

DR REDDYS LABORATORIES LTD

Form 6-K

October 07, 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**

For the month of September, 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

Dr. Reddy s announces ANDA filing for Rosiglitazone Maleate

Dr. Reddy s Safety, Health and Environment Annual Report Released

Dr. Reddy s announces USFDA approval for Nefazodone HCL tablets

Signatures

Table of Contents

Table of Contents

- (1) Press Release, Dr. Reddy s announces ANDA filing for Rosiglitazone Maleate, September 9, 2003.
- (2) Press Release, Dr. Reddy s Safety, Health and Environment Annual Report Released, September 16, 2003.
- (3) Press Release, Dr. Reddy s announces USFDA approval for Nefazodone HCL tablets, September 17, 2003.

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 announces ANDA filing for Rosiglitazone Maleate

Hyderabad, India, September 9, 2003:

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 Rosiglitazone Maleate tablets, equivalent to 2mg, 4mg and 8 mg, with a Paragraph IV Certification on two of the three Orange Book patents listed for the drug.

Dr. Reddy's notified GlaxoSmithKline, upon which the latter filed a lawsuit against the Company in the United States District Court for the District of New Jersey, alleging patent infringement on the 803 patent. Dr. Reddy's believes that it has the first-to-file status 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.

Rosiglitazone Maleate is the generic version of GlaxoSmithKline's Avandia® and is indicated for the management of type 2 diabetes. The brand had annual sales in the United States of approximately US \$1.1 billion (Source: IMS 2002).

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

Table of Contents

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.

Contact Information

Investors and Financial Analysts:

Nikhil Shah at nikhilshah@drreddys.com or on +91-40-55511532

Media: R Rammohan at rammohanr@drreddys.com or on +91-40-55511620 or Pratap Antony at pratapa@drreddys.com or on +91-40-55511634.

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 Safety, Health and Environment Annual Report Released

Hyderabad, India, September 16, 2003:

Dr. Reddy's Laboratories today released its first Corporate Safety, Health & Environment (SHE) Annual Report for the year 2002-2003. The report was released by Satish Reddy, Chief Operating Officer, Dr. Reddy's, at a function organized for employees at the Company's corporate office.

Speaking at the release function, GV Prasad, CEO, Dr. Reddy's said, "It is wonderful to witness the release of this report. It has been a dream for me since I first got involved in addressing environment related issues for the Company ten years ago. Harmony & Social Responsibility is our corporate value. We are backing the value with investments, commitment, passion and focus. It is our stated objective to make a difference to the communities we live in. Our experience has demonstrated that being eco-friendly actually helps to be competitive on a sustainable basis."

Dr. Reddy's has taken up several safety, health and environment initiatives. The Company has set up a Zero Liquid Effluent Discharge (ZLED) facility at its bulk actives manufacturing unit at Miryalguda, Andhra Pradesh. This has been operational for the last one year. The Company plans to commission Zero Liquid Effluent Discharge facilities in two of its Bulk Actives manufacturing units. Both these projects are expected to become operational during this financial year. This will make all the six Bulk Actives manufacturing units of Dr. Reddy's Zero Liquid Discharge plants.

For more details on the SHE initiatives of Dr. Reddy's, read the Corporate Safety, Health & Environment Annual Report available at <http://www.drreddys.com>.

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

Table of Contents

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.

Contact Information

Media: R Rammohan at rammohanr@drreddys.com or on +91-40-55511620 or Pratap Antony at pratapa@drreddys.com or on +91-40-55511634.

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 announces USFDA approval for Nefazodone HCL tablets

Hyderabad, India, September 17, 2003:

Dr. Reddy's Laboratories Limited (NYSE: RDY) announced today that the U. S. Food and Drug Administration has issued final approval for the Company's Abbreviated New Drug Application for Nefazodone Hydrochloride tablets 50, 100, 150, 200 and 250 mg. The product will be marketed through the Company's alliance partner, Par Pharmaceuticals.

Nefazodone hydrochloride is the AB-rated generic equivalent of Bristol Myers Squibb's Serzone®. Serzone® is indicated for the treatment of depression. As per IMS 2002, the product had annual US brand sales of approximately \$261 million.

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.

Table of Contents

Contact Information

Media: R Rammohan at rammohanr@drreddys.com or on +91-40-55511620 or Pratap Antony at pratapa@drreddys.com or on +91-40-55511634.

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

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: October 7, 2003

By: /s/ Santosh Kumar Nair

(Signature)*

Santosh Kumar Nair
Company Secretary

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