

DR REDDYS LABORATORIES LTD

Form 6-K

March 10, 2004

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 February, 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 ☐ []

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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www.drreddys.com

Dr. Reddy's receives FDA letter on AmVazTM (Amlodipine)

Hyderabad, India, February 7, 2004:

Dr. Reddy's Laboratories (NYSE:RDY) announced that the Company has received a letter from the US Food and Drug Administration (FDA) on February 5, 2004, indicating that the FDA plans an expedited reevaluation of its review of the AmVazTM NDA, which was granted final approval on October 31, 2003.

The FDA's letter indicated that the reevaluation was prompted by questions raised about the source of the data relied on by FDA in its review and that the agency would stay the approval for AmVazTM pending the expedited reevaluation. The FDA further indicated in the letter that it believes that the approval of AmVazTM did not rely on any proprietary data from Pfizer's NDA.

Commenting on the development, GV Prasad, CEO, Dr. Reddy's Laboratories, said, "We are confident that FDA's initial decision was correct and remain optimistic of a positive outcome of FDA's reevaluation."

AmVazTM (Amlodipine Maleate) was approved for marketing by the US Food and Drug Administration (FDA) on October 31, 2003 and is indicated for the treatment of hypertension (high blood pressure) and angina.

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.

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Dr. Reddy s signs definitive agreement for sale of Compact Electric Limited

Hyderabad, India, February 9, 2004

Dr. Reddy s Laboratories (NYSE:RDY) today announced that it has entered into a definitive agreement with Bangalore based Stumpp, Schuele & Somappa (SSS) for the sale of its wholly owned subsidiary, Compact Electric Limited.

Under the terms of the agreement, SSS will acquire 51% ownership and gain immediate management control and over the next 2 years will acquire the balance 49% share from Dr. Reddy s.

Compact Electric Limited, a wholly owned subsidiary of Dr. Reddy s, is an export oriented unit (EOU) engaged in the business of manufacture and sale of Halogen lamps. For the year ended March 31, 2003, Compact Electric recorded sales of Rs 89 million and currently has an employee base of 80.

Stumpp, Schuele & Somappa (SSS), a private limited company, based in Bangalore, is an automotive springs manufacturer with significant OE relationships.

Dr. Reddy s was advised by Ernst & Young on the deal.

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 develops, manufactures and markets a wide range of pharmaceutical products in India and overseas. Dr. Reddy s produces finished dosage forms, active pharmaceutical ingredients, diagnostic kits, critical care and biotechnology products. The basic research program of Dr. Reddy s focuses on cancer, diabetes, bacterial infections and pain management. Website: <http://www.drreddys.com>

Safe Harbor

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Dr. Reddy's confirms ANDA filing for Amlodipine Besylate tablets

Hyderabad, India, February 24, 2004:

Dr. Reddy's Laboratories (NYSE:RDY) today confirmed that the Company had filed an Abbreviated New Drug Application (ANDA) with the United States Food and Drug Administration for Amlodipine Besylate tablets 2.5, 5 and 10 mg, with a Paragraph IV certification on the two Orange Book patents listed for the drug. Dr. Reddy's notified Pfizer, upon which the latter filed a lawsuit against the Company in the United States District Court for the District of New York alleging patent infringement on the two Orange Book patents.

Amlodipine Besylate is the generic version of Pfizer's Norvasc® and is indicated for the treatment of hypertension and angina. The brand had annual sales in the United States of approximately \$ 2 billion (Source: IMS MAT September 2003).

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Dr. Reddy's Laboratories Announces Appeals Court Ruling On Amlodipine Maleate

Hyderabad, India, and New Jersey, February 27, 2004:

Dr. Reddy's Laboratories (NYSE: RDY) announced today that the US Court of Appeals for the Federal Circuit reversed a lower court ruling and determined that the patent extension covering Pfizer's Norvasc® (amlodipine besylate) is applicable to Dr. Reddy's amlodipine maleate.

GV Prasad, CEO of Dr. Reddy's Laboratories, said "We are clearly disappointed by the court decision and had expected that the views expressed by the Chief Judge in the dissent would have been the position of the majority. Despite today's ruling, we remain committed to investing the resources to create a sustainable US-based business of specialty products and new chemical entities as well as generic medicines. We are making good progress in advancing our product pipeline, which now includes several projects under development targeting high-potential primary care and select specialty segments.

Dr. Reddy's core businesses include active pharmaceutical ingredients and branded formulations. These operations provide the critical skills necessary to develop and commercialize generic and specialty drugs and new chemical entities, as well as the financial flexibility to invest in high potential opportunities.

The continuing growth in our core operations enables us to pursue opportunities in the higher-value segments of the pharmaceutical market, added Prasad. Based on our research strengths, commercialization expertise, new product pipeline and world-wide presence, we remain committed to moving up the value chain, migrating into a global specialty pharmaceutical company.

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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: March 10, 2004

By: /s/ V. Viswanath

(Signature)*

V. Viswanath
Company Secretary

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