

DR REDDYS LABORATORIES LTD

Form 6-K

November 08, 2004

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**FORM 6-K  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**Report of Foreign Private Issuer**

**Pursuant to Rule 13a-16 or 15d-16  
of the Securities Exchange Act of 1934**

**For the month of October, 2004**

**Commission File Number 1-15182**

**DR. REDDY S LABORATORIES LIMITED**

(Name of Registrant)

**7-1-27, Ameerpet  
Hyderabad, Andhra Pradesh 500 016, India  
+91-40-23731946**

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(Address of Principal Executive Offices)

Indicate by check mark whether registrant files or will file annual reports under cover of Form 20-F or Form 40-F.

Form 20-F  Form 40-F [  ]

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): \_\_\_\_\_

**Note:** Regulation S-T Rule 101(b)(1) only permits the submission in paper of a Form 6-K if submitted solely to provide an attached annual report to security holders.

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): \_\_\_\_\_

**Note:** Regulation S-T Rule 101(b)(7) only permits the submission in paper of a Form 6-K if submitted to furnish a report or other document that the registrant foreign private issuer must furnish and make public under the laws of the jurisdiction in which the registrant is incorporated, domiciled or legally organized (the registrant's home country), or under the rules of the home country exchange on which the registrant's securities are traded, as long as the report or other document is not a press release, is not required to be and has not been distributed to the registrant's security holders, and, if discussing a material event, has already been the subject of a Form 6-K submission or other Commission filing on EDGAR.

Indicate by check mark whether by furnishing the information contained in this Form, the registrant is also thereby furnishing the information to the Commission pursuant to Rule 12g3-2(b) under the Securities Exchange Act of 1934.

Yes [  ] No [X]

If  Yes  is marked, indicate below the file number assigned to registrant in connection with Rule 12g3-2(b):

Not applicable.

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- (1) Press Release, Dr. Reddy s Announces Litigation on ANDA for Finasteride tablets 1 mg, October 1, 2004.
- (2) Notice to Stock Exchange, October 14, 2004.
- (3) Press Release, Dr. Reddy s Q2 FY05 revenue at Rs.5,407 million; Net income at Rs.517 million, October 26, 2004.
- (4) Press Release, Novo Nordisk terminates further clinical development of Balaglitazone (DRF 2593) out-licensed by Dr. Reddy s, October 27, 2004.
- (5) Press Release, Dr. Reddy s announces USFDA approval for Citalopram Hydrobromide tablets, October 29, 2004.

Dr. Reddy s Laboratories Ltd.  
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[www.drreddys.com](http://www.drreddys.com)

**Dr. Reddy s Announces Litigation on ANDA for Finasteride tablets 1 mg**

Hyderabad, India, October 1, 2004:

Dr. Reddy s Laboratories (NYSE:RDY) today announced that the Company had filed an Abbreviated New Drug Application (ANDA) with the United States Food and Drug Administration for Finasteride tablets 1 mg with a Paragraph IV certification on three of the four Orange Book patents listed for the drug, in June 2002.

In September 2002, Dr. Reddy s notified Merck, upon which the latter did not file a lawsuit within the 45-day period under the Hatch-Waxman Act. On September 29, 2004, Merck filed a lawsuit against the Company in the United States District Court for the District of Delaware, alleging patent infringement on the 817 and 957 patents.

Finasteride tablets 1 mg is the generic version of Merck s Propecia® with annual brand sales in the United States of approximately \$ 112 million (Source: IMS MAT March 2004).

About Dr. Reddy s

Established in 1984, Dr. Reddy s Laboratories (NYSE: RDY) is an emerging global pharmaceutical company with proven basic research capabilities. The company is vertically integrated with a presence across the pharmaceutical value chain. It produces finished dosage forms, active pharmaceutical ingredients and biotechnology products and markets them globally, with focus on India, US, Europe and Russia. The Company conducts research in the areas of cancer, diabetes, cardiovascular, inflammation and bacterial infection.

This press release includes forward-looking statements, as defined in the U.S. Private Securities Litigation Reform Act of 1995. We have based these forward-looking statements on our current expectations and projections about future events. Such statements involve known and unknown risks, uncertainties and other factors that may cause actual results to differ materially. Such factors include, but are not limited to, changes in local and global economic conditions, our ability to successfully implement our strategy, the market acceptance of and demand for our

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products, our growth and expansion, technological change and our exposure to market risks. By their nature, these expectations and projections are only estimates and could be materially different from actual results in the future.

Contact Information

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Investors and Financial Analysts: Nikhil Shah at nikhilshah@drreddys.com or on +91-40-55511532.

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October 14, 2004

The Secretary  
Mumbai Stock Exchange  
National Stock Exchange  
Calcutta Stock Exchange  
New York Stock Exchange

Dear Sir,

The Board of Directors of the Company is scheduled to meet on October 26, 2004 to, inter alia, discuss and take on record the un-audited financial results of the Company for the quarter and half year ended September 30, 2004.

Kindly take the above information on record.

With regards,

/s/ V Viswanath

V Viswanath  
Company Secretary

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**Dr. Reddy s Q2 FY05 revenue at Rs.5,407 million;  
Net income at Rs.517 million**

Hyderabad, India, October 26, 2004:

Dr. Reddy s Laboratories Ltd. today announced its unaudited financial results for the second quarter ended September 30, 2004.

*Notes*

- 1. In line with global disclosure standards, the company commenced reporting its financials on a consolidated basis since Q1 FY03.*
- 2. Current quarter financial discussions below are on a consolidated basis as per the US GAAP.*
- 3. Detailed analysis of the financials is available on the Company s website at [www.drreddys.com](http://www.drreddys.com).*

**Key highlights**

- o Revenues at Rs 5.4 billion, a marginal growth of 0.6% over Q2 FY04.
- o Revenues outside India at Rs 3.4 billion as against Rs 3.2 billion in Q2 FY04; YoY growth of 6%; Contribution at 63% of total revenues.
- o Revenues from US and Europe together contribute Rs 1.9 billion in Q2 FY05; Contribution at 35% of total revenues
- o In Branded Formulations, international revenues increase by 68% to Rs 970 million as against Rs 576 million in Q2 FY04. The growth was primarily driven by the performance in Russia and allied markets.
- o In API, revenues from North America increase by 21% to Rs 523 million as against Rs 432 million in Q2 FY04.
- o Driven by improved geography and business mix, gross profit margins increase to 55% of revenues in Q2 FY05 as against 54% in Q2 FY04. Gross margins in Q1 FY05 were at 51%.
- o Operating income before forex at Rs 524 million as against Rs 865 million in Q2 FY04.
- o Net income is at Rs 517 million as against Rs 929 million in Q2 FY04. This translates to a diluted EPS of Rs 6.75 as against Rs 12.14 in Q2 FY04.





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- o R&D investments increase by 28% to Rs 627 million as against Rs 490 million in Q2 FY04. As a % of revenues, R&D expenditure is at 12% as against 9% in Q2 FY04.
- o Selling, General & Administration (SG&A) expenses increase by 18% to Rs 1.7 billion from Rs 1.5 billion in Q2 FY04.
- o Company filed 2 US DMFs and completed work on 2 additional DMFs and 6 ANDAs, which are expected to be filed by the end of October. Of these 6 ANDAs, 4 are Para I filings, 1 is a Para III filing and the remainder one is a Para IV.

Unaudited US GAAP Financials for the quarter ended September 30, 2004

*All figures in millions, except EPS*

*All dollar figures based on convenience translation rate of 1USD = Rs 45.91*

## EXTRACTED FROM THE UNAUDITED INCOME STATEMENT

| Particulars                                      | Q2 FY05 |       |     | Q2 FY04 |       |     | Growth % |
|--|---------|-------|-----|---------|-------|-----|----------|
|  | (\$)    | (Rs.) | %   | (\$)    | (Rs.) | %   |          |
| Net Product Revenues                             | 118     | 5,400 | 100 | 117     | 5,377 | 100 | 0        |
| License Fees                                     | 0       | 7     | 0   | 0       | 0     |     |          |
| Total Revenues                                   | 118     | 5,407 | 100 | 117     | 5,377 | 100 | 1        |
| Cost of revenues                                 | 53      | 2,440 | 45  | 53      | 2,454 | 46  | (1)      |
| Gross profit                                     | 65      | 2,967 | 55  | 64      | 2,923 | 54  | 2        |
| Selling, General & Administrative Expenses       | 38      | 1,729 | 32  | 32      | 1,471 | 27  | 18       |
| R&D Expenses                                     | 14      | 627   | 12  | 11      | 490   | 9   | 28       |
| Amortization Expenses                            | 2       | 87    | 2   | 2       | 95    | 2   | (8)      |
| Operating Income {before Forex (Gain)/Loss}      | 11      | 524   | 10  | 19      | 865   | 16  | (39)     |
| Forex Loss/ (Gain)                               | 1       | 49    | 1   | (2)     | (97)  | (2) | NC       |
| Operating income {after Forex (Gain)/Loss}       | 10      | 475   | 9   | 21      | 962   | 18  | (51)     |
| Equity in loss of affiliates                     | 0       | 16    | 0   | 0       | 13    | 0   | 19       |
| Other expenses/(income) net                      | (3)     | (137) | (3) | (4)     | (169) | (3) | (19)     |
| Income before income taxes and minority interest | 13      | 597   | 11  | 24      | 1,118 | 21  | (47)     |
| Income tax (benefit)/expense                     | 2       | 85    | 2   | 4       | 190   | 4   | (55)     |
| Minority interest                                | 0       | (5)   | (0) | 0       | 0     |     |          |
| Net income                                       | 11      | 517   | 10  | 20      | 929   | 17  | (44)     |
| Diluted EPS                                      | 0.15    | 6.75  |     | 0.26    | 12.14 |     |          |

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Segmental Analysis

Active Pharmaceutical Ingredients (APIs)

- o Revenues at Rs 1.8 billion as against Rs 2 billion in Q2FY04.
- o Revenues outside India at Rs 1.3 billion contributing 70% of the segment's revenues as against 67% in Q2 FY04.
- o North America contributed 29% of total revenues as against 21% in Q2 FY04. Revenue growth was driven by sales of existing products coupled with development quantities of new products.
- o Revenues in Europe decrease to Rs 217 million as against Rs 526 million in Q2 FY04. This decline was primarily on account of the decrease in revenues from ramipril following the launch of generic finished dosages in January 2004.
- o The Company filed 2 US DMFs and completed work on 2 additional DMFs during the quarter taking the total filings to 61.

Generics

- o Revenues in this segment at Rs 1 billion as against Rs 1.2 billion in Q2 FY04.
- o North America contributed 69% to the total revenues and Europe contributed 31%.
- o Revenues in Europe increase by 33% to Rs 324 million as against Rs 244 million in Q2 FY04. The growth was driven by increase in volumes of omeprazole coupled with revenues from new product launches in the last four quarters.
- o Fluoxetine capsules 40mg and tizanidine tablets 2 mg & 4 mg together contributed revenues of Rs 417 million as against Rs 713 million in Q2 FY04. The revenues declined on account of increased competition over the last four quarters. The revenues of Rs 417 million in Q2 FY05 compare with revenues of Rs 293 million in Q1 FY05.
- o During the quarter, the Company completed work on 6 ANDAs, which are expected to be filed by the end of October. Of these 6 ANDAs, 4 are Para I filings, 1 is a Para III filing and the remainder 1 is a Para IV.

Branded Formulations International

- o Revenues at Rs 970 million, an increase of 68% over Q2 FY04. The growth was primarily driven by the performance in Russia and allied markets.
- o Revenues in Russia grew by 63% to Rs 587 million as against Rs 360 million in Q2 FY04. The growth was driven primarily due to seasonal factors.
- o Other CIS markets grew by 43% to Rs 146 million as against Rs 102 million in Q2 FY04. The growth was driven primarily by key markets of Kazakhstan, Ukraine and Belarus.

Branded Formulations India

- o Revenues at Rs 1.3 billion, a decrease of 4% over Q2 FY04. This decline is primarily on account of the fall in revenues from Nise, which was partially offset by sales from new product launches.

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Other Businesses

- o Revenues in the critical care & biotechnology segment increased to Rs 130 million from Rs 89 million in Q2 FY04.
- o Revenues from Custom Pharmaceutical Services increased to Rs 98 million from Rs 28 million in Q2 FY04.

Income Statement Highlights

- o Gross Margins on total revenues at 55% as against 54% in Q2 FY04. This improvement is primarily on account of the better geography and business mix.
- o Investments in R&D at Rs 627 million as against Rs 490 million in Q2 FY04. As a %, R&D spend is at 12% of total revenues as against 9% in Q2 FY04.
- o Selling, General & Administration (SG&A) expenses increased to Rs 1.7 billion from Rs 1.5 billion in Q2 FY04. As a %, SG&A expenses are at 32% of total revenues as against 27% in Q2 FY04. This increase is primarily on account of higher marketing expenses and manpower cost. The SG&A expenses in Q1 FY05 were at Rs 1.6 billion.
- o Other income (net) is at Rs 137 million as against Rs 169 million in Q2 FY04.
- o Depreciation for the quarter is at Rs 238 million as against Rs 178 million for Q2 FY04.
- o Net income at Rs 517 million (10% of total revenues) as against Rs 929 million (17% of total revenues) in Q2 FY04. This translates to a diluted EPS of Rs 6.75 as against Rs 12.14 in Q2 FY04.

General information

The following items were considered and adopted by the Board of Directors of Dr. Reddy's Laboratories today:

- o Unaudited financial results for the quarter ended September 30, 2004 as required under Clause 41 of the listing agreement.

About Dr. Reddy's

Established in 1984, Dr. Reddy's Laboratories (NYSE: RDY) is an emerging global pharmaceutical company with proven research capabilities. The Company is vertically integrated with a presence across the pharmaceutical value chain. It produces finished dosage forms, active pharmaceutical ingredients and biotechnology products and markets them globally, with focus on India, US, Europe and Russia. The Company conducts research in the areas of cancer, diabetes, cardiovascular, inflammation and bacterial infection.

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**Novo Nordisk terminates further clinical development of Balaglitazone (DRF 2593) out-licensed by Dr. Reddy s**

Hyderabad, India, October 27, 2004:

Dr. Reddy s Laboratories (NYSE: RDY) announced today that Novo Nordisk has decided to terminate further clinical development of its partial PPAR (Peroxisome Proliferator Activated Receptor) gamma agonist Balaglitazone (DRF 2593), an oral treatment for patients with type 2 diabetes. Novo Nordisk has decided to terminate further clinical development of balaglitazone, as the preclinical results did not suggest a sufficient competitive advantage for balaglitazone compared to similar, marketed products within this therapeutic category.

Balaglitazone (DRF 2593) is an insulin sensitizer, which acts as a partial PPAR (Peroxisome Proliferator Activated Receptor) gamma agonist for the oral treatment of patients with type 2 diabetes. Dr. Reddy s licensed this molecule to Novo Nordisk in 1997.

Dr. Uday Saxena, Chief Scientific Officer of Dr. Reddy s, said: We are disappointed that the development of Balaglitazone had to be discontinued by Novo Nordisk. However, Dr. Reddy s remains committed to the research and development of new medicines to address unmet medical needs in the areas of diabetes and metabolic disorders.

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**Dr. Reddy s announces USFDA approval for Citalopram Hydrobromide tablets**

Hyderabad, India, October 29, 2004:

Dr. Reddy s Laboratories (NYSE: RDY) announced today that the U. S. Food and Drug Administration has granted final approval for the Company s Abbreviated New Drug Application (ANDA) for Citalopram hydrobromide tablets 10 mg, 20 mg and 40 mg. The Company will commence the commercial marketing of this product immediately.

GV Prasad, Chief Executive Officer of Dr. Reddy s said, We are pleased to be among the first to get the USFDA approval for Citalopram. We will be launching this product immediately through our own sales and marketing network and its represents a significant addition to our existing portfolio of generic products for the US market .

Citalopram hydrobromide is the AB-rated generic equivalent of Forest Laboratories Celexa®. Celexa® is indicated for the treatment of depression. As per IMS June 2004, the product had annual US brand sales of approximately \$1.4 billion.

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**Signatures**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

**Dr. Reddy s Laboratories Limited**

\_\_\_\_\_  
(Registrant)

Date: November 8, 2004

By: /s/ V. Viswanath

\_\_\_\_\_  
(Signature)\*

**V. Viswanath**  
**Company Secretary**

\* Print the name and title of the signing officer under his signature.