

Granules India Limited's strategy to beat declining realisations and increasing competition.



#### **BACKGROUND**

Granules India Limited ('Granules'), established in 1991, has emerged as a completely integrated formulations manufacturer possessing contemporary facilities to manufacture an extensive value chain: from several strategic APIs to several PFIs to a tableting capability. This has positioned the company uniquely in the international pharmaceutical markets as a cost-efficient and quality supplier of several products, APIs, PFIs and finished dosages. The company's facilities are located in and around Hyderabad, the pharmaceutical capital of India. The company has earned the distinction of having pioneered and popularised the manufacture of PFIs.

#### FINANCIALS

The company operations have been increasingly profitable in line with its strengthening position as a dependable outsourcing partner. Its earnings have gone up consistently over the years. In 2003-4, over a period of fifteen months, the company reported revenues of Rs 128.55 cr and a PAT of Rs 5.58 cr.

#### **NISIBILITY**

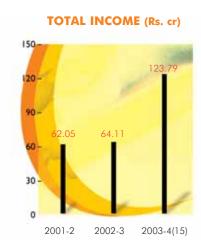
The company is listed on the Mumbai Stock Exchange in India and enjoyed with a market capitalisation of Rs. 64 cr as on 30 June 2004.

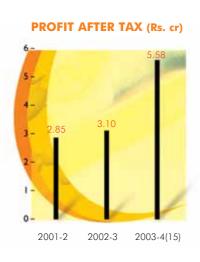
#### **▲ FACILITIES**

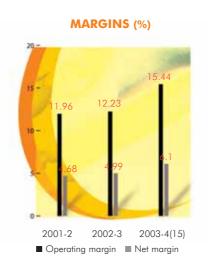
The company is supported by the following manufacturing facilities:

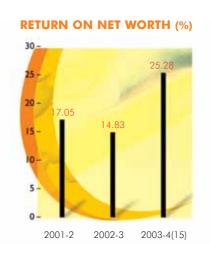
<b>Locations</b> Sales	Facility	Capacity	Approvals
Jeedimetla, Hyderabad	• PFIs	1200 TPA	Australian TGA / German HA
			US FDA
	• APIs	1041.60 T <mark>PA</mark>	US FDA
			WHO cGMP Certification
Bonthapally	• APIs	2400 TPA	Certificate of suitability-EDQM
Gagillapur	• PFIs	7200 TPA	US FDA / German HA /
			Australian TGA

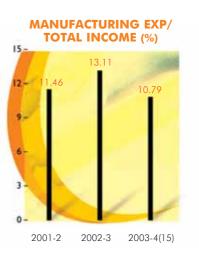
### Financial highlights.

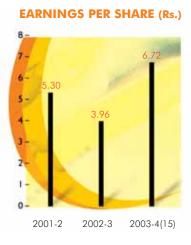














Dear Shareholders

IN AN INDUSTRY WHERE MARGINS ARE EXPECTED TO BE UNDER PRESSURE AS ONE GOES AHEAD FROM HERE, THE COMPANY THAT SURVIVES WILL BE THE ONE THAT MIGRATES TO PROGRESSIVELY HIGHER REALISATIONS AND COMPETITION-PROOF PRODUCTS.

As a progressive organisation, Granules India has embarked on just such a strategy: to continuously reaffirm its industry leadership through the introduction of innovative products supported by cutting-edge manufacturing practices.

#### OUTSOURCING TREND

The management at Granules India recognises that this combination - innovation in products and practices - must eventually serve an evident business reality.

This is so in its case as well: its increasing production of PFIs matches the growing need of international formulation manufacturers to reduce their costs. The resulting outsourcing is now a well-embraced strategy that is expanding from pharmaceutical companies in North America and Europe into other markets. This out sourcing trend is visible even in the bulk supply of finished dosages.

#### THE GRANULES STRATEGY

As a future-committed organisation, Granules has addressed this growing opportunity with unmistakable seriousness. It has commissioned the world's single largest PFI factory in Gagillapur: a cost-efficient batch size of 6,000 kilos and an annual capacity of 7,200 metric tonnes per annum, resulting in economical manufacture for the benefit of customers. The company has begun to enhance value through the compression of PFIs into value-added tablets in modest volumes today, but is expected to increase capacities significantly in the immediate future.

In view of this existing and emerging requirement, Granules has prudently created facilities, invested in equipment and incorporated practices that are at par with the best in the world

As a result, the company has strengthened its capability to make products in line with standards conforming to the best in the world at typically Indians costs, creating an irresistible business and customer proposition.

#### RELATIONSHIP-CENTRIC MARKETING

At Granules, we recognise that the key to sustainable profitability will lie in a continuously enhanced utilisation of its manufacturing assets. In turn, it will be possible to sustain this pipeline of orders through a central core of long-term customers in addition to periodic client accretion.

In view of this critical need for relationships-centric marketing, Granules USA was commissioned as a dedicated technical service and sales centre for North America in 2003. This visible presence in the largest pharmaceutical market in the world has already begun to translate into a growing market share of the company in North America and a dramatic increase in Mexico.

The appointment of a European distributor with re-structured marketing support is expected to translate into similar results on the continent.

#### • OUTLOOK

Looking ahead, Granules India expects to enrich its product mix with innovative and value-added products, expand organically in a continuous way, reward employees with career growth opportunities and appraise inorganic opportunities with a focus on value-enhancement. This we expect will lead to sustainable value enhancement for the benefit of those who own the company.

Sincerely,

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Dr. C. Nageswara Rao

Chairman





### From vendors to Onthes

To address a large and growing granulation opportunity, estimated at about 3,50,000 TPA, we have created a robust granulation outsourcing model.

This model represents a responsible win-win partnership proposition: remunerative business over the long-term for the company and a relatively stable and high value proposition for the customer. This outsourcing model is now being extended to manufacture and supply of finished dosages (bulk tablets) to our customers. This initiative is expected to strengthen the relationship across the long-term for a number of reasons: a substantial cost saving for the formulator customer and a scale-driven economy for the vendor on the other, leading to attractive margins for both.

Through this continuous focus on value-addition and cost reduction we have emerged as business-enhancing partners for our customers.



To mitigate the impact of a probable decline in select product realisations, we widened our product range.

We extended beyond the manufacture of Paracetemol-based PFIs to Guainefisin, Ibuprofen, Naproxin, Metformin and Aspirin. We also started offering finished dosages to our customers to help them further reduce their costs and liberate them from regulatory processes and requirements. This strengthened our business resilience: we progressively de-risked from a probable sluggishness in one product with a wider presence across others. We are now extending our focus beyond large but low margin industry spaces to narrow but high margin niches. We are reinforcing our strong OTC presence in developed markets with a growing exposure in the prescription drugs segment in the same geographies.

This is expected to translate into a remarkable business advantage: from an ability to supply products at prices dictated by the market to a scenario where the company's investment in product differentiation is reflected in enhanced realisations.





### From sales to We reinforced the manufacture of a single-entity PFI with the development of combination PFIs that used different basic APIs with other excipients, becoming the only company in the world to do so. We developed PFI solutions for complex products, deliverable in large batches, that emerged as low-cost alternatives in the manufacture of formulations. We then went a step further. We offered specialised solutions to our valued customers by granulating low volume but high margin ingredients that have been conventionally difficult to granulate. Over time, these various initiatives are expected to serve customers with solutions that address their specific needs, protecting value. We plan to further protect this value through the introduction of patentable processes over the near future. 14



# From validation to Certification

To protect the interests of our customers from a plausible inconsistency in quality, we have progressively graduated our standards from checks to comprehensive certification.

We have invested in systems and procedures that go beyond the correction of problems as they occur to the prevention of problems in the first place. This approach has a deep relevance to our business: the facilities that manufacture our key raw materials used in prescription products must be approved by the Regulatory Authorities of the various regulated markets. This priority has been reflected in our new 7200 TPA plant, which was inspected and approved by the US FDA within only nine months of commissioning and by the German Health Authority within five months of start-up. The US FDA approved our 1200 TPA PFI facility at Jeedimetla and it already enjoys international approvals

from the Australian TGA and German Health
Authorities. Our 1041.60 TPA API plant at Jeedimetla
enjoys a US FDA approval, the Certificate of Suitability
from the European Department for the Quality of
Medicines, Strasbourg and was very recently approved
by the WHO. Additionally, we possess approved US
Drug Master Files for our various APIs like Guaifenisin
and Metformin as well as DMFs for Compresso MF 95P
and Metformin from Health Canada. These
compliances have strengthened customer confidence,
leading to validations and approvals from customers in
the other geographies - multinational pharma giants
like Abbot, Novartis, Leiner, Perrigo, Merck Genesis,
Aventis, Ratiopharm and Sigma.

These approvals will enable the company to penetrate the prescription segment in the regulated markets, leading to higher margins and enhanced value.

## From innovation to

To effectively counter the potential inconsistencies in quality and also possible hikes in the prices of key raw materials, we have progressively reinforced our innovation with the selective in-house manufacture of raw materials like Paracetamol, Guaifenisin and Metformin.

This backward integration is more business-critical than it might appear: the units are developed with the objective of garnering US FDA approval within a year of commissioning, enabling them to address the growing demand in the relatively protected and lucrative regulated prescription markets. They will service in-house as well as merchant needs, resulting in cost reduction on one hand and income enhancement on the other. In view of this, we are setting up a worldclass facility for the manufacture of Paracetamol (installed capacity 6000 TPA), which is likely to be commissioned in May 2005.

We now plan to extend this advantage with an integration that starts from the manufacture of APIs at one end to PFIs and tablets in bulk at the other. We have already extended into tableting with an installed capacity of about one billion tablets annually. We now expect to take our - and our customers' - businesses ahead with a projected annual tableting facility of six billion tablets, enabling them to reduce their costs significantly and liberating them to concentrate on marketing and branding formulations. We also plan to file ANDAs for finished  $\,$ dosages that can then be repacked and marketed by our customers, thereby shortening their time-to-market and reducing costs.

Following the commissioning of a tableting line and the approval of ANDAs, we will be uniquely positioned as an integrated outsourcing partner, offering customers significant cost and time advantages in outsourcing the entire requirement from a single window, leading to a bigger value proposition.

