



## **Forward-looking statements**

In this Annual Report, we have disclosed forward-looking information to enable investors to comprehend our prospects and take 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 achievements of results are 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 keep 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.

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# Management Discussion and Analysis

## INDUSTRY OVERVIEW

### Global pharmaceutical industry

The global pharmaceutical industry grew by of 6.6% in 2011, compared to 4.5% in 2010, and reached a market size of US\$ 880 billion. The transformation of the global pharmaceutical market continues unabated, with focus steadily shifting from developed to developing countries and from patented drugs to generics. The overall pharmaceutical market is anticipated to reach US\$ 1.1 trillion by 2014 (Source: IMS Data).

### Growth in the global pharmaceutical market



(Source: IMS, Network Research)

The US is the major pharmaceutical market, globally. The contribution of the US to the global pharmaceutical growth increased to 20% in 2011, compared to 17% in 2010. Ageing population and constant demand for innovative therapies have triggered the pharmaceutical demand in 2011 and will continue in the years to come.



## Regulated markets

### US

The US (US\$ 320 billion market size) is the largest pharmaceutical market in the world growing at a CAGR of around 3%. It is also the largest generic market with a sizeable generic substitution (75% in terms of volume).

The US is expected to face the highest patent expiries (to the tune of US\$ 100 billion) over the next five years (Source: ICRA, March 2012). The share of the US in global pharmaceutical spending is set to decline to 31% in 2015, from 41% in 2005.

The US market is experiencing significant drug shortages in recent times. A total of 168 drugs are facing acute shortages. The major reasons for the drug shortages include manufacturing constraints, stringent manufacturing norms, consolidation in the generic drug industry and limited supplies of some vital ingredients (Source: IMS, Drug Shortage).

### Executive orders passed by the US government

- o USFDA to take measures to reduce current and future supply disruptions. It must inform the drug manufactures in advance in case of production discontinuation.
- o USFDA to expedite regulatory reviews, evaluate new drug suppliers, manufacturing sites, and production changes to mitigate potential drug shortages.
- o USFDA to inform The Department of Justice (DoJ) of any findings due to shortages that have led market participants to stockpile the affected drugs or sell them at exorbitant prices.

(Source: Motilal Oswal Research report, November 2011)

### European Union

The EU5\* markets have registered growth of 1-3% in 2011 and are poised to grow at an average CAGR of 2.5% up to US\$ 220 billion by 2016. The European pharmaceutical market ranks second in the world following USA. It accounts for around 17% of the total global pharma market. In most of the European countries a considerable share of healthcare expenditure is public expenditure. However, there has been significant regulatory changes over the past years on account of austerity measures and attempts to reduce healthcare expenditure. Focus is on price reduction and increasing generic substitution. (Source: Jefferies)

\*(German, France, Italy, Spain and UK)

### Japan

In 2011, Japan's pharmaceutical industry registered a growth of 5.7%. The overall Japanese Pharmaceutical Industry is projected to grow at a CAGR of 2.6% from 2012- 2016.

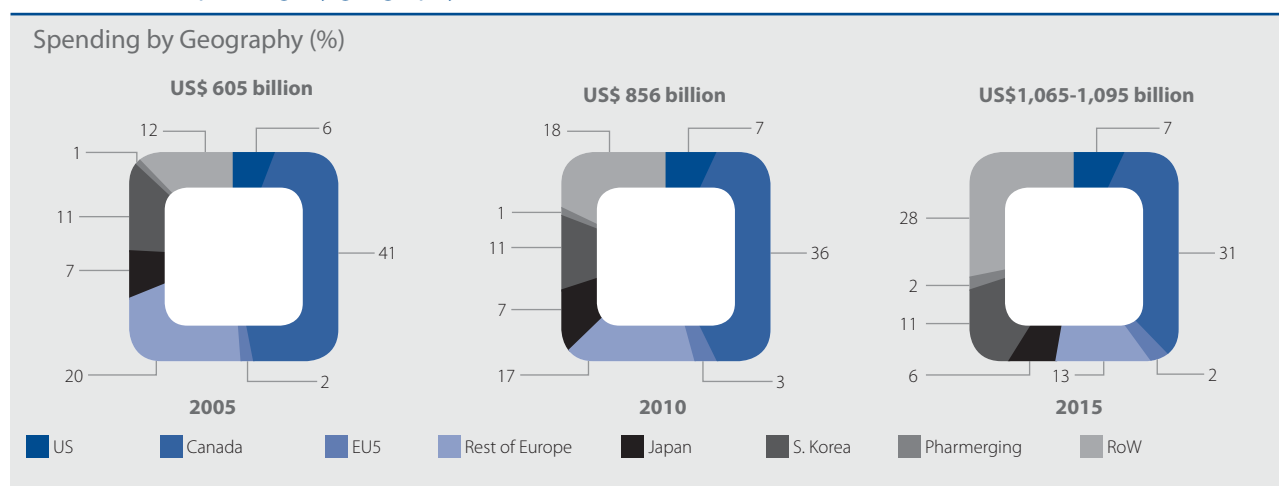
### Regulated market trends

[Patent expiries of blockbuster drugs](#)

[Cost containment strategies implemented by various governments](#)

[Shift towards affordable generics](#)

## Pharmaceutical spending (by geography)



(Source: IMS Health)



## Pharmerging market

The 17 'Pharmerging' countries\* are expected to contribute 28% to global pharmaceutical spending by 2015. They registered a growth of 15-17% in 2011 to reach a market value of ~US\$ 170 billion. The value contribution of the Pharmerging market has substantially increased from US\$ 73 billion in 2005 to US\$ 154 billion in 2010 (Source: IMS Health).

(\*India, China, Brazil, Venezuela, Poland, Argentina, Turkey, Mexico, Vietnam, South Africa, Thailand, Indonesia, Romania, Egypt, Pakistan, Ukraine and Russia.)

### Pharmerging market trends

Relatively low entry barriers in terms of product registration requirements and intellectual property rights.

Price sensitivity.

Favourable regulatory environment.

Rising disposable incomes.

Likely increase in health insurance schemes.

Low manufacturing cost.

Competitive local industry presence.

## Performance of Pharmerging countries

| Tier   | Countries     |               | 2009 GDP based on PPP *<br>valuation (Trillion US\$) | Incremental Pharma Market Growth<br>from 2009-13 (Billion US\$) |
|--------|---------------|---------------|--|---|
| Tier 1 | 1. China      |               | 9  | 40  |
| Tier 2 | 2. India      |               | 2-4  | 5-15  |
|        | 3. Russia     |               |  |   |
|        | 4. Brazil     |               |  |   |
| Tier 3 | 5. Venezuela  | 12: Thailand  | <2   | 1-5   |
|        | 6. Poland     | 13: Indonesia |  |   |
|        | 7. Argentina  | 14: Romania   |  |   |
|        | 8. Turkey     | 15: Egypt     |  |   |
|        | 9. Mexico     | 16: Pakistan  |  |   |
|        | 10: Vietnam   | 17: Ukraine   |  |   |
|        | 11: S. Africa |               |  |   |

(Source IMS Health)

\* Purchasing power parity (PPP)

(Source IMS Health)

\* Purchasing power parity (PPP)

## Active Pharmaceutical Ingredients (APIs)

Active Pharmaceutical Ingredients (API) or bulk drugs are the principal ingredients for finished pharmaceutical products. APIs cannot be administered directly to the patient, and other inactive substances called excipients are added to stabilise the mixture into an end product, which is called formulation.

The global API market can broadly be divided into regulated and semi-regulated markets. The semi-regulated markets offer low

entry barriers in terms of regulatory requirements and intellectual property rights.

The highly regulated markets, like the United States, Europe and Japan have high entry barriers in terms of intellectual property rights and regulatory requirements, including facility approvals. As a result, there is a premium for quality and regulatory compliance, along with relatively greater stability for both volumes and prices.

The API growth will be fuelled by rise in demand of generics and



biological drugs. The API market was valued at US\$ 101.08 billion in 2010, and is expected to grow at a CAGR of 7.9% from 2012 to 2016. Globally, Asia-Pacific is the third largest regional market for APIs by revenue after the US and Europe.

#### API growth drivers

- o API suppliers in Europe and the US are facing increasing pricing pressures due to presence of low-cost providers in developing markets, excess big pharma capacity and backward integration by certain generic companies.
- o The API outsourcing trend within the global pharmaceutical industry remains intact as pharmaceutical companies are increasingly looking to maintain focus on core competencies, access new technologies, preserve capital and ensure multiple sources of raw material supply.
- o China remains the largest manufacturer of APIs in the world, aided by large scale manufacturing capabilities and Government support. However, quality concerns as reflected by instances of product recalls due to contamination continue to hamper the ability of Chinese manufacturers to source APIs to advanced markets. This works as an advantage for the Indian API Industry.

(Source: Pharmaceutical Bulk Drug Industry: Trends & Outlook by ICRA, May 2011)

#### API market trend

Impending patent expiries and greater generic penetration likely to provide growth opportunities for domestic bulk drug manufacturers

Evolving presence of domestic bulk drug manufacturers in the global pharmaceutical supply chain

High therapeutic / product concentration due to focus on manufacture of smaller basket of APIs to ensure economies of scale

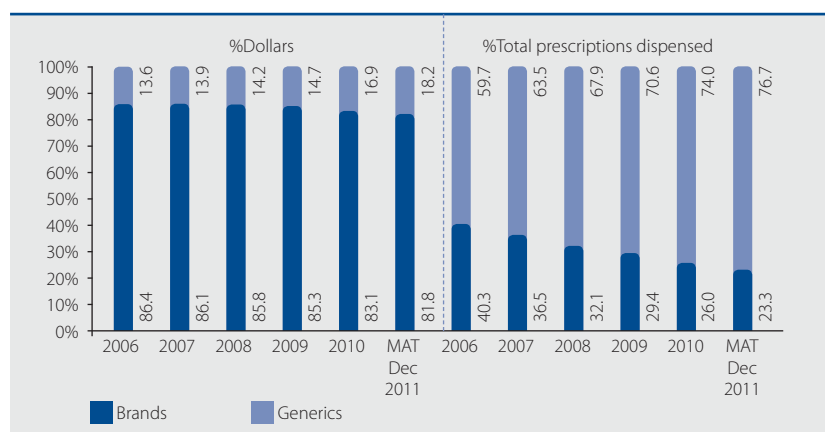
Increasing instances of pure-play bulk drug players foraying into generic formulations through filing of ANDAs and vice-versa, generic companies opting for backward integration.

(Source: Pharmaceutical Bulk Drug Industry: Trends & Outlook by ICRA, May 2011)

#### Generic drug (Formulations) industry

The global generics market reached a value of US\$ 225 billion in 2011 (Source: IMS Health: Pharma Voice, 2012). The patent expiries of blockbuster drugs commencing from 2012 provides a solid base for robust growth of generics. According to IMS, the global generics market is anticipated to reach US\$ 400-450 billion by 2015. Nearly 70% of this demand will be contributed by Pharmerging economies. The cost containment strategies implemented by governments, shift towards affordable generics, ageing population and chronic diseases will catalyze the generics markets (Source: IMS Health, Global Use of Medicines, 2011, Pharma Voice, 2012).

#### Generics share



Source, IMS Health, National Sales Perspective, Dec 2011



## Contract Research and Manufacturing Services (CRAMS)

The Contract Research and Manufacturing Services (CRAMS) segment involves research services outsourced on a contractual basis to aid the pharmaceutical and biotechnology industries. Going ahead, these services are anticipated to grow substantially as innovators are focusing on outsourcing pharmaceutical research and manufacturing to attain cost efficiencies.

### Factors driving growth

- o Increasing outsourcing trends in niche and high value segments.
- o US healthcare reforms.
- o Government support for the development of infrastructure and SEZ policy.
- o Requirement of affordable medications.
- o Strategic alliances.

(Source: Frost and Sullivan, Global contract manufacturing trends, 2010)

### CRAMS market trend

The global CRAMS market is expected to maintain a sustained growth rate.

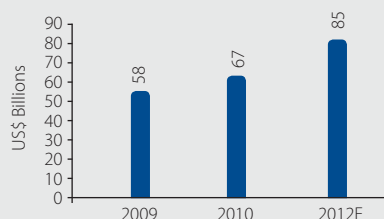
India, China, Russia and Brazil are the major markets for CRAMS.

India has the highest number of USFDA approved plants (200+ as of November 2011) outside the US.

Majority of outsourcing is done from the US and European markets to emerging Asian markets.

(Source: Network Research)

## Global CRAMS market



(Source: IMS, Network Research, February 2012)

## INDIAN PHARMACEUTICAL INDUSTRY

India ranks third in terms of manufacturing pharma products by volume. India's pharmaceutical industry is gaining its position as a global leader clearly topping the charts among the Indian science-based industries with significant expertise in the complex field of drug manufacture and technology. India's pharmaceutical market has registered a strong growth of 16% in 2012. This has been the highest growth in the past three years (Source: Edelweiss Monthly, April 2012). The Indian pharmaceuticals sector is poised to reach US\$ 55 billion by 2020, from US\$ 12.6 billion in 2009 (Source: Mckinsey, India Pharma 2020: Propelling access and acceptance realising true potential, 2010).

India tops in exporting generic medicines. The Indian pharma industry produces around 20% to 24% of the global generic drugs. Around 40% of the total pharmaceutical produce is exported (55% formulation and 45% APIs).

The Indian pharmaceutical market is expected to witness rapid and significant growth on the back of greater acceptance and penetration of generics, enhanced export opportunities, increasing global demand, and a large share of off-patent drugs in the future.

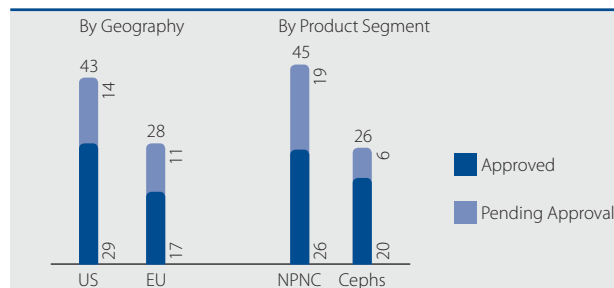
### Outlook

India's pharmaceutical industry is at an advantageous position compared to other emerging countries. With the advantage of being a highly organised sector, the Indian pharmaceutical companies are growing at the rate of 8-9% annually.

## ABOUT ORCHID

Incorporated in 1992, Orchid Chemicals & Pharmaceuticals Ltd. (Orchid) is a vertically integrated company, spanning the entire pharmaceutical value chain from discovery to delivery with established credentials in research, manufacturing and marketing. We have created niche pharmaceutical products and manufacturing platforms, ensuring sustainable growth and profitability.

## Finished Dosage Forms: Regulatory status

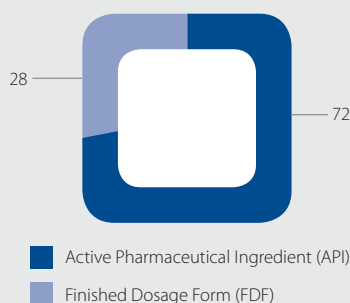




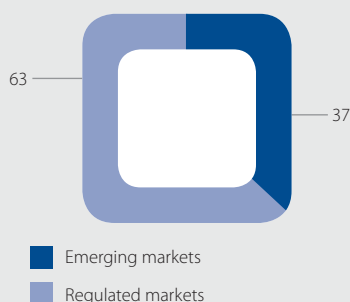


## Revenue pie in 2011-12

Product-wise (%)



Geography-wise (%)



## Highlights 2011-12

- o Received USFDA approval for several products including Venlafaxine ER Capsules, Olanzapine Tablets and Levofloxacin Tablets, among others.
- o Received the initial US\$ 1.5 million from Merck on the completion of a milestone in its anti-infectives research collaboration.
- o Successfully completed in Europe, Phase I trial of its orally administered PDE4 (phosphodiesterase 4 inhibitor) molecule OCID 2987, positioned for the treatment of inflammatory disorders, including COPD (Chronic Obstructive Pulmonary Disease).
- o Redeemed the outstanding Foreign Currency Convertible Bonds (FCCBs), including yield-to-maturity, aggregating to US\$ 167.64 million on the due date, February 28, 2012.
- o The state-of-the-art Cephalosporin API manufacturing facility was successfully re-inspected by USFDA.

- o Awarded with OHSAS 18000:2007 (Occupational Health and Safety Management System) certification for the API manufacturing facility at Alathur.
- o The API manufacturing facility at Alathur was re-assessed and was certified with ISO 9001:2008 (Quality Management System) and ISO 14001:2004 (Environmental Management System).

## The Road Ahead

The road ahead is challenging for the global and Indian pharmaceutical sector. Orchid is confident of continuing with a sustainable growth with long-term partnerships with major pharma companies assuring consistent revenue streams. The company's state-of-the-art integrated infrastructure, skilled professionals and cutting-edge technology at all production and research facilities have enabled it to be a preferred partner to several multinational pharmaceutical companies to associate with at any stage of its product life cycle.

Orchid continued its focus on US regulatory markets with the number of regulatory filings steadily increasing. Also, Orchid's investments in R&D over the years have started yielding results. With a focus on innovation and invention, Orchid aims to become a leading science and technology player, going forward.

Moving ahead, Orchid plans to ramp up the existing business verticals and establish footprints in new niche high growth therapeutic segments, delivering value to all stakeholders. Orchid plans to:

- o Diversify and further enhance reach in the regulated generics business.
- o Consolidate its presence in the API business segment by focusing on regulated markets.
- o Expand relationships with marque clients with additional new products.
- o Enhance market penetration with existing products.
- o Focus on long-term partnerships with major pharma companies.
- o Increase its operations in emerging markets.
- o Enhance its presence in the domestic formulations market.
- o Progress on drug discovery programmes.



## FINANCIAL REVIEW

In 2011-12, Orchid delivered a stable and sustainable performance, achieving a 4.38% increase in the revenue with a profit of Rs 103.12 crore, as against Rs 159.48 crore in the previous year, despite adverse events such as closure of the Alathur API plant for more than one month and the fire accident at the R&D centre, Shozhanganallur.

### A) Profit and loss account

#### Revenue

Revenue increased from Rs 1,663.34 crore in the year 2010-11 to Rs 1,736.33 crore in 2011-12. This increase was largely due to continuing supply of APIs to Hospira, contractual business with other large global pharmaceutical players in regulated markets, namely Europe and Japan and contribution from Karalex Pharma, a front end marketing organisation in the US.

#### Profitability

The EBIDTA stood at Rs 411.73 crore as on March 31, 2012 as against Rs 397.32 crore as on March 31, 2011. After providing for tax, the PAT stood at Rs 103.11 crore for 2011-12 as compared to Rs 159.48 crore for the previous financial year. This decline in profit was due to shrinking product margins, the API plant closure at Alathur and higher interest costs.

#### Expenditure

Total operational costs increased from Rs 1,314.84 crore in 2010-11 to Rs 1,380.41 crore in 2011-12 owing to overall increase in key operational parameters.

Power and fuel expenses increased to Rs 85.72 crore in 2011-12 as compared to Rs 72.53 crore in 2010-11 owing to an increase in fuel costs.

Material costs marginally decreased from Rs 787.95 crore in 2010-11 to Rs 785.86 crore due to decrease in production volumes and raw material consumption on account of the API plant closure during the year.

Employee costs increased to Rs 154.64 crore in 2011-12 as compared to Rs 141.38 crore in 2010-11, primarily due to the normal annual increments/promotions and additional recruitment.

Other expenditure including Directors' remuneration increased from Rs 312.94 crore in 2010-11 to Rs 354.18 crore in 2011-12, mainly on account of increase in R&D expenses, conversion charges, insurance charges and travelling & conveyance expenses.

Interest and finance charges increased from Rs 115.76 crore in 2010-11 to Rs 179.05 crore in 2011-12, due to a rise in borrowings on account of the FCCBs redemption and a steep rise in interest rates and finance charges.

Depreciation and amortisation expenses stood at Rs 149.05 crore in 2011-12 as compared to Rs 128.45 crore in 2010-11.

### B) Balance sheet

The capital employed in the business increased about 25.69% from Rs 1,984.08 crore as on March 31, 2011 to Rs 2,493.94 crore as on March 31, 2012. This increase was largely due to a rise in the term loans and reserves and surplus balance.

#### Net worth

Shareholders' fund (net worth) increased from Rs 1,134.02 crore as on March 31, 2011 to Rs 1,194.55 crore as on March 31, 2012.

#### Reserves

Balance in the reserve and surplus accounts stood at Rs 1,124.10 crore as on March 31, 2012 as against Rs 1,063.58 crore as on March 31, 2011. The Company ploughed 58% of the net profit to its reserves in 2011-12. Free reserves accounted for more than 98% of the reserves as on March 31, 2012.

The book value per share stood at Rs 169.58 as on March 31, 2012 as against Rs 160.99 as on March 31, 2011.

#### External funds

|                   | 2011-12           | 2010-11           |
|-------------------|-------------------|-------------------|
| Total borrowings  | Rs 1,999.30 crore | Rs 2,069.12 crore |
| Debt equity ratio | 1.67              | 1.82              |