2nd report 2004-05

torrent

Torrent Pharmaceuticals Limited

Contents

Growth is unceasing. Growth is untiring.

We have always looked at multifaceted growth.

Be it our R&D, domestic manufacturing or

international operations,

we realise that our successes are

offshoots of our investments and capabilities;

We see a healthier future tomorrow;

a future that drives our presence with commitment

and confidence...

That is why we continuously invest in our future.

Because for us, tomorrow is today.

Corporate Information

• Directors

Sudhir Mehta
Executive Chairman

Markand Bhatt

S. H. Bhojani

Dr. Prasanna Chandra

Kiran Karnik

Sanjay Lalbhai

Prof. S. Ramnarayan

Mihir Thakore

Dr. C. Dutt
Director (Research & Development)

Samir Mehta
Managing Director

• Audit Committee

Kiran Karnik
Chairman

S. H. Bhojani

Dr. Prasanna Chandra

Mihir Thakore

Samir Mehta

• Securities Transfer & Investors' Grievance Committee

Markand Bhatt
Chairman

Dr. C. Dutt

Samir Mehta

• GM (Legal) & Company Secretary

Mahesh Agrawal

• Auditors

C. C. Chokshi & Co.
Chartered Accountants

• Registered Office

Torrent House, Off Ashram Road,
Ahmedabad 380 009
Telephone: 079-26585090
Fax: 079-26582100

• Manufacturing Facilities

Village Indrad, Taluka Kadi,
Dist. Mehsana
Telephone: 02764-233671
Fax: 02764-233676

• Baddi Formulation Project Site

Village Bhud & Makhnu Majra,
Baddi, Tehsil Nalagarh,
Dist. Solan (H.P.)

• R & D Facility

Torrent Research Centre,
Near Kanoria Hospital,
Village Bhat,
Dist. Gandhinagar,
Telephone: 079-23969100
Fax: 079-23969135

• Website

www.torrentpharma.com

• Registrars & Transfer Agents

MCS Limited,
101, Subh Shatdal Complex,
Opp. Bata Showroom,
Ashram Road,
Ahmedabad 380 009
Telephone: 079-26582878
Fax: 079-26584027

Directors' Report

To,

The Shareholders

The Directors have the pleasure of presenting the Thirty Second Annual Report of your Company for the Financial Year 2004-05

FINANCIAL RESULTS, DIVIDEND AND ACCOUNTS

The summary of operating results for the year and appropriation of divisible profits is given below:

Rs. in lacs

	2004-05	2003-04
Sales & Operating Income	49759	44308
Operating Profits (PBDIT)	8179	10642
Less Depreciation	1818	1569
Less Net Interest Expense/(Income)	274	(24)
Profit Before Tax & Exceptional Items	6087	9097
Less Exceptional Items	—	160
Less Net Income Tax Expense	795	2519
Net Profit for the Period	5292	6417
Balance brought forward from Last Year	3905	6197
Distributable Profits	9197	12614
Appropriated as under:		
Transfer to General Reserve	3400	6800
Proposed Equity Dividend	1692	1692
Tax on Distributed Profits	238	217
Balance Carried Forward	3867	3905

Directors' Report

The Management Discussion and Analysis, giving a detailed analysis of performance for the year, has been included in the Annual Report.

The Board has recommended a dividend of Rs.8.00 per equity share (80% on fully paid up face value of Rs.10) (previous year Rs.8.00 per equity share, 80% on fully paid up face value of Rs.10), amounting to Rs.1692 lacs. The tax on distributed profits payable on this dividend is Rs. 238 lacs (previous year Rs. 217 lacs) making the aggregate distribution Rs.1930 lacs (previous year Rs.1909 lacs). The distributed profits are 36% (previous year 30%) of the net profits for the year. The proposed dividend would be tax free in the hands of the shareholders.

DIRECTORS' RESPONSIBILITY STATEMENT

In terms of Section 217 (2AA) of the Companies Act, 1956, in relation to financial statements for the year 2004-05, the Board of Directors state that:

i the applicable accounting standards have been followed in preparation of the financial statements and there are no material departures from the said standards;

ii reasonable and prudent accounting policies have been used in preparation of the financial statements, that they have been consistently applied and that reasonable and prudent judgments and estimates have been made in respect of items not concluded by the year end, so as to give a true and fair view of the state of affairs of the Company as at 31st March 2005 and of the profit for the year ended 31st March 2005;

iii proper and sufficient care has been taken for maintenance of adequate accounting records in accordance with the provisions of the Companies Act, 1956 for safeguarding the assets of the Company and for preventing and detecting fraud and other irregularities;

iv the financial statements have been prepared on a going concern basis.

CAPITAL AND BORROWINGS

The Company is implementing projects to expand its manufacturing and research facilities. In view of its zero debt status as of 31st March 2004 and low interest rates, the Company decided to finance the projects primarily out of long term loans. In this regard the Company contracted a mix of rupee and foreign currency term loans of Rs. 194 crores with banks / financial institution during the year of which Rs.181 crores was drawn as on 31st March 2005.

In order to meet its working capital requirements, the Company has also set-up working capital facilities with banks / financial institution. The Company had short term debt of Rs. 30 crores outstanding as on 31st March 2005.

The Company had cash and bank balances and current investments aggregating Rs. 155 crores as on 31st March 2005, representing term loans drawn pending utilization for capital expenditure and surplus internal accruals. The Company has sufficient financial flexibility, in terms of available liquid funds and committed facilities from banks / financial institution to finance the future growth plans and capitalize on emerging opportunities.

DOMESTIC BRANDED BUSINESS

Domestic branded business is the key revenue generator for the Company.

The domestic market witnessed the lowest growth in the last three financial years. This sluggishness can be largely attributed to statutory and competition driven price cuts, de-stocking by the distribution chain in the last quarter on account of VAT implementation by many States replacing the sales tax regime and unanticipated product withdrawals. Your Company was in particular affected by product withdrawals and VAT implementation (see further) during the year.

New Products

New products have been a consistent growth driver of the

market. The year witnessed introduction of a slew of new molecules and new combination products coupled with intense price competition particularly for new products introduced during past few years. The Company has well-established capabilities in early product development and continued its prominent position in the segment by introducing new molecules and also line extensions of existing brands. During the year 22 new products (including line extensions) were brought to the market including Zedott (Racecadotril), Toroxx A/AP (Aceclofenac), Nexpro RD (Esomeprazole + Domperidone), Torcoxia (Etoricoxib), Zetistat (Atorvastatin + Ezetemibe), Symbal (Duloxetine), and Tomoxetine (Atomoxetine). Of the products launched during the last two years, Nebicard, Torcoxia, and Nexpro RD performed very well during the financial year and achieved significant market share gains The Company will continue its focus on newer therapies and newer products which significantly contribute to the top line growth.

Turnover

The turnover for the year was Rs. 290 crores, registering a growth of 2% over the previous year. This low growth can be largely attributed to unanticipated product withdrawals, disruption in sales of certain psychotropic drugs, de-stocking by chemists and stockists due to VAT implementation and increased pricing pressures, especially on the new products launched during the year. Twenty brands (as compared to fifteen in the previous year) of the Company enjoyed leadership positions in the respective molecule segments and top 10 brands contributed to 54% of the total domestic formulation sales as against 55% during previous year. While the spillover of FY 2004-05 last quarter sales (due to VAT implementation) is expected to have a favourable impact on the FY 2005-06 sales, the Company expects pricing pressures to continue in the near term.

Sales Operations

In an increasingly competitive environment in the domestic market, the Company has created a strong foundation in the form of an extensive marketing network, equipped with technological support to compete effectively. During the year, Company invested in field force through recruitments, continuous training and also reinforced the standard work norms. It has thus created an extensive and effective marketing network across the country which enables faster introduction of new products, increases the capacity to handle larger product portfolio and can focus on complementary products at the same time. The Company adopted an online field communication system linking the 1959 strong field force across the country with the Head Office and also among themselves, through the internet.

Price Regulation

The price control regime continues to be governed by Drug Price Control Order, 1995. During the year, your Company implemented price reductions by NPPA, affecting 2 products of the Company, the impact of which on profit for the year was not significant. In addition, toward the end of the year, NPPA notified prices for certain medicines which were hitherto not under price control. The effect of price notifications in respect of these medicines will be felt in FY 2005-06. Over the years, due to introduction of products mainly in non-controlled segments, your Company has continuously seen the proportion of sales under price control falling down to current level of 11% from 13.5% in previous year.

INTERNATIONAL OPERATIONS

International generic opportunity is the future growth engine. The opportunity in this market segment is expanding due to many blockbuster drugs going out of patent protection over next few years. An added factor is the mounting health care

Directors' Report

costs in developed markets, which is paving way for a more favourable regulatory regime for generics in such countries. Generics now tomorrow get faster approvals and are actively encouraged by the governments. Over the last few years, the Company has developed a strategy and built infrastructure and capabilities focused on tapping this lucrative opportunity. The manufacturing facilities are upgraded to meet stringent quality assurance standards of the highly regulated developed countries; at the same time maintaining the competitive cost advantage. The R & D Center is upgraded to develop international generic versions of selected molecules in the required time frame and prepare the necessary regulatory dossiers for obtaining timely marketing approval. Going forward these processes will be further strengthened to sustain the growth.

Within the above-mentioned overall strategy, the current international operations are focused on five thrust areas: Brazil & Latin America, Russia & CIS countries, Europe, North America and Rest of the World comprising of less regulated countries of Africa and Asia.

In Brazil & Latin America, the Company operates through its subsidiary "Torrent do Brasil Ltda", which consolidated its business operations during the year. The Company has currently around 19 products in the market and has been able to achieve significant ramp up in sales during the completed financial year. The subsidiary has taken steps to increase the doctor coverage in the existing territories by increasing the sales force and also increase the geographical coverage to cover the almost entire Brazilian market. Also refer to the section on "Torrent do Brasil Ltda" in this report.

In Russia & CIS, operations are conducted through a wholly owned subsidiary, Zao Torrent Pharma and the Company also has a representative office for direct sales to distributors. During the year, the sales force was increased and four new products were introduced. While the Company registered a double digit growth, the same was lower than expectations from the larger sales force on the ground. The low productivity of sales force in Russia resulted in poor operating performance. Four new products are planned in FY 2005-06, and plans are afoot to expand the tender segment. With these steps the Company is positive about turning around the operations in Russia & CIS. Also refer the section on "ZAO Torrent Pharma" in this report.

In Europe, the Company's subsidiary, Torrent Pharma GmbH (TPG) is engaged primarily in business development and sales of dossiers, while the remaining operations are carried on directly. The Company commenced exports of Lamotrigine to the EU market, thereby accomplishing an important milestone in its foray into regulated generic markets. The Company's subsidiary, TPG, was successful in closing 23 additional product dossier licensing agreements (involving five products) during the year, which are linked to supply tie-ups with the Company. TPG also received its first marketing authorization in the European Union, which will enable your Company to enter the UK generics market, through supply arrangements with distributors. The Company has secured the necessary regulatory approval of the formulation manufacturing facility from Medicines & Health Care Products Regulatory Agency (MHRA) of UK. The Company has a good order position for supplying generic products going off-patent and a pipeline of 14 additional products under development for Europe. Also refer to the section on "Torrent Pharma GmbH" in this report.

Torrent Pharma Inc., the subsidiary in USA, is engaged in business development activities for North America, the world's largest and most profitable market for generic pharmaceuticals. During the year, the Company progressed on product development work for 8 products for filing abbreviated new drug applications (ANDA) and identified 12 additional products for ANDA development work. It is therefore committing significant research and development work for the market. The Company has filed the first DMF on 28th April 2005 and ANDA for 6 of the 20 products are scheduled to

be filed with the US FDA in 2005-06 out of which the first ANDA is expected to be filed in May 05. Also refer to the section on "Torrent Pharma Inc." in this report.

Sales and operating revenues in Rest of World (ROW) territory, comprising of Asian & African countries, increased by a healthy 61%, from Rs. 23 crores to Rs. 38 crores. The strategic focus was shifted to marketing and promotion from distribution. Consequently, the Company made significant inroads into its existing larger markets like Sri Lanka, Vietnam, Myanmar and Zimbabwe. Newer business models were explored, which facilitated in-roads in the large South Africa and Philippines markets. Future growth will come from expanding in the current markets and developing select new markets. Also refer to the section "Torrent Pharma Philippines Inc." in this report.

The successes in Brazil, Europe and ROW are giving the confidence to the Company to make further substantial investments to penetrate the European markets and commence operations in USA. The Company is well set to leverage its technical capabilities, cost advantages and geographical reach to improve the momentum in growth of exports in the coming years. The consolidated net sales of international operations increased from Rs. 6683 lacs to Rs. 13014 lacs, registering a strong growth of 95%. The international marketing initiatives, well complemented by the R&D and manufacturing capabilities, are expected to propel the Company towards recognition as an important player in global generics business.

MANUFACTURING

The highlight of the manufacturing operations was the approval of the oral solid formulation facility at Indrad by MHRA of U.K. This will not only open access to the U.K. market, but also facilitate approvals by other regulatory authorities across the world such as the Therapeutic Goods Administration (TGA) of Australia, MCC of South Africa and Anvisa of Brazil. In this context your Company has completed significant preparatory work for audit by US FDA, which is also expected to inspect t he plant during 2005-06. Medicine Control Agency of Zimbabwe (MCAZ) renewed their approvals during the year.

To support the entry into highly regulated markets of Europe and North America, the Company had embarked upon further expansion of the bulk drug plant capacity, along with construction of a process development laboratory. This capacity enhancement and consolidation of the bulk drug plant is now scheduled to be completed in second quarter of FY 2005-06.

The Indrad plant was the second pharmaceutical set-up in the country whose Quality Control laboratory received accreditation from the prestigious 'National Accreditation Board for Testing & Calibration Laboratories' (NABL) for compliance of ISO 17025. The Indrad plant also had successful surveillance of the ISO 9001, ISO 14001 & OHSAS 18001 certifications during the last year.

The construction of new plant at Baddi to manufacture tablets, capsules and oral liquids progressed satisfactorily during the year. Civil work for main plant buildings and utilities is in advanced stage. Detailed engineering and equipment ordering is substantially complete and equipment deliveries have commenced. The project is expected to be completed in September 2005. The Company will enjoy significant fiscal benefits in the form of exemption from excise duty and income-tax for production out of this facility.

RESEARCH AND DEVELOPMENT

In the previous year's Directors' Report we had mentioned that the Company was reviewing the data on its AGE (Advanced Glycosylation End-products) Breaker Compound with Novartis Pharma AG (Novartis) with a view to take it forward. During the year, the Company entered into a License Agreement with Novartis granting global rights for further

Directors' Report

development and commercialisation of its patented AGE Breaker Compound to Novartis. The Company received USD 3 million as upfront payment during the year. The Agreement envisages further milestone payments and royalties based on progress of the compound.

Your Company also signed a research collaboration agreement with AstraZeneca, another leading global pharmaceuticals company. The collaboration aims at discovering a novel drug candidate for the treatment of hypertension. Under the agreement, the Company and AstraZeneca will fund the research project jointly in equal proportion. The agreement envisages success-based R&D milestone payments to the Company, and also royalties based on the commercialization of the drug candidate. The Company will also get co-marketing rights of the products for its home market, India.

During the year, several new technologies for research processes were adopted: amongst the new technologies, the notable ones were Parallel Synthesis Apparatus and RP-HPLC MS Parallel Purification System for improving throughput and quality. During the year, the efforts were also focused on consolidating the discovery portfolio keeping in line the Company's strategy to remain focused in thrust therapeutic areas that have good commercial potential, require common technology platforms and in vivo models, and offer possible multiple applications. All this has enabled the Company to create a healthy discovery pipeline based on multiple biological targets and also work on collaborative research projects with large multinational pharma companies.

Currently, the Company is working on 5 in-house New Chemical Entities (NCE) projects 2 in diabetes and related complications, 1 in cerebro-vascular and 2 in obesity. The Company has cumulatively filed 210 patents for NCE from these and earlier projects in all major markets. The patent offices of USA, Japan, Europe, Czech Republic, Australia, Hong Kong, Russia and India have granted / accepted 32 patents so far. The Company intends to pursue suitable partnership opportunities with international drug companies at an appropriate stage to share the risks and resources required to take NCE to the commercial stage.

New product development capabilities for international generic markets continued at an accelerated pace. Significant investments were made in infrastructure and about 170 scientific staffs were added during the year, mainly to augment the generic product development capacities for the regulated markets of North America and Europe. Thus, your Company is gearing up very rapidly for developing and getting marketing approvals for large number of products in these developed markets.

22 new products (including 13 value-added line extensions and combinations) were introduced in the domestic market and 5 new products were introduced in Brazilian market during the year. The R&D activities are expected to provide the necessary impetus to the Company's plans for introduction of many new products in the domestic market as well, in the year 2005-06.

In order to augment its capability and capacity in research and development, the Company incurred capital expenditure of Rs. 16.8 crores during the year. In addition, the infrastructure at the research centre is being expanded at a capital cost estimate of Rs. 65 crores to accommodate additional scientific manpower and technological support over the next two years.

During the year, the total revenue expenditure on R&D was 10.2% (previous year 6.6%) of sales and operating income, approximately 27% (previous year 38%) of which was spent on discovery projects.

HUMAN RESOURCES

Your Company operates in a knowledge-based sector and the importance of human capital need not be underscored. New