

DR REDDYS LABORATORIES LTD

Form 6-K

November 04, 2003

Table of Contents

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**

November, 2003

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 ☒ 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 ☒

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

Not applicable.

TABLE OF CONTENTS

Signatures

Table of Contents

Table of Contents

- (1) Press Release, Dr. Reddy's receives final approval for AmVaz (Amlodipine Maleate), First Indian Pharmaceutical Company to receive FDA approval for a NDA under Sec. 505(b)(2) of the Federal Food, Drug and Cosmetics Act, November 3, 2003

2

Table of Contents

Dr. Reddy's Laboratories Ltd.
7-1-27 Ameerpet
Hyderabad 500 016 India

Tel: 91 40 2373 1946
Fax: 91 40 2373 1955

www.drreddys.com

Dr. Reddy's receives final approval for AmVaz™(Amlodipine Maleate)

First Indian Pharmaceutical Company to receive FDA approval for a NDA
under Sec. 505(b)(2) of the Federal Food, Drug and Cosmetics Act

Hyderabad, India, November 3, 2003: Dr. Reddy's Laboratories (NYSE:RDY) announced today that the U.S. Food and Drug Administration (FDA) has approved the Company's NDA for AmVaz (Amlodipine Maleate).

Commenting on the development, GV Prasad, CEO, Dr. Reddy's Laboratories, said, "the final approval, the first for an Indian Pharmaceutical Company, marks a significant milestone for Dr. Reddy's, setting the stage for the launch of our first specialty branded product in the United States. We have not made a final decision on the launch date. But we are making all necessary preparations for the launch and are in the process of finalizing a co-promotion partner for AmVaz (Amlodipine Maleate) in the United States.

The Company has active development programs on a number of differentiated compounds in major therapeutic categories and expects additional NDA filings during the current fiscal year.

The Company is also preparing to launch Amlodipine Maleate in Europe upon expiration of the Supplementary Protection Certificate in March 2004.

Dr. Reddy's US product pipeline currently comprises 27 ANDAs, 2 NDAs (including Amlodipine Maleate) and 44 DMFs. Of these ANDAs, 20 were submitted under Paragraph IV. During the current fiscal, the Company expects to file 15-18 ANDAs, 15 DMFs and additional NDAs.

Table of Contents

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 4, 2003

By:

/s/ Santosh Kumar Nair

(Signature)*

Santosh Kumar Nair
Company Secretary

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