



Granules India Limited

Annual Report  
2005-06

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Granules India Limited

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Evolution  
in a time of change

## Forward-looking statement

In this Annual Report we have disclosed forward-looking information to enable investors to comprehend our prospects and take informed investment decisions. This report and other statements - written and oral - that we periodically make contain forward-looking statements that set out anticipated results based on the management's plans and assumptions. We have tried wherever possible to identify

such statements by using words such as 'anticipate', 'estimate', 'expects', 'projects', 'intends', 'plans', 'believes', and words of similar substance in connection with any discussion of future performance.

We cannot guarantee that these forward-looking statements will be realised, although we believe we have been prudent in assumptions. The achievement of results is subject to risks, uncertainties and even inaccurate assumptions. Should known or

unknown risks or uncertainties materialise, or should underlying assumptions prove inaccurate, actual results could vary materially from those anticipated, estimated or projected. Readers should bear this in mind.

We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise.

# Corporate Information

<b>Board of Directors</b> Dr. C. Nageswara Rao, <i>Chairman</i> Shri. L. S. Sarma, <i>Director</i> Shri. A. P. Kurian, <i>Director</i> Shri. N. R. Ganti, <i>Director</i> Shri. C. Krishna Prasad, <i>Managing Director</i>		<b>Chief Financial Officer</b> Shri. Pranesh Raj Mathur	
<b>Registered Office</b> 8-2-293/A/A/2, Road No.2, Banjara Hills, Hyderabad- 500 033		<b>Company Secretary</b> Mrs. N.Madhavi	
<b>Share Transfer Agents</b> CIL Securities Limited 214, Raghava Ratna Towers, Chirag Ali Lane, Abids, Hyderabad Ph: 66661267, 66661276		<b>Auditors</b> M/s. Kumar & Giri, <i>Chartered Accountants</i> D.No. 1-11-126/D, Opp. Aeroview Towers, Begumpet, Hyderabad – 500 016	
<b>R &amp; D Centre</b> Gagillapur, Qutubullapur Mandal R. R. District, A.P – 500 043.	<b>Bankers</b> Andhra Bank ING Vysya Bank IndusInd Bank Bank of Baroda Union Bank of India Export-Import Bank of India State Bank of Travancore	<b>Plant Locations</b> Plot No.15/A/1, Phase-III I.D.A. Jeedimetla, Hyderabad – 500 055 Temple Road, Bonthapally Medak District, A.P – 502 313 Gagillapur, Qutubullapur Mandal R. R. District, A.P – 500 043	

## Contents

<b>2</b> Corporate identity		<b>14</b> MD's Message		<b>18</b> Research and Development		<b>22</b> Management discussion and analysis
	<b>37</b> Financial summary		<b>38</b> Board of Directors		<b>39</b> Senior management team	
<b>40</b> Directors' Report		<b>46</b> Corporate Governance		<b>57</b> Auditors' Report		<b>60</b> Balance Sheet
	<b>61</b> Profit and Loss Account		<b>62</b> Schedules		<b>74</b> Cash Flow Statement	
<b>75</b> Balance Sheet Abstract		<b>76</b> Section 212		<b>77</b> Consolidated Accounts		<b>92</b> Subsidiary Accounts

At Granules our vision revolves around three critical drivers.

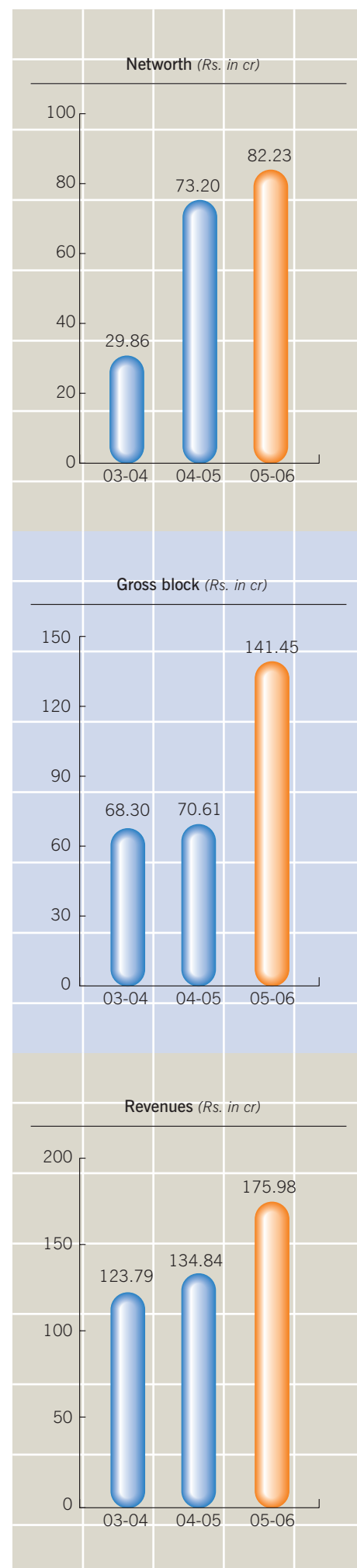
To become a large-scale consumer-healthcare focused service provider.

To achieve a global breadth in the delivery of our services.

To invest in cutting-edge infrastructure and technologies to support strong partnerships with industry leaders.

It gives us pleasure to state that in the last few years we evolved our business model in line with our vision. And emerged progressively relevant, global and competitive.





# Pharmaceuticals, outsourcing and Granules India Limited

The pharmaceutical industry is one of the largest the world over.

In this space, the outsourcing of products and services to low-cost, quality-driven geographies represents one of the most fundamental shifts in structure that the industry has seen over the last few decades.

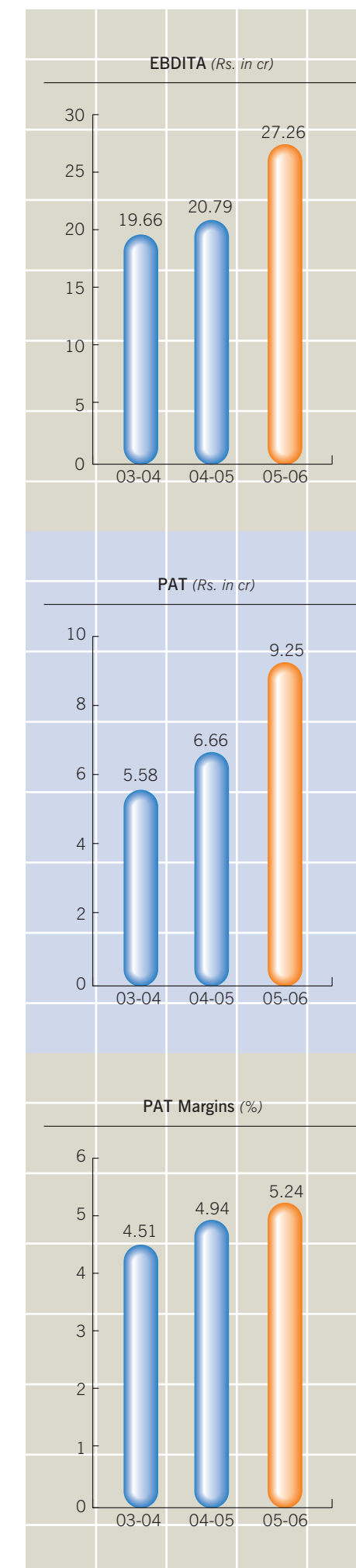
Going ahead, this represents a significant opportunity. For global brands to reduce costs and for selectively dispersed manufacturers to grow their size.

Granules India Limited is one of the creations of this global phenomenon. Over the last two decades, the company has capitalised proactively on this evident industry trend through its single minded vision to emerge as a dependable global outsourcing partner. With a difference.

Granules has evolved itself from a process outsourcing partner into an integrated outsourcing partner capable of offering formulations and regulatory outsourcing services as well.

The growing success of the company's business strategy is demonstrated in its financial results for 2005-06: a 30.51% increase in turnover to Rs.175.98 cr and a 38.88% increase in profit after tax to Rs.9.25 cr.

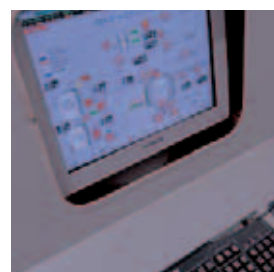
Both numbers were the highest ever in the company's existence.





# Differentiated business model.

This is what reinforces Granules' outsourcing proposition



In the global pharmaceutical industry, successful outsourcing is influenced by the nature of the service provider's business model.

This business model is influenced by the following: scale, cost leadership, regulatory strengths, global distribution capabilities and supply chain efficiencies.

At Granules, we have not just accounted for these drivers but are pleased to state that our business model is unmistakably distinctive for the following reasons:

**Extended value-chain:** At Granules, we address an extended value chain from the manufacture of API to PFI to Finished Dosages at one level and the research and development for regulatory approvals at the other. In doing so, the company possesses the strategic flexibility to convert an API customer into a PFI customer and vice-versa; or a PFI customer into a formulations customer or vice versa; or handhold a product partner into value-added research.

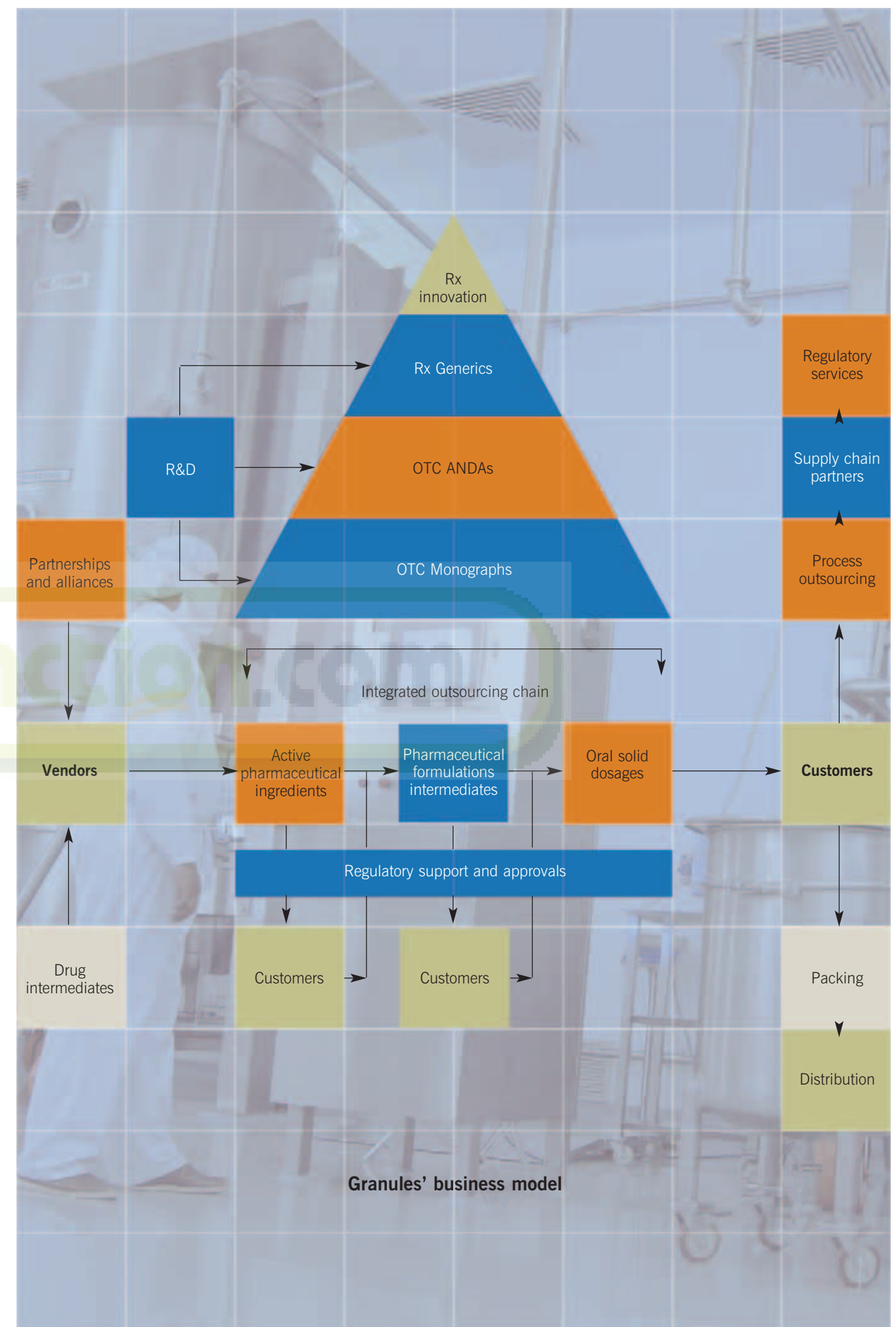
**Segment:** At Granules, we have focused significantly on the growth arising out of the voluminous OTC segment; we are also capitalising on opportunities to develop products for customers within the prescription segment through contracted partnerships.

**Partner, not vendor:** At Granules, we have consciously positioned

ourselves as a partner of our customers. The company has worked backwards to not just commission equipment, processes and practices compatible with the size and quality standards of our downstream users; the complement of a technical know-how, bringing in a differentiated service and cost offering, has resulted in repeat business making it possible for us to seek growth from the same customer and also achieve brand-enhancing referrals that can potentially lead us to other large customers.

**Product portfolio:** At Granules, we have de-risked our business model through structured and focused product selection process. Our products are those that have been subjected to significant erosion in margins. We add value using our unique know-how on products ranging from APIs to multi active PFIs and formulations, thereby offering different value chain options to our customers. At the same time, our service offerings in contract manufacturing, as well as on a partnership basis for prescription products enables us to benefit from market upsides, without the corresponding risks of value erosion.

As a result, Granules' business has emerged progressively de-risked, scalable, profitable and sustainable.



# Our focus on the niche PFI segment protected us from price declines and intensive competition



At Granules we went into business through the trading of APIs and extended gradually into relevant manufacture.

However, even as we were engaged in production, we responded to the threat of declining realisations and margins in the API space through the following initiatives:

- Venturing to work in the area of niche PFI manufacture, involving the production of a ready-to-compress mix of APIs and excipients (inactive substances used in formulations) that can be directly fed by formulators into the hopper for onward compression into tablets, a step higher than API manufacture in the pharmaceutical value chain. As a result, the Company was relatively protected from the intense competition affecting the latter segment.
- Extending to the manufacture of PFIs, extending global pharmaceutical players from the outsourcing of APIs to a granulated product, saving them time, people and overheads on the one hand and providing an opportunity to focus on business-enhancing R&D, marketing and distribution on the other.
- Expanding the PFI capacity to commission the world's largest stand-alone multi- product granulation facility at Gagillapur comprising the world's largest single batch capacity of 6,000 kgs, facilitating a further reduction in costs for its customers.

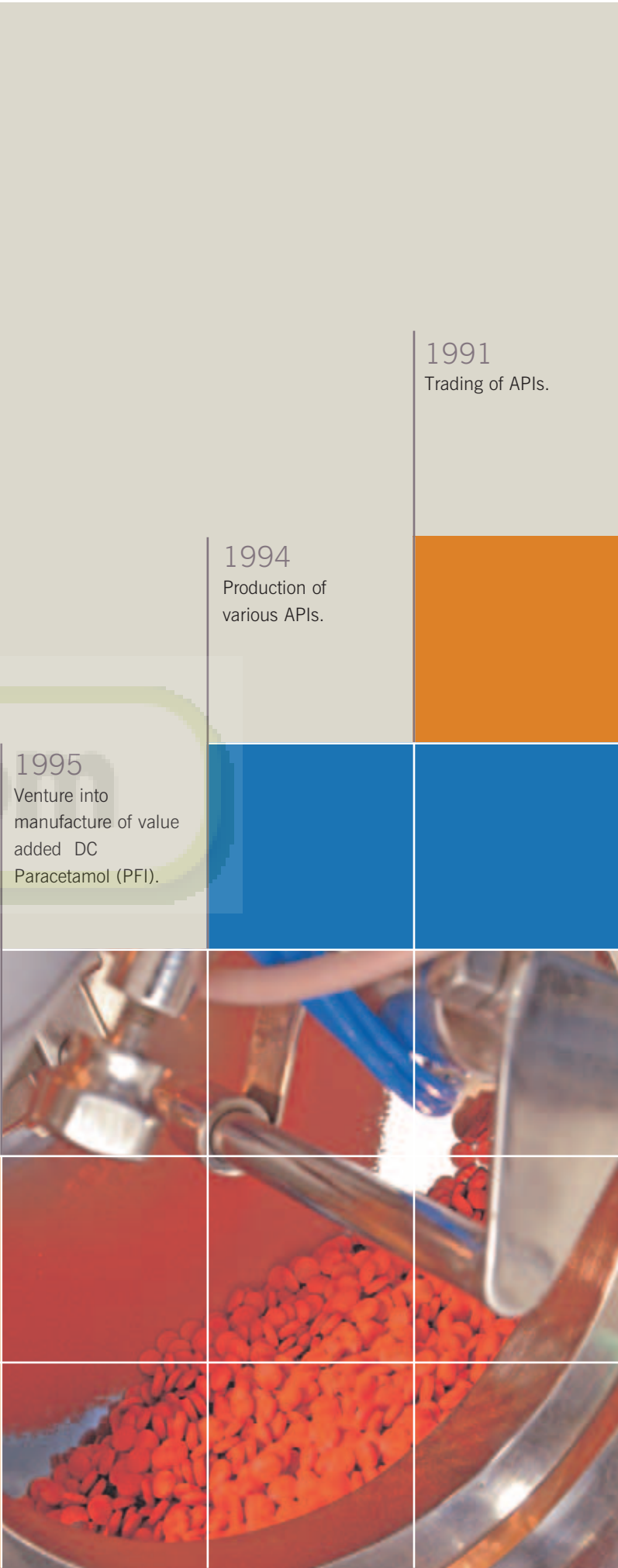
Today, Granules is one of the few in the

world enjoying regulatory approvals for its PFI plant from all the major regulatory authorities - the USFDA, the Canadian TPD, Australian TGA and the German HA – enabling it to service the growing needs of many of the largest global pharmaceutical majors.

At Granules, we are happy to state that even as most competing PFI manufacturers have selected to specialise in a single product, we have differentiated our business model through the following initiatives:

- We are the only Company in the world to manufacture PFIs beyond high bulk drugs like paracetamol and aspirin.
- We are among the few PFI manufacturers to extend beyond high volume products to relatively low volume, high cost products like guaifenesin and metformin.
- We are the only PFI Company in the world to commercially manufacture combination PFIs (using multiple APIs).

It is this ability to innovate that provides the Company a competitive edge, inspires customer confidence and distributes revenues across a wider product basket; this de-risks the business on the one hand and provides for sustainable growth on the other.





Graduating ourselves into the

# supply chain partners

of our customers resulted in a win-win proposition for customer, Company and consumer

2000

Backward integrating into Acetaminophen API through acquisition of Triton Laboratories

2000

USFDA approval for PFI and other APIs.

2001

Development of new PFIs such as Guaifenesin, Metformin, Ibuprofen etc.

2002

Filing of new DMFs of the new PFIs and moving up the value chain in OTC products.

At Granules, after we had established our presence in the area of PFI outsourcing, we sought partnering opportunities within the industry supply chain that would lead to sustainable relationships, revenues and win-win benefits for customers and the company.

As the pharmaceutical companies recognised the opportunities in outsourcing PFIs for their OTC products, Granules was among the first to identify that, to emerge as a successful outsourcing partner for formulator-customers, it required to consistently offer low cost solutions without compromising product properties and quality.

As an opportunity-focused manufacturer, Granules evolved its role from mere PFI outsourcing to supply chain partnership with accompanying benefits of bulk purchases, logistics and backward integration leading to a comprehensively low cost solution for our customers and enhanced margins for the company.

In doing so, the Granules business model provided for seeking margin increases through in-process improvements marked by the following initiatives:

**Role recognition:** At Granules, we do not just see ourselves as a supplier; we see ourselves as a critical partner in the supply chain of our formulator-customers. As a result, we do not only consider it important to manufacture products with a high quality standard, we consider it equally important to deliver customised solutions to requirements across the world.

**High volume purchasing:** At Granules, even as the raw material

going into most of its end products are the same, the varying proportion and different treatment has helped the Company manufacture a range of end products. The uniformity in inputs helped the Company purchase raw material in bulk and leverage related economies of scale; the fact that Granules is one of the largest buyers of select APIs and excipients in Asia (and the largest in India for some of the others) has enabled it to maximise purchase efficiencies for the benefit of its customers although servicing diverse formulae for the same product.

Over the years, Granules has strengthened its sourcing efficiencies through the following initiatives:

- Long-term contracts with vendors covering quantity and price.
- Preferred import of quality raw material to avail of the import duty exemption (since most of its plants are export oriented).
- Purchases in bulk, enabling it to negotiate lower prices.
- Ongoing monitoring of international price movements facilitating the purchase of the right quantity at the right time at the right price.
- Purchases from approved vendors who follow the international regulatory requirements reinforced by vendor plant audits.

**Backward integration:** Granules acquired Triton Laboratories, a leading manufacturer of raw material acetaminophen (Paracetamol), an effective API backward integration. Gradually, the Company extended beyond acetaminophen and today possesses an installed capacity of over

12,000 TPA of API capacity across three manufacturing plants. As the Company increases its market share in the OTC segment for PFIs, the new 8,000 TPA Bonthapally plant (commissioned in March 2006) will enable it to captively meet its entire requirement of paracetamol, a major raw material. This backward integration will enhance quality control, minimise production cost and protect delivery schedules.

**Value chain:** Within the API segment, Granules has climbed the value chain through an extension beyond manufacturing just OTC monographs to the manufacture of various complex APIs that are high in value.

**Scale:** Granules has reinforced its industry standing through an installed API capacity of over 12,000 TPA across three plants.

**Regulatory approval:** Granules' API facilities are benchmarked in line with international regulatory requirements with approvals from the USFDA, WHO cGMP and EDQM.

This sequence of low cost and high quality strengthens the outsourcing proposition at one level and enables the company's customers to pass on cost declines to their respective consumers, creating a virtuous cycle across the entire consumption chain.

A fully  
**integrated outsourcing partnership**  
is an over-riding value proposition for our customers

With the escalating competition in the pharmaceutical markets, there is a need for transactions to evolve into relationships and suppliers to extend their role into partnerships.

Over the years, Granules integrated its value chain in response to this growing need. As compared to a manufacturer and direct seller of highly competitive generic drugs, we embarked on a strategy based on strengthening our existing presence in the pharma value chain through the following initiatives:

**Formulations:** In climbing the value chain, Granules is developing its core competence around finished dosages with the launch of a 12 billion tableting capacity, making it the largest such facility in Asia. The phase I of the project (capacity six billion tablets per annum) will be commissioned by March 2007.

**One-stop:** Granules' integrated business model will help generate revenues from multiple sources (APIs, PFIs and Finished Dosages), enabling it to widen its customer portfolio, enhance margins and drive sustainable growth. This will represent a one-stop integrated pharmaceutical outsourcing solution.

**Scale:** Granules developed API and PFI manufacturing capacities benchmarked with the prevailing international standards. The company's 7,200 TPA PFI facility (Gagillapur) is the largest stand-alone multi-product granulation facility in the world, resulting in a capability to deliver material almost on-demand to customers the world over. Its largest

single batch manufacturing capacity of 6,000 kgs enables it to reduce operational and analytical testing costs for itself and customers. Its 12 billion finished dosage facility will be the largest in Asia.

**OTC focus:** The business model at Granules is focussed on generating aggressive growth from the OTC segment (where the cost of granulation and tableting constitutes a major cost in the finished dosages) through its integrated service offerings.

Granules' strategy to focus on the OTC segment is advantageous for yet another reason. Increased health awareness is driving the demand for OTC products in the developed markets such as North America, Japan and Western Europe, and also in emerging markets such as Eastern Europe and Asian markets including China, Indonesia, India and the Philippines. The US market for select over-the-counter (OTC) drugs at the manufacturer level has been estimated at over USD 10 billion. This will increase to approximately USD 13 billion by 2007. In UK, the total over-the-counter (OTC) pharmaceuticals market was estimated at £2.1 bn at retail selling prices (rsp) in 2005, a rise of 3.7% on 2004. As per a CII report, the OTC market in China, practically non-existent today as defined by Western standards, will grow at a compounded annual rate of 19%, from about USD 1 billion in 2000 to about USD 5.7 billion in 2010. Globally, the OTC segment is expected to grow from USD 59.70 bn in 2004 to USD 102 bn in 2009, at a CAGR of 11.31%.

Health awareness is expected to underpin the continuing consumer trend towards self-medication, as preventative medicine is deemed the more economic and convenient option over the increasingly high costs associated with visits to healthcare professionals. Problems associated with ageing like arthritis and osteoporosis, are key factors underpinning long-term demand for products such as analgesics, digestive remedies and dietary supplements in the developed economies of North America and Western Europe. Similarly in China, a booming economy, improvements in living standards and a higher level of disposable income have resulted in higher allocation of disposable income to self-medication, boosting demand for OTC healthcare products.

In line with its overall strategy of offering end-to-end solutions to companies on OTC products, Granules is also entering into a 50:50 Joint Venture agreement with Hubei Biocause Heilen Pharmaceutical Company (Biocause) of China, one of the largest Ibuprofen manufacturers and exporters in the world, to manufacture and sell pharmaceutical APIs starting with Ibuprofen. The high levels of GMP compliance of Biocause's facility and capability to manufacture Ibuprofen for Europe and the USA will provide the Company with a strong manufacturing base in China, one of the fastest growing pharmaceutical manufacturing bases in the world, in the area of high volume APIs.



**2003**  
Setting up of the world's largest, stand alone international standard PFI facility with a capacity of 7,200 TPA.



**2004**  
The only Company in the world to manufacture combination PFIs on a commercial scale using different basic APIs with other excipients.



**2005**  
Commenced construction of a 12 billion tablet per annum capacity facility, currently under implementation.

**2006**  
Commissioning of new 8,000 TPA internationally benchmarked API facility for paracetamol taking the total capacity to 12,000 TPA.







## Our regulatory services

provide us the global delivery breadth beyond process outsourcing

In the global pharmaceutical industry, there are two discernable trends: the shift in regulatory environment of most countries from easy-to-enter unregulated and semi-regulated markets to the more regulated markets, requiring pharmaceutical companies to upgrade their processes and products in line with this shift in the marketplace; there is also a rising pressure on global pharmaceutical companies to reduce their cost of manufacture.

As a future-focused organisation, Granules has responded to these needs in a timely way: it evolved into a regulatory supporting outsourcing partner with Amneal Pharmaceuticals LLC (United States). Amneal was given the USFDA approval for their metformin ANDA, filed with Granules' PFI.

- It was the first time that the USFDA approved an ANDA with PFI as its raw material, making it a landmark approval for the industry and company.
- The approval was received within 11 months of filing, reflecting the company's regulatory competence.
- The ANDA approval for metformin established the company's ability in improvising outsourcing offerings to products beyond OTC products. It has showcased the company's capability to commercialise the granulation concept not only at the lower levels of the value pyramid like OTC monographs but also at higher prescription product levels.
- The approval has opened out attractive opportunities as global pharmaceutical companies will now use

the PFI concept in their ANDAs to enhance their ANDA filing capacity and reduce the time-to-market (as most of the regulatory information usually contained in the ANDA is already available in the DMF for PFI)

Such contractual partnerships adapted for the prescription segment revolving around technology-based outsourcing will ensure that the Company does not compromise on the high value prescription market even as it aggressively targets growth opportunities in the high volume OTC segment.

Granules has strengthened its case through the following periodic investments:

- The Company commissioned its new Class hundred thousand 3,500 sq ft formulations research and development facility in January 2006.
- The facility received an approval from the Canadian TPD and the Australian TGA.
- This facility is equipped with state-of-the-art equipment, manned by a team of qualified and experienced R&D personnel
- The R&D team is qualified and experienced to deal with regulatory filings for stringently regulated markets like USA, UK, Canada and Australia, making the Company truly global in its R&D expertise.

R&D at Granules is targeted towards new product development leading to a wider portfolio, new process innovation and lower costs.

As a future focused company, Granules is also climbing the R&D value chain: having consolidated its position in the OTC monograph segment, the Company is consolidating its position in value-added OTC ANDAs with ANDAs of over five products currently under development (expects to file at least eight to 10 ANDAs over the next 12 months). The Company will gradually transcend immediate release dosage forms to value-added dosage forms (sustained release dosage forms, sachet type products, easily administrable Pressfit dosage forms like gelatine encapsulated tablets and fast disintegrating effervescent tablets).

This growing R&D strength in the area of formulations and regulatory compliance places Granules in the higher league of the pharmaceutical value chain, potentially protecting it from price erosions and strengthening its margins in the OTC segment.

After its successful partnership with Amneal Pharmaceuticals, the Company expects to forge more such partnerships in the growing prescription segment; the contractual partnership approach revolving around technology-based outsourcing will ensure that the Company does not yield ground in the high value prescription market even as it targets aggressive growth in the large OTC segment.



MD's message

"I am confident that as we at Granules transform these strategies into actions, we will emerge as a leading global service provider within the OTC segment."

## Dear Shareholders,

At Granules India Limited, we had a satisfactory year-2005-06 for a number of reasons:

- Our new 8,000 TPA API plant for paracetamol, benchmarked to cGMP standards was commissioned in March 2006 at Bonthapally; this will help us to integrate backwards towards low cost solutions, helping us consolidate our position within the OTC monograph segment.
- We strengthened our formulation expertise and services through the commissioning of a new formulations R&D centre in January 2006, strengthening our value chain.
- We are adding to our existing 300 million tablets per annum capacity with a greenfield 12 billion tablets per annum formulations plant; phase I of the project (capacity six billion tablets per annum) is expected to be commissioned by March 2007.
- While our revenues increased by 30.51% to Rs.175.98 cr, our net profit increased by 38.59% to Rs.9.23 cr, strengthening our net margin by 30 basis points to 5.24%.
- We generated a return of 13.74% on our employed capital (previous year 14.71%); the marginal decline was on account of increased investments in capacity expansion, the corresponding returns on which will accrue to the Company only over the coming years.

Going ahead, the future looks even more promising. In August 2006, for the very first time, the USFDA approved an ANDA with a PFI (Pharmaceutical Formulation Intermediate) as a raw material; this approval was for Amneal's metformin HCl ANDA

using the Granules' PFI.

This approval is exciting for a number of reasons:

- It vindicates our presence within the segment
- It has opened up the prescription market for Granules
- It has endorsed our ability to handle commercial granulations of any product, a know-how developed by us over the last ten years
- It has extended our understanding of the integration at our customers' end to formulations and regulatory approvals.

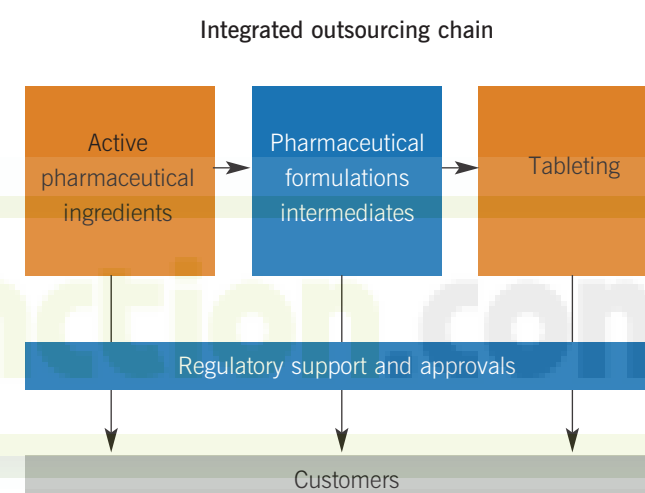
### Integrated outsourcing chain

At Granules, we have consciously positioned ourselves in the OTC segment, the largest end of the pharmaceutical value pyramid. In this competitive high-volume and low margin segment, we have protected our margins through a progressive extension from trading in APIs to the manufacture of APIs and PFIs to a strong backward integration into the manufacture of strategic APIs, emerging as a complete and dependable supply chain partner. Concurrently, the Company reinforced this positioning through an investment in scale with two objectives: to meet the growing needs of customers and to leverage related economies, a win-win benefit.

The result is that our expertise and experience in handling large-scale OTC monograph products is now well recognised. Following the commissioning of our 12 billion-tablet capacity formulations plant, the largest in Asia, Granules will leverage its experience and understanding of its core PFI business to

successfully integrate into the next stage – the compressing of granules into tablets. The Company will therefore emerge as a completely integrated outsourcing player within the OTC monograph segment with the competence to offer multiple product streams – API, PFIs and tablets.

This will be an important facility; benchmarked to cGMP standards with a capacity of 12 billion tablets, it will offer economies of scale and address the cost reduction needs of our large global pharmaceutical majors. Besides, an integrated presence across an extensive value chain will eliminate price additions at every point of conversion, thereby reducing costs for formulators and enhancing margins for Granules – a win-win proposition for both.



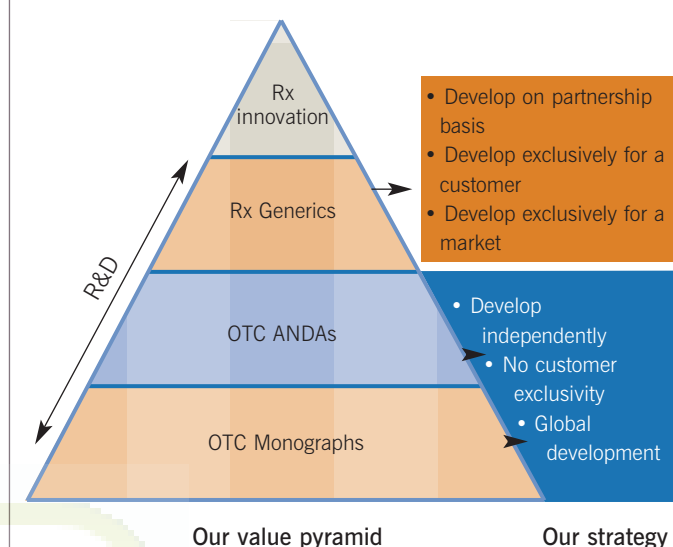
Following the consolidation of our presence within the OTC monograph segment, we realised that we need to climb the value chain of services. In view of this, we are now targeting OTC ANDA and prescription products.

### Research and development

Globally, pharmaceutical majors are looking at outsourcing to control operational costs. Over time, outsourcing is no longer limited to mere manufacturing but has extended to value-added research and development, inspiring Granules to build relevant R&D capabilities. As a result, the Granules Class 100,000 R&D facility is equipped with state-of-the-art infrastructure / equipment and approved by the Canadian TPD. The company's 16 member R&D team is qualified and rich in experience; it is headed by a highly experienced professional with over 14 years of experience in formulations R&D within the OTC segment.

Besides, our global product development approach ensures that our documents and dossiers address a substantial portion of the requirement of all the four major global regulated authorities - the US, Western Europe, Canada and Australia - thereby shrinking the application and regulatory approval time

for our customers. This technical competence and world-class infrastructure, combined with our regulatory competence and low cost solutions, offer an unbeatable value proposition to our global customers.



### Value pyramid

Going ahead, we intend to reinforce our OTC presence by widening our product portfolio to cover the entire range of OTC products – OTC monographs and OTC ANDAs. Besides, our portfolio of analgesics, cough and cold products will be complemented through the addition of anti-ulcer and anti-histamine OTC ANDA products by the end of 2007.

Since product development in the pharmaceutical industry is generally characterised by a lead time of at least 18 months before they can generate significant revenues, we are independently developing a range of OTC products and looking at partnering opportunities for prescription products like metformin to help us fund product development without compromising margins.

### Partnerships and alliances

At Granules, we are also seeking opportunities in partnerships and collaborations - raw materials and formulations - to strengthen our leadership position. For granulation and formulations, our alliance strategy shall address different industry marketing channels. Since different products are marketed in different ways in different countries depending upon the regulatory and product requirements, our alliances and partnerships will be based on the marketing strength - product or region specific - of our alliance partners. For instance, we shall partner with OTC players enjoying a significant retail and distribution presence while for prescription products we may look at partners with strengths in that specific therapeutic category.