

DR REDDYS LABORATORIES LTD

Form 6-K

June 06, 2012

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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**

**May and June 2012**

**Commission File Number 1-15182**

## **DR. REDDY S LABORATORIES LIMITED**

**(Name of Registrant)**

**8-2-337, Road No. 3, Banjara Hills**

**Hyderabad, Andhra Pradesh 500 034, India**

**+91-40-4900-2900**

**(Address of Principal Executive Offices)**

## Edgar Filing: DR REDDYS LABORATORIES LTD - Form 6-K

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.

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### **Press Release**

Dr. Reddy's Laboratories Ltd.  
8-2-337, Road No. 3  
Banjara Hills, Hyderabad - 500 034  
Andhra Pradesh, India

Tel: 91-40-4900-2900

Fax: 91-40-4900-2999

[www.drreddys.com](http://www.drreddys.com)

### **Dr. Reddy's announces the Launch of Clopidogrel Tablets, USP**

**Hyderabad, India, May 18, 2012:** Dr. Reddy's Laboratories (NYSE: RDY) announced today that it has launched CLOPIDOGREL TABLETS, USP 75 mg & 300 mg, a bioequivalent generic version of PLAVIX® in the US market on May 18, 2012. The ANDAs for Clopidogrel Tablets USP, 75 mg & 300 mg are approved by the United States Food & Drug Administration (USFDA). Dr. Reddy's Laboratories was among the first applicants to submit a substantially complete ANDA for Clopidogrel Tablets USP, 300 mg with a Paragraph IV certification, and was awarded 180 days of marketing exclusivity for this strength.

The PLAVIX® brand had U.S. sales of approximately \$6.740 billion for the most recent twelve months ending March 2012 according to IMS Health.

Dr. Reddy's Clopidogrel Tablets USP, 75 mg are available in bottle count sizes of 30, 90 and 500 and Clopidogrel Tablets USP, 300 mg are available in blister packs of 30's count.

### **Disclaimer**

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.

### **About Dr. Reddy's**

Dr. Reddy's Laboratories Ltd. (NYSE: RDY) is an integrated global pharmaceutical company, committed to providing affordable and innovative medicines for healthier lives. Through its three businesses - *Pharmaceutical Services and Active Ingredients*, *Global Generics* and *Proprietary Products* - Dr. Reddy's offers a portfolio of products and services including APIs, custom pharmaceutical services, generics, biosimilars, differentiated formulations and NCEs. Therapeutic focus is on gastro-intestinal, cardiovascular, diabetology, oncology, pain management, anti-infective and pediatrics. Major markets include India, USA, Russia and CIS, Germany, UK, Venezuela, S. Africa, Romania, and New Zealand. For more information, log on to: [www.drreddys.com](http://www.drreddys.com)

*Plavix® is a registered trademark of Sanofi-Aventis.*

IMS National Sales Perspectives: Retail and Non-Retail MAT March 2012

### **CONTACT INFORMATION**

#### **Investors and Financial Analysts:**

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Milan Kalawadia (North America) at [mkalawadia@drreddys.com](mailto:mkalawadia@drreddys.com) or at 908-203-4931

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### **Dr. Reddy's announces the Launch of Over-the-Counter Lansoprazole Delayed-Release Capsules**

**Hyderabad, India, May 21, 2012:** Dr. Reddy's Laboratories (NYSE: RDY) announced today that it has launched over-the-counter (OTC) Lansoprazole delayed-release capsules in the US market on May 18, 2012 following Dr. Reddy's ANDA approval by the United States Food & Drug Administration (USFDA).

Dr. Reddy's will market the product under store brand labels in the U.S. market. The product is the bioequivalent version of Novartis Consumer Health's Prevacid® 24 HR capsule which received Rx-to-OTC switch approval with 3 year exclusivity from the FDA on March 18, 2009. The Prevacid® 24 HR capsule market had brand sales of approximately \$115 million for the twelve months ending March 2012 according to SymphonyIRI InfoScan Reviews.

Dr. Reddy's Lansoprazole Capsule in 15 mg strength is available in 14, 28 and 42 count pack size.

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### **Trademarks**

*Prevacid® 24 HR is a registered trademark of Takeda Pharmaceuticals North America, Inc.*

*SymphonyIRI InfoScan Reviews; FDMx 52 weeks ending March 2012.*

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#### **Investors and Financial Analysts:**

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### **Media:**

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**Dr. Reddy's Laboratories Ltd. and Merck Serono announce collaboration to develop and commercialize Biosimilars**

- *Combined expertise of Dr. Reddy's and Merck Serono to deliver on promise of Biosimilars*  
**Hyderabad, India, June 6, 2012**

Dr. Reddy's Laboratories Ltd. [NYSE:RDY] and Merck Serono, a division of Merck KGaA, Darmstadt, Germany, announced today a partnership to co-develop a portfolio of biosimilar compounds in oncology, primarily focused on monoclonal antibodies (MAbs). The partnership covers co-development, manufacturing and commercialization of the compounds around the globe, with some specific country exceptions.

Dr. Reddy's has been a pioneer and leader in the biosimilars space through proven product development capabilities and the launch of four biosimilars molecules to date. The partnership with Merck Serono expands on Dr. Reddy's presence in the biosimilar space in select emerging markets and enables participation globally.

G. V. Prasad, Vice-Chairman and CEO of Dr. Reddy's Laboratories said, "We strongly believe that biosimilars is an important area of future growth and these products give us the opportunity to provide affordable and innovative medicines to patients across the globe. With the recent EMA and FDA guidance on biosimilars, it is clear that any significant player in the field will need strong biologics development, manufacturing and commercialization capabilities. Merck Serono's and Dr. Reddy's joint expertise in these fields makes for a powerful global partnership."

"Our expertise in developing, manufacturing, and commercializing biopharmaceuticals gives us a clear advantage in the biosimilars field, and the partnership with Dr. Reddy's will bring their first-in-market experience in biosimilars, as well as their expertise in generics and Emerging Markets, to the table," added Stefan Oschmann, Chief Executive Officer of Merck Serono. "Sharing know-how, risks and rewards is the right approach to enter the emergent biosimilars market and will be a win-win for both parties. It further strengthens Merck Serono's promise to live science and transform lives, by increasing access to quality medicines for patients, physicians and payers."

The deal structure calls for Merck Serono and Dr. Reddy's to co-develop the molecules included in the agreement. Dr. Reddy's will lead early product development and complete Phase I development. Upon completion of Phase I, Merck Serono will take over manufacturing of the compounds and will lead Phase III development. The agreement is based on full R&D cost sharing.

Merck Serono will undertake commercialization globally, outside the US and with the exception of select emerging markets which will be co-exclusive or where Dr. Reddy's maintains exclusive rights. Dr. Reddy's will receive royalty payments from Merck Serono upon commercialization. In the US, the parties will co-commercialize the products on a profit-sharing basis. Additional terms of the deal were not disclosed.

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estimates and could be materially different from actual results in the future.

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### **About Biosimilars**

Biologics, or large molecule pharmaceuticals are complex, highly targeted and generally expensive therapies that are a growing contributor to overall global healthcare spend. The burden on patients and payers has resulted in an increasing demand for generic alternatives to off-patent biologics, most commonly known as biosimilars. Patent expiries in the immediate future present opportunities to serve the global population with high quality, low cost equivalents of proprietary biopharmaceuticals, commonly known as biosimilars.

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### **About Merck Serono**

Merck Serono is the division for innovative prescription pharmaceuticals of Merck KGaA, Darmstadt, Germany, a global pharmaceutical and chemical company. Headquartered in Geneva, Switzerland, Merck Serono discovers, develops, manufactures and markets innovative small molecules and biopharmaceuticals to help patients with unmet medical needs. In the United States and Canada, EMD Serono operates through separately incorporated affiliates.

Merck Serono has leading brands serving patients with cancer (Erbix<sup>®</sup>, cetuximab), multiple sclerosis (Rebif<sup>®</sup>, interferon beta-1a), infertility (Gonal-F<sup>®</sup>, follitropin alfa), endocrine and metabolic disorders (Saizen<sup>®</sup> and Serostim<sup>®</sup>, somatropin), (Kuvan<sup>®</sup>, sapropterin dihydrochloride) as well as cardiometabolic diseases (Glucophage<sup>®</sup>, metformin), (Concor<sup>®</sup>, bisoprolol), (Euthyrox<sup>®</sup>, levothyroxine). Not all products are available in all markets. With an annual R&D expenditure of more than € 1 billion, Merck Serono is committed to growing its business in specialist-focused therapeutic areas including neurodegenerative diseases, oncology, fertility and endocrinology, as well as new areas potentially arising out of research and development in autoimmune and inflammatory diseases.

### **About Merck**

Merck is a global pharmaceutical and chemical company with total revenues of € 7.7 billion in 2009, a history that began in 1668, and a future shaped by approximately 40,000 (including Merck Millipore) employees in 64 countries. Its success is characterized by innovations from entrepreneurial employees. Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds an approximately 70% interest and free shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

For more information, please visit [www.merckserono.com](http://www.merckserono.com) or [www.merck.de](http://www.merck.de)

## **CONTACT INFORMATION**

### **Investors and Financial Analysts:**

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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: June 6, 2012

By: /s/ Sandeep Poddar  
Name: Sandeep Poddar  
Title: Company Secretary