DR REDDYS LABORATORIES LTD
Form 6-K
April 07, 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 March, 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

(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 x Form 40-F o

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 o 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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www.drreddys.com

Phase I trials of Dr. Reddy s dyslipidemia drug commence in Canada

Hyderabad, India, March 3, 2004:

The phase-I clinical trials of DRF 10945, a drug candidate discovered by Dr. Reddy s laboratories and targeted for the treatment of blood lipid dysfunction (dyslipidemia), has commenced in Canada on February 26, 2004. The Clinical Trial Application for DRF-10945, which represented the first new chemical entity (NCE) submission in Canada and overseas for the company, received no objection from the Therapeutic Product Directorate, Canada, for clinical investigation.

Dyslipidemia is a condition which results in abnormal levels of triglycerides and cholesterol in the blood and increases the risk of cardiovascular diseases. This is another significant and exciting milestone for Dr. Reddy s NCE discovery and clinical development program and attests to the commitment of the company in finding break-through medicines for unmet needs. DRF 10945 is a promising new oral drug candidate which by treating dyslipidemia will ultimately provide therapeutic benefits for treatment of cardiovascular disease, a rapidly growing menace worldwide, stated Dr. Uday Saxena, Chief Scientific Officer, Dr. Reddy s Laboratories. DRF 10945, a PPAR alpha agonist, represents a novel approach for reducing the risk for cardiovascular diseases (CVD) through effective management of dyslipidemia. It provides two beneficial effects It lowers the levels of blood triglycerides as well as increases high density cholesterol (HDL good cholesterol). Recently, HDL has obtained heightened importance due to the possibility of its contribution in reversing cardiovascular disease in patients. Also, due to its protective role, HDL levels may be a better predictor of cardiovascular disease than LDL levels. Novel medicines that can impact both triglycerides and HDL management will be important additions to the medical arsenal for managing cardiovascular diseases effectively. Besides DRF 10945, Dr. Reddy s is developing a diversified platform of compounds with distinct mechanisms of action for the treatment of dislypidemia, diabetes and associated cardiovascular disorders. Another significant drug candidate in Dr. Reddy s cardiovascular program is RUS 3108. It has a multi-pronged and direct disease attacking approach and is currently undergoing regulatory

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toxicology studies.

Dr. Reddy s Laboratories conducts its drug discovery research activities in facilities at Hyderabad and Atlanta. The company currently has eight new molecules under various stages of clinical development. DRF 2593 (Balaglitazone), which was outlicensed to Novo Nordisk in March 1997, has completed Phase-II clinical trials. DRF-1042, which is the company s first NCE in the anti-cancer area, is undergoing Phase II clinical trials and DRF 1644, the company s second molecule in the anti-cancer area, is undergoing Phase-I clinical trials.

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.

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 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.

Media:

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Dr. Reddy s Announces ANDA Filing for Levetiracetam tablets

Hyderabad, India, March 22, 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 Levetiracetam tablets, 250, 500 and 750 mg, with a Paragraph IV certification on the two Orange Book patents listed for the drug.

Dr. Reddy s notified UCB, upon which the latter filed a lawsuit against the Company in the United States District Court for the District of Georgia, alleging patent infringement on the two Orange Book patents. Dr. Reddy s believes that it has the first-to-file status along with one other filer, on all dosage strengths and if successful in its litigation, would enjoy a 180-day marketing co-exclusivity pursuant to the July 2003 FDA guidance on 180-day exclusivity when multiple ANDAs are filed on the same day.

Levetiracetam is the generic version of UCB s KeppraTM and is indicated for the treatment of epilepsy. The brand had annual sales in the United States of approximately $ 234 million (Source: IMS MAT September 2003).

About Dr. Reddy s

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Contact Information

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Notice to Stock Exchange

Dr. Reddy s Announces ANDA Filing for Moxifloxacin tablets

Hyderabad, India, March 29, 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 Moxifloxacin tablets 400 mg, with a Paragraph IV certification on all the Orange Book patents listed for the drug, on December 10, 2003 (the first day of eligibility for an ANDA filing with a Para IV certification).

Dr. Reddy s notified Bayer, upon which the latter filed a lawsuit against the Company in the United States District Court for the District of Delaware, alleging patent infringement on two of the three Orange Book patents.

Moxifloxacin is the generic version of Bayer s Avelox® and is indicated for the treatment of respiratory tract infections. The brand had annual sales in the United States of approximately $ 207 million (Source: IMS MAT September 2003).

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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: April 7,2004 By: /s/ V. Viswanath

(Signature)*
V. Viswanath
Company Secretary

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