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Pick of the Week

Granules India Ltd.

Aug 05, 2024

RETAILRESEARCH

Granules India Ltd.

Industry	LTP	Recommendation	Base Case Fair Value	Bull Case Fair Value	Time Horizon
Pharmaceuticals	Rs 646.1	Buy in the band of Rs 644-653 and add more on dips to Rs 580	Rs 706	Rs 758	2-3 quarters

HDFC Scrip Code	GRANULEQNR
BSE Code	532482
NSE Code	GRANULES
Bloomberg	GRAN: IN
CMP Aug 02, 2024	646.1
Equity Capital (Rs Cr)	24.2
Face Value (Rs)	1
Equity Share O/S (Cr)	24.2
Market Cap (Rs Cr)	15633
Book Value (Rs)	133
Avg. 52 Wk Volumes	2532118
52 Week High	649.9
52 Week Low	288

Share holding Pattern % (Jun, 2024)	
Promoters	38.87
Institutions	34.51
Non Institutions	26.62
Total	100

* Refer at the end for explanation on Risk Ratings

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Our Take:

Granules India Ltd. is a fully integrated pharmaceutical company having presence across API-PFI-FD value chain (Active Pharmaceutical Ingredients (API), Pharmaceutical Formulation Intermediates (PFI) and Finished Dosages (FD)). Granules has one of the largest PFI and single site FD facilities in the world and has the world's largest Paracetamol API facility.

Exports business contribution stands at 92-94% of overall business. Company has progressively moved from being an API to a fully integrated player with dominant finished dosage sales. Granules has a very strong presence in the US market, driven growth trajectory built on scale, manufacturing excellence, focused execution, and cost leadership. It is also making good inroads within Europe and contribution from the region has been on an upward trend.

After robust numbers in FY21 led by highest ever gross margin of 57%, the company reported steep decline in FY22. However, the company reported steady numbers in FY23 and accelerated operational performance H2FY24 and Q1FY25. We expect the company to report healthy growth in the medium term led by new launches and market share gains from existing molecules. Company has high dependency on few products, however it has reduced this gradually over the past three years. It has reduced to 75% as against 84% in FY23 and 81% in FY22.

Raw-material prices and freight costs are easing over the past few quarters. Measures taken to reduce dependence on China and initiating a price hike across customers would help it offset any concerns around China led API price increases. Commissioning of the MUPS block and a strong product pipeline across regions to support growth. Expected rise in R&D spending coupled with increased finance and depreciation costs, along with continued price erosion in the formulations segment could remain a concern. Nevertheless, strong sales growth coupled with productivity measures should help it offset its impact partially over the medium term.

The company had filed five ANDAs and six DMFs during FY24, which should drive further growth momentum in the US. Inventory build-up is largely to cater to US business. The project related to PAP is expected to be completed by FY25. The company spent Rs 380 crore on capex for FY24 and intends to spend Rs 350-400 crore in FY25. The backward integration of its core products (Paracetamol/Metformin) is also on track to improve overall profitability over the medium term. Its focus on enzyme and fermentation technology to build the pipeline of complex products in the regulated market will support overall growth over the next 12-18 months.

On Jan 16, 2024, we had issued a stock note on Granules India and recommended to buy in the band of Rs 430-434 and add more on dips

to Rs 384 for base case target price of Rs 470.5 and bull case target of Rs 507 over the next 2-3 quarters and our targets were achieved in the given time frame (Link). We issue a report on the stock given strong numbers in the past 2 quarters and positive momentum in the Pharma sector.

Valuation & Recommendation:

The company has been witnessing strong growth in its Formulation business, mainly in regulated markets like US and UK. H2FY24 and Q1FY25 witnessed better growth led by new product launches and volume growth. Strong sales growth coupled with productivity measures could lead to healthy growth in earnings in the medium term.

We expect Revenue, EBITDA and PAT to grow at CAGR of 12.6%, 22.4% and 33% respectively, over FY24-26E. US business is expected to grow at a robust pace led by steady base business, market share gains and new limited competition launches in the medium term. Company has witnessed a shift from API/PFI to Formulation business as visible in FY24 and Q1FY25. As most respiratory inhaler products are going to be limited competition, it will lead to sustainable margin expansion in the US. We feel investors can buy the stock in the range of Rs 644-653 and add more on dips to Rs 580 (19.5x FY26E EPS) for base case target of Rs 706 (23.75x FY26E EPS) and bull case target of Rs 758 (25.5x FY26E EPS) over the next 2-3 quarters.

Financial Summary

Particulars (Rs cr)	Q1FY25	Q1FY24	YoY (%)	Q4FY24	QoQ (%)	FY21	FY22	FY23	FY24	FY25E	FY26E
Total Revenue	1180	986	19.7	1176	0.3	3,238	3,765	4,512	4,506	5,061	5,719
EBITDA	259	137	89.3	256	1	855	722	914	855	1077	1282
Depreciation	53	49	7.3	53	-1	152	159	184	206	221	241
Other Income	2	0	500.0	2	14	27	18	14	4	6	8
Interest Cost	27	23	20.0	29	-6	26	23	56	106	95	79
Tax	47	18	165.9	46	2	155	145	171	142	198	249
PAT	135	48	181.0	130	4	550	413	517	405	569	721
EPS (Rs)						22.2	16.6	21.4	16.7	23.5	29.7
RoE (%)						27.4	17.3	19.1	13.4	16.3	17.5
P/E (x)						29.1	38.8	30.2	38.6	27.5	21.7
EV/EBITDA (x)						19.6	23.2	18.3	19.6	15.5	13.1

(Source: Company, HDFC sec)

Q1FY25 Result Update

Revenue for the quarter grew 19.7% YoY to Rs 1179.8cr as against the estimate of Rs 1202cr. Operating margin expanded 800bps YoY at 22% as against expectation of 22.2%. Gross margin expanded 760bps YoY at 59%. Net profit increased 180% YoY to Rs 134.6cr. Company's operations were impacted due to IT incident in Q1FY24, which had led to lower volumes in that quarter.
Revenue share from North America increased to 74% in Q1FY25 as compared to 61% in Q1FY24.

Active Pharmaceuticals Ingredients (API), Pharmaceutical Formulation Intermediates (PFI), and Finished dosages contributed 14%, 10%, and 76% of revenue from operations respectively for Q1FY25.

Company expects to launch 12 new products in the US, EU and other RoW markets in FY25; Gross margin to sustain at 58-59% in FY25. H2FY25 will have stronger earnings than H1FY25. EPS for the quarter stood at Rs 5.55. Net debt as on Jun-2024 stood at Rs 790cr.

Capex for Q1FY25 stood at Rs 140cr. Cashflow from operations for Q1FY25 was at Rs 215cr.

Conference Call Highlights

Guidance

- US business to grow at 20%+ in FY25, with major contribution from formulations.
- FD contribution is expected to be around 76% or a little above for FY25.
- In FY25, the company expects to launch three to four products in the US and around eight products in the RoW market.
- Gross margin to sustain in the range of 58-59% in FY25.

API, PFI & KSM

- Sales of Paracetamol API and PFI sales declined during the quarter due to higher customer inventory and price erosion.
- It expects to file a couple of products in the next few quarters.
- Paracetamol API prices have stabilized and are expected to pick up in FY26.

Formulation

- Formulation business continues to show strong growth, which led to an increase in formulation share in the business.
- The company launched products like Colchicine capsules and Esomeprazole capsules Rx in the US market.
- Europe business was majorly driven by formulation business through key partnerships and Dossier sales / BD deals on existing and new products.
- In the US, growth was majorly driven by an increase in market share and also to some extent from new launches.
- Europe sales declined 35% in rupee terms due to the recent shift from API to FDs. Europe was a paracetamol led business and is not performing well, as most of the customers have already built-up huge inventories. Paracetamol did not contribute in Q1FY25 and is

expected to remain muted in FY25.

- Latin America (LatAm) sales were mainly led by PFIs (Paracetamol and others PFIs). As paracetamol sales declined, the company managed to keep up with other PFI sales. Currently, the focus is to shift from PFI to FDs.
- Contribution from Finished Dosages has significantly improved to 76% in Q1FY25 from 65% in FY24.
- Share of non-legacy products has increased from 25% in FY24 to 35% in Q1FY25.
- The company's OTC private level portfolio through granules of consumer health is also gaining traction and contributing to growth in the US business. OTC contribution is 15% to the overall formulation sales.
- Granules has healthy product pipeline in oncology, the antibody diabetic segment, large volume molecules and select non-OSD dosage form.
- At GPI (a local manufacturing arm in the US) CNS and ADHD segment has performed well and are key drivers for growth in the US. Similarly, the capacity utilization at GPAK, (new packaging site in the US), is improving QoQ.
- The company launched five products in Q1FY25. In the US, the price erosion is stabilized at mid to high single digit.
- In diabetes, as the company is among the leaders in metformin, it is planning to work on several derivatives of Metformin. It is expected to contribute significantly to the top-line growth and most of the launches will be FTFs.
- Oncology product launches are expected to start from FY26.
- The company is focused on creating manufacturing technology infrastructure in the next two quarters and start validation of at least three molecules in Q3FY25. This platform is expected to bring global cost leadership, and manufacturing technology excellence and help the company to lead towards their journey of sustainability.
- It has also finalized investment plans to build infrastructure for the chosen products for the chemical steps. These projects will get into execution by Sept'24 and will take around 14 to 18 months to complete.
- The company anticipates sustained growth driven by strong growth outlook in formulation segment, and market expansion supported by building deep capabilities in APIs and select KSMs. The investments in R&D and a strong product pipeline, particularly in large volume molecules, oncology, anti-diabetic segments and CNS/ADHD segment will be driver in the medium to long term.
- Active Pharmaceuticals Ingredients (API), Pharmaceutical Formulation Intermediates (PFI), and Finished dosages contributed 14%, 10%, and 76% to revenue from operations respectively for Q1FY25.
- Company expects to start the validation of three molecules in enzymes from Q3FY25.
- R&D expenses stood at Rs 62cr in the quarter. Management expects that R&D costs could increase going forward.
- OTC sales witnessed double-digit growth, which was 15% of the overall formulation sales.
- Company is also building capacity for enzyme and fermentation, which would get completed in the next 12-15 months.

Facility inspection update

- The construction and capacity ramp-up of the new formulation facility at Genome Valley (part of Granules Life Sciences) is

progressing well. The plant successfully commenced operations in Mar-2024 for the first stage of 2bn capacity and validation activities are ongoing.

- Oncology products have been an important portfolio for the company. The company has already built world class infrastructure both in API and combinations at the Vizag facility. The portfolio includes Para IV, Para IV-181 and the first to launch in US, Europe and rest of the world.
- Management proposes to create a new oncology API manufacturing facility and augment finished dosage and other infrastructure enhancements. The project execution is likely to start from Sep/Oct-2024 and should take approximately 12 months to complete. This should enable to bring flexibility to Granules supply chain and enable it to become a significant player in the oncology segment.

Other Highlights

- Management has identified and finalized two plants: One at Vizag (12 acres) and another at Kakinada (100 acres).
- PAP Projection is expected to be completed by the end of FY25.
- Granules has approval for 63 products and 1 tentatively approved ANDA, 8 European dossiers in the UK, 6 in Canada, and 7 in other regions.
- The company had filed five ANDAs and six DMFs during FY24.
- Granules has a total of 39 US DMFs, 24 CEPs, 5 EDMFs, 8 KDMFs, 4 Canadian DMFs, 2 Japanese DMFs as on Mar-2024.
- There are about 28-30 products which are under various stages of development at Granules integrated product development center All these products are scheduled to be filed in the 3-4 quarters.
- Health Canada audit at Jeedimetla API plant was successfully completed with zero critical observations.
- Granules has started work on the backward integration of 10 additional critical products after Paracetamol and Metformin, which would give desired results in the next 2-3 quarters.
- Price erosion was partially offset by significant volume growth in North America business. Europe sales declined due to higher price erosion.
- Share of the PFI business has reduced YoY, as more customers are converting into FD from PFI. FD volumes increased significantly in the US across major products.
- Going forward, management believes FD will grow and PFI and API growth will be subdued.
- Management highlighted that legacy products will continue to grow, while new products will be more profitable but volumes may not be at the same level.
- The company has already received PLI approval for 8000 TPA DCDA projects and management plans to get approval beyond 8000 TPA (can be applied to receive approval for 30,000 TPA).

Volume growth in the US drives FD sales

FD segment showed a strong growth of 66%/3% YoY/QoQ in Q1FY25 on account of significant volume growth in the US, driven by CNS/ADHD portfolio and other new products. The company expects to launch an additional 3-4 new products in US and eight products in other geographies in subsequent quarters in FY25. With a ramp-up in new launches in the US and other geographies coupled with improved volumes, we expect FD segment revenue CAGR of 17.5% over FY24-26E.

APIs revenue declined 37% YoY but grew 15.7% QoQ in Q1FY25, primarily led by lower demand for its key product-paracetamol due to inventory build-up across US and EU. API prices are expected to recover from H2FY25. PFI segment declined 32.7% on YoY and QoQ basis in Q1FY25 on account of more customers converting into FDs from PFIs. Management believes the PFI segment sales will continue to decline due to a shift in portfolio towards FDs.

Business overview

Granules India operates in three primary business segments: active pharmaceutical ingredients (APIs), pharmaceutical formulation intermediates (PFI), and finished dosages (FD). PFI segment has emerged as one of India's largest, with six tons of batch processing capacity. FD segment has grown strongly in the last 3 years, and currently contribute over 75% of revenue. The company has 300+ customers across 80+ countries.

Granules has built one of the largest PFI and single site FD facilities in the world and has the world’s largest Paracetamol API facility. The company has two research and Development (R&D) centers in Hyderabad and Virginia, alongside its existing R&D facilities in Pune and Pragathi Nagar (Hyderabad). Company has progressively moved from being an API to a fully integrated player with dominant finished dosage sales. Company has very strong presence in the US market, driven growth trajectory built on scale, manufacturing excellence, focused execution, and cost leadership. It is also making good inroads within Europe and contribution from the region has been on an upward trend.

During FY23, the company inaugurated the new packing facility in Manassas, Virginia, US. The facility received US FDA approval. This facility will reduce the supply chain issues, cost reduction and improvement in the working capital cycle. Granules India has seven manufacturing units, of which six are India and one in the USA.

Company has emerged as a leading manufacturer and supplier of APIs such as Paracetamol, Metformin, Guaifenesin, and Methocarbamol. Company is working to improve API manufacturing capability to add new products. Most of the new PFI and FD products are supported by vertical integration of respective APIs. An emphasis on adopting advanced technology, backward integration to critical steps combined with the strength of a robust, resolute team, empowers to consistently meet evolving customer demands with precision and excellence. API business accounted for 22% of revenue in FY24.

Company is expanding formulation capabilities to meet growing demand with a new facility at Genome Valley that commenced operations in March-2024. When fully completed, this plant will add 8 billion dosages to overall capacity. It is enhancing enzyme manufacturing capabilities for biocatalysis and continuous manufacturing platforms.

Pharmaceutical Formulation Intermediates (PFI)

Company has emerged as one of India's largest PFI manufacturers with a batch processing capacity of six tons. The PFIs can be directly taken to the hoppers from the drums and it has help Granules become a preferred PFI supplier for some of the most renowned global pharma companies. PFI business accounted for ~14% of revenue in FY24. Currently, the company has PFI facilities at Jeedimetla and Gagillapur to further process into Finished Dosages.

Finished Dosages (FD)

Over the years, Granules has sustainably grown FD capabilities and it is currently contributing over 50% of revenue. The existing portfolio of finished dosages comprises Caplets, Tablets as well as Press-fit Capsules in Bulk, Blister packs and Bottles. The manufacturing facility at Gagillapur is equipped with automated processes, robust infrastructure, and superior quality systems to efficiently produce finished dosages that are marketed in 80+ countries, including the highly regulated markets of the US and Europe. It also produces Bi-layered tablets, Rapid release tablets, and Extended release (ER) tablets. Company developed own ANDAs and dossiers to offer an added advantage to customers.

Healthy revenue growth supported by growth across key molecules

Company reported revenue CAGR of ~15% over the past five years, supported by steady growth for some of its key molecules including paracetamol and metformin in key markets like North America, Europe and Latin America. Moreover, the growth momentum is expected to be sustained over the medium term supported by increasing sales of its existing key molecules, increased penetration in key markets and increasing revenue contribution from new launches. The recently commissioned multiunit pellet system (MUPS) facility in Gagillapur (Telangana) and upcoming FD facility in Hyderabad are also expected to support growth momentum.

Over the years, Granules has been able to largely maintain its operating margins (18-20% range) supported by significant backward integration with in-house manufacturing of four out of five key APIs and economies of scale from its sizeable manufacturing capacities at the Gagillapur and Bonthapally (Telangana). Although, the company started out as an API manufacturer, over the years it integrated its operations to manufacture FDs, which contributed to ~65% of its revenue in FY24. Moreover, the commissioning of the MUPS facility and the upcoming FD facility in Hyderabad, is expected to further support its FD sales, which provide better margins. Despite some volatility due to unpredictable raw material prices and forex risks, the margins are expected to continue to remain healthy supported by its increasing backward integration (in the Kakinada project) and cost optimisation initiatives.

Granules' business benefits from i) the continued increase in its already large scale of operations with revenue growing at CAGR of ~15% over FY15-24 through new product launches, increased market share in existing products and increased capacities; ii) increased focus on operational efficiencies, the integrated nature of its operations and process innovation, resulting in GIL being one of the largest cost competitive suppliers of the first-line-of-defence molecules such as paracetamol, metformin, ibuprofen, guaifenesin and methocarbamol to the regulated markets; iii) increased revenue contribution from higher margin FD segment of 50% in FY23 (FY22: 52%, FY17: 37%, FY11: 22%) iv) increased proportion of sales from the regulated markets of the US and Europe (FY24: 85%, FY22: 73%, FY17: 67%); and v) no adverse regulatory action by the regulators on the company's facilities. Over the years, the company witnessed improvement in the product mix towards FD segment, and that led to improvement in gross margin to 57% in FY21 from 52.6% in FY17.
However, gross margin reduced to 50% and 49% in FY22 and FY23. It bounced back to 55% in FY24 and further improved to 59% in Q1FY25. Management guided for gross margin of 58-59% in FY25.

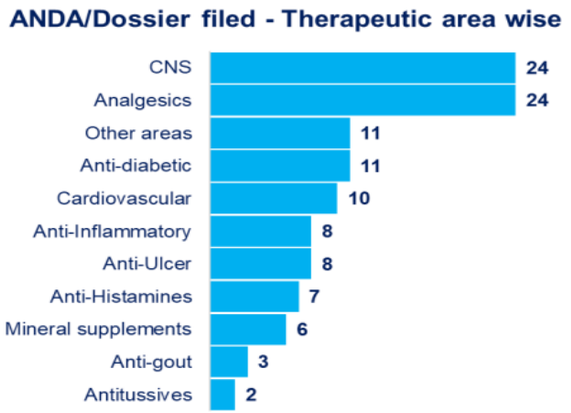
The company intends to further strengthen its business through product launches in emerging markets (Latin America and the rest of the world) that house medium-volume and medium-value products and segments with low-volume and high-value products that involve more complex R&D, niche molecules and differentiated release mechanisms from its US based subsidiary, Granules Pharmaceuticals.

R&D pipeline to support growth

We expect overall business to grow at a healthy pace over the next 2-3 years, driven by strong abbreviated new drugs application (ANDA) pipeline of 75+ products for the FD business in the US, of which 63 were approved and 17 pending approval with the US FDA as on Jun-2024. The company expects to continue filing of about 10 ANDAs and launch 8-9 products per year in the US market. To support the formulation business, the company filed six DMFs across therapies with US FDA, four certificates of suitability with the European Directorate for the Quality of Medicines and five European drug master files, which will be used for building future revenue from the API business.

Company will continue to strengthen its market position through dedicated research and launch of new products. It intends to strengthen its product portfolio through multiple release mechanisms such as immediate release, extended release, delayed release, multiple unit pellet system, and power and suspension dosages. As part of its vertical integration strategy, Granules aims to file ANDAs for several of these APIs to forward integrate into finished dosage forms (FDFs).

Filing Status		Approved	Tentatively Approved	Filed	Total Products
GPI IP	USA	27	0	5	32
GIL IP	USA	36	1	11	48
	Europe	8	-	3	11
	Canada	6	-	-	6
	RoW	7	-	8	15
	UK	2	-	-	2
Total		86	1	27	114



(Source: Company, HDFC sec)

MUPS Facility

Granules focuses on developing differentiated technologies to enable the production of complicated formulations. During the year FY23, the company completed a new finished dosage block for manufacture of MUPS (Multi-unit pellet system) products, with an investment of Rs 240 crore. MUPS has become one of specialized manufacturing facilities. It has already received approval for a number of products and are in the process of acquiring the remaining soon. The company is one of the largest suppliers of MUPS capacity across the world on the chosen set of approved molecules, which are going to get launched in the US and Europe market. Company is evaluating opportunities to offer product, process, and related services to customers in oncology. The commercial supplies from oncology block are expected as soon as receive regulatory approvals.

R&D

The new R&D facility at Genome Valley (MN Park) for Integrated Product Development has been set up in 20,000 sq. ft. and is functioning with more than 150 scientists across both the divisions. The new facility brings API R&D and Formulation R&D teams together under one umbrella. The common analytical resources help bring efficiency in the R&D processes.

Pragathi Nagar R&D at Hyderabad, has been established as a Center of Excellence (CoE) for the development of CII APIs. In addition to CII API products, we are also focusing on the development of KSMs and Intermediates for select APIs. To further strengthen presence in Controlled Substances, the company will continue to leverage research and development capabilities of Pragathi Nagar, in conjunction with

the FD R&D of subsidiary, Granules Pharma Inc. (GPI). The Bio Lab brings capabilities in the areas of fermentation and biotransformation along with lab and pilot scale manufacturing platform for the Enzyme led projects. R&D initiatives would help broaden capabilities, leading to increased focus on quality of portfolio and higher number of regulatory filings going forward.

For FY24, R&D expenses were at Rs 199cr or 4.4% of sales. It stood at Rs 62cr or 5.2% of sales in the quarter. Management expects that R&D costs could increase going forward.

US Generics Market

Generic drugs account for over 90% of prescriptions in the US healthcare system. US generics market has witnessed a transformation since 1984, post implementation of the Hatch Waxman Act. Indian pharmaceutical companies supply a substantial proportion of drugs to US residents, with four out of ten of all prescriptions filled in the US in 2022 supplied by Indian companies. Indian companies supplied 47% of all generic prescriptions filed in the US and 15% of the volume of biosimilars. Patent expiries over decades for products used by millions of patients have contributed to overall generic share of adjusted prescriptions reaching 92% - including branded generics.

US generic pharma industry has been grappling with pricing pressure, supply chain issues, and cost inflation, which impacts margin and profitability of the players. The price erosion is attributed to several factors such as customer consolidation, intensified competition, and the US government's measures to reduce drug prices for customers. Generic prices have been deflating for several years, driven by an increase in the number of generic approvals. However, in 2023 these were offset by volume growth and resulted in ~US$ 1 billion contribution to market growth on a net basis. This resultant pricing pressure will lead to the consolidation of the industry towards the stronger players who have better control over the supply chain and are capable of backward integration through innovative manufacturing technology. Losses of exclusivity in the US will likely amount to be US$ 140 billion with significant impact on spending for both small molecules and biologics. Small molecule expiries are expected to reduce brand spending by US$ 100 billion through 2028, more than double the impact of the last five years, including the impact of high profile products in the anticoagulant therapy area, including rivaroxaban (Xarelto).

European Generics

Generics, including biosimilar, are expected to add US$ 18 billion in growth over the next five years, about the same as in the past five years, despite a larger impact of Loss of Exclusivity (LoEs) as volume gain will be offset by price deflation. The effect of LoEs in the five largest European markets (Germany, France, Italy, Spain, and the UK), are expected to more than triple over the next five years and more than half of the impact is expected to be biologics with US$ 17 billion of US$ 32 billion total impact. Small molecule LoE is expected to double in terms of impact on brands in the next five years from US$ 8.5 billion in previous 5 years to US$ 14.5 billion in the next five years.
Spending in Europe is expected to increase by US$ 59 billion over the period 2023-2027, with a focus on generics and biosimilars, and escalating pressures on the value and negotiated prices of novel medicines.

Generics, including biosimilars, are expected to add US$ 12 billion in growth over the next five years (2023-27), about the same as in the past five years despite a larger impact of losses of exclusivity as volume gains will be offset by price deflation.

The impact of losses of exclusivity in the five largest European markets (Germany, France, Italy, Spain and the UK) are expected to be more than triple over the next five years, and more than half of the impact is expected to be biologics. Small molecule is expected to double in terms of impact on brands in the next five years even as they have been a smaller share of overall impact.

Over the Counter (OTC) Drugs Market

OTC or over-the-counter drugs are pharmaceutical products that are perceived to be safe to buy without prescription and are used to treat common symptoms for cold, body pain, allergy, flu, heartburn, acne, and other basic health problems. As per Global Market Insights Report of 2020, the OTC drugs market size was valued at US$ 152 billion in 2020 and is expected to grow at a CAGR of over 5% to reach US$ 209 billion in 2027. The Covid outbreak has considerably influenced the sales of OTC drugs with increased focus on personal health during the pandemic. This has significantly increased the intake of cold and flu products besides vitamins. However, in some regions, OTC drug sales were restricted to counteract stockpiling and maintain supply. Increasing availability and manufacturing of OTC drugs for a broad range of common disease conditions will significantly drive the over-the-counter drugs market revenue in the impending years. Repetitive occurrence of common flu and cold impels the demand for therapeutics. Awareness of and demand for vitamin supplements and weight loss products will majorly contribute to the industry value during the forecast period i.e. from 2020 to 2027. Cost-benefits, positive results and broader accessibility are projected to highly fuel demand for over-the-counter drugs.

Key Concerns

- Vulnerability in business due to currency movements, regulatory changes and geopolitical events across countries. Company derives about 90% of sales from US, Europe, LatAm and RoW markets. It has also borrowed debt in foreign currency.
- Elevated price erosion in the US generic business could hurt US revenue though pricing pressure has moderated and is currently in high single digit. Company's overall business has shifted to Finished Dosages (FD).
- Any disruption in sourcing KSMs as Granules depends on China for some of its products and any increase in prices of raw materials could weigh on net profit earnings estimates.
- Any escalation of regulatory issues at its key facility or delay in its resolution could weigh on earnings.
- High product concentration risk in mature molecules, although mitigated to some extent by healthy market share in these molecules. The top five molecules are first line of defence mature generic molecules. The company is exposed to product concentration risk as these molecules have continued to account for 80-85% of its revenues in recent years.
- A significant share of revenue is generated by North America (~66%) and Europe (20%), which have witnessed continued pricing pressure

over the recent past, which is likely to sustain. Moreover, the company has focused on enhancing its footprint in Europe and Latin America. A few key molecules would continue to contribute meaningfully to revenue.

- Granules' profitability continues to remain vulnerable to volatility in raw material prices, though its backward integrated operations provide some comfort. The capex plan in Kakinada (Andhra Pradesh) for manufacturing KSMs of its key products like paracetamol and metformin, which is expected to further support its profitability against volatility in raw material prices over the medium to long-term.
- Like its peers, Granules India continues to remain exposed to regulatory risks and litigations including scrutiny by agencies like US FDA and EU GMP. Considering the US contributed ~66% to its revenue in FY24, scrutiny by the US FDA continues to remain key for its overall operations. Granules' Gagilapur (Telangana) facility, which had received a Form 483 with three observations by the US FDA post inspection in Jan-2023, has subsequently received an establishment inspection report (EIR). Moreover, its two other facilities at Jeedimetla (Telangana) and Visakhapatnam (Andhra Pradesh) also completed US FDA inspections in Jun-2023 with zero Form 483 observations. It got 5 observations in the US FDA inspection of its US subsidiary in Dec-2023.
- Granules is in the midst of a large capex. Apart from execution risks it also faces the risk of underutilization of capacity once these projects get commissioned.

Company Background

Granules India Ltd. was incorporated as a private limited company in 1991 and was later converted into a public limited company in 1993. It started out as a merchant exporter of bulk drugs like paracetamol, Guaifenesin and Chloro Pheniramine Maleate. Granules India manufactures APIs, pharmaceutical formulation intermediates (PFIs) and FDs, which are marketed to more than 300 customers across more than 50 countries, primarily in North America, Europe, Asia and Latin America. Company has seven manufacturing plants across Hyderabad, Visakhapatnam and Virginia (USA), and two R&D centres in Hyderabad and Virginia, with an installed manufacturing capacity of 39,360 TPA of API, 24,640 TPA of PFI and 23.3 billion dosages of FDs. Granules has two research and Development (R&D) centers in Hyderabad and Virginia, alongside its existing R&D facilities in Pune and Pragathi Nagar (Hyderabad).

The products are being distributed to over 300+ customers in regulated and semi-regulated markets with a global presence extending to over 80+ countries with offices across India, US, and UK. Company has 7 manufacturing facilities out of which 6 are in India and 1 in the USA and 1 packaging facility in the USA and has regulatory approvals from US FDA, EDQM, EU GMP, COFEPRIS, WHO GMP, TGA, KFDA, DEA, MCC etc.

Granules India Limited (GIL) is a leading, vertically integrated pharmaceutical Company dedicated to manufacturing Active Pharmaceutical Ingredients (API), Pharmaceutical Formulation Intermediates (PFI) and Finished Dosages (FD) products. Company has presence across the United States of America, Canada, Latin America, Europe, Asia, and India. Exports contribute to over 90% of revenue. Company has

progressively moved from being an API to a fully integrated player with dominant finished dosage sales. It is making good inroads within Europe and contribution from the region has been on an upward trend. During the year, the company completed new finished dosage block for the manufacturing of MUPS (multi-unit pellet system) products in existing manufacturing plant.

Manufacturing Facilities

	Manufacturing Units	Capacity	Regulatory Approvals
API	► Bonthapally, Telangana	► 34,560 TPA	► U.S. FDA, EDQM, WHO, COFEPRIS,INFARMED
	► Jeedimetla, Telangana	► 4,800 TPA	► U.S. FDA, EDQM, COFEPRIS, WHO, CDCSO
	► Vizag (Unit IV), Andhra Pradesh	► 380 KL	► U.S. FDA, KFDA, EU GMP, WHO GMP, EDQM
	► Vizag (Unit V), Andhra Pradesh	► 15 KL	► EU GMP
	► Bonthapally II (API Intermediate, Telangana)	► 61.5 KL	
PFI	► Gagillapur, Hyderabad	► 23,200 TPA	► US FDA, COFEPRIS, TGA, MCC, INFARMED
	► Jeedimetla, Telangana	► 1,440 TPA	► WHO GMP, COFEPRIS, INFARMED
FD	► Gagillapur, Hyderabad	► 26.8 Bn	► US FDA, MCC, COFEPRIS, TGA, INFARMED
	► Virginia, USA	► 1.5 Bn	► US FDA, DEA
	► Vizag (Unit V), Andhra Pradesh	► 1.1 Bn	► EU GMP
Packaging	► Virginia, USA	► 2 OTC lines and 1 Rx line	► US FDA

(Source: Company, HDFC sec)

Peer Comparison

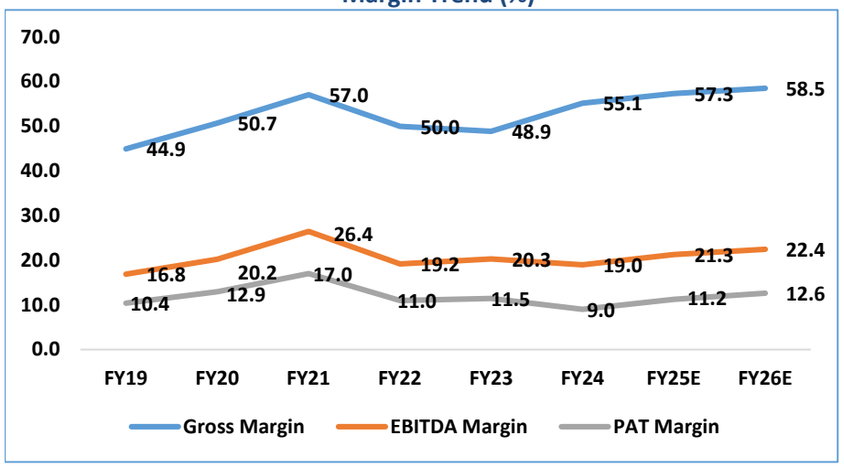
Company	Mcap (Rs cr)	Revenue				EBITDA Margin (%)				PAT				RoE			
		FY23	FY24	FY25E	FY26E	FY23	FY24	FY25E	FY26E	FY23	FY24	FY25E	FY26E	FY23	FY24	FY25E	FY26E
Granules India	15633	4512	4506	5061	5719	20.3	19.0	21.3	22.4	517	405	569	721	19.1	13.4	16.3	17.5
Caplin Point Laboratories	12461	1467	1694	1943	2269	30.1	32.6	32.8	33.7	376	457	508	593	22.4	21.8	20.0	19.5
Marksans Pharma	9310	1852	2177	2535	2890	18.4	21.1	22.4	23.0	266.3	313.7	384	458	18.1	16.8	17.5	17.8

Company	EV/EBITDA (x)				P/E			
	FY23	FY24	FY25E	FY26E	FY23	FY24	FY25E	FY26E
Granules India	18.3	19.6	15.5	13.1	30.2	38.6	27.5	21.7
Caplin Point Laboratories	25.4	20.3	17.5	14.6	33.1	27.3	24.5	21.0
Marksans Pharma	23.9	17.0	14.4	12.3	35.0	29.7	24.2	20.3

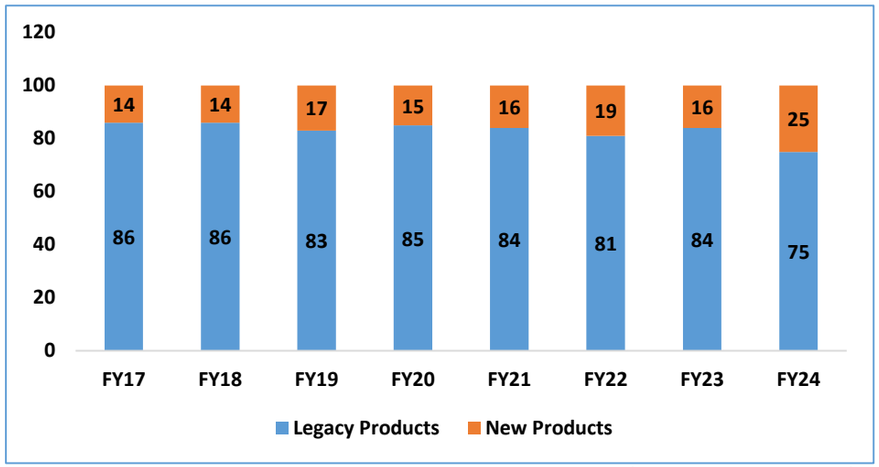
(Source: Company, HDFC sec)

Granules India Ltd.

Margin Trend (%)

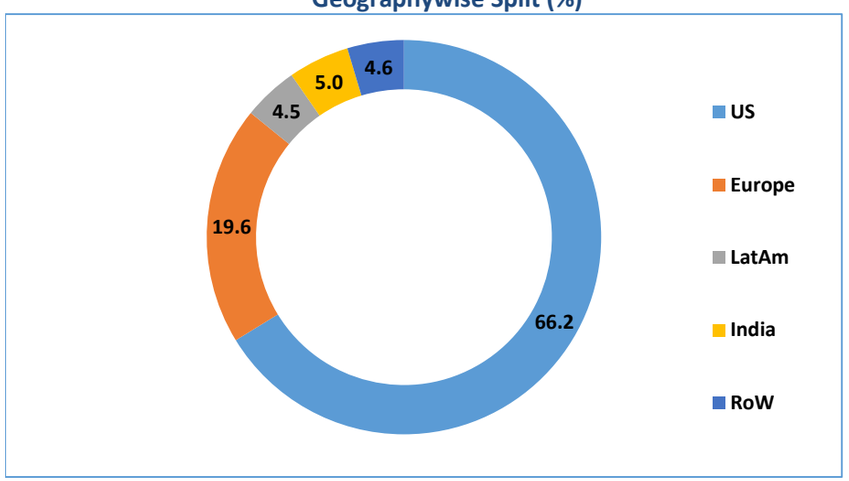


Revenue Mix (%)



(Source: Company, HDFC sec)

Geographywise Split (%)



Granules India Ltd.

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Financials (Consolidated)

Income Statement

(Rs Cr)	FY22	FY23	FY24	FY25E	FY26E
Net Revenue	3765	4512	4506	5061	5719
Growth (%)	16.3	19.8	-0.1	12.3	13.0
Operating Expenses	3043	3598	3651	3984	4437
EBITDA	**722**	**914**	**855**	**1077**	**1282**
Growth (%)	-15.5	26.5	-6.4	26.0	19.0
EBITDA Margin (%)	**19.2**	**20.3**	**19.0**	**21.3**	**22.4**
Depreciation	159	184	206	221	241
EBIT	564	730	649	856	1041
Other Income	18	14	4	6	8
Interest expenses	23	56	106	95	79
PBT	558	687	548	767	969
Tax	145	171	142	198	249
RPAT	**413**	**517**	**405**	**569**	**721**
Growth (%)	-24.9	25.2	-21.6	40.3	26.7
EPS	16.6	21.4	16.7	23.5	29.7

Balance Sheet

As at March	FY22	FY23	FY24	FY25E	FY26E
SOURCE OF FUNDS					
Share Capital	24.8	24.2	24.2	24.2	24.2
Reserves	2562	2811	3201	3747	4442
Shareholders' Funds	**2587**	**2835**	**3226**	**3772**	**4466**
Long Term Debt	234	149	69	78	67
Net Deferred Taxes	1	-5	-31	-31	-31
Long Term Provisions & Others	37	100	121	129	136
Total Source of Funds	**2858**	**3079**	**3385**	**3948**	**4638**
APPLICATION OF FUNDS					
Net Block	1596	1858	2116	2274	2384
Intangible Assets	302	291	252	252	252
Non Current Investments	20	21	22	28	35
Long Term Loans & Advances	78	148	173	163	153
Total Non Current Assets	**1995**	**2318**	**2562**	**2717**	**2824**
Current Investments	0	0	0	0	0
Inventories	979	1149	1301	1220	1347
Trade Receivables	925	949	986	1106	1250
Short term Loans & Advances	8	1	1	2	5
Cash & Equivalents	409	313	386	677	908
Other Current Assets	184	163	231	261	316
Total Current Assets	**2506**	**2574**	**2905**	**3267**	**3826**
Short-Term Borrowings	859	910	1154	1062	913
Trade Payables	639	782	750	767	858
Other Current Liab & Provisions	122	107	166	190	214
Short-Term Provisions	23	15	12	18	27
Total Current Liabilities	**1643**	**1814**	**2082**	**2036**	**2012**
Net Current Assets	863	761	823	1231	1814
Total Application of Funds	**2858**	**3079**	**3385**	**3948**	**4638**

(Source: Company, HDFC sec)

Granules India Ltd.

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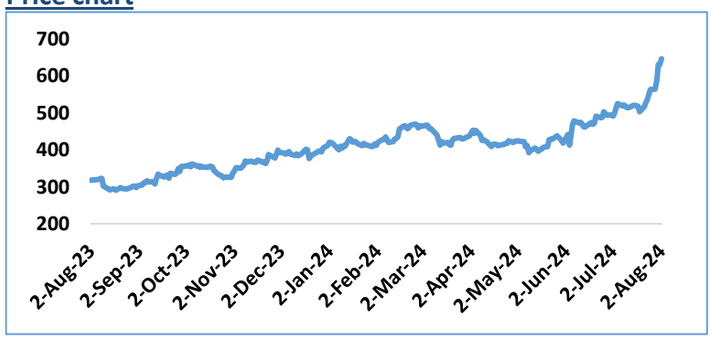
Cash Flow Statement

(Rs Cr)	FY22	FY23	FY24	FY25E	FY26E
Reported PBT	558	687	548	767	969
Non-operating & EO items	-18	-14	-4	-6	-8
Interest Expenses	23	56	106	95	79
Depreciation	159	184	206	221	241
Working Capital Change	-245	1	-226	-118	-352
Tax Paid	-145	-176	-190	-198	-249
OPERATING CASH FLOW (a)	**332**	**739**	**439**	**762**	**680**
Capex	-398	-411	-379	-380	-350
Free Cash Flow	-66	328	60	382	330
Investments	0	206	15	4	3
Non-operating income	18	14	4	6	8
INVESTING CASH FLOW (b)	**-380**	**-192**	**-360**	**-370**	**-340**
Debt Issuance / (Repaid)	251	-55	150	16	-3
Interest Expenses	-23	-56	-106	-95	-79
FCFE	161	218	105	303	248
Share Capital	0	-1	0	0	0
Dividend/Buyback	-37	-329	-36	-23	-26
FINANCING CASH FLOW (c)	**190**	**-440**	**8**	**-101**	**-109**
NET CASH FLOW (a+b+c)	**142**	**107**	**87**	**290**	**232**

Price chart



Key Ratios

	FY22	FY23	FY24	FY25E	FY26E
Profitability (%)					
Gross Margin	50.0	48.9	55.1	57.3	58.5
EBITDA Margin	19.2	20.3	19.0	21.3	22.4
EBIT Margin	15.0	16.2	14.4	16.9	18.2
PAT Margin	11.0	11.5	9.0	11.2	12.6
RoE	17.3	19.1	13.4	16.3	17.5
RoCE	19.6	23.6	18.9	21.4	22.2
Solvency Ratio (x)					
Net Debt/EBITDA	0.9	0.8	1.0	0.4	0.1
D/E	0.4	0.4	0.4	0.3	0.2
Net D/E	0.3	0.3	0.3	0.1	0.0
PER SHARE DATA (Rs)					
EPS	16.6	21.4	16.7	23.5	29.7
CEPS	23.0	29.0	25.2	32.6	39.7
BV	104	117	133	156	184
Dividend	0.4	0.4	0.5	0.9	1.0
Turnover Ratios (days)					
Debtor days	90	77	80	80	80
Inventory days	85	86	99	88	86
Creditors days	96	98	99	94	95
VALUATION (x)					
P/E	38.8	30.2	38.6	27.5	21.7
P/BV	6.2	5.5	4.8	4.1	3.5
EV/EBITDA	23.2	18.3	19.6	15.5	13.1
EV / Revenue	4.4	3.7	3.7	3.3	2.9
Dividend Yield (%)	0.1	0.1	0.1	0.1	0.2
Dividend Payout (%)	2.4	1.9	3.0	3.6	3.4

(Source: Company, HDFC sec)

Kushal Mahendra Rughani

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HDFC Sec Retail Research Rating description

Green Rating stocks

This rating is given to stocks that represent large and established business having track record of decades and good reputation in the industry. They are industry leaders or have significant market share. They have multiple streams of cash flows and/or strong balance sheet to withstand downturn in economic cycle. These stocks offer moderate returns and at the same time are unlikely to suffer severe drawdown in their stock prices. These stocks can be kept as a part of long term portfolio holding, if so desired. This stocks offer low risk and lower reward and are suitable for beginners. They offer stability to the portfolio.

Yellow Rating stocks

This rating is given to stocks that have strong balance sheet and are from relatively stable industries which are likely to remain relevant for long time and unlikely to be affected much by economic or technological disruptions. These stocks have emerged stronger over time but are yet to reach the level of green rating stocks. They offer medium risk, medium return opportunities. Some of these have the potential to attain green rating over time.

Red Rating stocks

This rating is given to emerging companies which are riskier than their established peers. Their share price tends to be volatile though they offer high growth potential. They are susceptible to severe downturn in their industry or in overall economy. Management of these companies need to prove their mettle in handling cyclicality of their business. If they are successful in navigating challenges, the market rewards their shareholders with handsome gains; otherwise their stock prices can take a severe beating. Overall these stocks offer high risk high return opportunities.

Disclosure:

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