AG launch of gVasostrict) and 25+ guided launches including high potential gRevlimid and gCopaxone should support growth in the medium term.

**Exhibit 20: High value, limited competition products to support US business growth**



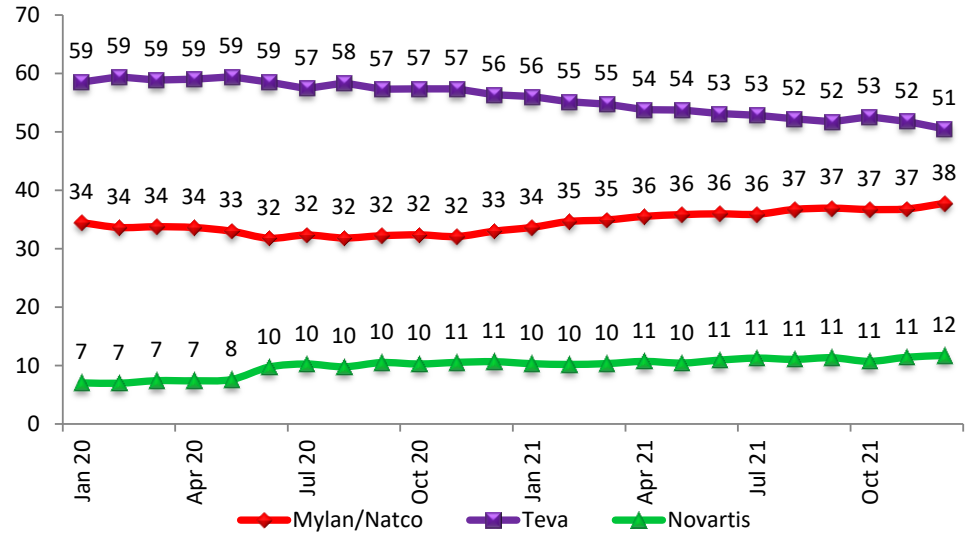

*Source: Company, Systematix Institutional Research*

Over the last two years, new launches have contributed an estimated USD 100mn incremental sales every year for DRRD. We believe FY22 has been an anomaly and witnessed much higher price erosion than normal as channel partners focused on reducing inventory post stocking up in FY21 due to COVID. We expect price erosions to revert to the normal 5-7% range in FY23 and thereby a 2% revenue CAGR in DRRD's US business over FY22-24E.

## Delayed/ Uncertain launch of the lucrative gCopaxone

DRRD's gCopaxone launch has been delayed beyond normal due to USFDA queries. However, we believe it is still an attractive opportunity as it remains a three-player market with the innovator dominating the market even after 36 months of launch of the first generic. There is currently no clarity on the launch timeline even as the Street expects the launch in FY23 (we factor in a 2HFY23 launch). Assuming the current market dynamics prevail at the time of DRRD's launch, we believe it can fetch USD 25mn-30mn and 50mn-55mn in revenues with an EPS contribution of ~Rs 4 and Rs 8 in FY23 and FY24E respectively.

**Exhibit 21: Copaxone market share (%) on Trx count**



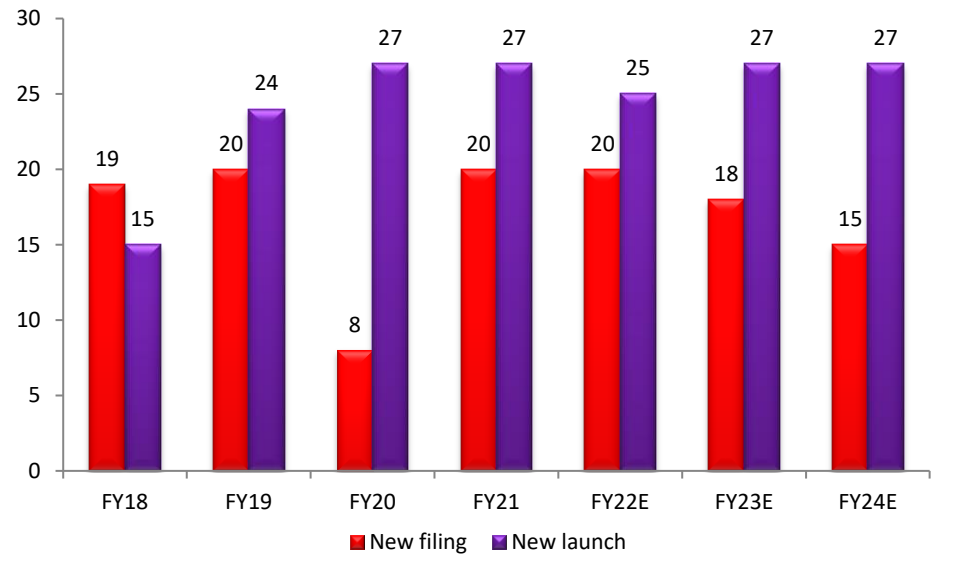

*Source: Company, Systematix Institutional Research*

**Exhibit 22: DRRD – Key recent launches and upcoming pipeline**

| Brand (API) | Innovator | Market size | Current status | Expected launch | Competitive scenario |
|---|---|---|---|---|---|
| Copaxone | Teva | USD 800-900mn | DRRD received CRL twice for copaxone and recently has replied to the queries. Amneal expected to launch in 2QCY22 while Biocon and Apotex are also known filers | 2HFY23E | A 3-player market – Teva (Innovator), Mylan/ Natco and Sandoz |
| Nuvaring | Merck | ~USD 350mn | Acquired from Teva in 2016; received CRL twice for the product and got approval recently. Merck is the innovator; launched its AG before generic launched | FY23E | Amneal first generic in CY19 and Teva received approval in Jan-21. DRRD is yet to launch the product |
| Vascepa | Amneal | ~USD 500mn | Received approval in Nov-20 but launched in Jun-21 due to API issue while Hikma. Launched in Nov-20 after receiving favourable outcome from the court in Sep-20. According to DRRD claims, Amneal had foreclosed all the suppliers of icosapent ethyl API who had sufficient capacity to support a timely commercial launch | Launched in Jun-21 | Hikma also launched while Teva discontinued the ANDA; Apotex has generic settlement |
| Avigan (Favipiravir) | Fuji Toyama Chemical | | Entered into a licensing agreement with Fuji Toyama Chemical Co. Ltd to develop, and sell Favipiravir in all countries other than Japan, China and Russia. Currently conducting trials in US for out-setting patients | - | - |
| Kuvan (Sapropterin Dihydrochloride Powder) | Biomarine | ~USD 400mn | DRRD and Par Pharma are the only two generic players approved | Launched in Apr-21 | |
| Ciprodex (ciprofloxacin 0.3% and dexamethasone 0.1%) | Bayer | ~USD 453mn | DRRD was the first generic to get approval in Aug-20 | Aug-20 | DRRD the only generic player till now |

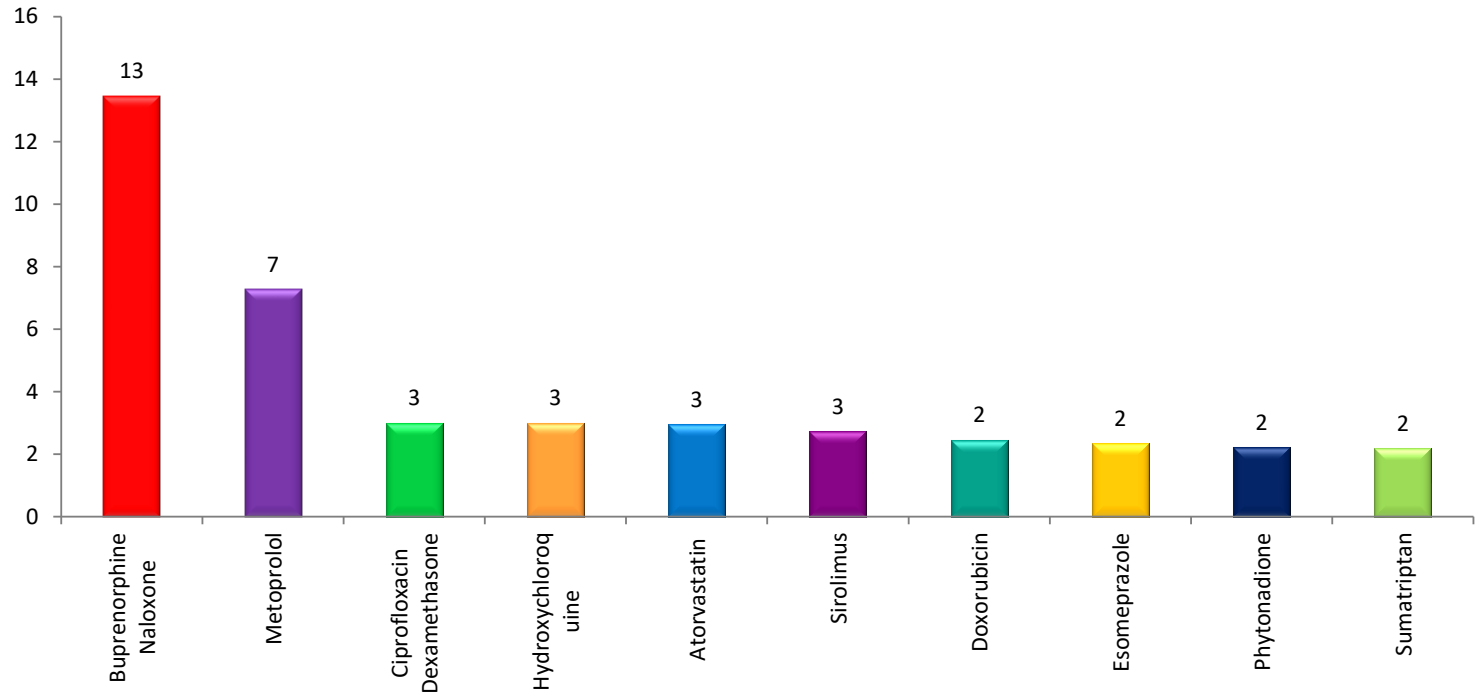
*Source: Company, Systematix Institutional Research*

**Exhibit 23: ANDA filing trend (nos.)**




*Source: Company, Systematix Institutional Research*

**Exhibit 24: Top-10 products in the US (% of US sales in FY21)**




*Source: Industry, Company, Systematix Institutional Research*

**Exhibit 25: DRRD – Para-IV filings**

| Brand | Molecule | Market size (USD) | Innovator | Litigation filed | Status of litigation | Patent expiry | Comments |
|---|---|---|---|---|---|---|---|
| Rydapt | Midostaurin Capsules | USD 91mn (IQVIA MAT Dec-20) | Novartis | Jul-21 | Open | Apr-24 | Dr Reddy's, Lotus Pharma, and Teva also known filers. Lotus pharma has the FTF status |
| | | | | | | | |
| Nexavar | Sorafenib | USD 895mn (CY20) | Bayer | Jul-21 | Open | Feb-23 | Mylan (Natco), Teva, Apotex, and Dr Reddy's filers for the drug; Mylan (Natco) and Teva have final approval. Mylan has FTF status for Nexavar |
| | | | | | | | |
| Xarelto | Rivaroxaban | USD 6.9bn (CY20) | Bayer | May-21 | Open | Nov-24 | Aurobindo, Breckenridge, Microlabs, Mylan, SigmaPharma, Torrent, Prinston Pharma, Sun (Taro), Teva, Alembic, Lupin, Macleods, Accord (Intas), Hec Pharma and Unichem have also filed for the product |
| | | | | | | | |
| Bendeka | Bendamustine HCL-Inj | USD 450mn (CY19) | Teva | May-21 | Open | Jan-31 | Apotex, Slayback Pharma, Fresenius Kabi, Mylan, Hospira Inc, Lupin, Aurobindo and Accord (Intas) are other known filers |
| | | | | | | | |
| Aptiom | Eslicarbazepine Acetate | USD 215mn (CY19) | Sunovion Pharma | Feb-21 | Open | Aug-32 | Alkem, Hetero, Jubiliant, Torrent, Shanghai Zhongxi, Lupin and Apotex other known filers |
| | | | | | | | |
| Pomalyst | Pomalidomide | USD 957mn (CY20) | BMS | Feb-19 | Open | Jun-31 | Hetero, Par Pharma, Teva, Apotex, Aurobindo, Mylan, Alvogen, Synthon Pharma, Breckenridge (Natco), Dr Reddy's, BMS and Breckenridge have settled the US district court litigation with respect to this product |
| | | | | | | | |
| Ocaliva | Obeticholic Acid | USD 234mn (CY20) | Intercept Pharma | Jan-21 | Open | Apr-36 | Apotex, Amneal, Lupin, Optimus pharma and MSN Labs are known filers |
| | | | | | | | |
| Ibrance | Palbociclib | USD 5.3bn (CY20) | Pfizer | Nov-20 | Open | Feb-34 | Aizant, Alembic, Apotex, Aurobindo, Cipla, Hetero, Mylan, Natco, Qilu Pharma, Sun Pharma, Teva, Zydus Cadila and MSN Labs other known filers |
| | | | | | | | |
| Venclexta | Venetoclax | USD 300mn (CY20) | Abbvie | Sep-20 | Open | Jan-32 | Dr Reddy's and Alembic the only two filers till date |
| | | | | | | | |
| Januvia | Sitagliptin | USD 5.5bn (CY20) | Merck | Jun-20 | Open | Nov-26 | 10+ known Para-IV filers. Undisclosed settlement with a few filers |
| | | | | | | | |
| Aptiom | Eslicarbazepine Acetate | USD 215mn (CY19) | Sunovion Pharmaceuticals | Jul-20 | Open | Aug-32 | Alkem, Lupin, Hetero, Jubiliant,, Torrent, Shanghai Zhongxi and Apotex other known filers |
| | | | | | | | |
| Entresto | Sacubitril and Valsartan | USD 2.5bn (CY20) | Novartis | Jun-21 | Open | May-27 | 18 players have submitted ANDAs |

| Brand | Molecule | Market size (USD) | Innovator | Litigation filed | Status of litigation | Patent expiry | Comments |
|---|---|---|---|---|---|---|---|
| Jardiance | Empagliflozin | USD 2.8bn (CY20) | Boehringer Ingelheim | Aug-19 | Open | Jun-34 | 14 known filers for the drug |
| | | | | | | | |
| Lexiscan | Regadenoson | NA | Gilead | Jun-19 | Open | Feb-27 | Apotex, Sandoz, Sun Pharma, Wockhardt, Dr Reddy's, Accord (Intas), International Medication, Gland, Glenmark, USV, Hospira Inc, Meitheal, Mylan, American Regent known filers |
| | | | | | | | |
| Vasostrict | Vasopressin | USD 786mn (CY20) | Par Pharma | Dec-20 | Open | Jan-35 | Eagle pharma has FTF status and received CRL from the regulator. The FDA has assigned a GDUFA date of Dec-15, 2021, and the company expects a commercial launch prior to year-end. Athenex Pharma, Sandoz, Watson (Amphstar), Amneal, American Regent, Fresenius Kabi are other known filers |
| | | | | | | | |
| Sprycel | Dasatinib | USD 1.3bn (CY20) | BMS | Jul-19 | Closed | Mar-26 | Apotex, Lupin, and Teva are other known filers. Apotex entered into the settlement with BMS for generic launch in Sep-24 |
| | | | | | | | |
| Ibrance | Palbociclib | USD5.39bn (CY20) | Pfizer | Apr-19 | Closed | Mar-27 | Aizant, Alembic, Apotex, Aurobindo, Cipla, Dr Reddy's, Hetero, Mylan, Natco, Qilu Pharma, Sun Pharma, Teva, Zydus Cadila, MSN Labs |
| | | | | | | | |
| Alimta | Pemetrexed | USD 1.26bn (CY20) | Eli Lilly | Mar-19 | Closed | May-20 | 15+ Para-IV filed for the product. |
| | | | | | | | |
| Cerdelga | Eliglustat | USD 328mn (CY20) | Genzyme | Nov-18 | Closed | Jun-26 | Aizant, Cipla, Dr Reddy's, Apotex, Teva, Zenara Pharma are the known filers |
| | | | | | | | |
| Otezla | Apremilast | USD 1.79bn (CY20) | Amgen | Nov-18 | Closed | Sep-23 | 15+ Para-IV filed for the product |

*Source: USFDA, Industry, Company, Systematix Institutional Research*

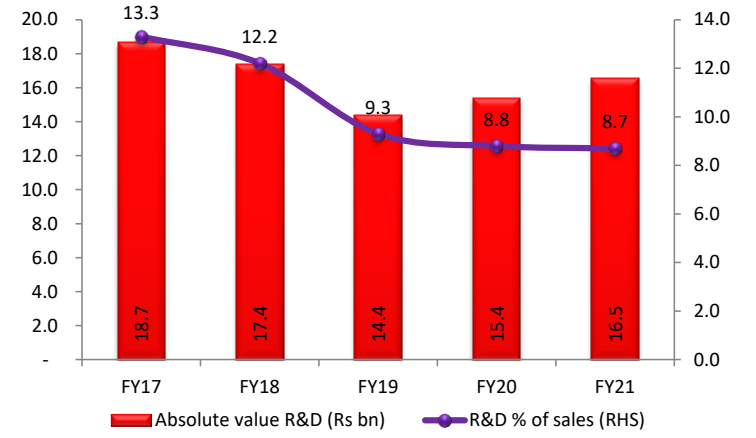
## Cost control measures: Scope for further rationalization

Over FY18-21, DRRD's US business witnessed a nominal 1% CAGR with increased pricing pressure and compliance issues at key plants leading to delayed product approvals and launches. As highlighted earlier, the company has shifted its focus sharply towards cost rationalization. As a result, EBITDA margins were up 730bps, to 25%, over this period (while peers struggled to protect 20-21% margins). Further, DRRD has also moved away from commercializing Specialty products to save on upfront spending and avoid commercial risk associated with these products.

We believe there is scope for further cost rationalization at DRRD in the areas of buying efficiencies and improvement in R&D productivity (i.e., a higher number of filings at the same spend). The company has carried out a detailed assessment of all cost items and has been taking steps to reduce costs and improve efficiencies.

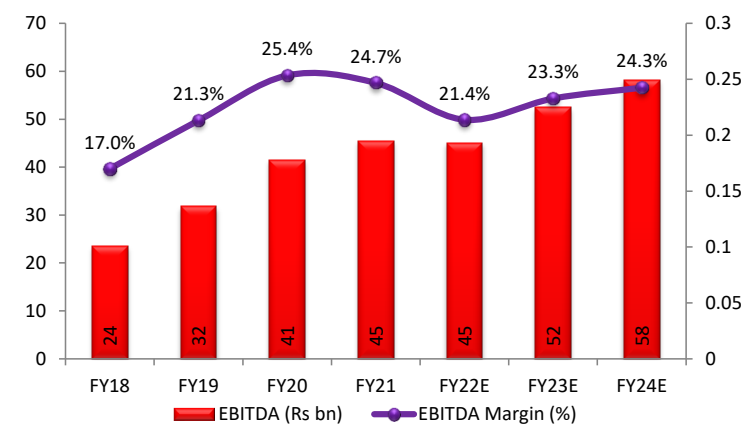
Further, the increasing contribution of branded markets like India and RoW should support gross margins. Going forward, DRRD expects to achieve its target of 25% margins and sustain at these levels even without any large one-off product opportunity; notably, this has already been validated in recent quarters. Meanwhile, reinvestments in the business are likely to go up with its drive to go digital.

**Exhibit 26: DRRD's R&D spend has reduced in recent years**




*Source: Company, Systematix Institutional Research*

**Exhibit 27: Significant EBITDA margin improvement over FY18-21**




*Source: Company, Systematix Institutional Research*

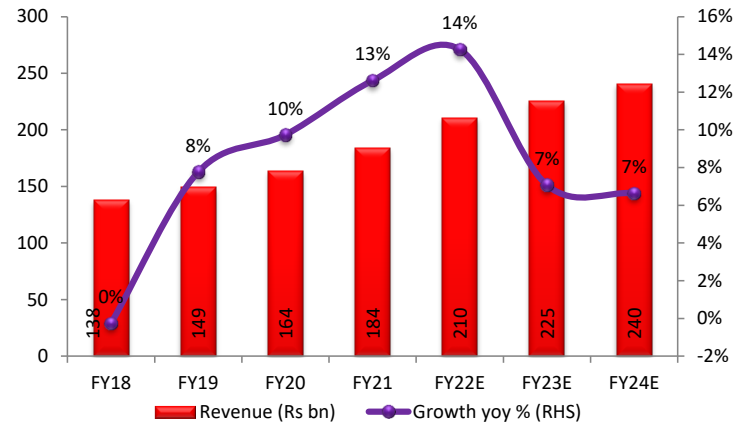
We believe a large part of the cost rationalization is over as DRRD has divested its non-profitable assets. In the medium term, the company will strive to maintain strict control on overhead expenses, capital deployment, and R&D spends. This is expected to yield a higher operating matrix for DRRD compared to peers. We expect the company to post an EBITDA margin of 24.3% in FY24E.

## Financial Analysis

### Domestic formulations and EMs to drive topline growth

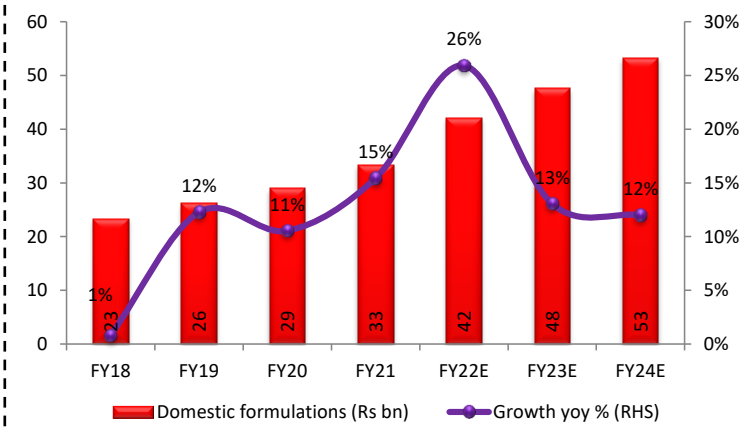
We expect DRRD to register a revenue CAGR of 7% over FY22-24E, led by: 1) 13% CAGR in its domestic formulations business with renewed focus on the segment, and 2) 2% CAGR in US (Gx) with price erosion limited to 5-7% in the base business and on new launches. We are also building in an EBITDA margin close to the guided level of 25% in FY24E, led by strict cost control measures.

**Exhibit 28: Revenue CAGR of 7% over FY22-24E**



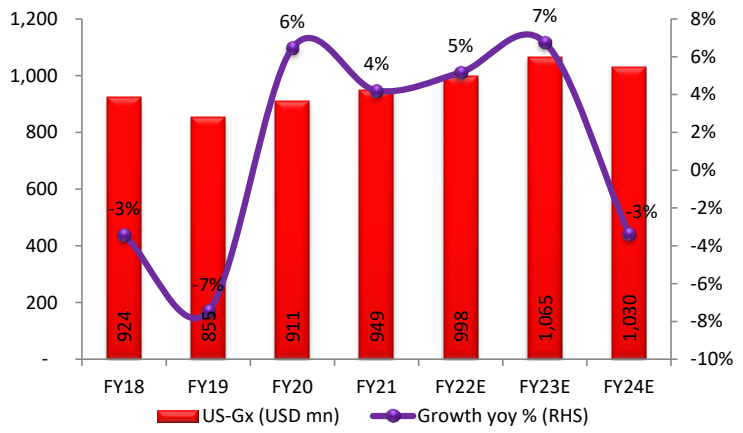

*Source: Company, Systematix Institutional Research*

**Exhibit 29: Domestic formulations to outperform IPM**



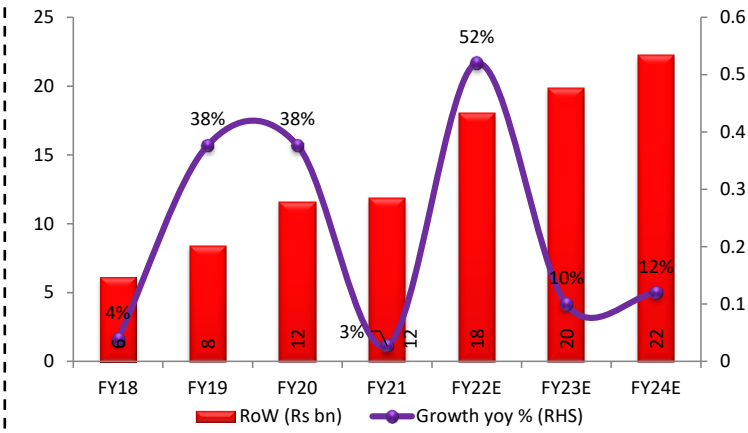

*Source: Company, Systematix Institutional Research*

**Exhibit 30: US base business stable, new launches to drive growth**



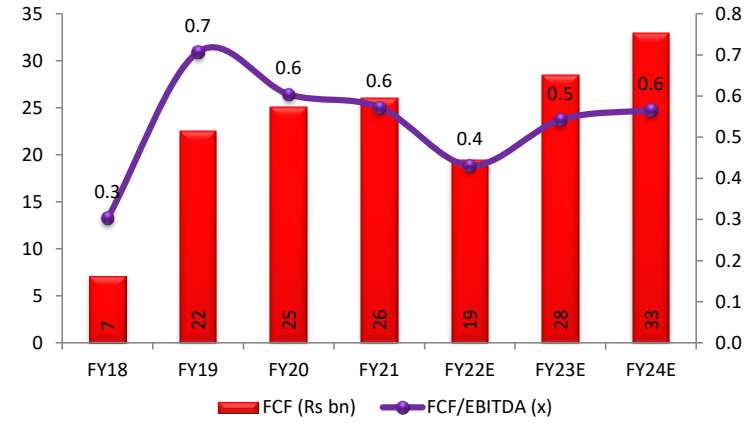

*Source: Company, Systematix Institutional Research*

**Exhibit 31: China growth holds the key for RoW geographies**



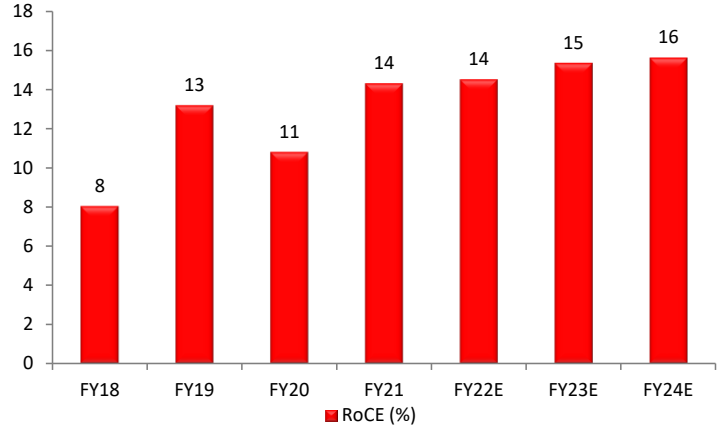

*Source: Company, Systematix Institutional Research*

**Exhibit 32: FCF (Rs bn) and FCF/ EBITDA (x) trend**



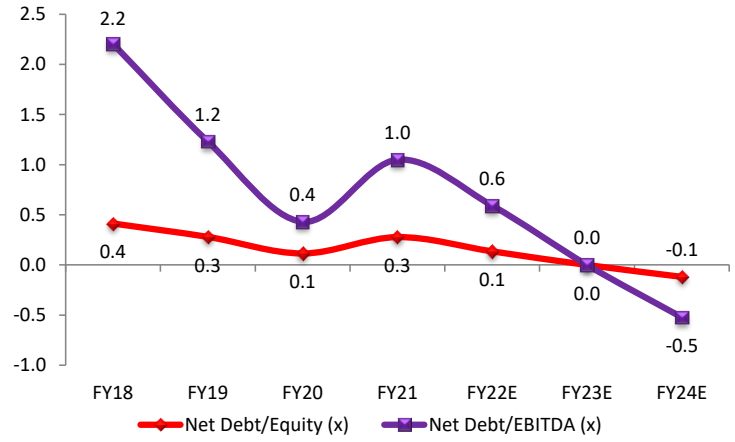

*Source: Company, Systematix Institutional Research*

**Exhibit 33: RoCE expected to improve**



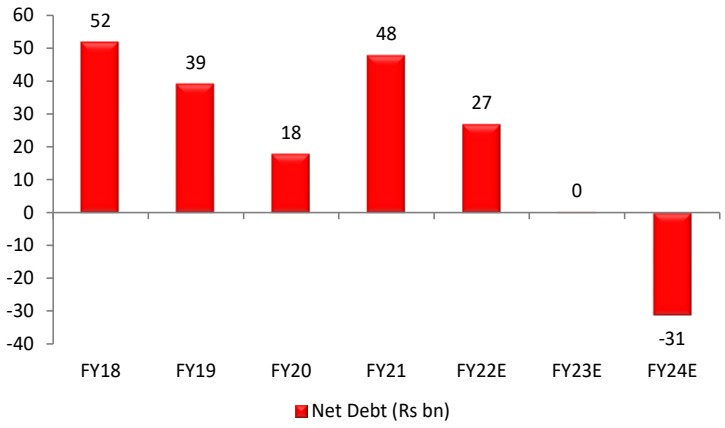

*Source: Company, Systematix Institutional Research*

**Exhibit 34: Leverage ratios to remain efficient (x)**



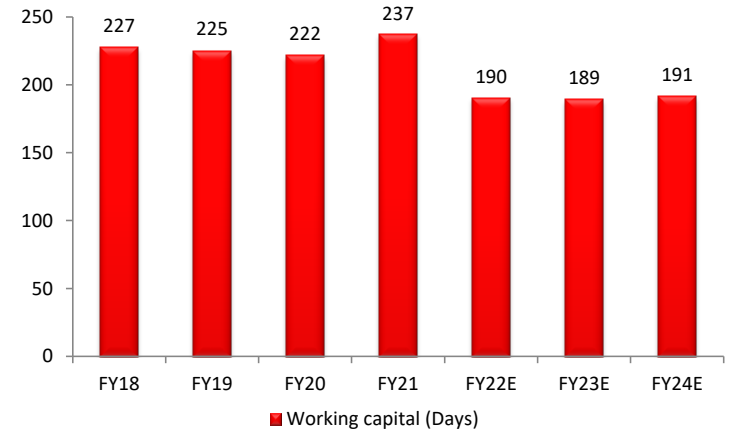

*Source: Company, Systematix Institutional Research*

**Exhibit 35: Net debt trend**



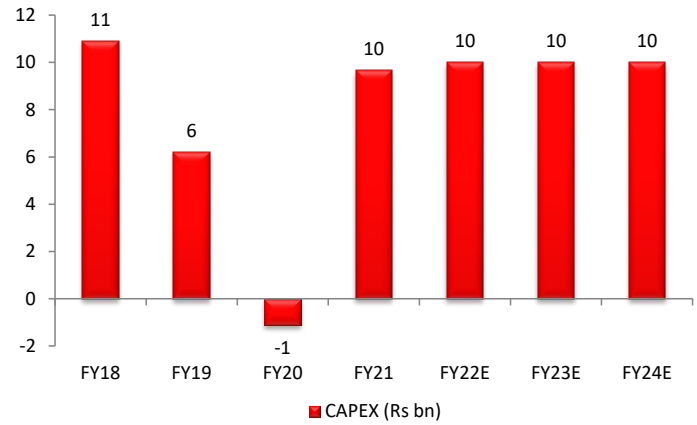

*Source: Company, Systematix Institutional Research*

**Exhibit 36: Working capital cycle**




*Source: Company, Systematix Institutional Research*

**Exhibit 37: Capex trend**




*Source: Company, Systematix Institutional Research*

## Valuations & View

Initiatives to grow the domestic formulations business, a stable US business and scale-up in new product launches in China would remain the key growth catalysts for DRRD over FY22-24E. The company is expected to generate a cumulative FCF of Rs 81bn over the period, thereby further improving its leverage ratio. We expect DRRD to scout for brand acquisitions in the domestic market, which would expand its product offerings and bring sustainable growth. Driven by the change in its business mix and cost rationalization initiatives, we expect the company to register 7% revenue CAGR, 14% EBITDA CAGR and 15% EPS CAGR over FY22-24E.

At CMP, the stock trades at 18x FY24E EPS of Rs 228 (ex Revlimid), a discount of 14% to its 5-year average of 21x. We expect a re-rating in the stock based on the following:

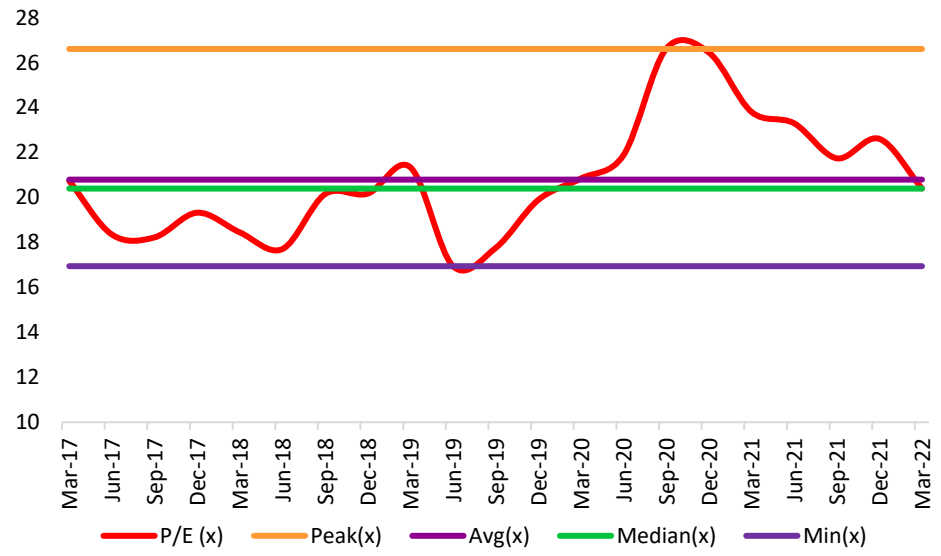
a) Change in its business mix, leading to a larger contribution from domestic formulations

b) Stable outlook for the US (Gx) business, and

c) Sustainable EBITDA margin in the range of 25%

We initiate coverage on the stock with a BUY rating and arrive at an SOTP-based price target of Rs 5,015 by valuing the core business at 21x FY24E earnings of Rs 228 and adding Rs 200 as NPV for its gRevlimid launch (which has exclusivity on select dosages).

**Exhibit 38: P/E**




*Source: Company, Systematix Institutional Research*

# Annexures

## Company Background

DRRD was established by Dr Anji Reddy in 1984 with the vision to make medicine accessible to everyone. In the initial years, DRRD focused on the manufacture of APIs of Ibuprofen and Methyldopa, which were previously unavailable in India. In 1988, DRRD became the largest exporter of Ibuprofen API in India with sales to the US, Spain, Italy and Japan. The company also began to export API ingredients for Norfloxacin and Ciprofloxacin to Europe and the Far East in 1990. It was in the year 1991 that it commenced formulation exports to Russia and filed its first ANDA for Ranitidine in 1997 with the USFDA. DRRD (along with LPC and SUNP) was an early entrant in the US market and was the first Indian company to win 180-day exclusivity for a generic drug (under brand Zocor) in the US.

In 2001, DRRD ventured into CPS (Custom Pharmaceutical Services) space by creating the segment to cater to strategic outsourcing needs of global innovators. Acquisition of Roche's API business in 2005 helped the company expand the CPS segment by adding unique steroid manufacturing capabilities. In Sep-08, the company combined its CPS and API segments to form a new segment called PSAI (Pharmaceutical Services and Active Ingredients). Subsequently, DRRD extended its footprint to other regions – Australia, Italy, South Africa, Germany, Venezuela, Europe etc, through acquisitions, joint ventures and licensing deals. In 2016, it acquired eight ANDAs (including key products like Suboxone and NuvaRing) from Teva for USD 350mn.

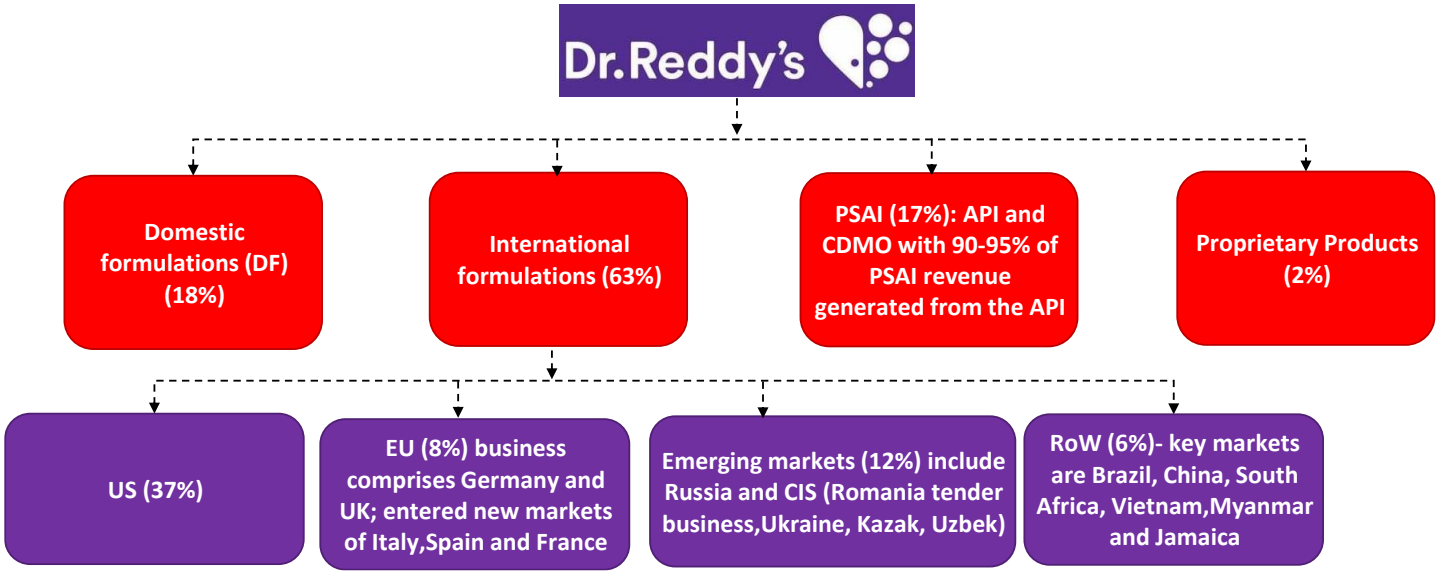
DRRD elevated Mr Erez Israeli as CEO in Jul-19, and the company's focus has shifted to non-US regions such as India and EMs, led by strict cost control measures with focus on profitability. Also, DRRD has emerged clean from USFDA regulatory issues after five years and it is currently one of the few Indian companies with all its plants cleared by the FDA. With focus on non-US markets, DRRD has divested its proprietary products Tosymra, Zembrace and Promiseb as also non-core facilities in Jeedimetla (API) and the US (antibiotics).

**Exhibit 39: Key management personnel**

| Name of Person | Designation | Education | Roles and achievements |
|---|---|---|---|
| K Satish Reddy | Chairman | B.S. in Chemical Engineering from Osmania University; M.S. in Medicinal Chemistry from Purdue University, Indiana (USA) | Son of late founder-chairman Mr Anji Reddy. Joined DRRD in 1993 as executive director; elevated to Managing Director in 1997. Led the company's transition from a manufacturer of APIs to one with a diverse product portfolio of finished dosage formulations |
| G V Prasad | Co-Chairman & Managing Director | Bachelor's degree in Chemical Engineering from Illinois Institute of Technology; M.S. in Industrial Administration from Purdue University, Indiana (USA) | Son-in-law of Mr Anji Reddy and a member of the company's board since 1986. He leads the core team that drives growth and performance at DRRD |
| Erez Israeli | CEO | Master of Business Administration (MBA) Finance; General - Bar Ilan University, Israel | Prior to joining DRRD as COO in CY18, Mr Erez Israeli had spent 23 years with Teva in various roles. At DRRD, elevated to CEO within a short period. Post his appointment, DRRD has seen a marked shift in strategy with focus on non-US markets and tight control on costs |

*Source: Company, Systematix Institutional Research*

**Exhibit 40: Business segments**




*Source: Company, Systematix Institutional Research*

**Exhibit 41: FY21 Annual report highlights**

| | | | | |
|---|---|---|---|---|
| **Domestic Formulations** | Grew 15% in FY21, attributable mainly to contribution from the acquired portfolio of products from Wockhardt and launch of new products including those related to COVID-19 | During FY21, DRRD launched 20 new brands in India while Wockhardt portfolio had 62 brands | DRRD integrated related sales, marketing and manufacturing plant in Baddi during FY21 | Launched COVID-19 related products Remdesivir,Favipiravir and 2DG. Also working on Molnupiravir, Baricitinib and several other COVID-19 drugs for treatment of mild to severe conditions |
| **US (Gx)** | Launched 27 new products with major launches being Ciprofloxacin Dexamethasone, OTC Diclofenac, Sapropterin, Abiraterone (Canada) and Colchicine tablets | Filed 20 new ANDAs and one NDA under section 505(b)(2); these comprises some complex products across different dosage forms with focus on injectables | Gained market share in certain key products, such as Omeprazole DR and Metoprolol ER, while witnessed pricing pressure in Buprenorphine and Naloxone sublingual films, Atorvastatin, Metoprolol and Liposomal Doxorubicin | Will maintain focus on complex formulations, primarily injectables and oral solid dosage forms, as well as OTC brands in the medium term, and 505(b)(2) generics, controlled substances under class II, and non-substitutable generics in the longer term |
| **Emerging Markets** | Significant part of the growth on account of increased revenues from base business, new product launches and scale-up of CIS (including Romania) and RoW businesses | In Russia, key products — Nise, Omez, Nasivin, Cetrine and Ibuclin — ranked among the top 200 best-selling formulation brands. CIS growth led by Ukraine, Kazakhstan, Uzbek and Romania including certain tender sales | First company to win a national tender in China in FY20. Olanzapine sales continued to drive growth in China. RoW growth also led by scaling up other markets such as Vietnam, Myanmar and Jamaica | Strategy for EMs is to build a healthy pipeline including differentiated and oncology products, and expansion of biosimilars across markets. Focus on scaling up in major markets, including Russia, China, Brazil, South Africa and Ukraine |
| **Europe & Proprietary Products** | Significant growth in existing regions while newer markets also aided to growth | Scaled up businesses in newer markets of Italy, Spain and France; expect it to grow by leveraging in-house portfolio. Seeking in-licensing opportunities | Proprietary Products revenue declined 93% following the divestment of commercialized products from neurology franchise in FY20 | Sold US and select territory rights for its commercialized portfolio of Derma and Neurology products being marketed in USA |
| **Vaccine** | In Sep 2020, DRRD signed up with the Russian Direct Investment Fund (RDIF) to cooperate on clinical trials and distribution of Sputnik V vaccine in India. Upon regulatory approval in India, RDIF committed to supply 100mn doses to DRRD | Commenced clinical trials of Sputnik V in Dec-20. Based on satisfactory data from Phase II trials, received approval from the Drugs Controller General of India (DCGI) to conduct Phase III clinical trial on 1,500 subjects | On 1 May 2021, first consignment of imported doses of Sputnik V vaccine landed in India. These received regulatory clearance from the Central Drugs Laboratory, Kasauli on 13 May 2021 | Soft launch of the vaccine commenced; first dose of the vaccine was administered in Hyderabad on 14 May 2021 |

*Source: Company Annual Report, Systematix Institutional Research*

## Plant details

**Exhibit 42: Hyderabad Unit**


*Source: Company, Systematix Institutional Research*

**Exhibit 43: Technology Development Centre in UK**


*Source: Company, Systematix Institutional Research*

**Exhibit 44: Formulations plant details**

| Plant -Name | Location | Plant-Name | Location |
|---|---|---|---|
| FTO 1 | Hyderabad | FTO SEZ PU 2 | Srikakulam |
| FTO 2 | Hyderabad | FTO 11 | Srikakulam |
| FTO 3 | Hyderabad | FTO 12 | Srikakulam |
| FTO 6 | Hyderabad | Biologics | Bachupally |
| FTO 7 | Hyderabad | Kunshan Rotam Reddy | China |
| FTO 8 | Hyderabad | Formulations Shreveport Plant | US |
| FTO 9 | Hyderabad | Dr. Reddy's Laboratories | UK |
| FTO SEZ PU 1 | Srikakulam | - | - |

*Source: Company, Systematix Institutional Research*

# FINANCIALS

### Profit & Loss Statement

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **Net Revenues** | **163,574** | **184,202** | **210,461** | **225,335** | **240,178** |
| YoY gr. (%) | 10 | 13 | 14 | 7 | 7 |
| Cost of Goods Sold | 55,544 | 60,789 | 98,496 | 102,527 | 108,080 |
| Gross Profit | 108,030 | 123,413 | 111,965 | 122,807 | 132,098 |
| Margin (%) | 66 | 67 | 53 | 55 | 55 |
| Employee Cost | 33,802 | 36,299 | 49,458 | 51,437 | 52,877 |
| Other Expenses | 44,353 | 47,920 | 17,500 | 18,900 | 21,000 |
| **EBITDA** | **29,875** | **39,194** | **45,007** | **52,471** | **58,221** |
| YoY gr. (%) | 30 | 10 | -1 | 17 | 11 |
| Margin (%) | 18 | 21 | 21 | 23 | 24 |
| Depn and Amort. | 28,398 | 12,288 | 11,931 | 12,796 | 13,276 |
| **EBIT** | **1,477** | **26,906** | **33,075** | **39,675** | **44,945** |
| Margin (%) | 1 | 15 | 16 | 18 | 19 |
| Net Interest | 983 | 970 | -1,578 | -2,253 | -2,402 |
| Other Income | 6,206 | 2,914 | 2,736 | 2,253 | 2,402 |
| **Profit Before Tax** | **6,700** | **28,850** | **37,390** | **44,181** | **49,748** |
| Total Tax | -1,403 | 9,319 | 9,347 | 11,045 | 12,437 |
| Effective tax rate (%) | -21 | 32 | 25 | 25 | 25 |
| **Profit after tax** | **8,103** | **19,531** | **28,042** | **33,136** | **37,311** |
| EPS | 122 | 118 | 172 | 202 | 228 |
| YoY gr. (%) | 4 | -4 | 46 | 18 | 12 |

*Source: Company, Systematix Institutional Research*

### Balance Sheet

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| Equity Share Capital | 831 | 832 | 832 | 832 | 832 |
| Res. & Surp. (Ex OCI) | 155,157 | 171,522 | 195,879 | 224,498 | 256,461 |
| **Net Worth** | **155,988** | **172,354** | **196,711** | **225,330** | **257,293** |
| Short term debt | 17,836 | 60,505 | 60,505 | 60,505 | 60,505 |
| Long term debt | 2,055 | 2,055 | 2,055 | 2,055 | 2,055 |
| Trade payables | 15,248 | 18,109 | 20,181 | 21,607 | 23,031 |
| Other Provisions | 40,534 | 38,677 | 41,652 | 44,219 | 46,781 |
| Other liabilities | 0 | 0 | 0 | 0 | 0 |
| **Total Liabilities** | **231,661** | **291,700** | **321,104** | **353,717** | **389,665** |
| | | | | | |
| Net block | 68,503 | 106,535 | 104,604 | 101,807 | 98,531 |
| CWIP | 15,351 | 15,643 | 15,643 | 15,643 | 15,643 |
| Other Non-current asset | 0 | 0 | 0 | 0 | 0 |
| Investments | 26,778 | 29,270 | 25,871 | 25,871 | 25,871 |
| Cash and Cash Equi. | 2,053 | 14,829 | 35,947 | 62,554 | 92,994 |
| Debtors | 50,278 | 49,641 | 63,426 | 67,909 | 72,382 |
| Inventories | 35,067 | 45,412 | 43,245 | 46,302 | 49,352 |
| Other current asset | 33,631 | 30,370 | 32,368 | 33,631 | 34,892 |
| **Total Assets** | **231,661** | **291,700** | **321,105** | **353,717** | **389,665** |

*Source: Company, Systematix Institutional Research*

### Cash Flow

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| PBT | 18,296 | 28,835 | 37,390 | 44,181 | 49,748 |
| Depreciation | 16,278 | 12,288 | 11,931 | 12,796 | 13,276 |
| Interest | 262 | 970 | -2,460 | -3,135 | -3,284 |
| Others | -11,137 | 7,614 | 475 | 475 | 475 |
| Working capital | -1,161 | -8,288 | -8,569 | -4,809 | -4,799 |
| Direct tax | 1,403 | -5,716 | -9,347 | -11,045 | -12,437 |
| **Net cash from Op.** | **23,941** | **35,703** | **29,419** | **38,463** | **42,980** |
| Net Capital expenditure | 1,113 | -9,656 | -10,000 | -10,000 | -10,000 |
| Others | 1,726 | -13,004 | 4,281 | 882 | 882 |
| **Net Cash from Invst.** | **2,839** | **-22,660** | **-5,719** | **-9,118** | **-9,118** |
| Issue of share cap. | 1 | 269 | 0 | 0 | 0 |
| Debt changes | -20,545 | 6,848 | 0 | 0 | 0 |
| Dividend paid | -3,911 | -4,147 | -4,160 | -4,992 | -5,824 |
| Others | -2,500 | -3,155 | 1,587 | 2,253 | 2,402 |
| **Net cash from Fin.** | **-26,955** | **-185** | **-2,573** | **-2,739** | **-3,422** |
| **Net change in cash** | **-175** | **12,858** | **21,127** | **26,607** | **30,440** |

### Ratios

| YE: Mar | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **Per Share (Rs)** | | | | | |
| EPS | 122 | 118 | 172 | 202 | 228 |
| CEPS | 293 | 232 | 244 | 280 | 308 |
| BVPS | 940 | 1038 | 1185 | 1357 | 1550 |
| DPS | 20 | 20 | 25 | 30 | 35 |
| **Return Ratio (%)** | | | | | |
| RoCE | 11 | 14 | 14 | 15 | 16 |
| RoE | 14 | 12 | 15 | 16 | 16 |
| **Balance Sheet** | | | | | |
| Net Debt: Equity (x) | 0.1 | 0.3 | 0.1 | 0.0 | -0.1 |
| Net Working Capital (Days) | 222 | 237 | 191 | 191 | 193 |
| **Valuation(x)** | | | | | |
| PER | 36 | 37 | 25 | 22 | 19 |
| EV/EBITDA | 0 | 17 | 17 | 14 | 12 |
| EV/Sales | 0 | 4 | 4 | 3 | 3 |

*Source: Company, Systematix Institutional Research*

| Revenue details (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **Domestic formulations** | **28,946** | **33,419** | **42,086** | **47,583** | **53,293** |
| **US** | **64,659** | **70,495** | **73,854** | **80,978** | **80,318** |
| EU | 11,707 | 15,404 | 16,328 | 17,961 | 19,757 |
| Russia & other CIS | 23,400 | 22,705 | 24,670 | 23,175 | 25,211 |
| ROW | 11,567 | 11,881 | 18,059 | 19,865 | 22,249 |
| Total Global Generics | 140,279 | 153,904 | 174,997 | 189,562 | 200,828 |
| PSAI | 25,747 | 31,982 | 30,703 | 33,773 | 37,150 |
| Proprietary products | 10,730 | 3,336 | 4,761 | 2,000 | 2,200 |
| **Total Revenues** | **176,756** | **189,222** | **210,461** | **225,335** | **240,178** |

*Source: Company, Systematix Institutional Research*

# Lupin Limited

28 March 2022

## Weak execution; margin recovery hinges on gSpiriva approval

**INITIATING COVERAGE**

**Sector: Pharmaceuticals** | **Rating: SELL**

**CMP: Rs 756** | **Target Price: Rs 622**

**Stock Info**

| | |
|---|---|
| Sensex/Nifty | 57,362/17,153 |
| Bloomberg | LPC IN |
| Equity shares | 454mn |
| 52-wk High/Low | Rs 1,268/679 |
| Face value | Rs 2 |
| M-Cap | Rs 343bn/ USD 4.6bn |
| 3-m Avg value | USD 18mn |

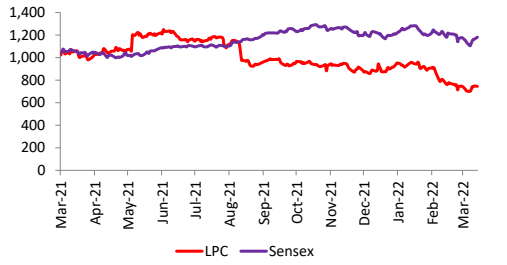
**Financial Snapshot (Rs mn)**

| Y/E March | FY22E | FY23E | FY24E |
|---|---|---|---|
| Revenue | 161,542 | 172,939 | 186,111 |
| Gross profit | 97,733 | 107,222 | 119,111 |
| Gross Margin (%) | 61 | 62 | 64 |
| EBITDA | 20,127 | 25,286 | 32,085 |
| Margin (%) | 12 | 15 | 17 |
| PAT | 11,449 | 12,910 | 17,718 |
| EPS | 25 | 28 | 39 |
| DPS (Rs) | 5 | 5 | 5 |
| ROCE (%) | 6 | 10 | 13 |
| P/E (x) | 17 | 27 | 19 |
| EV/EBITDA (x) | 17 | 13 | 10 |

**Shareholding pattern (%)**

| | Jun-21 | Sep-21 | Dec-21 |
|---|---|---|---|
| Promoter | 46.8 | 46.8 | 46.8 |
| –Pledged | - | - | - |
| FII | 15.2 | 15.6 | 15.2 |
| DII | 21.8 | 24.8 | 24.8 |
| Others | 12.8 | 12.8 | 12.8 |

**Stock Performance (1-year)**




**Once a promising business, Lupin's (LPC) performance in the last five years has been less than satisfactory. A large but misplaced acquisition, failed investments in the Specialty business, price erosion in some of its key products and compliance issues at important facilities have been the key pain points. While the company is trying to correct its course, a recovery seems far away. LPC trades at 19x FY24E EPS of Rs 39 – a 14% discount to its 5-year average. We see a case for de-rating of the stock as consensus expectations on key products are still high. We initiate coverage on the stock with a SELL rating and target price of Rs 622 based on 16x FY24E EPS.**

**Promising business, but weak execution:** LPC's EBITDA has declined at 15% compounded annually while margins have plummeted by ~1,300bps over FY17-22E. This is despite an exit from the lower-margin Japanese business, rationalization of Solosec spending and launch of high-margin products like gAlbuterol. LPC faces price erosion in some of its US products and compliance issues at plants. Further, unlike peers, LPC has a relatively higher share of lower-margin in-licensed products in India (15-17%) and the US. We believe its margins have hit a trough at 8.9% in 3QFY22 and should stabilize at 13-14% in the next few quarters though this is still sub-optimal. LPC has little room to further reduce Opex and a significant margin expansion is highly contingent on the approval for gSpiriva.

**USA – Product concentration still high:** Top-5 products contribute ~30% of LPC's US sales with ~15% from gAlbuterol, as per our estimates. This is a major risk to its US business as key facilities are still under the FDA scanner and meaningful product approvals are likely only in 2HFY23. Thus, any competition in the medium term can have a material impact on margins in these products. Although LPC's market share in gAlbuterol is close to the management's target of 20%, a further ramp-up seems difficult. LPC's margin trajectory is highly dependent on a few products rather than broader cost rationalization measures undertaken by other companies (e.g., DRRD).

**Return ratios to remain weak in the medium term:** The misplaced acquisition of Gavis has significantly impacted LPC's return ratios with most of the acquisition value being written off. Initiatives for Specialty products (Solosec) and US investments (especially oral contraceptives) have also underperformed expectations, dragging its RoCE down. While concerns related to Gavis are largely behind and Solosec opex has been reduced to USD 15mn annually (USD 60mn earlier), we do not see any marked improvement in RoCE due to upcoming investments in the diagnostics business.

**Initiating coverage with SELL:** The stock currently trades at 19x FY24E EPS of Rs 39 – a 14% discount to its 5-year average. The valuation discount should widen further because of the sub-optimal margin profile compared to peers and headwinds in LPC's US business. We expect the stock to de-rate to 16x FY24E earnings. Initiating coverage with a **SELL** rating and target price of Rs 622.

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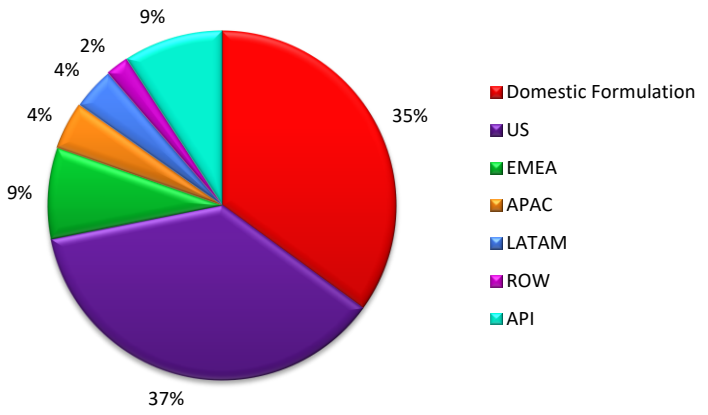
**Investors are advised to refer disclosures made at the end of the research report.**

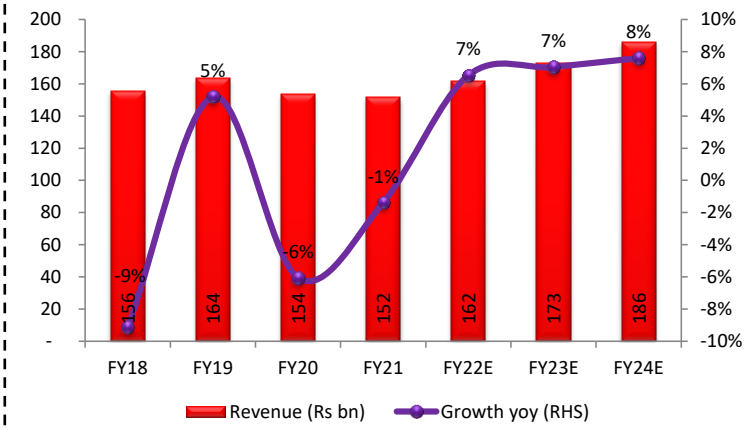
## Story in charts

**Exhibit 1: Business mix (%; FY21)**



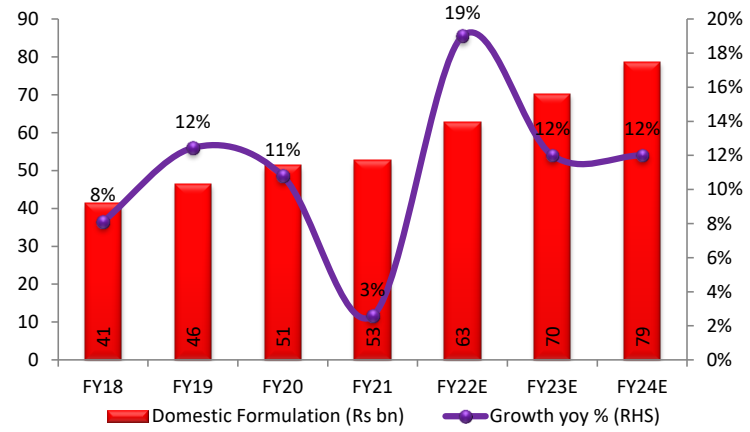

*Source: Company, Systematix Institutional Research*

**Exhibit 2: Expect revenue CAGR of 7% over FY22-24E**



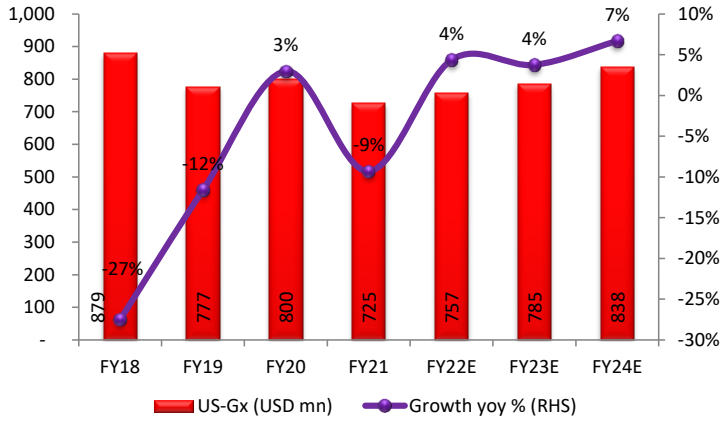

*Source: Company, Systematix Institutional Research*

**Exhibit 3: Domestic business to outpace IPM on in-licensed products**



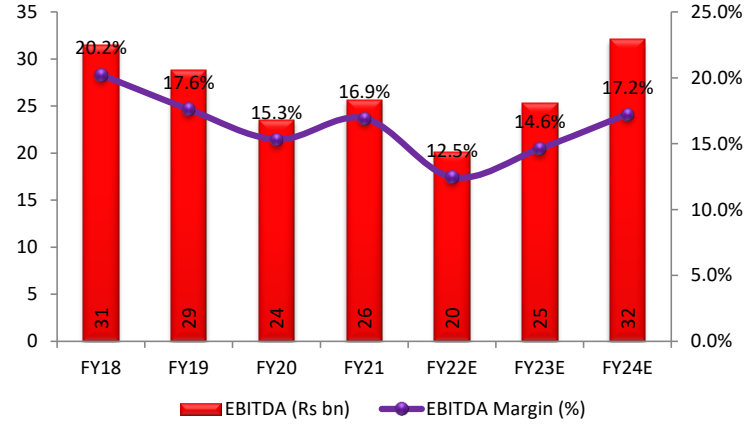

*Source: Company, Systematix Institutional Research*

**Exhibit 4: Competition in key products to keep US growth muted**



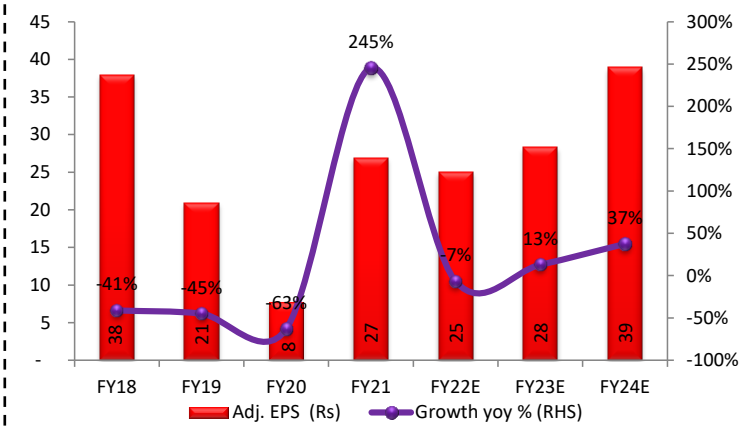

*Source: Company, Systematix Institutional Research*

**Exhibit 5: EBITDA margin to remain weakest among peers**




*Source: Company, Systematix Institutional Research*

**Exhibit 6: Earnings growth depends significantly on gSpiriva launch**




*Source: Company, Systematix Institutional Research*

## Executive Summary

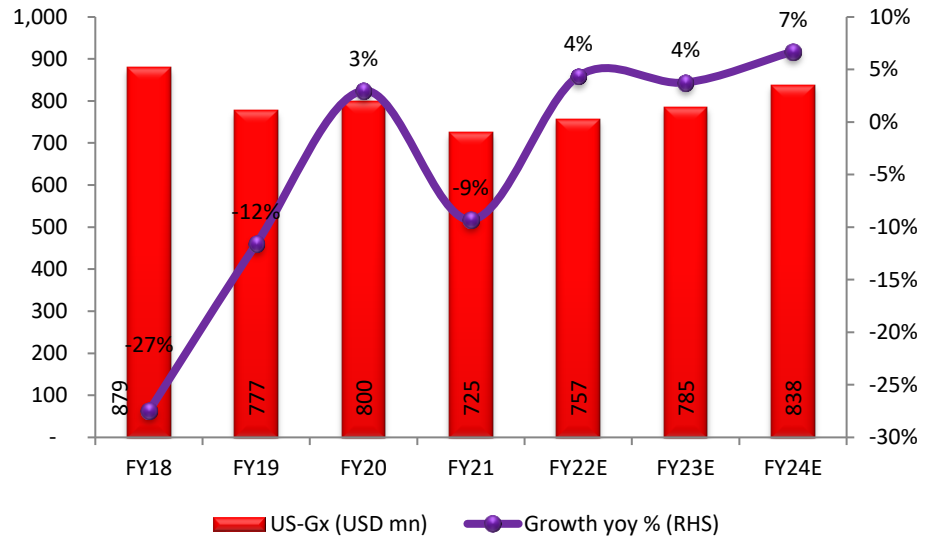
LPC has had a tumultuous journey in the last few years, and we believe the pain is far from over. A large but misplaced acquisition, failed investments in specialty business, price erosion in some of its key products and compliance issues at important facilities have been the key pain points over the last five years. While the company has subsequently written off its investments in Specialty business as well as in Gavis, we believe a full-fledged margin recovery is still far away. Street expectations on key products (gSpiriva and gPegfilgrastim) have scope for disappointment.

**Multiple headwinds weigh on the US business**

LPC's US business has been the biggest drag on its performance, with a 12% compounded annual decline in revenues over FY17-21 and the region's share falling from 48% to 37% in the overall pie. We believe the challenges faced in the US are unlikely to be resolved in the near term as: 1) regulatory issues on key plants could stretch further even after the completion of CAPA, 2) competition in its key molecules Famotidine, gAlbuterol and Levothyroxyin can intensify with the entry of new players, 3) Pegfilgrastim launch can disappoint with a lower-than-expected market share, 4) gSpiriva litigation settlement with the innovator can delay the launch beyond FY23, and 5) *Solosec* can remain a drag.

We expect a tepid 5% revenue CAGR in LPC's US business over FY22-24E to USD 838mn in FY24E.

**Exhibit 7: US (Gx) growth to remain muted due to price erosion**




*Source: Company, Systematix Institutional Research*

**Scale-up in biosimilars remains an uphill task as many players already present**

We expect a peak market share of 4-5% for LPC in Pegfilgrastim as: 1) first-to-launch biosimilars tend to capture a significant portion of the market than later entrants; also, price erosion increases with the entry of every new player, 2) large US-focused companies dominate this segment because of their drug management strategy program with PBM (Pharmacy Benefit Managers), and 3) Indian players usually launch specialty products through front-end partners to manage costs as setting up own front-end for a single product is difficult.

We expect a peak revenue of USD 40mn-50mn for LPC from this product in FY25E.

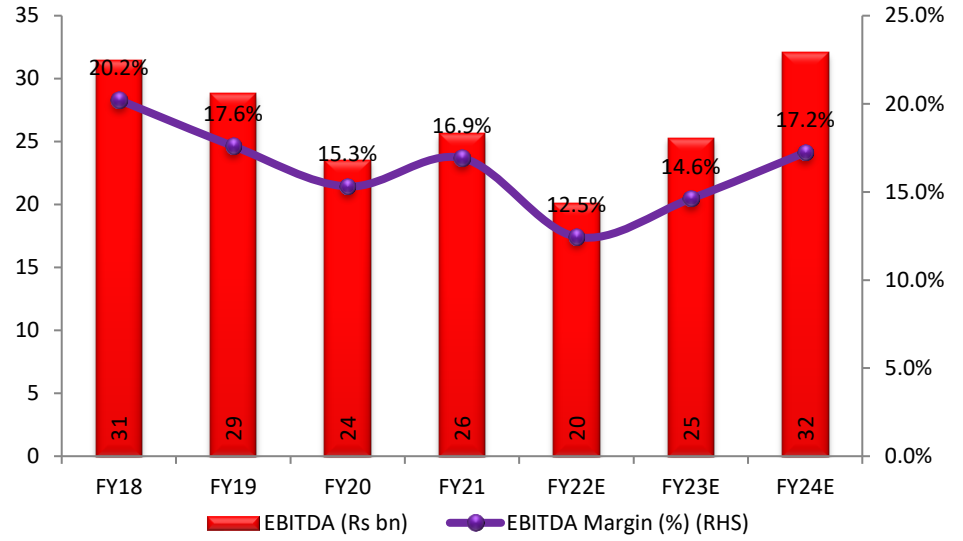
**Expectations are high on Spiriva**

Spiriva currently has a market size of USD 700mn-800mn, with the last patent expiring in Apr-30. LPC enjoys the FTF (First-to-File) status with no other known filers yet and the company has guided for a 2HFY23E launch, subject to approval. While Spiriva is an important launch for LPC to drive growth in the US market in FY23/ 24E, we believe there is a fair chance of the product approval getting delayed as complex inhalers usually go through multiple cycle reviews. We estimate Spiriva to generate USD 40mn and USD 110mn in revenues for LPC in FY23 and FY24E, translating into EPS contribution of Rs 2 and Rs 6 respectively.

**In-licensed products in domestic formulations portfolio have low margins**

Despite a high contribution from Chronic/ Sub-chronic products and being the third-largest player in anti-diabetic and cardiac therapy areas with a market share of 9.3% and 7% respectively, LPC's margin profile in the India market remains weak. We believe LPC has a relatively weaker margin profile given a higher share of in-licensed/ partnered products (15-17% of India revenues). In-licensed products tend to have margins lower than in core products due to the large incentives paid out to partners.

**Exhibit 8: Margins to improve but remain lower than peers'**

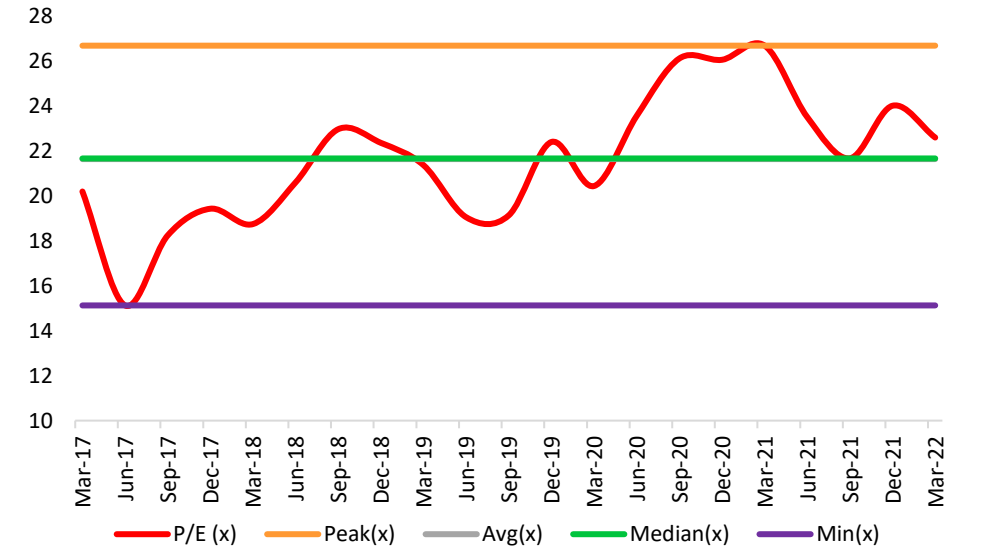



*Source: Company, Systematix Institutional Research*

**Valuations and outlook**

LPC currently trades at 19x on FY24E EPS of Rs 39, which is a 14% discount to its 5-year average. The valuation discount should widen further because of the sub-optimal margin profile compared to peers and headwinds in the company's US business. We expect the stock to de-rate to 16x its FY24E earnings and initiate coverage with a **SELL** rating and target price of Rs 622.

**Exhibit 9: P/E**




*Source: Systematix Institutional Research*

## Key Risks

**Extended phase of limited competition for gSpiriva**

To date, LPC is the only filer for gSpiriva. In case of limited competition, LPC can potentially garner a significant market share, making it difficult for new players to scale up. This could eventuality drive an upgrade in our estimates for FY24E.

**Early resolution of plants facing US regulatory issues**

Regulatory issues have been an overhang on LPC's performance since Nov-17. Its Pithampur Unit-2, Tarapur, Mandideep Unit-1 and Somerset (US) facilities continue to be under the FDA radar. An earlier-than-expected resolution will be viewed as a positive event by the market.

**Increased focus on domestic formulations**

As of 2HFY22, LPC has Rs 12.8bn in cash and cash equivalents that could be utilized to increase focus on the domestic formulations market by acquiring targeted brands with higher revenue visibility than in export markets. This could lead to a better growth and margin profile than we have built in.

## Milestones

**Exhibit 10: LPC – Key milestones and events**

| |
|---|
| **2016-2017 – Stream of acquisitions to expand global footprint and US growth held back due to competition and regulatory concerns** |
| 2016 – Acquisition of Gavis (US) and branded product portfolio from Shionogi (Japan) |
| 2017 – Acquisition of Symbiomix *(US)* |
| 2017 – WL issued for Goa and Indore (Pithampur Unit II) |
| **2018-2021 – Launch of Specialty products** |
| 2018 – Received approval of Solosec |
| 2019 – Divested entire stake in Kyowa |
| 2020 – Launch of gProAir (US) and biosimilar Enbrel (etanercept) in EU |
| 2021 – Approval of first branded generic of asthma inhalation drug Fostair for UK market and acceptance of Biologics License Application (BLA) for biosimilar Neulasta by USFDA |
| **2022-2025 – Focus on launch of complex products and resolution at its key plants** |
| Launch and ramp-up of biosimilars in the export markets |
| Approval of injectable and inhalation products in the US |
| Resolution of key plants (Indore and Goa) under the USFDA scanner |
| Entry in China |

*Source: Company, Systematix Institutional Research*

## Investment Analysis

**US business – challenges to persist**

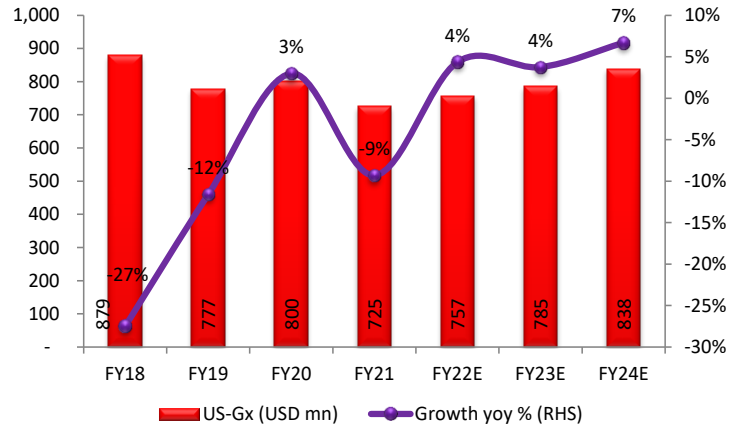
LPC's US business has shrunk in the recent past due to price erosion and the misplaced Gavis acquisition. The company continued to invest in R&D through this phase (average 11% of sales over FY17-21) in complex generics and building difficult-to-make dosage forms like inhalers, depot injectables and biosimilars. LPC has seen initial success with the approvals of gAlbuterol. Biosimilar product filings have been accepted by the US and Europe regulators and we expect a potential launch of these products in FY23/ 24E.

**Gaining market share in biosimilars a tall order:** We believe biosmilars are unlikely to contribute meaningfully to LPC's bottom-line. Acquiring a market share of these products will be a challenge given higher competitive intensity due to the presence of large global players. Also, LPC's investment in depot injectables is yet to convert into filings but pipeline products like gVelphoro offer respite. The regulatory issue for Somerset and Indore facilities will restrict near-term growth and we expect re-inspection to be deferred to FY23E in view of the COVID situation.

**Competition and compliance the key headwinds**: The US business has been the biggest drag on LPC's performance, with a 12% compounded annual decline in revenues over FY17-21 and the region's share falling from 48% to 37% in the overall pie. Key factors for the dismal performance include: 1) competition in key molecules like Metformin and related products, Methergine and Suprax, 2) compliance issues at several facilities including Goa and Pithampur-2, 3) misplaced acquisition of Gavis, and 4) lower than expected sales from *Solosec* – its branded product.

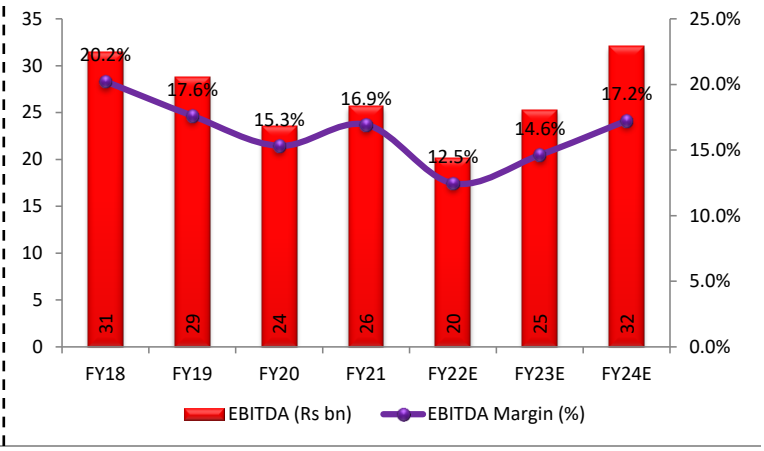
**Margin profile to remain weak despite some improvement:** The subdued US performance has also resulted in overall EBITDA margins declining from 26% in FY17 to 17% in FY21, given 1) an increase in Opex with incremental costs related to remediation of facilities, 2) upfront investment in setting up front-end infrastructure for *Solosec*, 3) higher R&D outlay towards building specialty products pipeline for the US market, and 4) negative operating leverage.

**Exhibit 11: US (Gx) growth to remain muted due to price erosion**




*Source: Company, Systematix Institutional Research*

**Exhibit 12: Margins to improve but remain lower than peers'**




*Source: Company, Systematix Institutional Research*

We believe the challenges faced in the US business are unlikely to be resolved in the near term as: 1) the regulatory issue could stretch further even after the completion of CAPA, 2) competition in its key molecules Famotidine, gAlbuterol and Levothyroxyin can intensify with the entry of new players, 3) Pegfilgrastim launch can disappoint with a lower-than-expected market share, 4) gSpiriva litigation settlement with the innovator can delay launch beyond FY23, and 5) *Solosec* can remain a drag.

We expect a tepid 5% revenue CAGR in LPC's US business FY22-24E to USD 838mn in FY24E.

**US recovery hinges partly on the resolution of compliance issues**

So far, LPC has received an Establishment Inspection Report (EIR) from the USFDA on its Goa plant while other plants remain under the FDA scanner. We believe 30-40% of the company's ANDAs are from Goa and Pithampur and compliance issues there have hit its ability to launch new products in the US. LPC has seen common problems across these facilities relating to out-of-specification issues; and while it is not a given, clearance of the Goa plant raises hopes that the management will be able to address these issues comprehensively and soon. While a clearance will pave the way for new launches, not all products will be viable for launch given the delay in launch and competition already catching up.

**Exhibit 13: LPC's plant status**

| Facility | Latest Inspection | Current FDA Status | % of LPC's US sales | Comments |
|---|---|---|---|---|
| Goa | Sep-21 | EIR | 20-25% | FDA issued a joint warning letter for Goa and Pithampur Unit 2 in Nov-17. The facility was reinspected on Feb-19 and Sep-21 (seven observations) and LPC has now received Establishment Inspection Report (EIR) with Voluntary Action Indicated (VAI) |
| Pithampur Unit 2 | Jan-19 | Warning letter | 15% | Received warning letter in Nov-17 and the plant was reinspected in Jan-19. LPC has completed Corrective and Preventive Action (CAPA) and is awaiting US FDA inspection |
| Tarapur | Sep-19 | OAI | <5% | Tarapur plant received OAI status after FDA inspection in Sep-19 and the status is maintained |
| Mandideep Unit 1 | Dec-18 | Warning letter | <5% | Plant received OAI status in Mar-19, and later received a warning letter in Sep-19 |
| Somerset (US) | Nov-20 | Warning letter | <5% | OAI status issued in Mar-19 after facility inspection in Dec-18; FDA reinspected the plant in Sep-Nov-20 and issued a Form 483 with 13 observations. FDA issued a warning letter in Jun-21 citing repeat violation at multiple facilities |

*Source: Company, Systematix Institutional Research*

**Competition to intensify in key products**

LPC's key products – Famotidine, Mesalamine, Levothyroxine and Albuterol – could witness significant price erosion and market share loss as new generic players have received approval for these products over the last 12 months. With these products having a combined 25-30% share in LPC's US revenues in FY21, market share loss is bound to put growth at risk in the coming years. Notably, these are comparatively new products launched over FY19-20 and saw limited competition initially. With Famotidine, Mesalamine and Levothyroxine being orally administered and easy to manufacture, price erosion for LPC could be steep (in double-digits over FY22-24E).

**Exhibit 14: Competitive environment for LPC's key products**

| API | Launch date | Details of incremental competition |
|---|---|---|
| **Famotidine** | Jul-10 | Famotidine was LPC's largest product in FY21; single-source supplier for oral suspension dosage while tablet form has many players approved. Overall market for Famotidine at ~USD 900mn with 60% being oral suspension. Novitium received FDA approval for Famotidine oral suspension generic in Apr-21 and LPC's latest quarterly financials already indicate the impact |
| | | |
| **Mesalamine** | May-20 | Mesalamine was the second largest product for LPC in FY21. As per the settlement agreement with Bausch Health, Teva was granted a non-exclusive license effective 1st Oct-2021 and Bausch has agreed to modify its prior sub-license agreement with LPC. The last patent expires in 2030 and two other paragraph IV filings remain |
| | | |
| **Levothyroxine** | Mar-19 | LPC received approval for the first indication in Jan-18 and third in Nov-19. It faced challenges in achieving its guidance of 20% share in the Levothyroxine market by FY21. LPC currently holds ~15% market share and the entry of Accord Pharma in Oct-20 and Teva in April-21 would make it difficult to achieve its target/ maintain existing share |
| | | |
| **Albuterol** | Aug-20 | LPC has a 16% market share in overall Albuterol (Brand and Gx) and 20% in the generic Albuterol market. It has signed long-term contracts that offer lower gross margins and will impact US revenues. With Sandoz also entering the space, LPC will find it difficult to grow its revenue from gAlbuterol |

*Source: Company, Systematix Institutional Research*

**LPC to ride the 3rd wave of biosimilars via Pegfilgrastim launch**

The market size for Pegfilgrastim in the US is pegged at ~USD 900mn, with four biosimilar players already approved by the regulator, three awaiting approval and a few more in the clinical trial stage. The first biosimilar Pegfilgrastim approval was given to Mylan/ Biocon in Jun-18 under the *Fulphila* brand name, and Coherus joined within the next six months. Since the first biosimilar launch in the US, Pegfilgrastim has seen a steep price erosion and its market size has reduced by 70-75% from USD 3.9bn in CY18 to ~USD 900mn.

We expect a peak market share of 4-5% for LPC in Pegfilgrastim as: 1) first-to-launch biosimilars tend to capture a significant portion of the market than later entrants; also, price erosion increases with the entry of every new player, 2) large US-focused companies dominate this segment because of their drug management strategy program with PBM, and 3) Indian players usually launch specialty products through front-end partners to manage costs as setting up own front-end for a single product is difficult.

Companies that have launched biosimilars in the second wave have gained 3-6% market share in the second year of launch and are struggling to gain further ground. We expect Pegfilgrastim market size to decline by 15% each year, led by price erosion due to the entry of new players and existing players trying to capture incremental share. We expect a peak revenue of USD 40mn-50mn for LPC from this product in FY25E.

**Exhibit 15: Approved players for Pegfilgrastim in the US**

| Company | Biosimilar name | Approval date |
|---|---|---|
| Mylan/ Biocon | Fulphila | Jun-18 |
| Coherus | Udenyca | Nov-18 |
| Sandoz | Ziextenzo | Nov-19 |
| Pfizer | Nyvepria | Jun-20 |

*Source: Company, Systematix Institutional Research*

**Exhibit 16: Players awaiting approval and in clinical stage for Pegfilgrastim**

| Company | FDA filing date | FDA decision expected |
|---|---|---|
| Lupin | Jun-21 | FY23 |
| Fresenius Kabi | May-20 | Awaiting site inspection to enable completion of application review. Estimated launch in CY22 |
| Kashiv Phamra | - | Awaiting approval |
| Apotex | Dec-14 | No FDA action reported |

*Source: Company, Systematix Institutional Research*

**Spiriva opportunity key to margin improvement**

Spiriva currently has a market size of USD 700mn-800mn, with the last patent expiring in Apr-2030. LPC has an edge in Spiriva (Tiotropium DPI) as it enjoys the FTF (First-to-File) status with no other known filers yet. In Aug-18, Boehringer Ingelheim filed a suit against LPC and blocked the generic launch. A bench trial was expected to commence from Jan-22; however, LPC recently entered into a settlement agreement with the innovator, though details remain undisclosed. The settlement agreement removes the litigation risk for LPC and the company has guided for a 2HFY23E launch, contingent on approvals.

The innovator (Boehringer Ingelheim) is salvaging the opportunity through the launch of Respimat, an improved, easy to use (mist formation vs powder) and convenient (no capsule) device with a lower dosage requirement. Respimat has rapidly gained ground (almost half of Spiriva's US sales), thereby reducing the opportunity size for impending generics.

At this point, a successful USFDA approval for the product is critical for LPC to launch in 2HFY23, though we believe Spiriva Handihaler, being a DPI product, may undergo multiple review cycles by the regulator before a final approval is granted. In Exhibit 17, we list details of recent inhaler products' initial filing date and conclude that final approvals are granted an average 40-45 months after the filing date.

**Exhibit 17: Historically, inhaler products have missed the initial launch date**

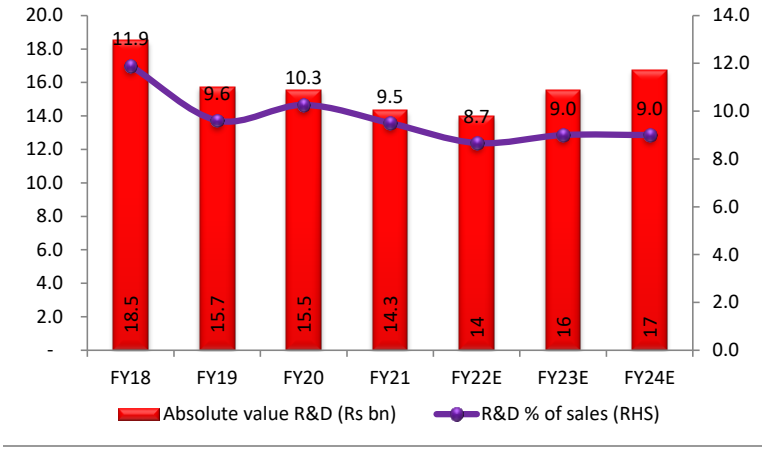
| Company | Product | Initial file date | Approval date | No. of years for launch after filing date |
|---|---|---|---|---|
| Cipla | Albuterol | Aug-17 | Apr-20 | 2.7 |
| Lupin | Albuterol | Jan-17 | Aug-20 | 3.6 |
| Perrigo | Albuterol | Dec-16 | Feb-20 | 3.2 |
| Hikma | Advair | Apr-16 | Dec-20 | 4.7 |
| Mylan | Advair | Feb-16 | Feb-20 | 4.0 |

*Source: Company, Systematix Institutional Research*

We factor in a 2HFY23 launch for LPC, in line with the management guidance, but see a fair chance of delay. We estimate Spiriva to generate USD 40mn and USD 110mn in revenues for LPC in FY23 and FY24E, translating into an EPS contribution of Rs 2 and Rs 6 respectively.

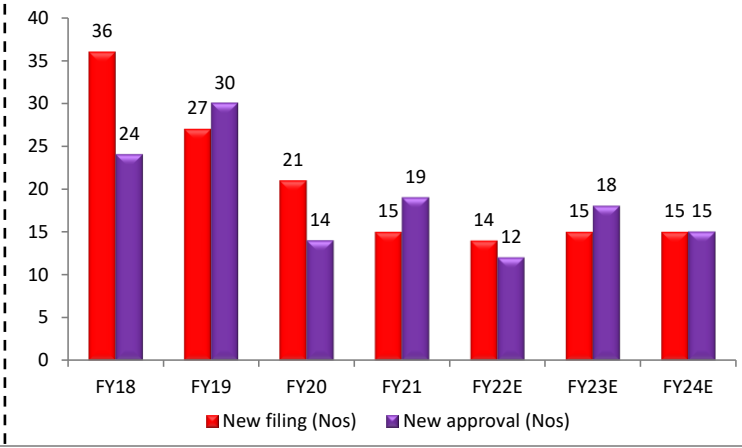
## Key statistics related to the US market

**Exhibit 18: Despite consistently high R&D spend…**



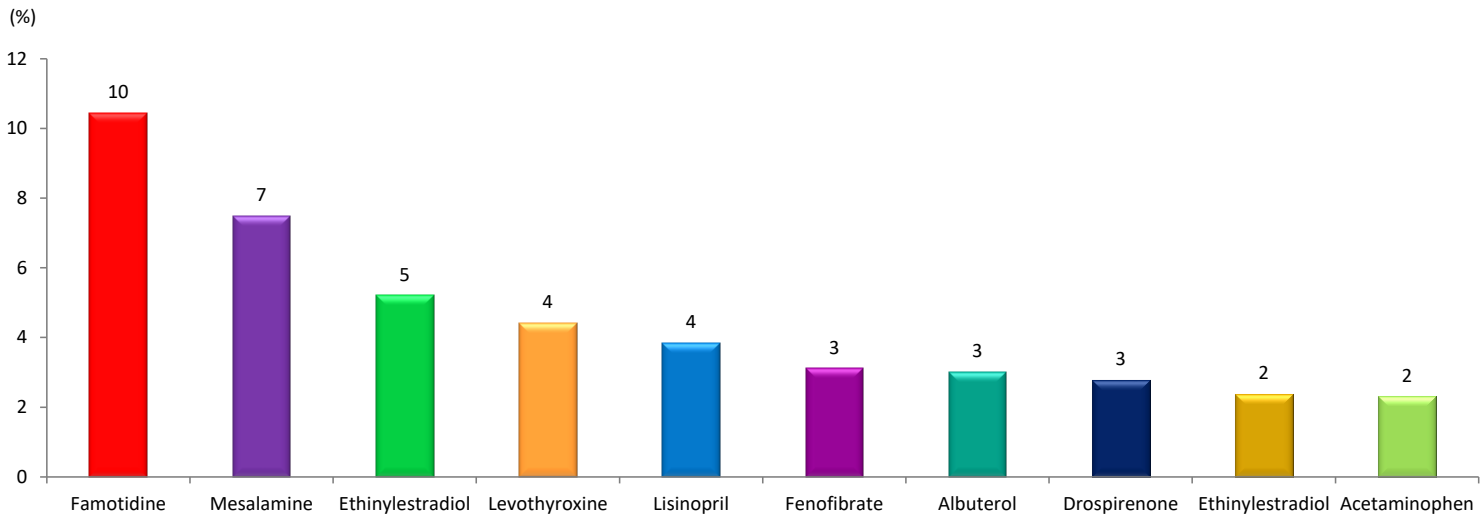

*Source: Company, Systematix Institutional Research*

**Exhibit 19: …ANDA filings have been declining**




*Source: Company, Systematix Institutional Research*

**Exhibit 20: Contribution of key products to US revenues (%; FY21)**




*Source: Industry,Company, Systematix Institutional Research*

**Exhibit 21: Product pipeline**

| Brand (API) | Innovator | Country | Market size | Current status | Expected launch | Competitive scenario |
|---|---|---|---|---|---|---|
| Spiriva | Boehringer Ingelheim | USA | USD 2.5bn | LPC has an FTF status and guided for launch in FY23E. Litigation proceeding would commence from Sep-21. Responded to CRL for the same and confident of launching in 2HFY23E despite an additional round of query | 2HFY23E | FTF status and sole filer |
| Injectable - Guidance | | USA | | LPC has guided for filing 6-8 injectables every fiscal FY22E onwards | | |
| Ganirelix- (Peptide Inj) | Organon's | USA | USD 60mn-70mn (IQVIA) | | FY23E | Sun Pharma and innovator present in the market |
| Paliperidone (Depo Inj) | J&J | USA | ~USD 1.5bn (IQVIA) | In Sep-21, J&J got regulatory approval for a twice-yearly version vs monthly and three-monthly versions earlier | FY23E | Only Teva and J&J have approval |
| Risperidone (Depo Inj) | J&J | USA | USD 300mn-350mn | Teva filed for FDA approval of a new monthly or two-monthly formulation of risperidone injectable while existing products may start with twice-daily | FY23E | Only J&J approved in injectable |
| Doxorubicin (Liposomal Inj) | Pfizer | USA | ~USD 124mn (IQVIA) | Many players present in the market; a part of in-license deal with ForDoz | FY23E | Many players |
| Ambisome (Liposomal Inj) | Gilead | USA | ~USD 70mn | Gilead is the only player; the product is a part of in-license deal with ForDoz | FY23E | |
| Neulasta-Pegfilgrastim | Amgen | USA | ~USD 900mn | LPC filed the product with the regulator on Jun-21; expects to launch in FY23E post FDA inspection | FY23E | Four players have launched in the US |
| Dulera | Merck | USA | ~USD 200mn | Filed in CY20 and received CRL from the agency. No patent on the product | FY23E | |

*Source: Company, Systematix Institutional Research*

**Exhibit 22: LPC's Para-IV filings**

| Brand | Molecule | Market Size (USD) | Innovator | Litigation filed | Patent expiry | Comments |
|---|---|---|---|---|---|---|
| Rydapt | Midostaurin Capsules | USD 91mn (IQVIA MAT Dec-20) | Novartis | Jul-21 | Apr-24 | Dr Reddy's, Lotus Pharma and Teva known filers. Lotus Pharma has the FTF status |
| | | | | | | |
| Xywav | calcium, magnesium, potassium, and sodium oxybates oral solution | USD 15mn (CY20) | Jazz Pharma | Jun-21 | Jul-23 | LPC the only ANDA filer for Xywav. Product launched in Nov-20 |
| | | | | | | |
| Ingrezza | Valbenazine Tosylate | USD 993mn (CY20) | Neurocrine | Jun-21 | Nov-27 | Teva, Crystal Pharmaceuticals and Zydus Cadila have filed Para-IV filings |
| | | | | | | |
| Kalydeco | Ivacaftor | USD 800mn (CY20) | Vertex pharma | Jun-21 | Aug-29 | Sun Pharma and LPC the only filers |
| | | | | | | |
| Austedo | Deutetrabenazine | USD 638mn (CY20) | Teva | Jun-21 | Sep-33 | Aurobindo and LPC the only filers |
| | | | | | | |
| Jynarque | Tolvaptan | USD 620mn (CY20) | Otsuka | Jun-21 | Apr-30 | LPC the sole filer till now |
| | | | | | | |
| Plenvu | Polyethylene glycol and others | USD 615mn (CY20) | Bausch | Dec-20 | Sep-33 | Teva and LPC the only filers |
| | | | | | | |
| Trijardy | Empagliflozin-Linagliptin-Metformin HCL XR | NA (launched in Jan-20) | Boehringer | Apr-20 | May-30 | Sun Pharma and LPC the only filers |
| | | | | | | |
| Myrbetriq | Mirabegron | USD 1.5bn (CY19) | Astellas Pharma | Feb-21 | Nov-23 | Actavis, Aurobindo, Prinston Pharma, Sandoz, Zydus Cadila, Windlas Pharma, Apotex, Sawai and Alkem have also filed. **LPC and a few other players** have already received tentative approval |
| | | | | | | |
| Xarelto | Rivaroxaban | USD 4.1bn (CY19) | Bayer | Mar-21 | Nov-24 | 10+ players have filed Para-IV |
| | | | | | | |
| Entresto | Sacubitril and Valsartan | USD 2.5bn (CY20) | Novartis | Jun-20 | May-27 | 18 players have submitted ANDAs |
| | | | | | | |
| Rexulti | Brexpiprazole | USD 420mn (CY20) | Otsuka | Sep-20 | Oct-32 | 18 players have submitted ANDAs |
| | | | | | | |
| Consensi | Amlodipine Besylate/Celecoxib | NA (launched in Mar-20) | Purple Biotech | Jun-20 | Jun-38 | LPC the only filer |
| | | | | | | |
| Ocaliva | Obeticholic acid | USD 234mn (CY20) | Intercept | May-20 | Apr-36 | Five ANDAs filed |
| | | | | | | |
| Procysbi | Cysteamine Bitartrate | USD 170mn (CY20) | Horizon | May-20 | Aug-36 | LPC the only filer |

| Brand | Molecule | Market Size (USD) | Innovator | Litigation filed | Patent expiry | Comments |
|---|---|---|---|---|---|---|
| Briviact | Brivaracetam | USD 386mn (CY20) | UCB Biopharma | May-20 | Feb-21 | Annora Pharma, Apotex, Aurobindo, MSN Labs, Zydus Cadila, Microlabs and Sunshine Pharma are other filers |
| | | | | | | |
| Revlimid | Lenalidomide | USD 10bn (CY20) | BMS | May-20 | Apr-26 | Dr Reddy's, Cipla, Sun Pharma, Hetero, Apotex, ANDA Inc, Lotus Pharma, Natco, Zydus Cadila, Mylan, Aurobindo, Hikma, Biocon and Torrent have filed Para-IV. Natco has the final approval while Dr. Reddy's, Cipla, Sun Pharma, Lotus and Cadila have settled the litigation |
| | | | | | | |
| Edarbi | Azilsartan Kamedoxomil | NA | Takeda | Apr-20 | Mar-28 | LPC the only filer |
| | | | | | | |
| Synjardy XR | Empagliflozin/Metformin | USD 374mn (IQVIA MAT Nov-20) | Boehringer Ingelheim | Oct-19 | Apr-27 | MSN Labs, Aurobindo and LPC other known filers |
| | | | | | | |
| Jardiance | Empagliflozin | USD 2.8bn (CY20) | Boehringer Ingelheim | Oct-18 | Jun-34 | 14 known filers for the drug |
| | | | | | | |
| Trintellix | Vortioxetine | USD 270mn (CY20) | Takeda | May-18 | Jun-27 | 16 known Para-IV filers with Alkem, Amneal, Cipla and Sandoz having tentative approvals |
| | | | | | | |
| Sprycel | Dasatinib | USD 1.3bn (CY20) | BMS | Jun-20 | Mar-26 | Apotex, Dr Reddy's and Teva other known filers. Apotex entered into settlement with BMS for a generic launch in Sep-24 |
| | | | | | | |
| Januvia | Sitagliptin | USD 5.5bn (CY20) | Merck | Jun-20 | Nov-26 | 10+ known Para-IV filers. Undisclosed settlement with a few filers |
| | | | | | | |
| Aptiom | Eslicarbazepine Acetate | USD 215mn (CY19) | Sunovion Pharmaceuticals | Jul-20 | Aug-32 | Alkem, Dr Reddy's, Hetero, Jubiliant, Torrent, Shanghai Zhongxi and Apotex other known filers |
| | | | | | | |
| BromSite | (bromfenac ophthalmic solution) | NA | Sun Pharma | Feb-20 | Aug-29 | LPC the only filer |
| | | | | | | |
| Evomela | Melphalan HCl (Inj) | USD 15mn (CY20) | CyDex | Oct-19 | Feb-33 | Alembic, Teva and LPC the only filers. Undisclosed settlement |
| | | | | | | |
| Banzel | Rufinamide | USD 285mn (CY20) | Eisai | Jul-19 | Nov-22 | Glenmark, Hetero, LPC, Mylan and Roxane are the filers. A few players have already launched. **LPC too has launched the product** |
| | | | | | | |
| Spiriva | Tiotropium bromide | USD 1.5bn (CY20) | Boehringer Ingelheim | Nov-19 | Apr-30 | LPC the only filer for Spiriva and has FTF status |
| | | | | | | |
| Venclexta | Venetoclax | USD 804mn (CY20) | Abbvie | Jul-20 | Jan-32 | Dr Reddy's and Alembic the only two filers |

*Source: Company, Systematix Institutional Research*

## LPC: A history of bad acquisitions

LPC has a track record of making large acquisitions which, in the longer run, have not been so successful and are less profitable than its core domestic formulations business. LPC has expanded in the export markets mainly through the inorganic route with small acquisitions (Kyowa being the larger one) in APAC, EMEA and LATAM regions. In the US, the acquisition of Gavis in 2016 for USD 880mn has been one of the largest executed by an Indian player. Due to several less profitable investments, LPC's RoCE has declined from 37% to 10% over FY16-21.

**Kyowa and Gavis – large off-target investments**

LPC acquired Kyowa in 2007 and scaled up its revenues to JPY 180bn, ~80% of its APAC revenues. The company became the 6th largest generics company in Japan, with growth primarily driven by huge investments in acquisitions or tie-ups in injectables, biosimilars and branded products. Meanwhile, the Japanese government, while increasing its focus on the usage of generic drugs (80% share in total market), further reduced the prices of the drug (through annual price revisions vs biannual earlier). In this backdrop, LPC's investment did not pay off and it started witnessing pressure on its financials due to lower margins in the Japanese business.

**Exhibit 23: List of acquisitions by LPC**

| Date | Acquisitions and tie-ups |
|---|---|
| **2007** | Acquired Kyowa - Revenues of JPY 7.4bn with focus on cardiovascular, respiratory, allergies and gastro segments |
| **2008** | Acquired injectables company Pharmaceutical IP with sizeable presence in hospitals |
| **2014** | JV with Yoshindo for clinical development of biosimilars |
| **2016** | Acquired 21 branded products from Shionogi |
| **2017** | Entered into an agreement with Astellas to promote quetiapine fumarate tablets |

*Source: Company, Systematix Institutional Research*

Gavis has been the biggest drag for LPC, with the acquisition valued significantly higher at 9x EV/ Sales vs peer deals at 1-3x and its foray into highly regulated controlled substances. LPC's strategy to reap benefits from this venture did not advance as planned. Post acquisition of Gavis, LPC's US revenues declined at 12% compounded annually over FY17-21 along with an impairment of USD 600mn (75% of the acquired value). The revenue hit was mainly on account of: 1) pricing pressure in key products, 2) countermeasures against the usage of opioids in the US market, and 3) a slow pace of approvals.

**Exhibit 24: Historically, large acquisitions executed at 1-3x EV/ Sales**

| Target | Acquirer | Deal value (USD mn) | Deal date | EV/ Sales (x) |
|---|---|---|---|---|
| **Gavis** | **Lupin** | **880** | **Jul-15** | **9.0** |
| Actavis | Intas | 767 | Oct-16 | 1.0 |
| Betapharm | Dr. Reddy's | 572 | Feb-06 | 2.0 |
| Medpro | Cipla | 512 | Feb-13 | 3.0 |
| Invagen | Cipla | 550 | Feb-16 | 2.5 |
| Ranbaxy | Sun Pharma | 3200 | Apr-14 | 2.2 |

*Source: Company, Systematix Institutional Research*

## Diagnostic foray: Meaningful contribution a few years away

LPC announced the launch of its diagnostics business in India in Dec-21. It currently has a predominant presence in the western and eastern regions through 11 regional labs, including a 45,000 square feet National Reference Lab (NRL) in Navi Mumbai and 200 collection points (36 operational) in Mumbai.

Over the next three years, LPC plans to open more than 100 labs and 1,000 collection points with ~90% of the centers run by franchises. Like incumbent diagnostic players, LPC will operate its business on a hub-and-spoke model with a pan-India network comprising labs, collection points, pickup points, hospital and retail lab management, and home collection. Under the model, while all routine and a few specific tests will be done at regional labs, more complex/ specialty tests will be conducted at the Reference lab. Test offerings cover preventive health checkups and a comprehensive range of tests including molecular diagnostics, cytogenetics, flow cytometry, microbiology, serology, histopathology, cytology, hematology, immunology, etc.

LPC expects the diagnostics foray to leverage its doctor-connect to tap a largely unorganized sector with low entry barriers offering a better RoCE and margin profile than the pharmaceuticals business. Given that the industry is already hyper-competitive in both organized and unorganized formats, it will take some time to see a meaningful scale-up in this business.

While LPC appears to be aggressively building its diagnostics business, these are still early days. Nevertheless, the business can potentially prove to be an additional value driver over the medium to longer term. Our key concern stems from the recent trend of expensive inorganic growth in the sector, which LPC may also end up opting for.

**Exhibit 25: Inorganic growth has been the key focus for diagnostics players**

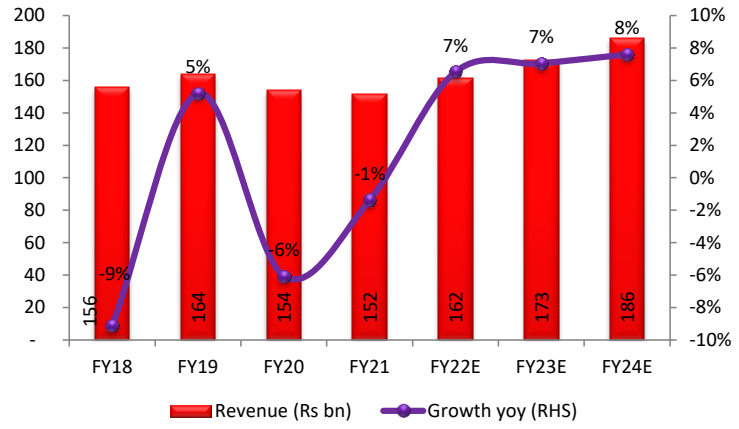
| Acquirer | Acquired | Deal value (Rs mn) | EV/ EBITDA (x) |
|---|---|---|---|
| Metropolis | Hi tech | 6,250 | 13 |
| Dr. Lal | Surburban | 11,500 | 20 |
| PharmEasy | Thyrocare | 45,460 | 27 |

*Source: Company, Systematix Institutional Research*

## Financial Analysis

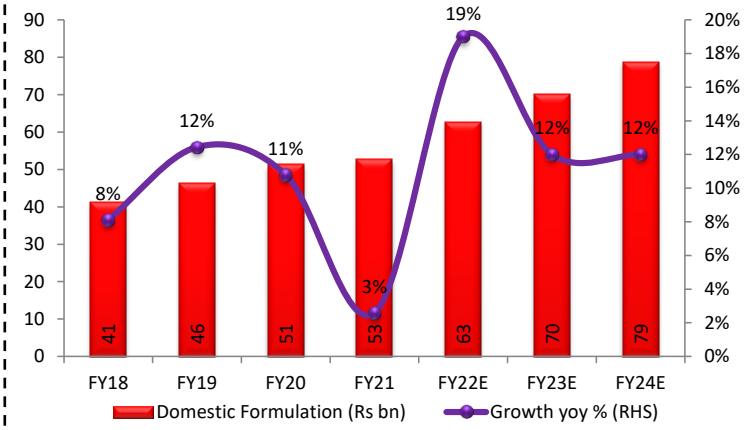
We expect 7% CAGR in LPC's revenues over FY22-24E, driven by: 1) 12% growth in domestic formulations, albeit on a low base, and higher share of low-margin in-licensed products, and 2) a subdued 5% CAGR in the US business due to increased competition in key products and challenges in scaling up of biosimilars.

**Exhibit 26: Expect revenue CAGR of 7% over FY22-24E**



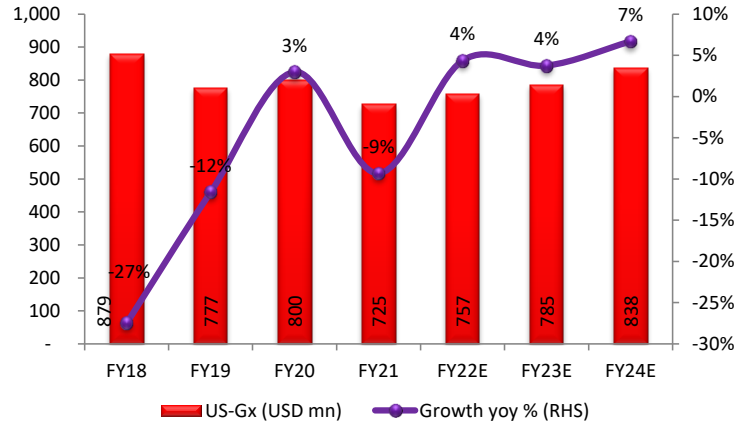

*Source: Company, Systematix Institutional Research*

**Exhibit 27: In-licensed products drive domestic formulations**



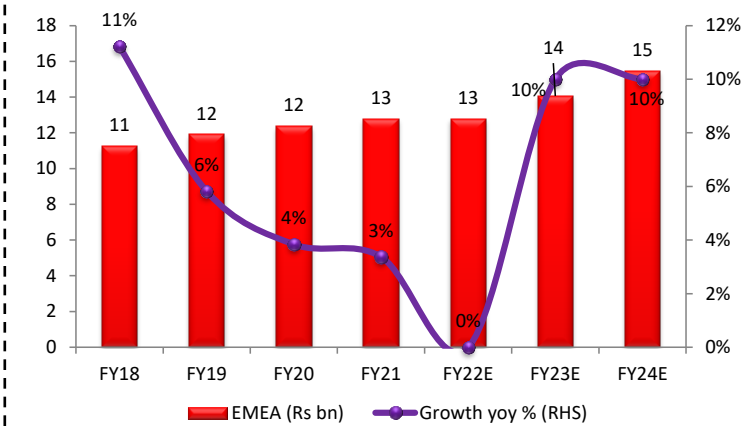

*Source: Company, Systematix Institutional Research*

**Exhibit 28: Challenges to persist in the US business**




*Source: Company, Systematix Institutional Research*

**Exhibit 29: EMEA growth to remain muted**



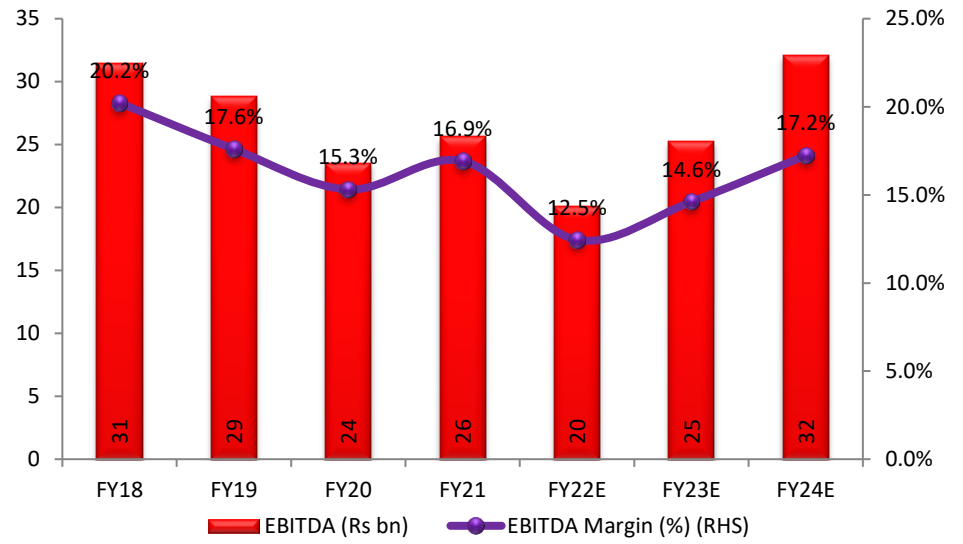

*Source: Company, Systematix Institutional Research*

**US to remain a drag on margins**

We expect LPC's EBITDA margins to remain lower than its comparable peers with the same business mix, mainly due to increased competition in the US in key molecules such as Albuterol, Famotidine and Levothyroxine (25-30% share in US revenues). In the domestic formulations business too, margins have been under pressure with 15-17% of revenues accruing from the lower-margin in-licensed products (even as 48% of revenues come from cardiac and anti-diabetes segments). The new diagnostics venture, we believe, will also weigh on margins due to higher Opex (mainly marketing and staff costs).

Despite a 470bps margin expansion over FY22-24E to 17% owing to lower R&D spend on complex molecules and rationalization of the front-end team for Solosec in the US, LPC's margins will still be significantly lower than comparable peers due to price erosion in US products.

**Exhibit 30: EBITDA margins to remain lower than peers**

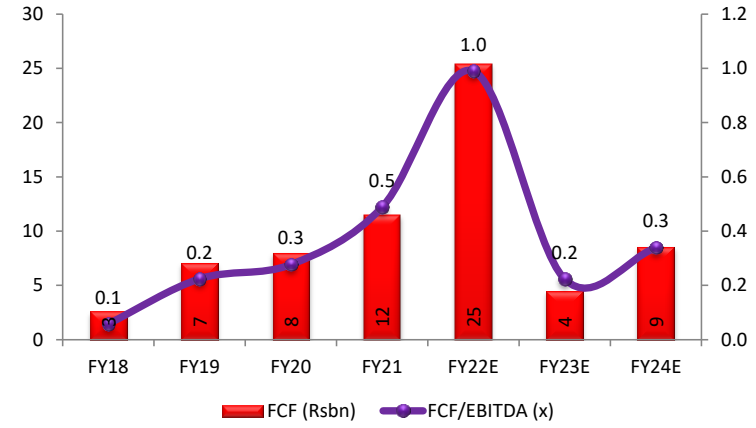



*Source: Company, Systematix Institutional Research*

**Expect RoCE to remain weak in the near term**

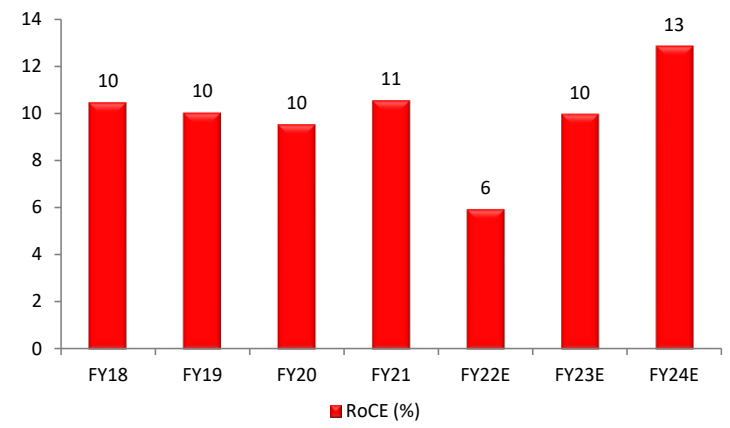
The acquisition of Gavis has significantly impacted LPC's return ratios, with most of the acquisition value already been written off. Initiatives like Specialty products (Solosec) and US investments (especially Oral contraceptives) have underperformed expectations, dragging RoCE further down. While concerns related to Gavis (as a large part of the investment is already written off) and Solosec (Opex rationalized from USD 60mn annually to USD 15mn currently) are behind, we still do not see any material improvement ahead, especially with upcoming investments in the diagnostics business. We expect LPC's RoCE and EBITDA at 13% and 17% respectively to remain the weakest among peers in FY24E.

**Exhibit 31: Cumulative FCF of Rs 38bn over FY22-24E**



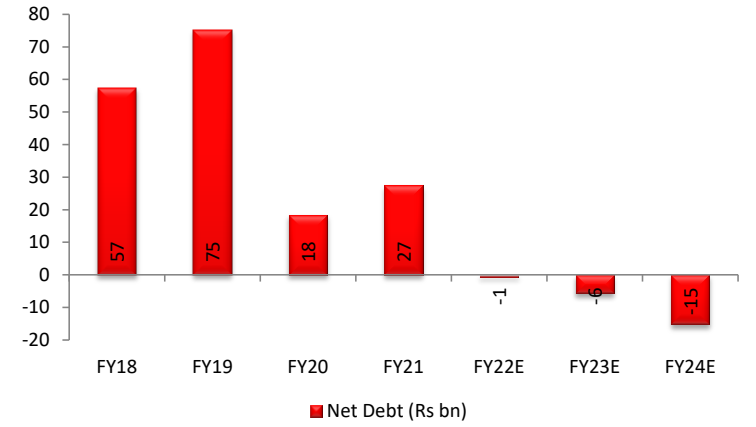

*Source: Company, Systematix Institutional Research*

**Exhibit 32: RoCE to remain weak**



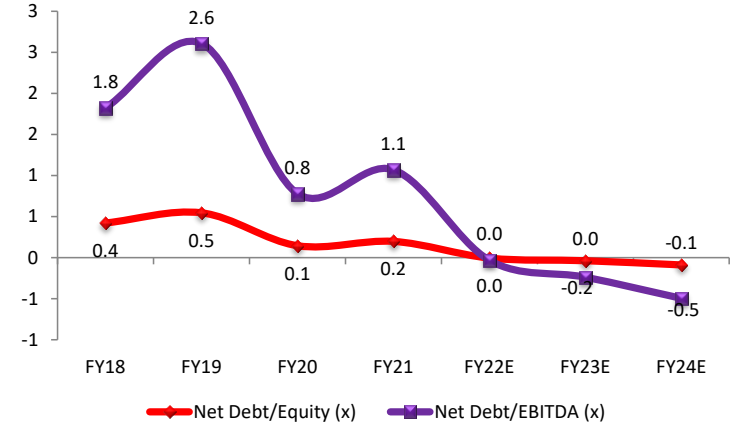

*Source: Company, Systematix Institutional Research*

**Exhibit 33: Net debt to improve**



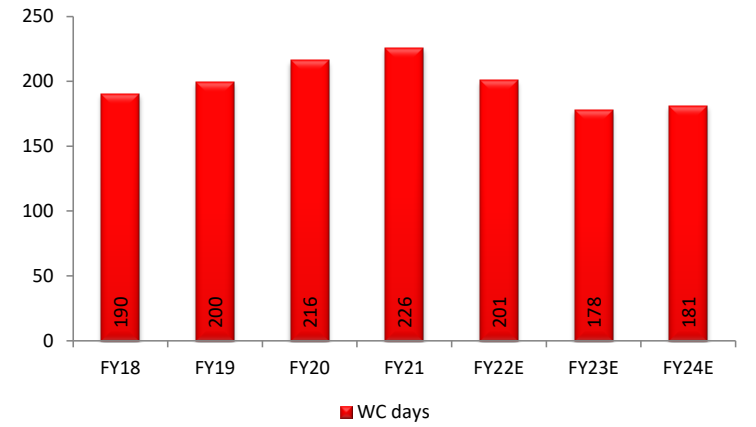

*Source: Company, Systematix Institutional Research*

**Exhibit 34: Leverage ratio expected to improve**



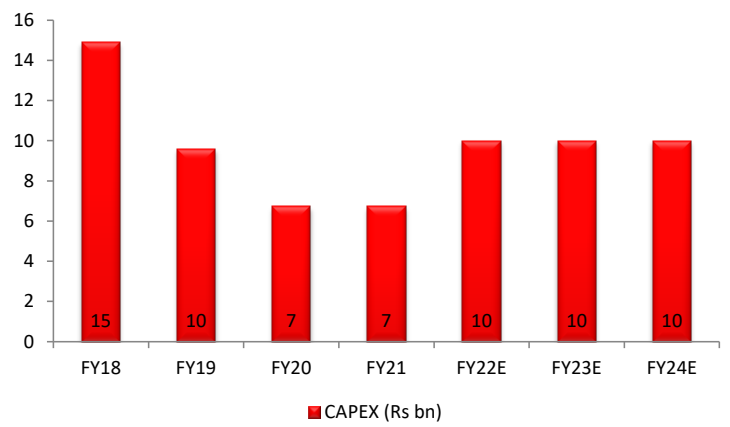

*Source: Company, Systematix Institutional Research*

**Exhibit 35: Working Capital trend**




*Source: Company, Systematix Institutional Research*

**Exhibit 36: Capex trend**




*Source: Company, Systematix Institutional Research*

## Valuations & View

The US business, with increased competition in key molecules, unresolved regulatory issues and a weak product pipeline, remains LPC's biggest concern. Even in the case of a complete resolution of regulatory issues at its plants in the near term, we will largely maintain our estimates as key products filed from these facilities have either been shifted to other facilities or are unviable for launch due to a changing competitive environment. We estimate a 5% CAGR in LPC's US revenues over FY22-24E with launch of gSpiriva expected in 2HFY23E post its settlement with the innovator.

At CMP, the stock trades at 19x FY24E EPS of Rs 39, which is a 14% discount to its 5-year average; we believe there is scope for a further de-rating given the following:

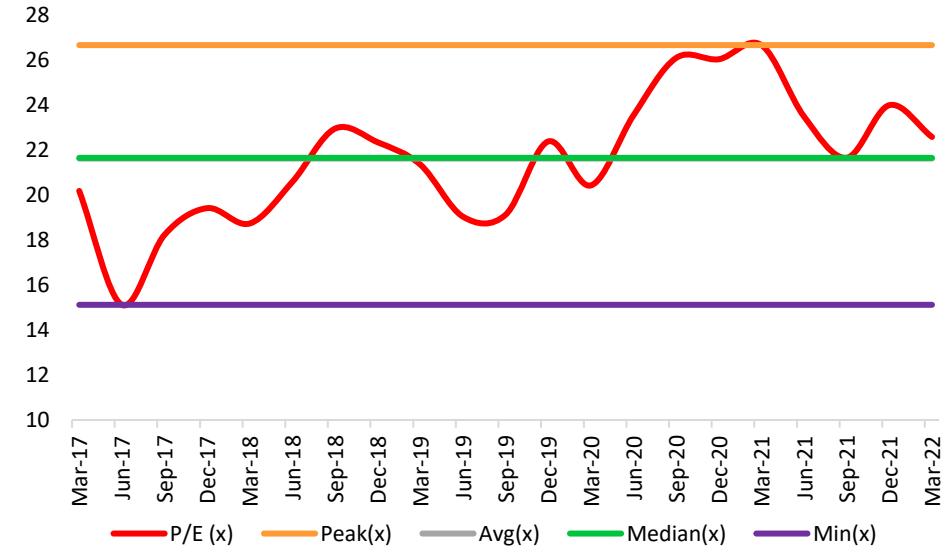
a) Weak prospects in the US market with increasing competition in key molecules (Famotidine, gAlbuterol and Levothyroxyin) contributing 25-30% of US revenues

b) Possibility of products like Spiriva and Pegfilgrastim failing to meet expectations

c) Weak EBITDA margins and RoCE profile vis-à-vis peers

We believe the valuation discount should widen further because of LPC's sub-optimal margin profile compared to peers and headwinds in its US business. We expect the stock to de-rate to 16x FY24E earnings and initiate coverage with a **SELL** rating for a target price of Rs 622.

**Exhibit 37: P/E**




*Source: Systematix Institutional Research*

# Annexures

## Company Background

LPC was founded in 1968 by Dr Desh Bandhu Gupta and first gained recognition when it became one of the world's largest manufacturers of tuberculosis drugs. Having transformed from a pure API to plain oral solids to a complex generics player over the last few decades, LPC has made investments in expanding its presence globally through acquisition of companies and brands. LPC entered the US markets much earlier than its peers in 2000 with the launch of injectable Cefotaxime (the first Indian company to get approval for the injectable).

LPC is now one of the leading Indian players, ranking 5$^{th}$ by prescription in the US market. The company ranks 6$^{th}$ in the IPM (value-wise) with a market share of 3.8%. It has one of the best Chronic/ Acute mix of 76%/ 24% among peers given in-license deals with innovators and focus on therapies like anti-diabetic, cardiac and respiratory.

US and India are the two largest markets for LPC, accounting for 72% of its total revenues. It also has presence in EMEA, LATAM and APAC. The company has expanded its presence in the export markets mainly by acquiring brands/ companies and partnership modules. Kyowa (Japan) in CY07 and Gavis (USA) in CY16 are among the key acquisitions made by LPC in the last two decades.

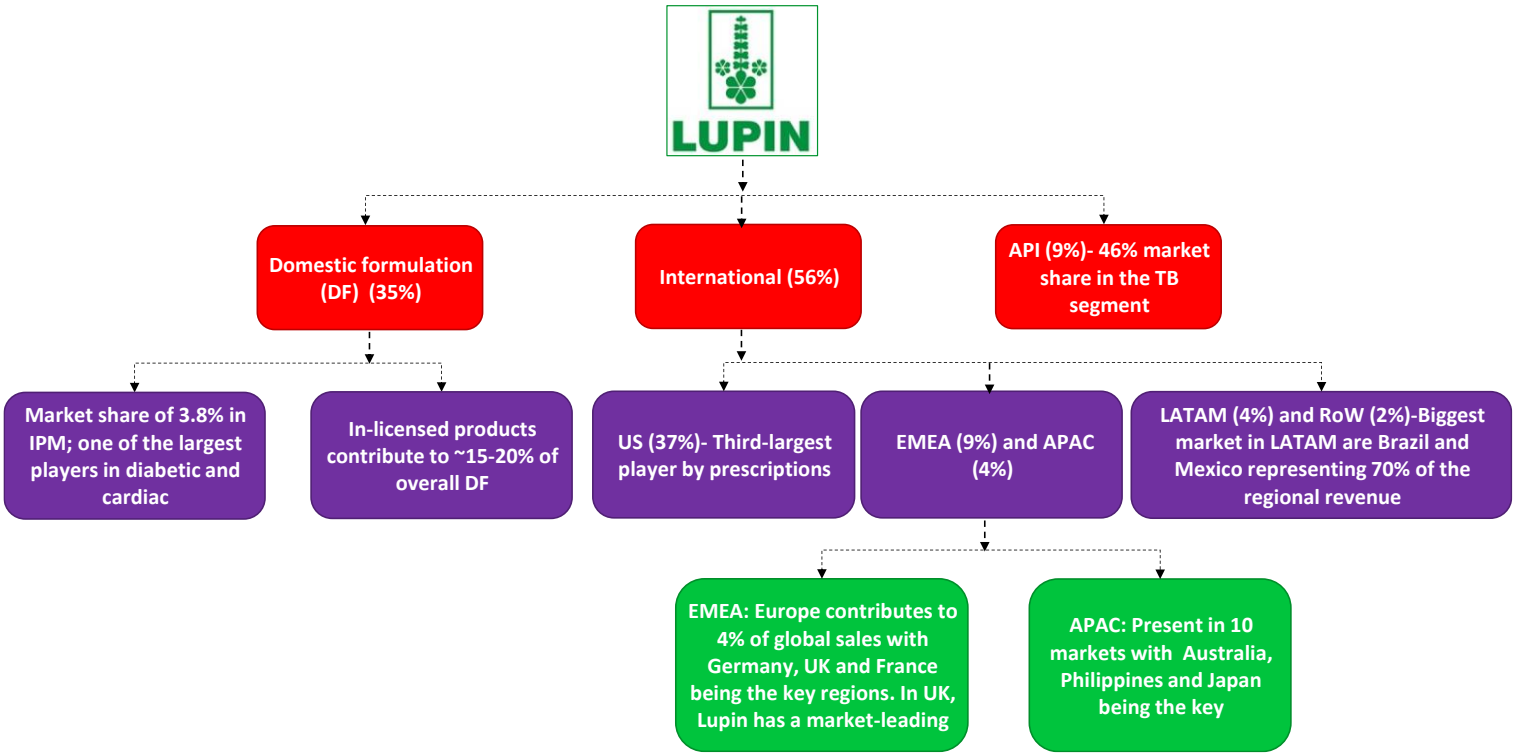
Meanwhile, given the increasing genericization in Japan, LPC exited the market in CY19 and wrote off 75% of its investment in Gavis, citing an unfavourable macro environment and pricing pressure. With the US business leading to muted new launch activity on regulatory concerns and pricing pressure on existing molecules, LPC is exploring entry into China through the partnership and acquisition route to leverage its existing inhalation products and with a launch timeline of 3-4 years. The recent launch of Fostair in the UK, Enbrel in the EU, and the filing of its first BLA in the US for Pegfilgrastim demonstrates its increased focus on building specialty products, mainly for export markets.

**Exhibit 38: Key management personnel**

| Name of Person | Designation | Education | Roles and achievements |
|---|---|---|---|
| Vinita D. Gupta | CEO | Pharmacy graduate (University of Mumbai); holds a management degree from JL Kellogg Graduate School of Management (USA) | Started her career at LPC's Aurangabad site before heading to the US to pursue an MBA. She did an internship with Abbot as an analogy to get LPC into developed markets. After completing her MBA in 1992, she was assigned the task of developing the blueprint to take LPC to the US and other countries, and then execute it. In 2013, she was appointed as the CEO of the company; she is in charge of US operations |
| Nilesh D. Gupta | Managing Director | Bachelor's degree in chemical engineering from the University Department of Chemical Technology, (Mumbai) and an MBA from the Wharton School, University of Pennsylvania, US in 2002 | Joined LPC in 1996 and was appointed as MD in 2013. He oversees the integral backend, including LPC's core research and development (R&D) and manufacturing operations, out of Mumbai. Given the direct responsibility of overseeing LPC's domestic business, he manages a field force of around 7,000+ MRs across India |

*Source: Company, Systematix Institutional Research*

**Exhibit 39: Business segments**




*Source: Company, Systematix Institutional Research*

## Annual report analysis

**Exhibit 40: FY21 Annual Report takeaways**

| | | | | |
|---|---|---|---|---|
| **Domestic formulations** | Five key therapies - Cardiology, Anti-diabetes, Respiratory, Anti-infective and Gastro - contributed 76% of domestic sales. In-licensing remains a critical strategy to widen the product offering and drive growth; focus on chronic therapies | Expanding offering within the Gynaecology, Dermatology, Urology, and Pediatrics therapy segments in India. Field force of 7,000+ for domestic formulations | LupinLife (OTC) grew 28% despite the impact of COVID-19. Flagship brand *Softovac* led the growth, clocking 30% YoY growth with current market share of 46% (IMS MAT March 2021 – Bulk Laxatives) | Newly launched products Aptivate and Lupizyme delivered strong growth of 19% and 30% respectively. Introduced the LupiSafe range of sanitizers, wipes and sprays; also introduced BeOne |
| | | | | |
| **USA** | Launched 15 new products in the US and ramped up Albuterol and Levothyroxine market share. gGlumetza market share reached ~50% post the NDMA concern. Strong performance in products such as *Famotidine, Lisinopril* and *Levothyroxine* in FY21 | Initiated a cost optimization program involving optimizing procurement, renegotiating contracts, rationalization of sales force – to drive margin expansion in FY22 | 3rd largest generics player (prescriptions) with a leading share in 53 products. Focus on complex generics in inhalation, biosimilars and injectables. Filed first biosimilar product Peg-filgrastim | In FY21, LPC settled 11 US and one UK litigations. It received favorable court decisions in Kerydin and Tecfidera patent challenges in the US. Filed three major inhalation products in the US (generics to ProAir, Spiriva and Brovana) |
| | | | | |
| **EU and APAC** | UK approved Fostair for which LPC is the first generic to be approved. Key growth drivers included portfolio expansion in German subsidiary, and scale-up of NaMuscla beyond UK, Germany and France. In the UK, maintained its leadership position in the ARV segment | German court's favorable decision for Truvada SPC challenge. On the CNS front, focus is on Neurology, with orphan drug NaMuscla launched in the UK, Germany, France and other European countries | Present in 10 markets in the region including Australia, Philippines and Japan/ Korea in APAC | The Australian subsidiary (Generic Health) ranks 4th among generic players in the region; supplies generic prescriptions and OTC medicines to pharmacies and hospitals in Australia |
| | | | | |
| **LATAM** | Brazil and Mexico represent 70% of LPC's LATAM revenues. In Mexico, LPC ranks 2nd in the ophthalmic reference market (by units) | The ophthalmic market hit hard by the pandemic as patients ceased treatment of acute conditions while private ophthalmologist practices were closed. Lab Grin's portfolio consists of 50 ophthalmic products and 10 primary care products | Brazil is the key pharmaceutical market within LATAM. Valued at USD 21bn, it accounts for 47% of the region's sales | LPC's Brazilian subsidiary has 570 personnel; now ranks 13th in value in the region and is the 5th-largest in its reference market (by units), commanding a 6.4% share. LPC outpaced industry growth with 35% growth in BRL terms |
| | | | | |
| **South Africa, API and other details** | Key segments include Cardiovascular and CNS as well as the OTC franchise. The benchmark-pricing band structures being used by medical aid funding agencies have been driving prices down | LPC maintained its leadership in the CVS space, led by key brands – *Amloc (Amlodipine), Fedaloc (Nifedipine)* and *Bilocor (Bisoprolol).* Complementary medicines franchise and OTC segment augmented by cough and cold brands, further fueled by the immune booster and Flu products range | API business further forward integrated into Global Institutional Business (GIB) and Principal to Principal (P2P) business. The former aims to eradicate high burden diseases such as Tuberculosis (TB), HIV and Malaria through partnerships with government agencies and organizations across the globe | Three focus areas for Complex Generics – Inhalation, Biosimilars and Complex Injectables. Specific to these areas, LPC has built a strong pipeline and will continue to focus on delivering on this pipeline |

*Source: Company Annual Report, Systematix Institutional Research*

## Key formulation plants

**Exhibit 41: Goa facility**


*Source: Company, Systematix Institutional Research*

**Exhibit 42: Mandideep facility**

*Source: Company, Systematix Institutional Research*

**Exhibit 43: Key plants for LPC**

| Plant | Dosage | Regulatory Approvals | Capacity |
|---|---|---|---|
| Mandideep Unit 1 | OSD | ANSM, USFDA, Russia MOH, CDSCO, Kenya FDA, Philippines FDA, TGA | 0.9bn units |
| Pithampur Unit 1 | Oral Contraceptives | USFDA, MHRA, WHO & CDSCO, WHO Geneva, LAGeSo Berlin (Germany), Ministry of Industry and Trade of the Russian Federation | 1bn units |
| Pithampur Unit 1 | High Potent Drug | USFDA, MHRA, WHO & CDSCO, WHO Geneva, LAGeSo Berlin (Germany), Ministry of Industry and Trade of the Russian Federation | 1.5bn units |
| Pithampur Unit 2 | OSD/ Ophthalmic | USFDA, MHRA, Berlin Authority, ANVISA Brazil, CDSCO and Indian FDA | 4bn units/ 45mn bottles |
| Pithampur Unit 3 | MDI and DPI/ Derma | USFDA, Accreditation Certificate of foreign Drug Manufacturers from MHLW, Japan | 70mn packs/ 0.35mn packs |
| Nagpur Unit 1 (Block 1 &2) | OSD | MHRA, TGA, WHO, USFDA, ZAZIBONA, WHO (Geneva), National Drug Authority-Uganda, Republic of the Philippines | 100mn units (Block 1)/ 12bn units (Block 2) |
| Nagpur Unit 2 | Injectables | Indian FDA | 13mn packs |
| Goa Unit 1 & 2 | OSD & Oral Suspension | USFDA, UK MHRA, WHO, ANVISA, JAPAN-PMDA, KOREA-MFDS. Accreditation Certificate of foreign Drug Manufacturers from MHLW, Japan | 6bn units |
| Aurangabad | OSD/ Dry powder | USFDA, WHO, FDA-Taiwan, German | 5bn units/ 1mn units |
| Somerset, NJ, USA | Finished dose manufacturing and packaging | USFDA | Up to 2.5bn doses |

*Source: Company, Systematix Institutional Research*

# FINANCIALS

### Profit & Loss Statement

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **Net Revenues** | **153,748** | **151,630** | **161,542** | **172,939** | **186,111** |
| YoY gr. (%) | -6 | -1 | 7 | 7 | 8 |
| Cost of Goods Sold | 54,306 | 53,622 | 63,809 | 65,717 | 67,000 |
| Gross Profit | 99,442 | 98,007 | 97,733 | 107,222 | 119,111 |
| Margin (%) | 65 | 65 | 61 | 62 | 64 |
| Employee Cost | 29,868 | 28,259 | 30,661 | 33,114 | 35,763 |
| Other Expenses | 46,025 | 44,079 | 46,945 | 48,822 | 51,263 |
| **EBITDA** | **23,548** | **25,669** | **20,127** | **25,286** | **32,085** |
| YoY gr. (%) | -18 | 9 | -22 | 26 | 27 |
| Margin (%) | 15 | 17 | 12 | 15 | 17 |
| Depn. and Amort. | 9,702 | 8,874 | 15,468 | 10,580 | 11,180 |
| **EBIT** | **13,846** | **16,795** | **4,659** | **14,706** | **20,905** |
| Margin (%) | 9 | 11 | 3 | 9 | 11 |
| Net Interest | 3,630 | 1,406 | 1,249 | 1,099 | 949 |
| Other Income | 4,838 | 1,363 | 6,139 | 4,323 | 4,653 |
| **Profit Before Tax** | **15,054** | **16,751** | **9,549** | **17,931** | **24,609** |
| Total Tax | 11,571 | 4,485 | -1,900 | 5,021 | 6,891 |
| Effective tax rate (%) | 77 | 27 | -20 | 28 | 28 |
| **Profit after tax** | **3,483** | **12,266** | **11,449** | **12,910** | **17,718** |
| EPS | 8 | 27 | 25 | 28 | 39 |
| YoY gr. (%) | -63 | 245 | -7 | 13 | 37 |

*Source: Company, Systematix Institutional Research*

### Balance Sheet

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| Equity Share Capital | 906 | 907 | 907 | 907 | 907 |
| Res. & Surp. (Ex OCI) | 124,906 | 137,674 | 155,324 | 165,880 | 181,245 |
| **Net Worth** | **125,812** | **138,581** | **156,231** | **166,788** | **182,153** |
| Short term debt | 24,928 | 30,494 | 25,494 | 20,494 | 15,494 |
| Long term debt | 17,933 | 6,133 | 6,133 | 6,133 | 6,133 |
| Trade payables | 24,123 | 20,144 | 23,983 | 25,675 | 27,631 |
| Other Provisions | 43,282 | 35,648 | 35,705 | 35,705 | 35,705 |
| Other liabilities | 10,527 | 553 | 553 | 553 | 553 |
| **Total Liabilities** | **246,604** | **231,553** | **248,099** | **255,348** | **267,668** |
| | | | | | |
| Net block | 79,381 | 80,436 | 74,967 | 74,388 | 73,208 |
| CWIP | 9,396 | 8,515 | 8,515 | 8,515 | 8,515 |
| Other Non-current asset | 0 | 0 | 0 | 0 | 0 |
| Investments | 23,743 | 24,287 | 24,287 | 24,287 | 24,287 |
| Cash and Cash Equi. | 24,543 | 9,206 | 32,293 | 32,660 | 37,536 |
| Debtors | 54,459 | 44,743 | 54,143 | 57,963 | 62,378 |
| Inventories | 34,569 | 40,920 | 34,368 | 36,793 | 39,595 |
| Other current asset | 20,512 | 23,446 | 19,525 | 20,742 | 22,148 |
| **Total Assets** | **246,604** | **231,553** | **248,099** | **255,348** | **267,668** |

*Source: Company, Systematix Institutional Research*

### Cash Flow

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| PBT | 8,768 | 16,765 | 9,549 | 17,931 | 24,609 |
| Depreciation | 11,596 | 8,874 | 15,468 | 10,580 | 11,180 |
| Interest | 3,630 | 1,406 | -4,890 | -3,225 | -3,704 |
| Others | 517 | 253 | 8,470 | -85 | -85 |
| Working capital | -4,710 | -1,926 | 4,912 | -5,769 | -6,668 |
| Direct tax | -5,112 | -7,155 | 1,900 | -5,021 | -6,891 |
| **Net cash from Op.** | **14,688** | **18,217** | **35,409** | **14,411** | **18,441** |
| Net Capital expenditures | -6,713 | -6,714 | -10,000 | -10,000 | -10,000 |
| Others | 17,783 | -5,682 | 6,139 | 4,323 | 4,653 |
| **Net Cash from Invt.** | **11,070** | **-12,396** | **-3,861** | **-5,677** | **-5,347** |
| Issue of share cap. | 1 | 1 | 0 | 0 | 0 |
| Debt changes | -1,504 | -13,677 | -5,000 | -5,000 | -5,000 |
| Dividend paid | -2,730 | -2,723 | -2,269 | -2,269 | -2,269 |
| Others | -4,673 | -2,452 | -1,249 | -1,099 | -949 |
| **Net cash from Fin.** | **-8,906** | **-18,851** | **-8,517** | **-8,367** | **-8,217** |
| **Net change in cash** | **16,853** | **-13,030** | **23,030** | **367** | **4,876** |

### Ratios

| YE: Mar | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **Per Share (Rs)** | | | | | |
| EPS | 8 | 27 | 25 | 28 | 39 |
| CEPS | 13 | 46 | 78 | 52 | 64 |
| BVPS | 277 | 305 | 344 | 367 | 401 |
| DPS | 5 | 5 | 5 | 5 | 5 |
| **Return Ratio (%)** | | | | | |
| RoCE | 10 | 11 | 6 | 10 | 13 |
| RoE | -3 | 9 | 14 | 8 | 10 |
| **Balance Sheet** | | | | | |
| Net Debt: Equity (x) | 0.1 | 0.2 | 0.0 | 0.0 | -0.1 |
| Net Working Capital (Days) | 216 | 226 | 201 | 178 | 181 |
| **Valuation (x)** | | | | | |
| PER | 97 | 28 | 17 | 27 | 19 |
| EV/EBITDA | 1 | 1 | 17 | 13 | 10 |
| EV/Sales | 0 | 0 | 2 | 2 | 2 |

*Source: Company, Systematix Institutional Research*

| Revenue details (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **Domestic Formulation** | **51,386** | **52,712** | **62,727** | **70,255** | **78,685** |
| **US** | **58,213** | **55,520** | **56,017** | **58,897** | **62,829** |
| EMEA | 12,363 | 12,780 | 12,780 | 14,058 | 15,464 |
| APAC | 6,069 | 6,656 | 6,457 | 7,102 | 7,812 |
| LATAM | 6,143 | 5,836 | 7,295 | 8,024 | 8,827 |
| ROW | 2,815 | 3,237 | 3,302 | 3,797 | 4,367 |
| API | 12,999 | 13,823 | 10,464 | 8,005 | 5,327 |
| Other operating income | 3,760 | 2,000 | 2,500 | 2,800 | 2,800 |
| **Total Revenue** | **153,748** | **152,564** | **161,542** | **172,939** | **186,111** |

*Source: Company, Systematix Institutional Research*

# DIVI'S Laboratories

28 March 2022

## Going from strength to strength

**INITIATING COVERAGE**

**Sector: Pharmaceuticals** **Rating: BUY**

**CMP: Rs 4,457** **Target Price: Rs 5,180**

| Stock Info | |
|---|---|
| Sensex/Nifty | 57,362/17,153 |
| Bloomberg | DIVI IN |
| Equity shares | 265mn |
| 52-wk High/Low | Rs 5,425/3,392 |
| Face value | Rs 2 |
| M-Cap | Rs 1183bn/USD 16bn |
| 3-m Avg value | USD 36mn |

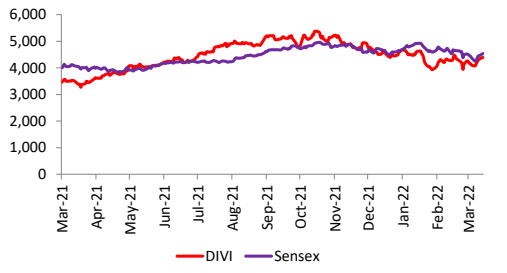
**Financial Snapshot (Rs mn)**

| Y/E March | FY22E | FY23E | FY24E |
|---|---|---|---|
| Revenue | 88,862 | 91,175 | 106,736 |
| Gross profit | 59,579 | 60,428 | 71,377 |
| Gross Margin (%) | 67 | 66 | 67 |
| EBITDA | 38,393 | 37,176 | 45,748 |
| Margin (%) | 43 | 41 | 43 |
| PAT | 28,144 | 27,057 | 33,829 |
| EPS | 106 | 102 | 127 |
| DPS (Rs) | 16 | 16 | 16 |
| ROCE (%) | 34 | 28 | 29 |
| P/E (x) | 42 | 44 | 35 |
| EV/EBITDA (x) | 30 | 31 | 24 |

**Shareholding pattern (%)**

| | Jun-21 | Sep-21 | Dec-21 |
|---|---|---|---|
| Promoter | 51.9 | 51.9 | 51.9 |
| –Pledged | - | - | - |
| FII | 20.6 | 20.7 | 19.3 |
| DII | 16.6 | 16.4 | 17.8 |
| Others | 10.9 | 11.0 | 11.0 |

**Stock Performance (1-year)**




**Key beneficiary of the rising trend in outsourcing:** Global outsourcing trends remain favorable with increasing R&D funding and a conducive regulatory environment (>18,500 drugs in active development). As per Pharma Projects, the annual R&D pipeline witnessed a 7% CAGR over FY15-21 vis-à-vis 5% CAGR over FY10-15. Industry tailwinds should also prevail as customers seek to diversify their sourcing vendor base to reduce dependency on China. Given DIVI'S established track record, stringent IPR adherence policy, sticky customer base and robust execution skills, we see it as the best placed among peers to benefit from higher outsourcing.

**Huge capex in recent years imparts strong growth visibility:** DIVI'S is known for its tight capex policy, investing only when there is order visibility. Over FY19-21, the company embarked on its most extensive capex program of Rs 25bn at DC-SEZ Unit-1 and DCV-SEZ Unit-2 dedicated to: 1) capacity expansion for existing and new generic molecules, 2) custom synthesis projects, 3) debottlenecking of existing capacities, 4) backward integration to reduce dependency on imported KSM, and 5) Molnupiravir API capex. It has further chalked out a strong capex plan for FY22-24E with an annual spend of Rs 10bn-20bn towards Kakinada (Unit-3) and Nellore (Unit-4) facilities. This should translate into strong earnings growth over the next few years.

**Focus on six key growth engines:** 1) Improving global market share in generic molecules from 20-30% to 60-70% by augmenting capacity, 2) benefit from Molnupiravir approval by regulatory agencies for COVID-19 treatment, 3) ramping-up volumes of Sartan-related products post the backward integration of critical starting materials, 4) increasing focus on contrast media by introducing new products and increasing the capacity of existing ones, 5) targeting newer molecules going off-patent between 2023-25, and 6) commercialization of custom synthesis projects.

**Initiate with BUY:** DIVI'S is likely to sustain its growth momentum while maintaining cost discipline. The stock trades at a 16% premium to its 5-year average PE of 30x. We expect the premium multiple to sustain given the long growth runway and an improving returns profile. We initiate coverage on the stock with a **BUY** rating and a target price of Rs 5,180 based on 41x FY24E EPS, a 35% premium to its 5-year average valuation given the improving margin profile and focus on custom synthesis.

**Praful Bohra**
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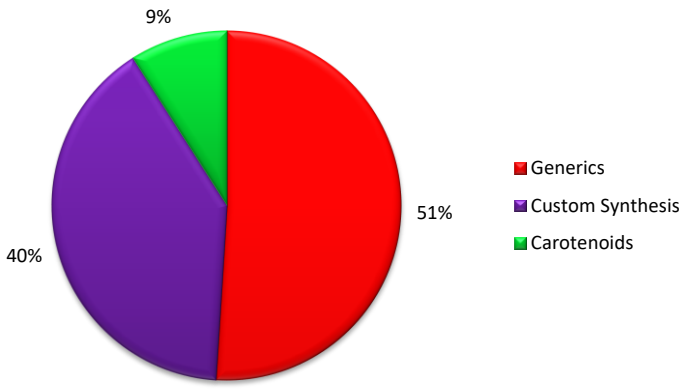
+91 22 6704 8064

**Investors are advised to refer disclosures made at the end of the research report.**

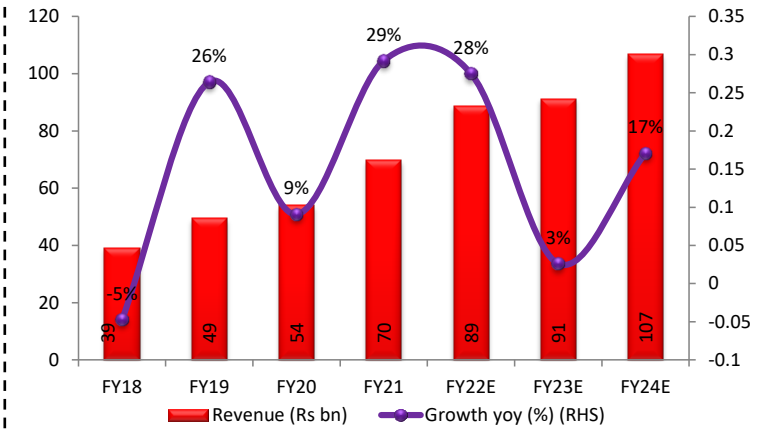
## Story in charts

**Exhibit 1: Business mix (%; FY21)**



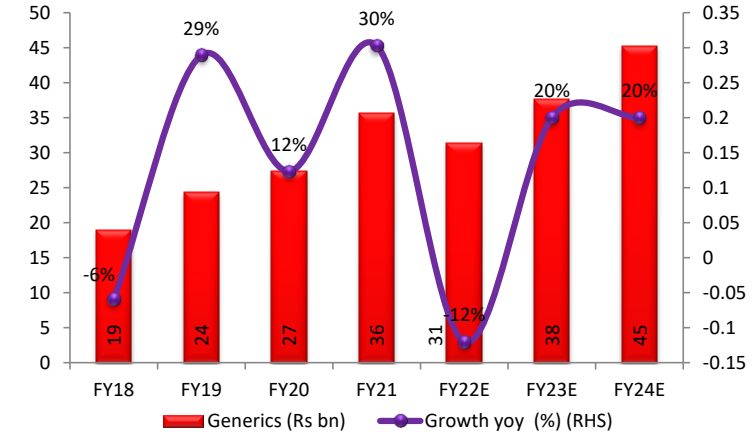

*Source: Company, Systematix Institutional Research*

**Exhibit 2: Revenue CAGR of 10% over FY22-24E**



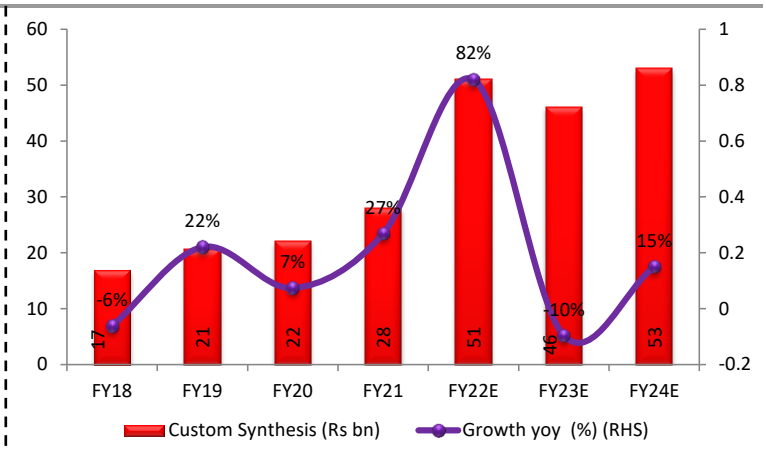

*Source: Company, Systematix Institutional Research*

**Exhibit 3 : New off-patent molecules to drive growth over FY23-24E**



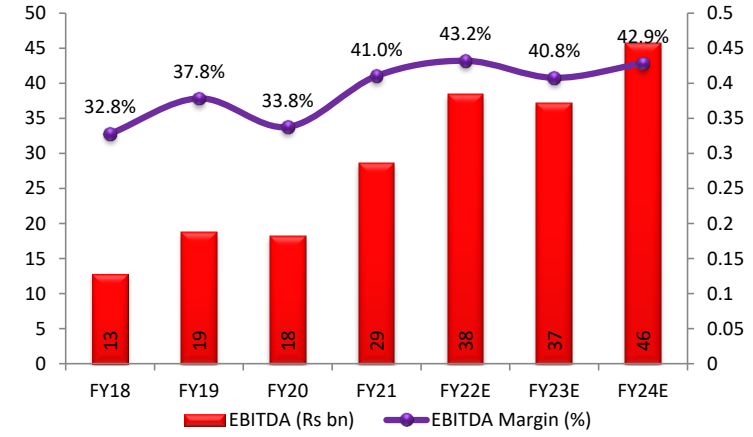

*Source: Company, Systematix Institutional Research*

**Exhibit 4: New projects to drive growth for Custom Synthesis**



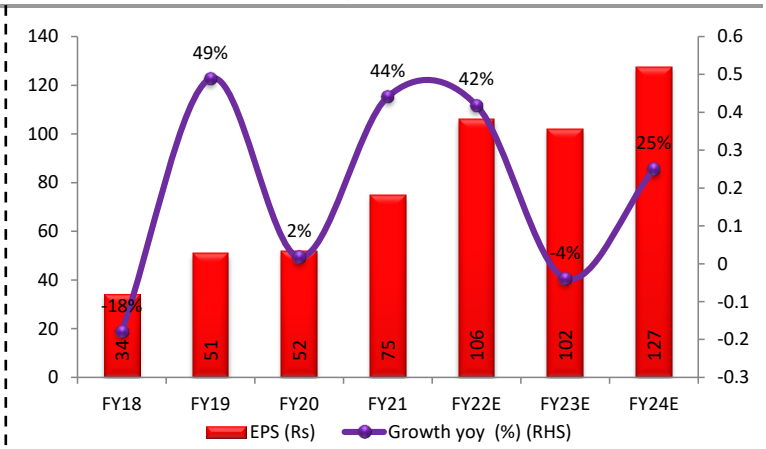

*Source: Company, Systematix Institutional Research*

**Exhibit 5: Margins to sustain at >40% led by backward integration**




*Source: Company, Systematix Institutional Research*

**Exhibit 6: EPS CAGR of 10% expected over FY22-24E**




*Source: Company, Systematix Institutional Research*

## Executive Summary

DIVI'S is one of the best positioned pharma companies in India to benefit from the ever-increasing outsourcing trend, led by an early-mover advantage in CRAMS, its policy of following strict IP adherence and well-entrenched relationships with pharma majors. It is India's most successful CRAMS company, as reflected in the strong 33% EPS CAGR registered over FY18-22. The company is now well-geared for the next leg of growth, led by its six growth engines. DIVI'S has embarked on a major capex spree, investing ~Rs 25bn over the last three years with a further capex of Rs 20bn earmarked for upcoming projects. Historically, the company is known for its tight capex policy and, thus, is a good proxy for growth visibility.

**Exhibit 7: Details of capex undertaken over FY20-21**

| | Details | Capex amount (Rs bn) | Existing Capacity (MTA) | New Capacity (MTA) | % Change |
|---|---|---|---|---|---|
| Debottlenecking | Unit 1 & 2 | 3 | | | |
| Backward integration | Unit 1 & 2 | 3 | | | |
| DC-SEZ Unit-1 | Capacity increased for existing generic molecules and new product addition including Molnupiravir supply to Indian VL partners | 6 | 2,744 | 5,806 | 112 |
| DCV-SEZ Unit-2 | Capacity increased for existing generic molecules; new products added including Molnupiravir exports | 6 | 10,740 | 11,888 | 11 |
| Custom Synthesis | Fast track project completed in Mar-21 at DCV-SEZ Unit-2 by adding 2 new blocks | 4 | | | |
| Unallocated capex | | 3 | | | |
| | **Total** | **25** | **13,484** | **17,694** | 31 |

*Source: Company, Systematix Institutional Research*

**What differentiates DIVI'S from peers**

DIVI'S has emerged as a key beneficiary of increased outsourcing to India on the back of its strong execution skills and client relationships. Despite all odds, the company has stuck to its core philosophy of IPR adherence and focus on profitability. Unlike competitors, DIVI'S has stayed away from unnecessary ambitious investments to gain manufacturing presence outside India and, instead, has leveraged its low-cost India manufacturing base. More importantly, the facilities are highly fungible and able to switch products or scale/ reduce production levels as per client needs.

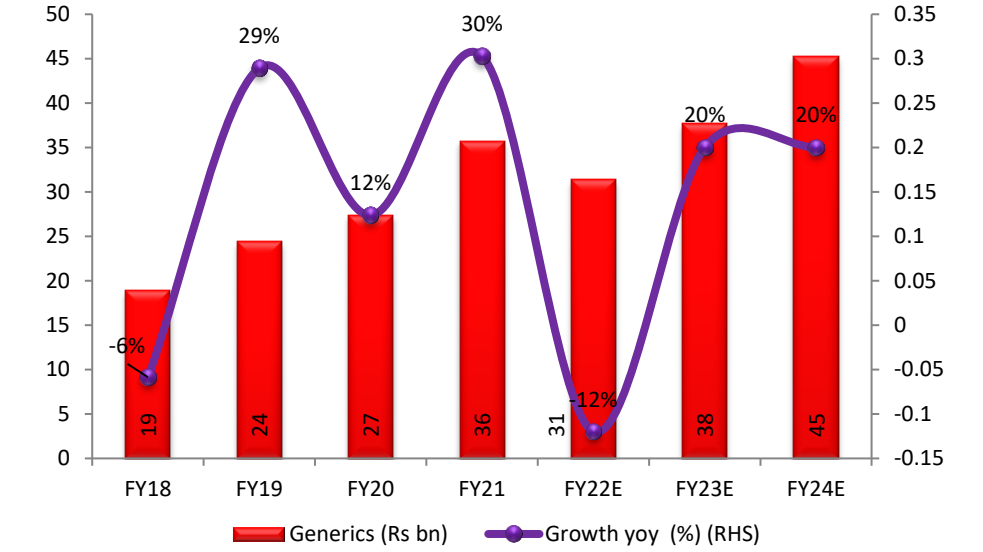
**Next phase of growth to be driven by its six key growth engines**

DIVI'S plans to sustain its impressive performance on the back of growth initiatives including: 1) an improving market share in generic molecules, 2) benefit from Molnupiravir approval by various regulatory agencies for COVID-19 treatment, 3) ramping up volumes of Sartans products post backward-integration of main starting materials, 4) increasing focus on contrast media products, 5) targeting newer molecules going off-patent between 2023-25, and 6) commercialization of its fast-track project related to Custom Synthesis. These measures, we believe, will lay the foundation for the next leg of growth for DIVI'S.

**Higher share in existing molecules, patent expiries to drive growth in generics**

Apart from the legacy molecules, where DIVI'S already enjoys 50-60% market share, it has gained market share in relatively newer generic molecules as well (currently at 20-30%). The target is to increase the share further to 50-60% in the coming years. In addition, the company has identified a few products which are due for patent expiry over FY23-25E – these products offer a global market size of USD 23bn. The company is already working on product development and will file these products soon. We expect a revenue CAGR of 20% for the segment over FY22-24E, led mainly by new molecules and followed by volume expansion in existing molecules.

**Exhibit 8: Generics growth to be led by existing products, patent expiries over FY23-24E**




*Source: Company, Systematix Institutional Research*

### Next leg of expansion to focus on Kakinada and Nellore

Post a capex of Rs 25bn over the last three years, DIVI'S has now commenced work for the next phase of expansion at Kakinada (Unit-3) and Nellore (Unit-4) facilities. The projects have a total capex outlay of ~Rs 20bn over FY22-24E including a new capacity of 28,878 MTA – 63% higher than the cumulative existing capacity, and a large part of the capex will be over by FY23E. This further adds to revenue visibility, as DIVI'S historically is known to incur capex only when it has order visibility.

**Exhibit 9: Upcoming expansion plans**

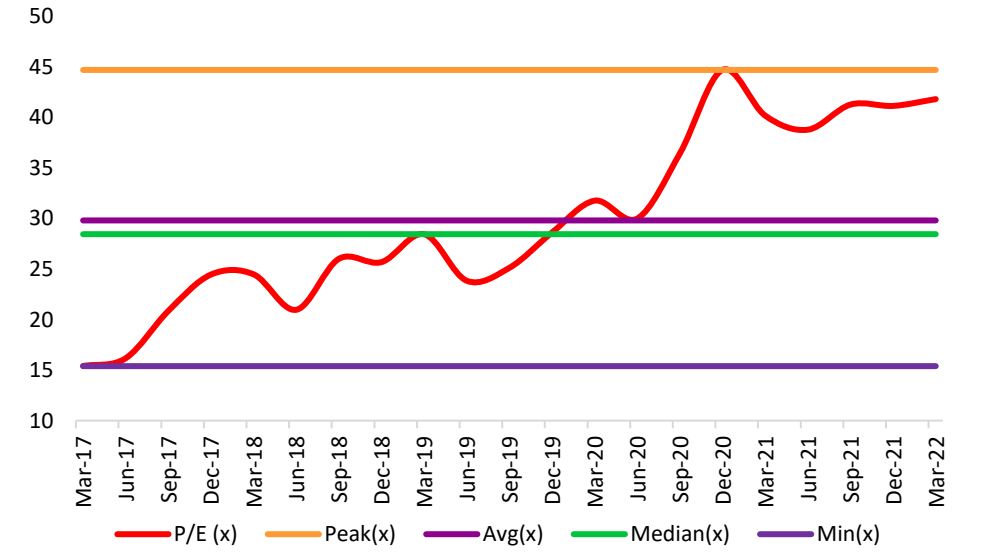
| New Project | | Capex amount (Rs bn) | Capacity (MTA) |
|---|---|---|---|
| Kakinada - (Unit-3) | Greenfield project with construction commenced in CY21. Phase -1 expected to be completed in 15-18 months; another 15 months for project validation | 15 | 18,395 |
| Nellore - (Unit 4) | New project with construction to begin post completion Unit-3 | 5 | 10,483 |

*Source: Company, Systematix Institutional Research*

### Valuations and outlook

We expect DIVI'S to sustain its growth momentum while maintaining cost discipline. The stock trades at a 16% premium to its 5-year average PE of 30x. We expect the premium multiples to sustain given the long growth runway and an improving returns profile. We initiate coverage on the stock with a **BUY** rating and a target price of Rs 5,180 based on 41x FY24E EPS, a 35% premium to its 5-year average valuation. We believe the premium is justified given the improvement in margin profile and focus on Custom Synthesis.

**Exhibit 10: PE**




*Source: Company, Systematix Institutional Research*

## Key risks

**Significant exposure to INR/ USD movement**

DIVI'S has significant exposure to INR/ USD movement as ~85% of its revenues are billed in USD while most of its costs are INR-denominated (only ~40% of raw materials imported). The company passes along currency benefits on 40% of its long-term contracts to customers while retaining benefits on the remaining 60%. As per our calculations, 33% of DIVI'S net revenues benefit from INR depreciation with a 100bps expansion in operating margins for a 10% depreciation in INR/ USD.

**Outsourcing industry vulnerable to macro shocks**

While the outsourcing environment has improved since the 2009-10 slowdown, any pressure on macro drivers for the sector, such as biotech funding and client product pipelines, could significantly impact the company's performance.

**High client and product concentration**

DIVI'S has a high concentration risk with its top-5 products/ clients contributing 43%/ 41% of its total revenues. However, the company appears to be well insulated owing to its dominant position (~70% global market share) in top products and the sticky nature of its business (strong relationships and early-stage partnerships with clients); this has helped DIVI'S retain clients and get repeat business.

**Limited visibility on CCS contracts**

There is limited visibility on the potential of DIVI'S Custom Synthesis business given the confidential nature of its contracts.

## Milestones

**Exhibit 11: DIVI'S – Key milestones and events**

| 2019-21 – Expansion projects |
|---|
| DC-SEZ Unit-1 – Capex of Rs 6bn towards incremental capacity and new product addition |
| DCV-SEZ Unit-2 – Capex of Rs 6bn towards incremental capacity and new product addition |
| Capex of Rs 6bn towards backward integration and de-bottlenecking |
| |
| **Three-year strategy – 2022-2024** |
| Commercialization of New Custom Synthesis project by end of FY22E |
| Completion of Unit-3 in Kakinada in FY23E |
| Completion of Unit-4 in Nellore in FY24E |

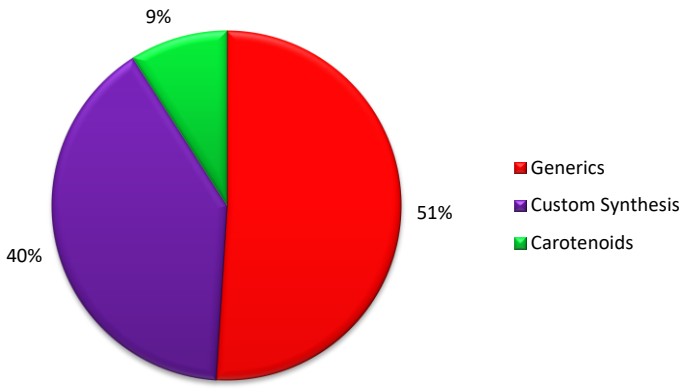
*Source: Company, Systematix Institutional Research*

## Investment Analysis

**Strong positioning, competitive edge**

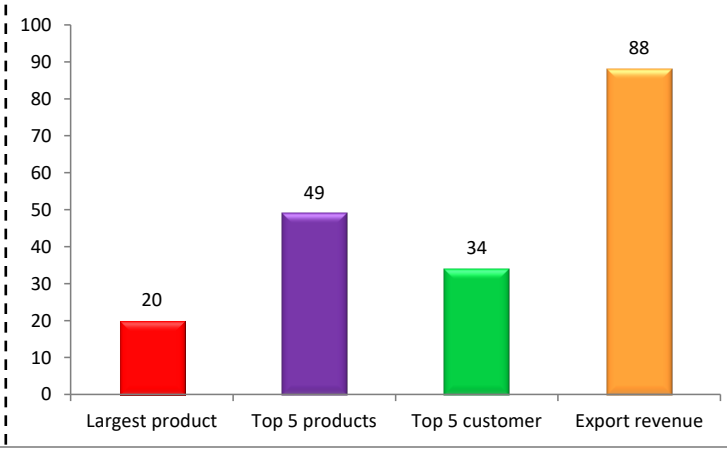
DIVI'S was set up in 1990 as an API manufacturer by Dr Murli Divi, a first-generation entrepreneur with extensive experience at Cheminor — a Dr. Reddy's Labs entity. DIVI'S subsequently ventured into Custom Synthesis and steadily forged a rapport with pharma majors. Since then, it has evolved into India's leading CRAMS company, led by 33% revenue CAGR over FY18-22. Strong chemistry skills and strict adherence to IPR norms helped DIVI'S establish robust relationships with 20 of the top-25 global pharma players. Besides supplying intermediates and APIs to generic players, DIVI'S caters to innovator pharma players for their patented products (under clinical trials and post launch) via its Custom Synthesis business.

**Exhibit 12: Business mix (%; FY21)**



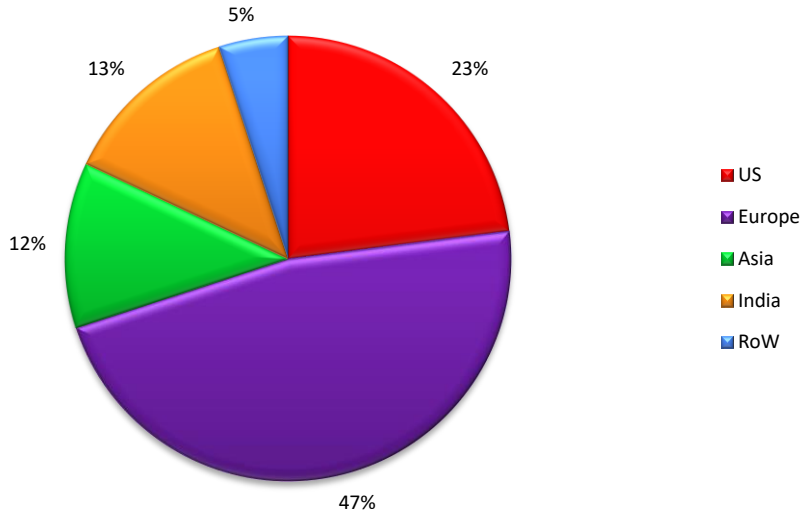

*Source: Company, Systematix Institutional Research*

**Exhibit 13: Share (%) of products/ customers/ export in revenues**




*Source: Company, Systematix Institutional Research*

**Exhibit 14: Revenue break-up geography wise**




*Source: Company, Systematix Institutional Research*

## What differentiates DIVI'S from peers

DIVI'S has emerged as a key beneficiary of increased outsourcing to India on the back of its strong execution skills and client relationships. Despite all odds, the company has stuck to its core philosophy of IPR adherence and focus on profitability. We believe the following characteristics differentiate DIVI'S from peers:

**Strict adherence to client IPR:** DIVI'S follows a stringent policy of IPR adherence and refrains from filing its own products in client markets. This holds significant value for clients as it gives them comfort in sharing important product-related data. DIVI'S has successful business partnerships with 20 of the world's top-25 pharma players.

**Low-cost India-centric manufacturing base:** Unlike peers, DIVI'S has refrained from making expensive acquisitions abroad and, instead, has leveraged on its India-centric low-cost manufacturing base. Given that manufacturing costs in India are less than half of that in regulated countries, DIVI'S has clocked high profits even during down-cycles (eg: in FY10).

**Astute product selection:** DIVI'S follows a rigorous filtering process and selects only those products wherein it can command a large market share, control pricing, or involve complex technologies that limit competition.

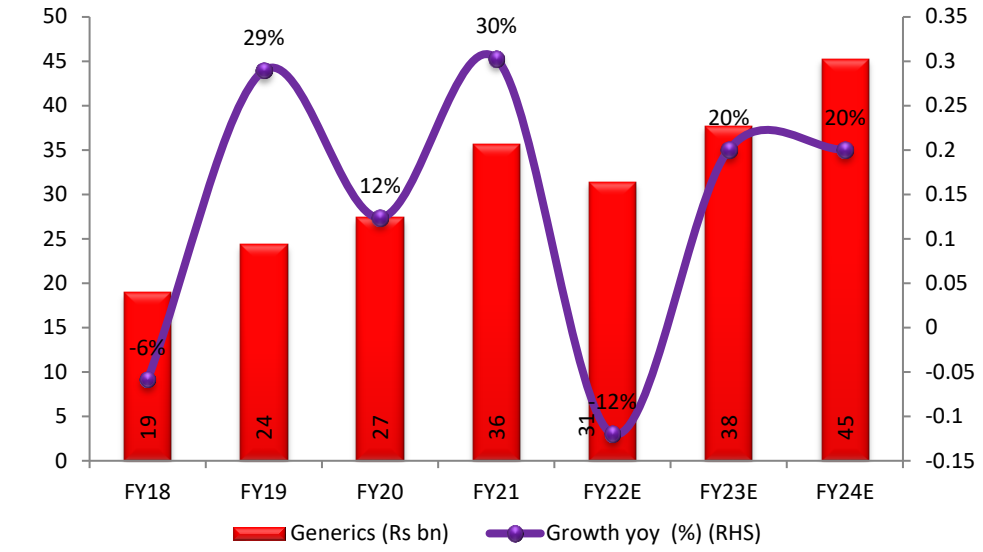
**Flexibility in manufacturing:** Unlike peers in regulated markets that usually have large capacities for a small base of products, the company's manufacturing facilities are fungible and able to switch products or scale/ reduce production levels as per client needs.

## Generics business: Aiming for global leadership, high volumes

**Strong process chemistry**

Under the generics business which constitutes 51% of its revenues, DIVI'S supplies intermediates and APIs to generic companies and develops alternate, non-infringing processes for APIs for innovators. The generics portfolio is not very large, with 49% share of top-5 products in total revenues. However, the revenue scale-up to Rs 31bn (14% CAGR over FY18-FY22) has been impressive, reflecting the company's astute product selection process.

**Exhibit 15: Generics trajectory led by volume growth**

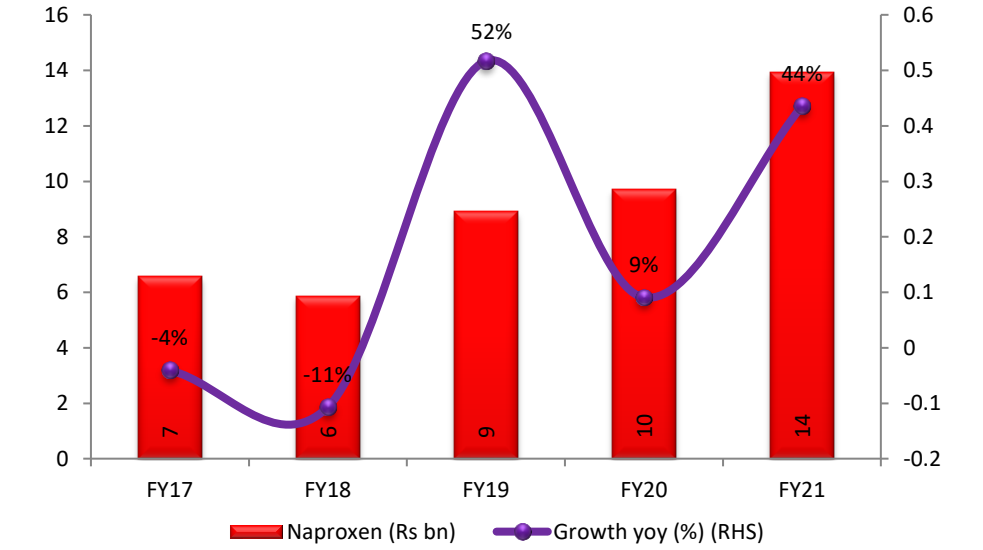



*Source: Company, Systematix Institutional Research*

The strategy is simple — DIVI'S usually selects a few high-volume APIs that involve complex chemistry, are high in cost (as a percent of sales) and offer scope for process improvement. This enables the company to gain a larger market share by reducing costs for clients.

For instance, more than 20 API suppliers (including large players like Lonza) for anti-inflammatory drug Naproxen entered the market before DIVI'S. However, DIVI'S developed a new production process using enzymes as catalysts instead of chemicals, which was eco-friendlier and more cost-effective. Therefore, despite being a late entrant, it captured market share from incumbents and is the largest supplier of the API globally with a 70% market share.

**Exhibit 16: Naproxen growth and revenues trend**




*Source: Company, Systematix Institutional Research*

In addition to Naproxen, DIVI'S enjoys global leadership in other mature products, including Dextromethorphan and Nabumetone, with >70% market share. Given that mature products, being well-established, typically do not face sharp price erosion, DIVI'S portfolio should remain a cash cow in the medium term. Due to the company's global leadership and cost competitiveness, new competitors will find it difficult to make inroads here.

DIVI'S has also gained market share in relatively newer generic molecules where it holds a 20-30% share and targets to increase it further to 50-60% in the coming years. Pricing is usually stable in these products and, with the recent capacity addition, it expects this portfolio to grow by ~10% over the next few years.

In addition, DIVI'S has identified a few products which are due for patent expiry over FY23-25E – these products offer a global market size of USD 23bn. The company is already working on product development and will file these products soon. We expect this business to clock a revenue CAGR of 20% over FY22-24E, led mainly by new molecules followed by volume expansion in existing molecules.

## Contrast Media APIs: Iodinated products offer a large market

DIVI'S is aggressively targeting the contrast media segment by adding new products and increasing the capacity of existing ones. The company has been selling Iopamidol for the last few years and has a capacity of 180 MTA (Unit 1). It has recently added Iopromide to the list and set up a 200 MTA (Unit 1) capacity. The global contrast media segment is concentrated with top five players (GE, Bayer, Bracco, Mallinckrodt and Guerbet) holding 85-90% of the USD 5bn-6bn industry, and the remaining 10-15% is with several generic players from the Asian region. It is estimated that Bayer and GE together command more than 50% of the total market.

**Exhibit 17: DIVI'S contrast media capacity**

| API | Existing capacity (MTA) - Unit 1 | Upcoming capacity (MTA) - Unit 3 | Details |
|---|---|---|---|
| Iopromide | 200 | - | Included product to the list during FY19-21 capex plan |
| Iopamidol | 180 | 300 | Old capacity of 180 MTA mainly used for exporting to the EU and US clients for past several years. Another 300 MTA to be added post Unit-3 completion in FY23-24E |
| Iohexol | - | 300 | Had capacity of 15 MTA in Unit 1 but was discontinued in FY19-20. New larger capacity to come on stream in Unit-3 from FY23-24E |

*Source: Company, Systematix Institutional Research*

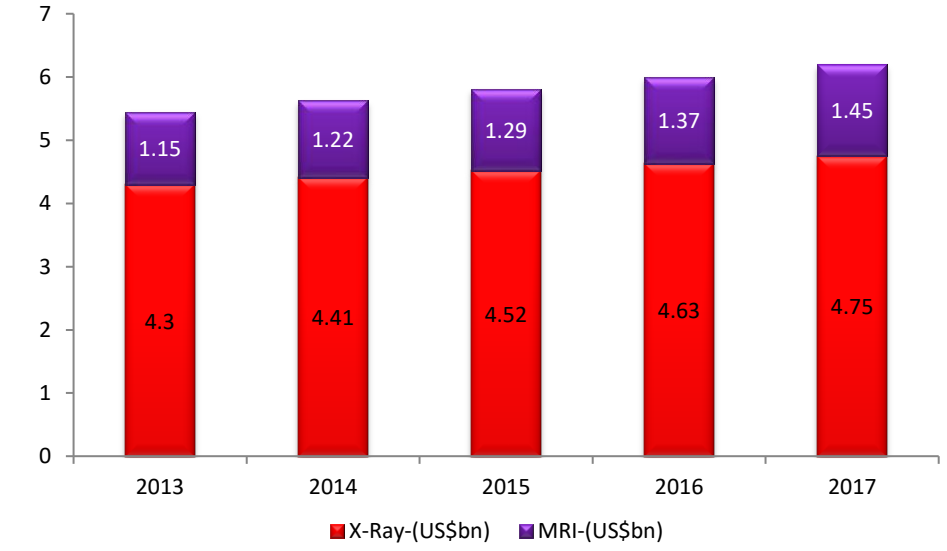
### DIVI'S focus on Iodinated products owing to its large share of X-ray and CT scans

Contrast agents help in advanced visualization of biological structures and help capture hard-to-image anatomical regions. They allow radiologists to distinguish between normal and abnormal tissues and are relatively higher volume products (ranging from 20-60 grams per individual).

Iodinated products are mainly used for X-rays and CT scans while gadoliniums are used for MRIs. With X-ray agents constituting ~75% of the overall contrast media APIs and Iodinated products growing at 2-3% consistently, DIVI'S interest seems to be in the right direction to capture the share in this segment (pegged at ~USD 4.7bn).

The market for gadolinium APIs, growing at 5-6% for the past few years, has reached ~USD 1.5bn in size and competition has been heating up recently. A case in point is Gadopentetate, one of the leading gadolinium APIs, which now has more than 10 generic manufacturers and several API manufacturers across the globe.

**Exhibit 18: Contrast Media market size**




*Source: Industry reports*

**Economies of scale and new technology of recovering iodine offer cost advantage**

DIVI'S has been supplying Iopamidol to European companies for the last several years. The addition of Iopromide to the list would further benefit DIVI'S as economies of scale drive its cost of production lower compared to competitors. DIVI'S sees a huge cost advantage in producing contrast media APIs on a large scale as the KSM can be purchased at a lower price and iodine can be completely recycled and used efficiently (iodine accounts for a major part of the costs).

While there are a few manufacturers globally producing contrast media, small and medium scale producers find it difficult to recover iodine from organic to the inorganic stage. DIVI'S has proven technology with Iopamidol to recycle all iodines that are going into the waste streams and reduce its production cost. With the same process being implemented in other contrast media compounds, we are confident of DIVI'S securing a reasonably high market share in the US. Notably, competition is less intense in the US compared to other regions and the company's India manufacturing base offers an added advantage of lower price of production.

**Exhibit 19: Key products in contrast media in the less competitive US market**

| API | Innovator | US DMF filers | API suppliers for Ex-US region |
|---|---|---|---|
| Iohexol | GE | Hovione and Zhejiang Starry | More than 10 |
| Iopamidol | Bracco | Total 9 DMFs filed with USFDA including DIVI'S, Abbott and Zhejiang Starry | More than 10 |
| Iodixanol | GE | Imax Diagnostic and Jiangsu Hengrui | More than 10 |
| Iopromide | Bayer | Daewoong Bio and Alp Pharma | More than 10 |

*Source: Company, Systematix Institutional Research*

**Strict regulatory requirements of innovator a high entry barrier for new entrants**

There are limited suppliers of both gadoliniums and iodine-based contrast APIs. This is attributable to requisite capabilities to meet an innovator's requirement given instances of adverse allergic and physiological events post administration of contrast media. DIVI'S seems to have an edge with its impeccable compliance track record and deep relationships with the top companies.

Contrast media products are usually mature products with GE Healthcare's Omnipaque (iohexol) and Visipaque (iodixanol), and Bayer's Magnevist (gadopentetate dimeglumine) and Ultravist (iopromide) together generating more than USD 2bn in revenues. Around 90% of the suppliers for these products are in Asia, mainly India and China. As these products are mature, pricing holds the key for clients.

DIVI'S has added Iopromide to its product offerings – currently under validation and expected to be commercialized in the next six months – while expanding capacity for Iohexol. With the company is all set to offer the three largest iodine-based contrast media products by FY23-24E, we expect a ramp-up in the business hereon.

## Custom Chemical Synthesis: A sticky client base

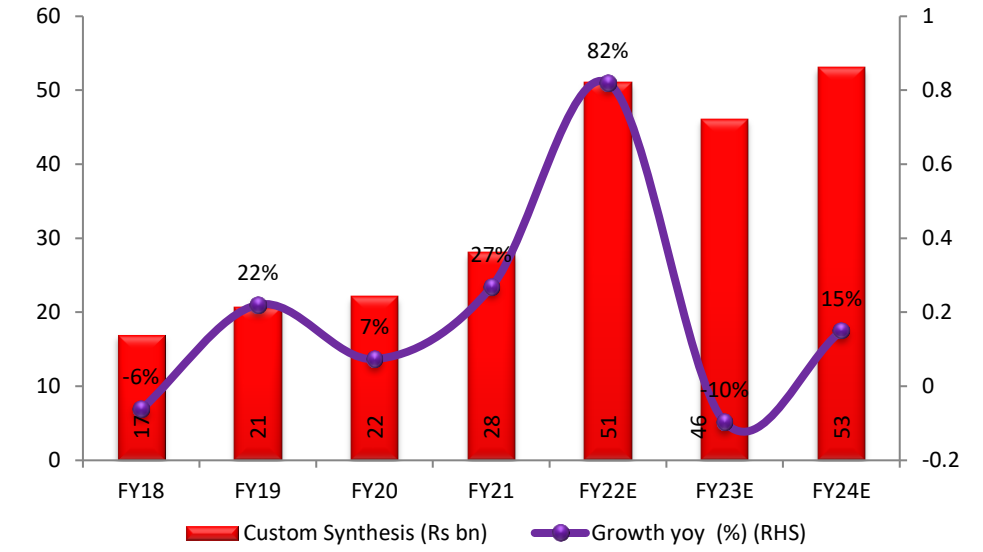
**High entry barriers, higher profitability**

Custom Chemical Synthesis (CCS) is the most profitable segment for DIVI'S, accounting for 40% of its revenues and more than half of profits as lower scale entails higher margins and vice versa. The Custom Synthesis process involves development and mass manufacturing for innovators from an early stage of the drug lifecycle, synthetic chemistry services such as process design for new drug candidates, development up to gram/ kilo scale, impurity profile studies, process validation and safety studies. The business has two advantages: 1) high entry barriers, as it takes years to build relationships with large clients, and 2) a sticky client base. A manufacturer is involved from the early stages of development and, hence, remains a key supplier post product commercialization as well.

The company's custom synthesis revenues declined by 20% in FY10 due to a systemic slowdown as, amid adverse economic conditions, clients rationalized their product pipelines and funding options dried up for biotech and R&D companies. Since then, the segment has recovered smartly and posted revenue CAGR of 19% over FY11-22.

The CRAMS industry is strongly linked to macro factors. Over 2009-10, most CRAMS players across the globe saw sharp declines due to stalled order flows amid a lack of R&D funding and inventory destocking by distributors in the wake of a downturn in the economic cycle. However, the industry has recovered since then. As per Pharma Intelligence, a website tracking global R&D pipelines, 16,252 drugs were in the pipeline as of FY20 from pre-clinical to registration phase. We expect growth to normalize over FY22-24E (2% CAGR) as FY22 growth was higher due to Molnupiravir.

**Exhibit 20: Custom Synthesis growth to normazile post COVID opportunities in FY22**



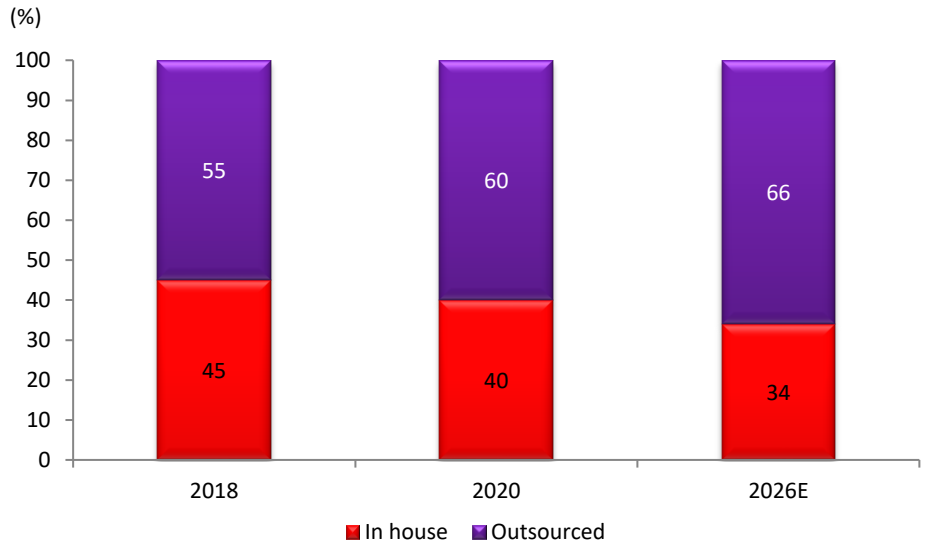

*Source: Company, Systematix Institutional Research*

## Trends in Clinical Research Outsourcing industry

High costs, long timelines, lower success rates, regulatory hurdles, and other variables converge to make drug development a tough proposition. In this backdrop, Clinical Research Organizations (CROs) have emerged as efficient providers of value-added services for pharma companies.

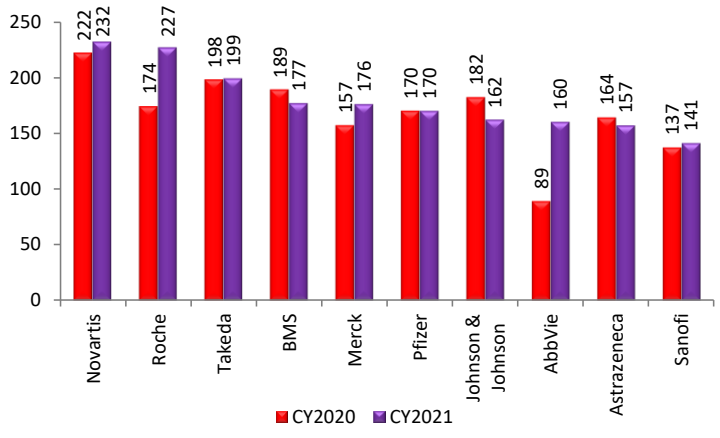
As players focus on driving internal efficiencies and optimizing cost structures, CROs have benefited from increased outsourcing of R&D functions as well as increasing outsourcing of service offerings beyond the traditional clinical work. Besides a higher share of outsourcing, growth in the global CRO market is also being driven by a shift in the industry – as more companies focus on rare diseases with unmet medical needs in terms of research, they need to invest heavily in R&D. While the CRO market is expected to reach USD 90.8bn by 2026, outsourcing penetration will likely increase to 66%, implying healthy growth prospects for the Indian CRO market.

**Exhibit 21: Global CRO market penetration – share of Outsourced set to increase**



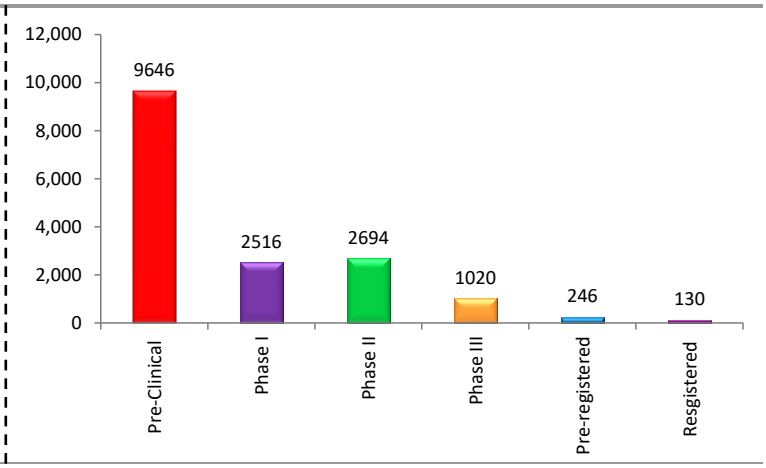

*Source: Company, Systematix Institutional Research*

**Exhibit 22: Big pharma drugs under development**




*Source: Company, Systematix Institutional Research*

**Exhibit 23: Drugs under development pipeline**




*Source: Company, Systematix Institutional Research*

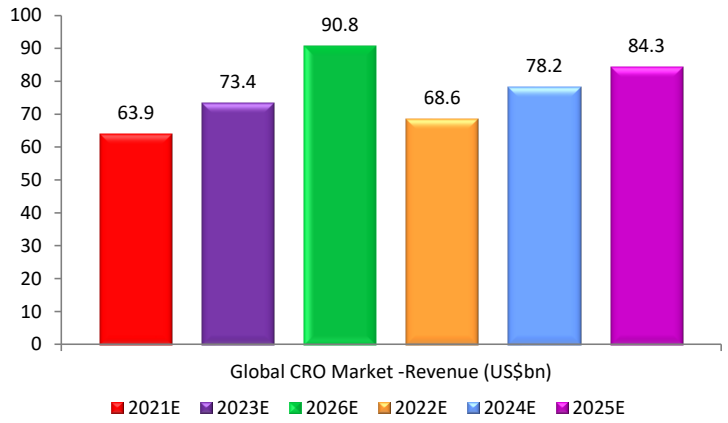
## Rising patent losses benefitting generics…and CROs

Patent and exclusivity losses for innovator drugs have been rising for the last few years. To put it in perspective, at least 56 drugs lost their patent between 2020 and 2022 and 107 drugs stand to lose patents from 2023 to 2025. Even as drug makers respond to the COVID-19 pandemic by developing new vaccines and therapeutics, many are losing patent protection on older and once-lucrative medicines. This has been driving growth in the generics industry and, in turn, supporting growth for the global CRO market.

**USD 57bn of innovative drug sales at risk in 2023, paving the way for generics and, hence, more opportunity for BA/ BE studies:** High market erosion is expected in 2023 as ~USD 57bn of innovative product sales are at risk due to patent expiration, followed by USD 32bn in 2024. This could be a promising opportunity for CROs globally as pharmaceutical companies would look to reduce costs on R&D and clinical trials to survive the sales erosion phase by outsourcing to CROs.

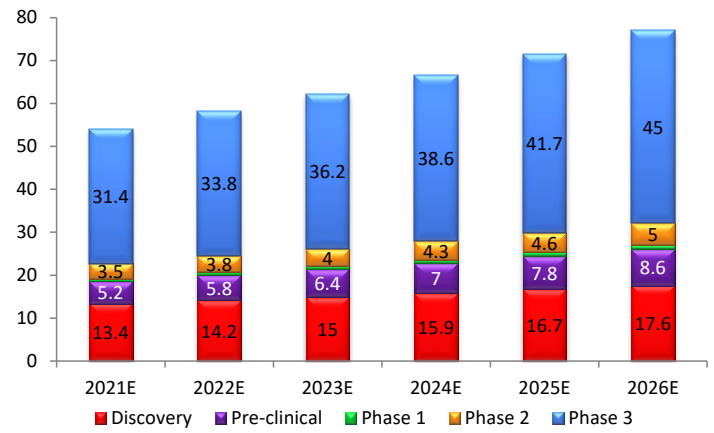
**Global CRO market size offers a huge opportunity:** The global CRO market is valued at ~USD 63.9bn as of 2021 and expected to witness 7% CAGR over FY21-26E. The key growth drivers are higher R&D expenditure, increased outsourcing of R&D activity and an increasing number of clinical trials. Innovator pharma companies currently focusing on outsourcing research require materials to gain a competitive edge by lowering their R&D costs. Notably, the average cost of developing and commercializing a drug is up ~10% from USD 1.18bn in 2010 to USD 1.3bn in 2020. The annual R&D spending, at ~USD 195bn in 2021E, is estimated to increase to ~USD 233bn by 2026, a CAGR of ~3.6%.

**Exhibit 24: CRO market to register 7% CAGR over FY21-26E**




*Source: Company, Systematix Institutional Research*

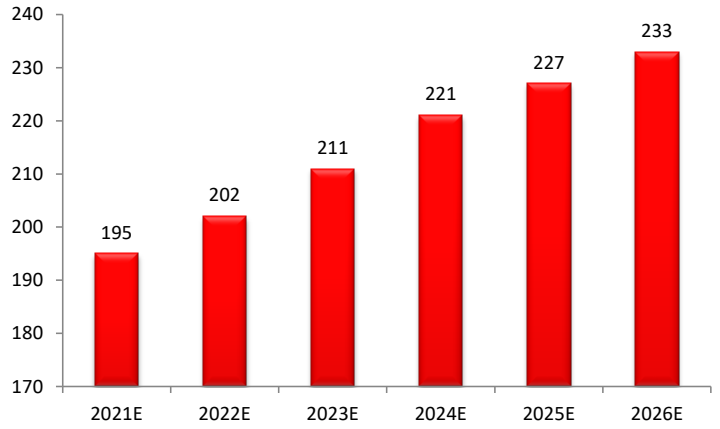
**Exhibit 25: Global CRO market**




*Source: Company, Systematix Institutional Research*

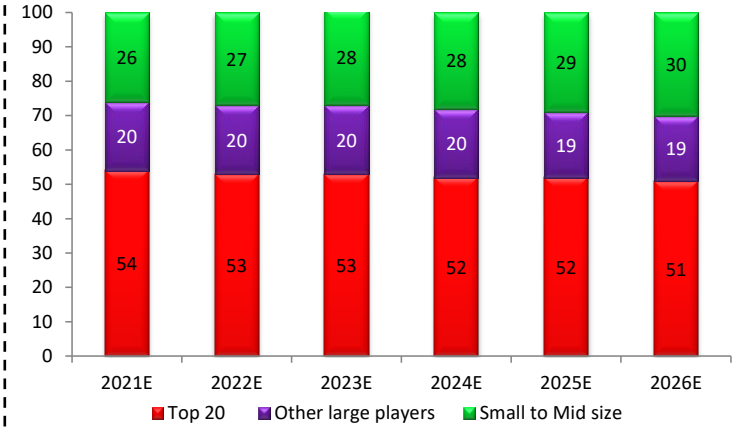
**Number of molecules in the R&D stage also on the rise:** There are more than 17,000 molecules currently in preclinical development, attributable to the constant effort of discovering new drug candidates. Pharmaceutical companies continue to invest in developing new drugs, which supports large-scale drug discovery activities. In 2020, 17,737 molecules were in the R&D stage of development and the growth rate also shot up to 9.62% in 2020 vis-à-vis 5.99% in 2019 and 2.66% in 2018.

**Exhibit 26: Global R&D spend – 4% CAGR to USD 233bn by 2026E**



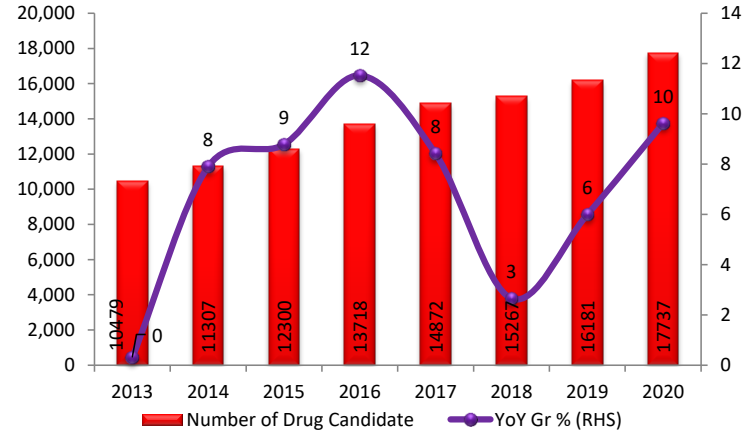

*Source: Company, Systematix Institutional Research*

**Exhibit 27: Top-20 companies contribute 54% of overall R&D spend**



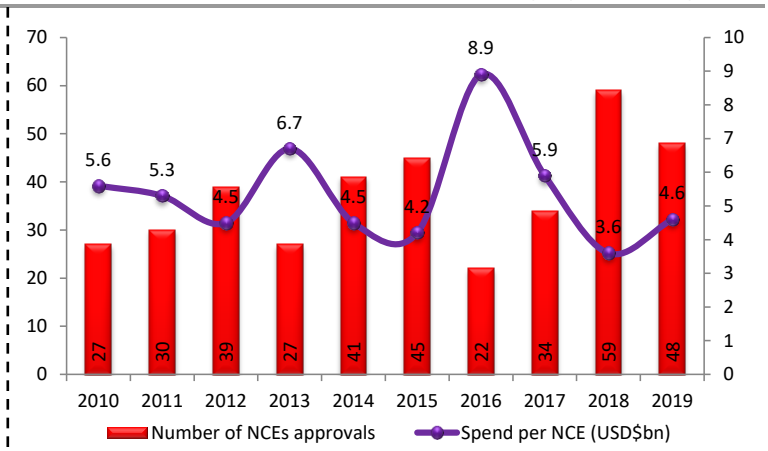

*Source: Company, Systematix Institutional Research*

**Exhibit 28: Number of drug candidates on a constant rise**




*Source: Company, Systematix Institutional Research*

**Exhibit 29: Number of NCEs and cost of developing increasing**




*Source: Company, Systematix Institutional Research*

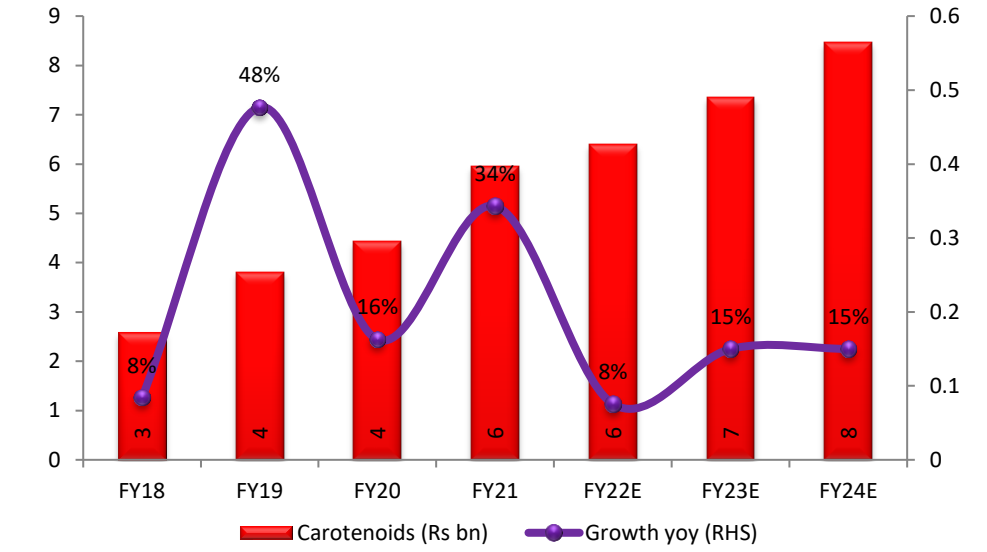
## Carotenoids: Slow ramp-up but strong potential

**A marginal player so far in global carotenoids; revenue contribution set to increase**

DIVI'S has been a marginal player in the >USD 1bn global carotenoids market, with less than 1% market share. While the company entered this segment more than 10 years ago and enjoys a significant cost advantage over incumbents, the ramp-up has been slower than expected due to certifications required from separate governing agencies across end-user markets such as feeds and food manufacturers. Also, given that DSM and BASF together control more than half of the market, penetration has been rather difficult for new entrants with a limited portfolio (such as DIVI'S).

Since FY09, DIVI'S has expanded its carotenoids portfolio aggressively. This, we believe, should ensure a faster ramp-up for the company. Further, its strategy to develop customer-specific products should pay off in the long run. As acceptability of its products rises gradually, we expect 15% CAGR in carotenoids revenues for the company over FY22-24. In FY22, the segment revenues are expected to be Rs 6bn – 7% of its total revenues.

**Exhibit 30: Higher capacity of Carotenoids led growth over FY18-22**




*Source: Company, Systematix Institutional Research*

## Molnupiravir: A potential windfall

Merck (MSD) and Ridgeback Biotherapeutics partnered and developed oral (Q12H for five days) – an investigational antiviral medicine Molnupiravir (MK-4482, EIDD-2801) – for the treatment of mild-to-moderate COVID-19 patients with oxygen levels above 93. Molnupiravir is an ucleoside analogue drug, an important component of modern antiviral therapy.

As per the interim analysis of phase 3 study data released in Oct-21, Molnupiravir reduces the risk of hospitalization or death by 50% compared to placebo for patients with mild or moderate COVID-19. Merck is also considering studying Molnupiravir as a preventive treatment, to be deployed after a person is exposed but before falling ill. That would allow the drug to be used more broadly in the fight against COVID-19 and increase the addressable market size. Merck has received emergency use authorization (EUA) for the drug; USFDA and many other global regulators have approved the use of Molnupiravir for COVID treatment.

**Molnupiravir has an edge over other oral treatments in the pipeline but falls short compared to Paxlovid:** Many COVID-19 treatments have emerged in the last two years and Remdesivir (injection) was the first officially approved drug by the USFDA among them (administered only in hospital settings). While most treatments for COVID-19 continue to be from off-label drugs, Molnupiravir and Paxlovid are the biggest breakthroughs as they are the first oral drugs to have been approved in regulated markets (US and EU) backed by clinical trials. While other drugs are in various stages of clinical trials for COVID-19 treatment, we believe Molnupiravir and Paxlovid have an early approval advantage to capture the market share; while other candidates are still in Phase-2/3 trials and have failed to meet the desired outcome, Molnupiravir claims to reduce the risk of death by 50% and Pfizer's Paxlovid by 89%.

**Exhibit 31: COVID-19 oral treatments**

| Drug | Drug mechanism | Stage | Details |
|---|---|---|---|
| **Molnupiravir** | **Nucleoside analogue** | **USFDA authorized with Emergency Use Authorization status** | **Reduced risk of hospitalization or death by ~ 50%** |
| Avigan | Nucleotide analogue | Clinical trials ongoing | Avigan was approved as an emergency flu treatment in Japan in 2014. Fujifilm initiated a new late-stage trial of Avigan in Japan for COVID-19 in April-21 after the regulator concluded trial data as inconclusive in Dec-20 The drug has been approved in India, Russia and Indonesia |
| PF-07321332 (Pfizer)/ Ritonavir | Protease Inhibition | USFDA authorized with Emergency Use Authorization status | Intended to be administered in combination with low-dose ritonavir to maintain plasma levels of PF-07321332 for duration of the treatment. Analysis of Phase 2/3 claims suggest 89% reduction in risk of hospitalization or death by 89% compared to placebo in non-hospitalized high-risk adults with COVID-19 |
| AT-527 (Atea Pharmaceuticals) | Nucleotide analogue | Phase 2 studies concluded in Oct-21; failed to meet the primary goal of international Phase II clinical trial in subjects with mild/ moderate COVID-19 in outpatient setting. Results of the full trial expected to end in the second half of CY22 | Assessing the Phase 3 trial result for modifications to ensure the best possible outcome for the program |

*Source: Company, Systematix Institutional Research*

**Molnupiravir can be a meaningful opportunity**

DIVI'S has been engaged with Merck since the development stage of the drug by supplying the required API quantities during clinical trials. It is one of the few authorized manufacturers of Molnupiravir API for Merck for the export markets. For the Indian market, Merck has partnered with DIVI'S and Everest Organic to supply APIs to its licensed partners of the formulation. Through these agreements, Merck aims to accelerate the availability of Molnupiravir in India and other low-middle-income countries (LMICs), but has retained API supply rights for the US, EU and other regulated markets.

DIVI'S had invested Rs 4bn in three supply streams (two for exports and one for supply to Merck's VL partners in India), which have already commenced. Merck has signed a contract with the US government to supply 1.7mn courses of Molnupiravir for USD 712 per course (amounting to USD 1.2bn) for delivery over 12 weeks post Emergency Use Authorization (EUA) with an option to purchase up to another 3.5mn treatment courses if needed. Merck has been in talks to secure supply agreements with other governments/ healthcare systems. It plans to adopt a tiered pricing approach to ensure Molnupiravir availability globally to a wider population.

Assuming DIVI'S supplies 60% of Merck's API requirements (being an integrated player) and assuming the API cost at 10%, the total opportunity size works out to around USD 175mn and USD 93mn for CY21 and CY22E respectively.

With Covid cases fading off and Paxlovid showing better efficacy, windfall sales witnessed in FY22 (USD 200mn per our estimates) are unlikely to sustain in the coming years. We have accordingly factored in USD 30mn of sales in FY23.

**Exhibit 32: Number of treatments already ordered for Molnupiravir**

| Molnupiravir current order book (Assuming per of USD 712/ course) | No. of treatments (mn) | Cost per treatment (USD) | Order size (USD mn) |
|---|---|---|---|
| US government-(CY21-June to CY22) | 1.7 | 712 | 1,200 |
| US government (option to buy incremental treatments) | 3.5 | 712 | 2,492 |
| Australia | 0.3 | 712 | 214 |
| Malaysia | 0.2 | 712 | 107 |
| South Korea | 0.0 | 712 | 27 |
| **Total** | **5.7** | | **4,039** |
| Singapore-Secured the deal but details not available | | | |
| UK (Approved) | | | |
| LMIC (Approved) | | | |

*Source: Company, Systematix Institutional Research*

## A measured and judicious capex policy

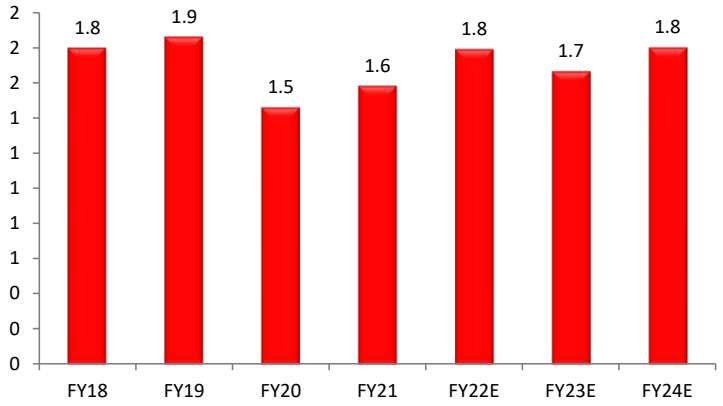
DIVI'S has always been prudent towards its capex program, investing only when it has substantial visibility on order flows. To better understand its capex policy, we examined DIVI'S new manufacturing unit, DSN, at Vizag SEZ in FY11. The unit was set up with an initial outlay of Rs 2bn and expanded subsequently at an added cost of Rs 1.5bn over FY12-14. Revenue contribution from the unit crossed Rs 8bn in FY15, implying an asset turnover of 2.3x in the first full year of operations.

DIVI'S embarked on its largest capex so far of Rs 25bn over FY20-21 at DC-SEZ Unit-1 and DCV-SEZ Unit-2, dedicated to: a) expansion of capacities for existing generic molecules (legacy/ relatively newer), b) addition of new generic molecules to the offering, c) fast track approval of Custom Synthesis projects, d) debottlenecking of existing capacities, e) backward integration to reduce dependency on imported KSM, and f) capex for Molnupiravir API.

The recent capex program has increased DIVI'S overall capacity to 17,694 MTA, an increase of 31%, with Unit-1 and Unit-2 capacity increasing by 112% and 11% respectively. Also, by undertaking backward integration to reduce dependency on imported KSM, DIVI'S is significantly ahead of peers in anticipating the issue. The benefits of the current program are already visible with 9HFY22 revenues increasing by 13% and EBITDA margin crossing 40%.

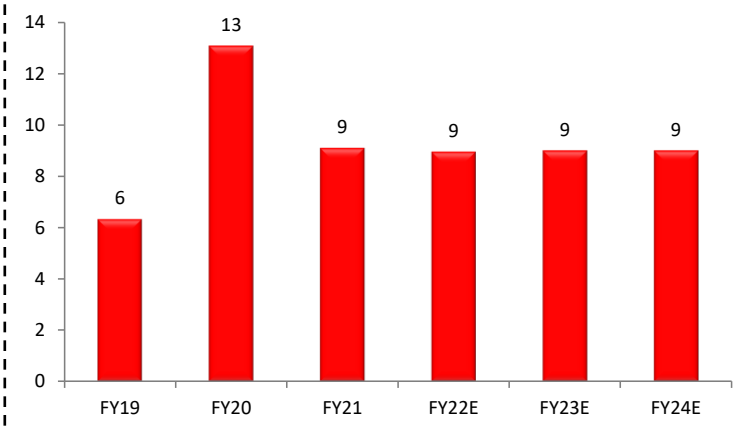
Over the long term, DIVI'S has managed to maintain a fixed turnover ratio of 2x, with manufacturing sites operating at 85-90% utilization post the completion of capex plans. To put things in context, while DIVI'S the company historically achieved an asset turnover of 2x, a marginally lower ratio of 1.7x/ 1.8x for FY23E/ 24E as part of the capex is towards backward integration which will help expand EBITDA margins. We believe a revenue CAGR of 10% over FY22-24E is easily achievable with an even higher EBITDA growth led by gross margin improvement.

**Exhibit 33: Asset turnover (x) to normalize in FY22-24E**




*Source: Company, Systematix Institutional Research*

**Exhibit 34: Capex outlay in FY22-23E would be mainly for Unit-3**




*Source: Company, Systematix Institutional Research*

**Exhibit 35: Details of capex undertaken over FY20-21**

| | Details | Capex amount (Rs bn) | Existing Capacity (MTA) | New Capacity (MTA) | % Change |
|---|---|---|---|---|---|
| Debottlenecking | Unit 1 & 2 | 3 | | | |
| Backward integration | Unit 1 & 2 | 3 | | | |
| DC-SEZ Unit-1 | Capacity increased for existing generic molecules and new product addition including Molnupiravir supply to Indian VL partners | 6 | 2,744 | 5,806 | 112 |
| DCV-SEZ Unit-2 | Capacity increased for existing generic molecules; new products added including Molnupiravir exports | 6 | 10,740 | 11,888 | 11 |
| Custom Synthesis | Fast track project completed in Mar-21 at DCV-SEZ Unit-2 by adding 2 new blocks | 4 | | | |
| Unallocated Capex | | 3 | | | |
| | **Total** | **25** | **13,484** | **17,694** | 31 |

*Source: Company, Systematix Institutional Research*

**Unit 1 expansion details:** Before the expansion undertaken during FY19-21, Unit-1 contributed 35-40% of DIVI'S total revenues and 35% of the total capacity in volumes – with Naproxen and Levetiracetam contributing 37% and 22% of total Unit-1 capacity by volumes. Among the existing molecules in Unit-1, capacity was increased for Naproxen, Levetiracetam and Bromo OTBN, forming 38%, 12% and 29% respectively of the overall new capacity. Also, the new contrast media product Lopromide was added during this capex phase.

**Exhibit 36: Unit-1 capacity doubled in the recent expansion plan**

| Capacity (MTA) | Existing capacity | New capacity | Capacity added | % change in capacity | % of new capacity for Unit-1 |
|---|---|---|---|---|---|
| **Unit-1** | 2,744 | 5,806 | 3,062 | 112 | |
| **Key products for which capacity increased** | | | | | |
| DL-Naproxen | 1,008 | 2,208 | 1,200 | 119 | 39 |
| Levetiracetam | 600 | 960 | 360 | 60 | 12 |
| Bromo OTBN | 15 | 900 | 885 | 5,900 | 29 |
| Dextromethorphan HBr | 250 | 372 | 122 | 49 | 4 |
| Nabumetone | 100 | 200 | 100 | 100 | 3 |
| Fumaraldehyde Bis | 25 | 120 | 95 | 380 | 3 |

*Source: Company, Systematix Institutional Research*

**Exhibit 37: Contrast Media Lopromide added to capacity**

| New products added to Unit-1 | New capacity (MTA) | % of new capacity |
|---|---|---|
| Lopromide | 200 | 7 |
| Rivaroxaban | 30 | 1 |
| Nicotine | 20 | 1 |
| Dolutegravir | 10 | 0 |

*Source: Company, Systematix Institutional Research*

**Unit-2 expansion details:** The plant contributed 60-65% of DIVI'S total revenues and accounted for 80% of its capacity in FY19. During FY19-21, the overall capacity increased by 11%. Naproxen (including Naproxen Sodium) was the key candidate with a 27% increase, post which it formed 40% of Unit-2's total capacity. The other existing key products that saw capacity increases include Mesalamine, Losartan and Pregabalin. Capacity for new products related to COVID-19 were also set up in Unit-2 during this phase.

**Custom Synthesis and Molnupiravir:** DIVI'S spent Rs 4bn to fast track the project at DCV-SEZ Unit-2 by adding two new blocks after higher product visibility from one of its clients. The site includes capacity for export of Molnupiravir while supplies to Indian VL partners would be from Unit-1.

**Exhibit 38: Naproxen capacity increased by 52% in Unit-2 in the recent capex program**

| Capacity (MTA) | Earlier capacity | New capacity | Capacity added | % change in capacity | % of new capacity |
|---|---|---|---|---|---|
| **Unit-2** | 10740 | 11888 | 1148 | 11 | |
| **Key products for which capacity increased** | | | | | |
| Naproxen | 1200 | 1800 | 600 | 50 | 52 |
| Naproxen (Sodium) | 1800 | 2000 | 200 | 11 | 17 |
| Atipadichloride/ Lohexol | 250 | 350 | 100 | 40 | 9 |
| Levodopa | 200 | 250 | 50 | 25 | 4 |
| Mesalamine | 250 | 400 | 150 | 60 | 13 |
| Losartan | 10 | 100 | 90 | 900 | 8 |
| Pregabalin | 200 | 400 | 200 | 100 | 17 |

*Source: Company, Systematix Institutional Research*

**Exhibit 39: COVID products added to the list in Unit-2**

| New products added to Unit-2 | New capacity (MTA) | % of new capacity |
|---|---|---|
| Favipiravir | 300 | 26 |
| Hydroxy Chloroquine | 300 | 26 |
| Remdesivir | 100 | 9 |

*Source: Company, Systematix Institutional Research*

## Kakinada, Nellore will see the next leg of capex

After completing its largest capex plan of Rs 25bn over FY20-21 at Unit-1 & -2, DIVI'S has commenced work for the next leg of expansion at Kakinada (Unit-3) and Nellore (Unit-4). The total capex outlay for the projects is ~Rs 20bn over FY22-24E with a new capacity of 28,878 MTA – 63% higher than the cumulative existing capacity. A large part of the capex outflow will be over by FY23E. However, full capacity realization from these units would commence only from FY24E as project validation and other regulatory processes require 15-18 months. After analyzing the project report of these units, we believe a large part of the capacities would be utilized for backward integration and to reduce dependency on imported KSM. An increase in existing capacities (including for contrast media products) would also be a part of the project.

**Exhibit 40: Upcoming expansion plans**

| New Project | | Capex amount (Rs bn) | Capacity (MTA) |
|---|---|---|---|
| Kakinada - (Unit-3) | Greenfield project with construction commenced in CY21. Phase -1 expected to be completed in 15-18 months; another 15 months for project validation | 15 | 18,395 |
| Nellore - (Unit 4) | New project with construction to begin post completion Unit-3 | 5 | 10,483 |

*Source: Company, Systematix Institutional Research*

**Exhibit 41: Key products at Unit 3 - Kakinada**

| | Capacity (MTA) | % of total capacity |
|---|---|---|
| **Total capacity** | **18,395** | |
| 2-Acetyl-6-methoxy naphthalene | 5,000 | 27 |
| Atipadichloride | 1,210 | 7 |
| Octamandalate Base | 780 | 4 |
| P-Methyl phenyl acetic acid (PMPA) | 780 | 4 |
| 4-Bromomethylbiphenyl-2-Carbonitrile | 630 | 3 |
| Benzyladrinone HCl | 560 | 3 |
| 2-(1-Cyclohexenyl) ethyl amine (CHEA (100%)) | 540 | 3 |
| 5-[4-Methylbiphenyl-2yl]-2-trityl-2Htetrazole | 500 | 3 |
| Naproxen | 500 | 3 |
| Gabapentin | 500 | 3 |
| Levodopa | 500 | 3 |
| Carbidopa | 500 | 3 |
| (+) N-Formyl Octa Base | 450 | 2 |
| Beta-Ionylidine ethyl triphenyl phosphene bromide | 400 | 2 |
| N-Octyl-d-glucamine (NOG) | 400 | 2 |
| L-Valine methyl ester HCl | 382 | 2 |
| 2,4,5-Trifluorophenylacetic acid | 350 | 2 |
| Triazole HCl | 350 | 2 |
| Dextromethorphan HBr | 350 | 2 |
| 3-Hydroxy acetophenone(3-HAP) | 330 | 2 |
| Iopamedal | 300 | 2 |
| Iohexol | 300 | 2 |
| 2-(n-Butyl)-4-Chloro-5-formyl imidazole | 250 | 1 |
| Mesalamine | 200 | 1 |
| Others | 2,333 | 13 |

*Source: Company, Systematix Institutional Research*

**Exhibit 42: Key products at Unit 4-Nellore**

| | Capacity (MTA) | % of total capacity |
|---|---|---|
| **Total capacity** | **10,483** | |
| 1-(6-methoxy-2-naphthyl) ethenone | 5,000 | 48 |
| p-methoxy phenyl acetic acid | 780 | 7 |
| Octamandalate | 780 | 7 |
| 2-(1-cyclohexenyl) ethylamine | 540 | 5 |
| Benzyladrinone HCl | 500 | 5 |
| Dextromethorphan HBr | 420 | 4 |
| Beta-iolidine ethyl triphenyl phosphene bromide | 380 | 4 |
| 3- Hydroxy acetophenone | 320 | 3 |
| ATIPA DICHLORIDE | 300 | 3 |
| 2(n-butyl)-4-chloro-5-formyl imidazole | 300 | 3 |
| Z-L Valine | 180 | 2 |
| Others | 983 | 9 |

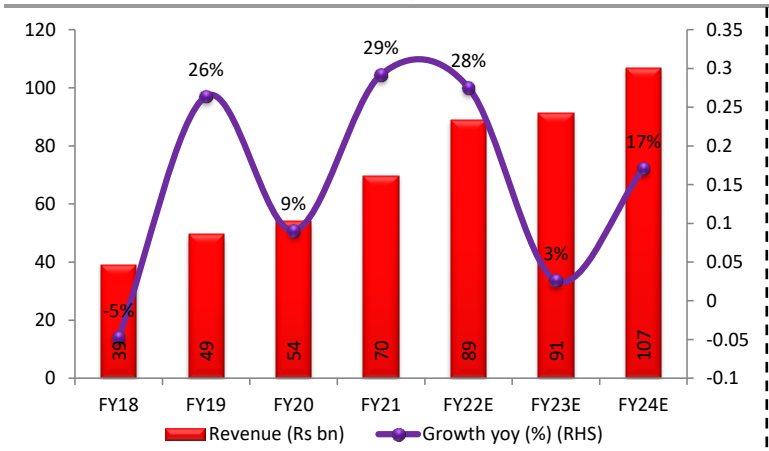
*Source: Company, Systematix Institutional Research*

## Financial Analysis

### Growth momentum to continue

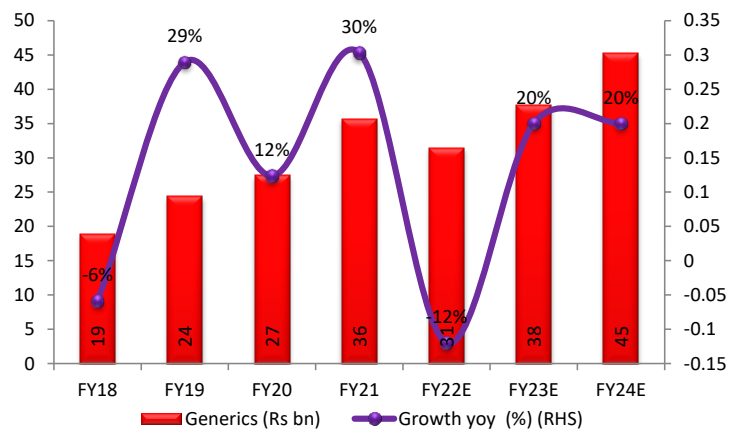
We expect 10% CAGR in DIVI'S revenues over FY22-24E, led by: a) a 20% CAGR in generics business on launch of new molecules and volume expansion of existing products, b) a 2% CAGR for custom synthesis post Molnupiravir benefit in FY22, and c) a 15% CAGR in the carotenoids business.

**Exhibit 43: Revenue CAGR of 10% expected over FY22-24**



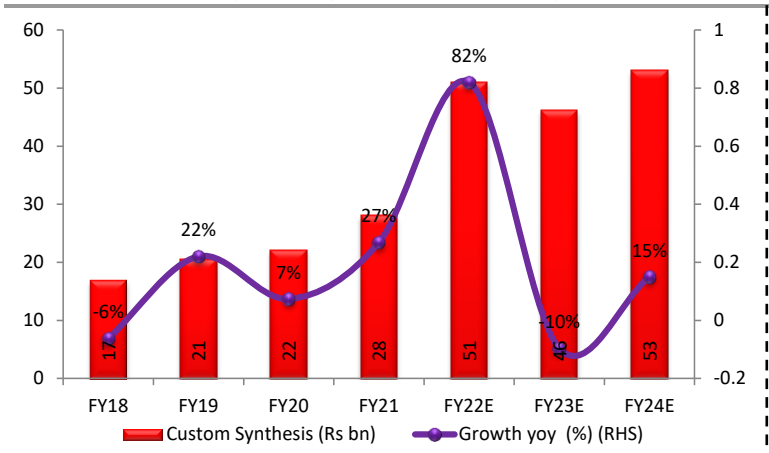

*Source: Company, Systematix Institutional Research*

**Exhibit 44: Generics – launch of new products to drive growth**



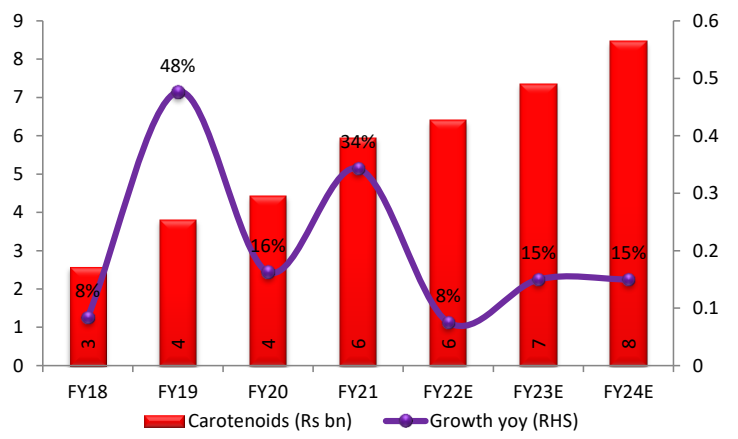

*Source: Company, Systematix Institutional Research*

**Exhibit 45: Custom Synthesis growth to normalize post COVID benefit**




*Source: Company, Systematix Institutional Research*

**Exhibit 46: Carotenoids growth momentum to be maintained**

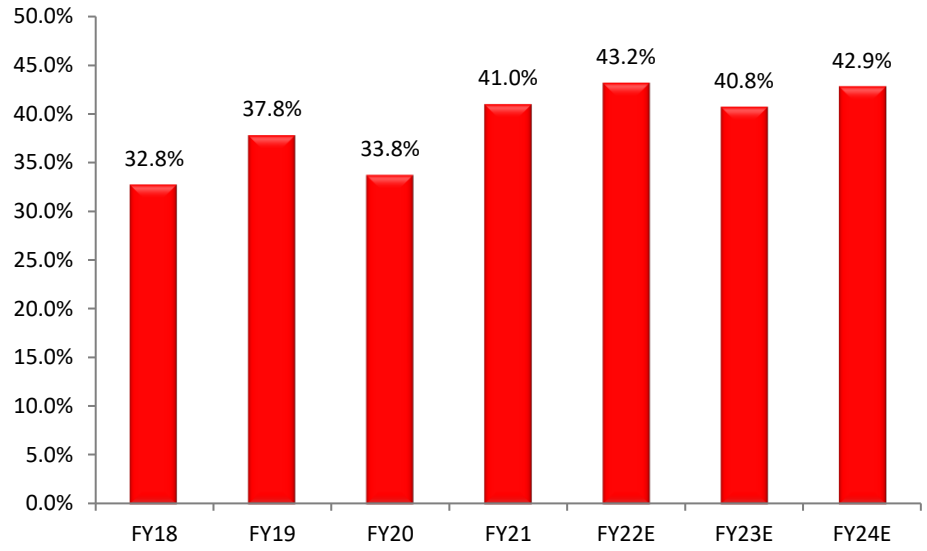



*Source: Company, Systematix Institutional Research*

**Multiple margin levers**

We expect EBITDA margins to sustain at 40%+ levels over FY22-24E as revenue contribution from the high-margin CCS business increases, and the investment in backward integration program over FY20-21 starts yielding results. Further, commercialization of Unit-3 and Unit-4 in FY23-24E will contribute materially to the improving margin profile. Notably, significant product additions are related to backward integration, thereby reducing dependence on imports.

**Exhibit 47: EBITDA margin to sustain at >40%, primarily led by backward integration**



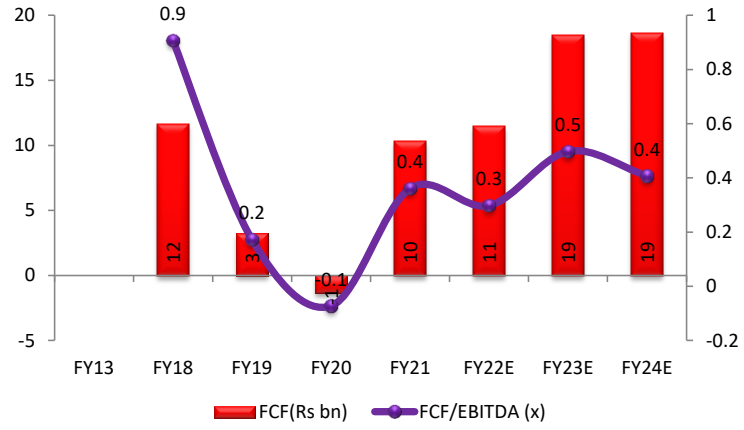

*Source: Company, Systematix Institutional Research*

**High return ratios, prudent capital allocation**

DIVI'S has remained committed to capital efficiency. The company has stayed away from expensive acquisitions, maintained tight control on operational costs and undertaken capex only on order flow visibility. Even during the downturn of FY10, when the industry was plagued by a liquidity crisis and inventory de-stocking, DIVI'S reported a 20% decline in sales but retained operating margins above 40%. Since FY08, it has managed to maintain margins between 37-40% (barring FY18, due to an import alert). We expect the trend to continue for the medium term.

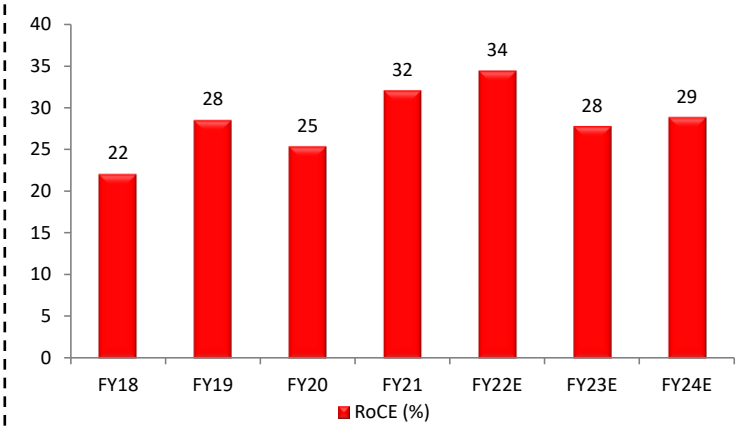
DIVI'S ability to swiftly ramp up capacity utilization and efficiently manage existing capacities have yielded higher production with strong return ratios. Over the last decade, DIVI'S RoCE has been 25%+, barring FY18 (import alert). On the back of its strong growth trajectory, we expect RoCE to remain around 30% from here.

**Exhibit 48: Cumulative FCF of Rs 49bn over FY22-24E**



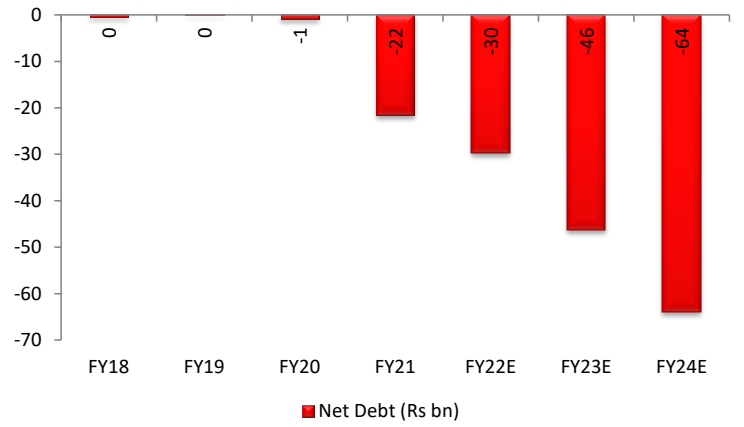

*Source: Company, Systematix Institutional Research*

**Exhibit 49: RoCE to be among the highest in industry**



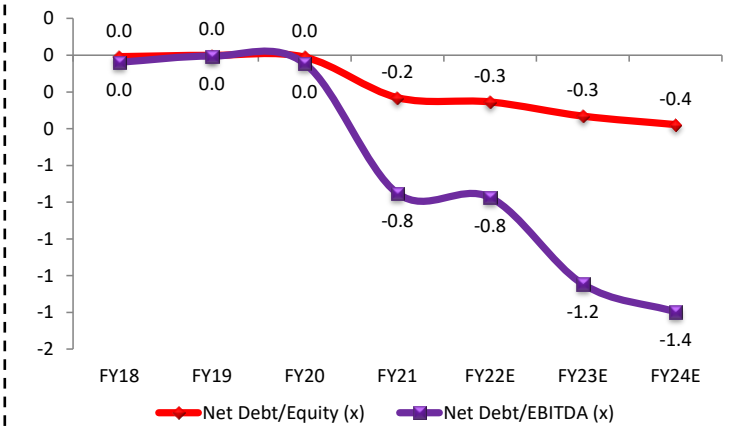

*Source: Company, Systematix Institutional Research*

**Exhibit 50: DIVI'S remains a net cash company**



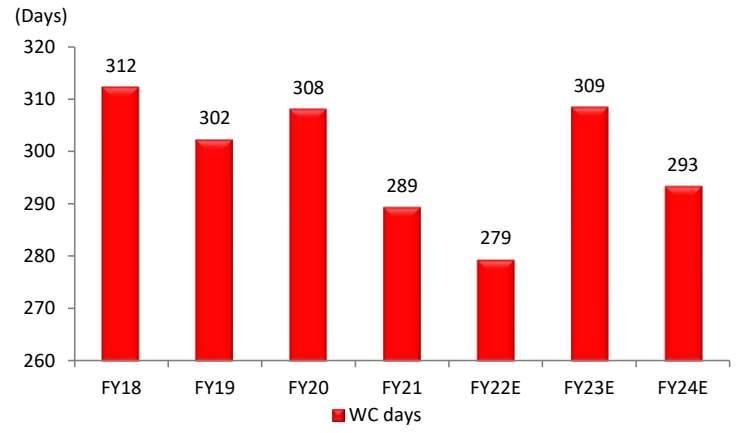

*Source: Company, Systematix Institutional Research*

**Exhibit 51: Leverage ratio remains efficient**



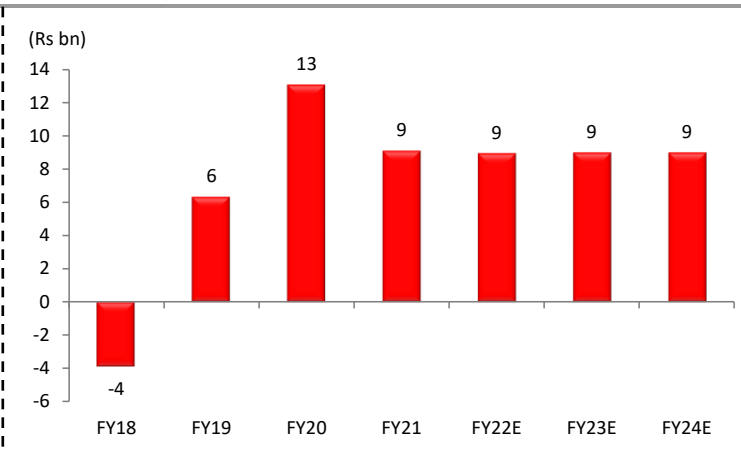

*Source: Company, Systematix Institutional Research*

**Exhibit 52: Working Capital cycle likely to remain high**




*Source: Company, Systematix Institutional Research*

**Exhibit 53: Capex over FY22-24E to be allocated to Unit-3 & -4**




*Source: Company, Systematix Institutional Research*

## Valuations & View

The import alert in FY18 came as a setback to DIVI'S in what otherwise had been an impeccable journey so far. Nevertheless, the early resolution indicates how critical DIVI'S is from a global supply standpoint, given its leadership position in several APIs.

Notably, the stock has corrected 20% from the peak of its valuation of 45x and currently trades at 35x FY24E EPS of Rs 127. With a strong margin profile and healthy growth prospects, DIVI'S current valuation seems reasonable and we believe it deserves a higher multiple led by:

a) Improving business fundamentals with a stronger margin profile and increased revenue share from CCS

b) Strong growth prospects with 10% earnings CAGR over FY22-24E

c) Free cash flow of Rs 49bn over FY22-24E

d) RoCE of ~29% and EBITDA margin above 40%

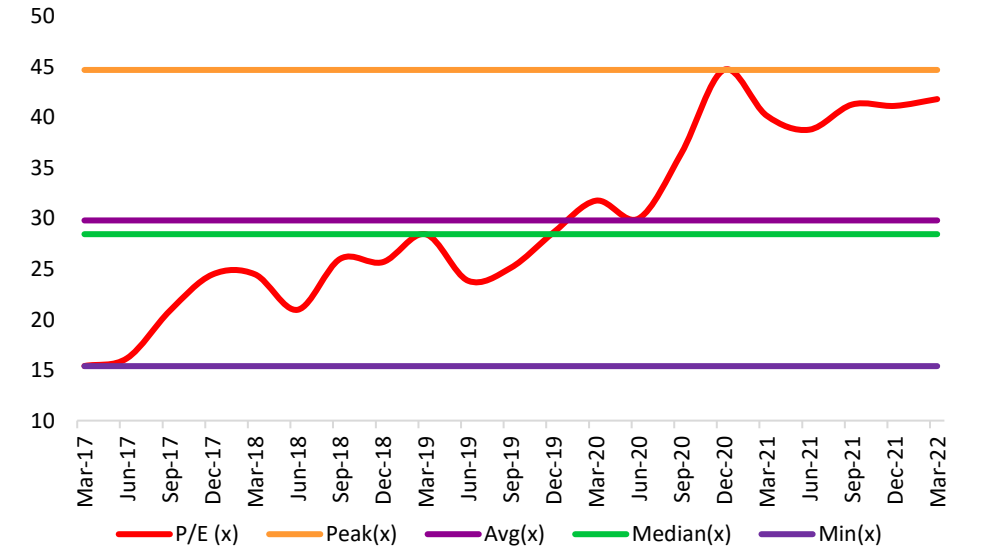
Historically, the stock has traded at a premium to peers given its consistent profit delivery, industry-leading EBITDA margin of 40%+, debt-free balance sheet, superior asset-turnover ratio and strong business model. In view of the sustained performance expected in the coming years, we expect its valuation premium to be sustained. We value DIVI'S at 41x its FY24E EPS to arrive at a target price of Rs 5,180. Initiating coverage on the stock with a **BUY** rating.

**Exhibit 54: India's leading CDMO and API players**

| Company | Business mix |
|---|---|
| **Domestic Companies** | |
| Piramal Pharma | Pharma CDMO (55% of Piramal Pharma revenues), Complex Hospital Generics (32%) and India Consumer Healthcare (13%); 13th largest CDMO globally. EBITDA margin of 22% from the pharma business. Phase-2 & 3 contributing 30% each of revenues while Phase 1 and pre-clinical each form 20%. EBITDA margin for the overall pharma business at 22% in FY21 |
| Solara | 90% API and 10% CRAMS. Entered in CRAMS segment in FY19 |
| Suven Pharma | 61% CDMO Pharma and 30% CDMO spec chem; the remaining business is formulations |
| Dishman Carbogen | 75% of revenues from CRAMS and 25% from marketable molecules. EBITDA margin for CRAMS segment at 24% (FY20) with export CRAMS EBITDA margin at 17-18% |
| Syngene | Pure play focus on CRAMS with discovery, development and manufacturing services, and dedicated R&D centers contributing to 35%, 33% and 32% respectively of revenues |
| Neuland lab | Around 69% of revenues from generic drug substances (including prime and specialty APIs and 28% from CMS). CMS business and certain specialty products command margins higher than generic APIs |
| Hikal | The pharmaceutical segment contributes 61% to revenues with remaining coming from crop protection. Within pharma, CDMO accounts for 41% (25% of total revenues) and own products account for the remaining. EBIT margin for pharma and crop protection at 15-16% |
| Jubilant Pharmova | The pharmaceutical segment (specialty pharma-Radiopharma, CDMO and generics) contribute 94% to total revenues and EBITDA; Contract Research and Proprietary Novel Drugs contribute the remaining. Margins at 23% in Pharma business and 27% in Contract Research |

*Source: Company, Systematix Institutional Research*

**Exhibit 55: P/E**




*Source: Systematix Institutional Research*

# Annexures

## Company Background

DIVI'S was established in 1990 after the founder **Dr Murali Krishna** parted ways with Dr Reddy's Laboratories where he had joined as a director. DIVI'S is one of the leading manufacturers of Active Pharmaceutical Ingredients (APIs) and intermediates, offering high-quality products to more than 95 countries with the US and Europe accounting for 71% of its overall revenues. The company operates in three business segments – generic APIs (50% of total revenues), Custom Synthesis (41%) and Nutraceuticals (9%) – with two manufacturing units (Unit 1 in Hyderabad and Unit 2 in Visakhapatnam). With a 50%+ share within the generics segment, DIVI'S is one of the largest manufacturers of Naproxen, Dextromethorphan, Gabapentin, Lopamidol and Levetiracetam.

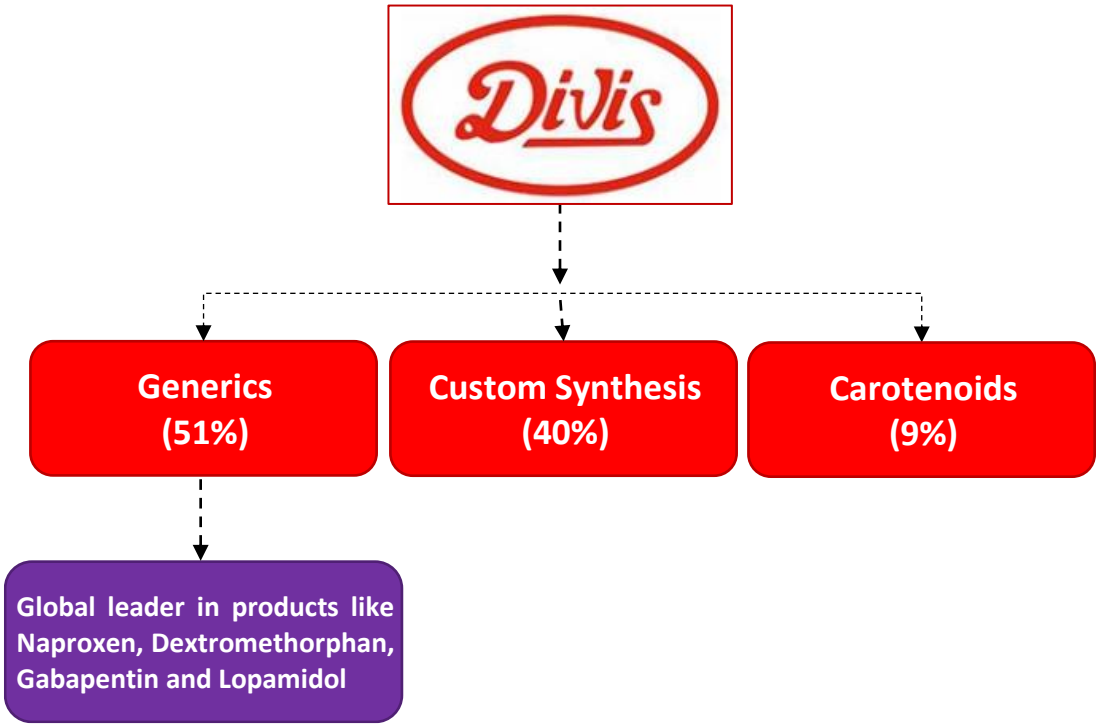
DIVI'S top-5 products contribute 49% of its total revenues while the top-5 customers contribute 34%. Over FY19-21, the company incurred a capex of Rs 25bn towards expanding the capacity of existing products, addition of new generic molecules, debottlenecking and Custom Synthesis.

**Exhibit 56: Key management personnel**

| Name of Person | Designation | Education | Roles and achievements |
|---|---|---|---|
| Dr Murali K. Divi | Managing Director | Ph.D. in Pharmaceutical Sciences from Kakatiya University, India | Prior to starting DIVI'S, he had extensive experience of >15 years in the Pharma industry, leading various Research and Manufacturing teams globally |
| N.V. Ramana | Executive Director | Graduate in chemistry from Osmania University, India | Has been with DIVI'S for the past 25 years. Oversees all functions of Strategic Planning, Sales & Marketing, Custom Manufacturing, Contract Research and Nutraceutical Ingredients Development |

*Source: Company, Systematix Institutional Research*

**Exhibit 57: DIVI'S focus on three key business segments**




*Source: Company, Systematix Institutional Research*

## Annual Report Analysis

**Exhibit 58: Annual report highlights : Capex and timelines**

| | | | |
|---|---|---|---|
| **FY21** | Set up a new DC-SEZ unit on land available at Unit-1 and commenced partial commercial operations at this facility from Feb-20 and full operations from 1HFY22. Also, set up a new DCV SEZ at Unit-2 which commenced commercial operations in Mar-20 | Investment of Rs 6bn each at DCV SEZ and DC SEZ. Capex of Rs 4bn for fast-tracking the customs synthesis project that became operational in Mar-21; project completion and utilization scheduled for 1HFY22 | The debottlenecking and backward integration project taken up in the last two years became fully operational, leading to reduced dependency on KSM imported for production with cost-efficiency |

*Source: Company, Systematix Institutional Research*

## Plant details

**Exhibit 59: DC-SEZ Unit-1 - Hyderabad**

*Source: Company, Systematix Institutional Research*

**Exhibit 60: DCV-SEZ Unit-2 - Visakhapatnam**

*Source: Company, Systematix Institutional Research*

**Exhibit 61: DIVI'S plant capacity**

| Location | Capacity (MTA) |
|---|---|
| DC-SEZ Unit-1-Hyderabad | 5,806 |
| DCV-SEZ Unit-2-Visakhapatnam | 11,888 |
| | |
| **Upcoming Units** | |
| Unit-3-Kakinada | 18,395 |
| Unit 4-Nellore | 10,483 |

*Source: Company, Systematix Institutional Research*

# FINANCIALS

### Profit & Loss Statement

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **Net Revenues** | **53,944** | **69,694** | **88,862** | **91,175** | **106,736** |
| YoY gr. (%) | 13 | 29 | 28 | 3 | 17 |
| Cost of Goods Sold | 21,085 | 23,241 | 29,283 | 30,748 | 35,360 |
| Gross Profit | 32,859 | 46,453 | 59,579 | 60,428 | 71,377 |
| Margin (%) | 61 | 67 | 67 | 66 | 67 |
| Employee Cost | 6,211 | 8,258 | 9,331 | 10,264 | 11,291 |
| Other Expenses | 8,427 | 9,596 | 11,855 | 12,988 | 14,338 |
| **EBITDA** | **18,222** | **28,599** | **38,393** | **37,176** | **45,748** |
| YoY gr. (%) | -3 | 57 | 34 | -3 | 23 |
| Margin (%) | 34 | 41 | 43 | 41 | 43 |
| Depn. and Amort. | 1,862 | 2,556 | 3,352 | 3,892 | 4,432 |
| **EBIT** | **16,359** | **26,044** | **35,041** | **33,284** | **41,316** |
| Margin (%) | 30 | 37 | 39 | 37 | 39 |
| Net Interest | 61 | 9 | 1 | 1 | 1 |
| Other Income | 1,896 | 626 | 1,043 | 2,318 | 3,198 |
| **Profit Before Tax** | **18,195** | **26,660** | **36,082** | **35,601** | **44,512** |
| Total Tax | 4,429 | 6,818 | 7,938 | 8,544 | 10,683 |
| Effective tax rate (%) | 24 | 26 | 22 | 24 | 24 |
| **Profit after tax** | **13,765** | **19,843** | **28,144** | **27,057** | **33,829** |
| EPS | 52 | 75 | 106 | 102 | 127 |
| YoY gr. (%) | 2 | 44 | 42 | -4 | 25 |

*Source: Company, Systematix Institutional Research*

### Balance Sheet

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| Equity Share Capital | 531 | 531 | 531 | 531 | 531 |
| Res. & Surpl. (Ex OCI) | 72,568 | 92,415 | 116,286 | 139,068 | 168,623 |
| **Net Worth** | **73,099** | **92,946** | **116,817** | **139,599** | **169,154** |
| Short term debt | 0 | 0 | 0 | 0 | 0 |
| Long term debt | 389 | 48 | 48 | 48 | 48 |
| Trade payables | 5,907 | 7,632 | 9,731 | 9,984 | 11,688 |
| Other Provisions | 3,123 | 3,674 | 3,674 | 3,674 | 3,674 |
| Other liabilities | 2,005 | 2,379 | 2,379 | 2,379 | 2,379 |
| **Total Liabilities** | **84,522** | **106,679** | **132,649** | **155,685** | **186,944** |
| | | | | | |
| Net block | 27,819 | 37,039 | 42,637 | 47,745 | 52,313 |
| CWIP | 9,197 | 7,106 | 7,106 | 7,106 | 7,106 |
| Other Non-current asset | 0 | 0 | 0 | 0 | 0 |
| Investments | 11,213 | 1,130 | 1,130 | 1,130 | 1,130 |
| Cash and Cash Equi. | 1,226 | 21,560 | 29,792 | 46,367 | 63,956 |
| Debtors | 14,134 | 16,765 | 21,911 | 22,482 | 26,319 |
| Inventories | 18,639 | 21,452 | 27,998 | 28,727 | 33,629 |
| Other current asset | 2,296 | 1,627 | 2,074 | 2,128 | 2,491 |
| **Total Assets** | **84,523** | **106,680** | **132,649** | **155,685** | **186,945** |

*Source: Company, Systematix Institutional Research*

### Cash Flow

| YE: Mar (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| PBT | 18,195 | 26,660 | 36,082 | 35,601 | 44,512 |
| Depreciation | 1,862 | 2,556 | 3,352 | 3,892 | 4,432 |
| Interest | 61 | 0 | 0 | 0 | 0 |
| Others | -1,722 | -691 | -1,069 | -2,345 | -3,224 |
| Working capital | -2,183 | -2,641 | -10,040 | -1,100 | -7,399 |
| Direct tax | -4,452 | -6,444 | -7,938 | -8,544 | -10,683 |
| **Net cash from Op.** | **11,761** | **19,441** | **20,387** | **27,504** | **27,638** |
| Net Capital exp. | -13,079 | -9,102 | -8,951 | -9,000 | -9,000 |
| Others | 13,046 | -887 | 1,043 | 2,318 | 3,198 |
| **Net Cash from Invt.** | **-33** | **-9,989** | **-7,908** | **-6,682** | **-5,802** |
| Issue of share cap. | 0 | 0 | 0 | 0 | 0 |
| Debt changes | -668 | -333 | 0 | 0 | 0 |
| Dividend paid | -10,241 | 0 | -4,247 | -4,247 | -4,247 |
| Others | -59 | -16 | 0 | 0 | 0 |
| **Net cash from Fin.** | **-10,968** | **-349** | **-4,247** | **-4,247** | **-4,247** |
| **Net change in cash** | **760** | **9,103** | **8,232** | **16,575** | **17,589** |

### Ratios

| YE: Mar | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| **Per Share (Rs)** | | | | | |
| EPS | 52 | 75 | 106 | 102 | 127 |
| CEPS | 59 | 84 | 119 | 117 | 144 |
| BVPS | 275 | 350 | 440 | 526 | 637 |
| DPS | 39 | 0 | 16 | 16 | 16 |
| **Return Ratio (%)** | | | | | |
| RoCE | 25 | 32 | 34 | 28 | 29 |
| RoE | 19 | 24 | 27 | 21 | 22 |
| **Balance Sheet** | | | | | |
| Net Debt: Equity (x) | 0.0 | -0.2 | -0.3 | -0.3 | -0.4 |
| Net Working Capital (Days) | 308 | 289 | 279 | 309 | 293 |
| **Valuation (x)** | | | | | |
| PER | 86 | 60 | 42 | 44 | 35 |
| EV/EBITDA | 65 | 31 | 30 | 31 | 24 |
| EV/Sales | 22 | 13 | 13 | 12 | 10 |

*Source: Company, Systematix Institutional Research*

| Revenue details (Rs mn) | FY20 | FY21 | FY22E | FY23E | FY24E |
|---|---|---|---|---|---|
| Generics | 27,397 | 35,693 | 31,410 | 37,692 | 45,231 |
| Custom Synthesis | 22,117 | 28,051 | 51,052 | 46,123 | 53,042 |
| Carotenoids | 4,430 | 5,950 | 6,400 | 7,360 | 8,464 |

*Source: Company, Systematix Institutional Research*

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**DISCLOSURES/APPENDIX**

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I, **Praful Bohra**, hereby certify that (1) views expressed in this research report accurately reflect my/our personal views about any or all of the subject securities or issuers referred to in this research report, (2) no part of my/our compensation was, is, or will be directly or indirectly related to the specific recommendations or views expressed in this research report by **Systematix Shares and Stocks (India) Limited (SSSIL)** or its group/associate companies, (3) reasonable care is taken to achieve and maintain independence and objectivity in making any recommendations.

| Disclosure of Interest Statement | Update |
|---|---|
| Analyst holding in the stock | No |
| Served as an officer, director or employee | No |

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