

DR REDDYS LABORATORIES LTD

Form 6-K

March 05, 2003

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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 February, 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.

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Press Release, Dr. Reddy s files lawsuit against Pfizer regarding Sertraline ANDA

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- (2) Press Release, Dr. Reddy's Laboratories and Leiner Health Products to sign exclusive 15-year OTC product development and marketing agreement; Dr. Reddy's CEO to join Leiner's Board of Directors, February 24, 2003.
- (3) Press Release, Dr. Reddy's files lawsuit against Pfizer regarding Sertraline ANDA, February 24, 2003
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**Press Release**

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

**Novo Nordisk to move forward on development of Dr. Reddy s Balaglitazone (DRF 2593); Not to pursue further development of Ragaglitazar (DRF 2725)**

Hyderabad, India, February 6, 2003:

Dr. Reddy s Laboratories (NYSE: RDY) announced that Novo Nordisk has completed analysis of Phase 2 data on the insulin sensitiser Balaglitazone (DRF 2593; NN 2344). Based on the good clinical efficacy and safety profile obtained in these studies, Novo Nordisk has decided to progress the development of Balaglitazone. This compound was out-licensed by Dr. Reddy s to Novo Nordisk in March 1997.

The Company also announced that Novo Nordisk has decided not to pursue further development of Ragaglitazar (DRF2725; NN622). The decision has been taken after Novo Nordisk performed a renewed benefit/risk assessment of the compound, including analysis of both the clinical Phase 3 data and the tumour findings in the long-term animal studies. This compound was out-licensed by Dr. Reddy s to Novo Nordisk in August 1998. The financial terms and conditions of the original agreement remain unchanged.

Balaglitazone (DRF 2593; NN2344) is a potent insulin sensitizer that acts as a partial PPAR (peroxisome proliferator-activated receptor) gamma agonist. Ragaglitazar (DRF 2725; NN622) is an insulin sensitizer that acts as a dual PPAR (peroxisome proliferator-activated receptor) alpha and gamma agonist. In July 2002, Novo Nordisk had announced that it was suspending Phase 3 clinical trials of Ragaglitazar (DRF 2725; NN622) after it found tumors in one mouse and several rats in long-term animal studies.

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 programme of Dr. Reddy s focuses on cancer, diabetes, bacterial infections and pain management.

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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

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

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**Dr. Reddy's Laboratories and Leiner Health Products sign exclusive 15-year OTC product development and marketing agreement;  
Dr. Reddy's CEO to join Leiner's Board of Directors**

Hyderabad, India, and Carson, California, February 24, 2003:

Dr. Reddy's Laboratories (NYSE: RDY) and Leiner Health Products today announced the completion of a 15-year exclusive product development and marketing agreement. This agreement is exclusively for Dr. Reddy's over-the-counter (OTC) drug products. Key elements of the agreement include: An exclusive marketing partnership with Leiner to distribute OTC products, a comprehensive Rx-to-OTC product pipeline, development of innovative private label OTC products and establishment of an executive steering committee to manage product development.

The companies also announced that G. V. Prasad, Vice Chairman and CEO of Dr. Reddy's Laboratories Limited, will join the Board of Directors of Leiner Health Products on March 27, 2003.

The partnership combines Dr. Reddy's scientific and technical expertise in pharmaceutical product development with Leiner's trusted leadership in private label sales, marketing and distribution in the United States market, said Mark Hartman, Executive VP, Generics Business, Dr. Reddy's Laboratories. "We chose Leiner to help us expand our OTC business as a complement to our growing generics business in the United States because of its dedication to private label sales and expertise in bringing self-care solutions to market quickly and efficiently," Hartman added.

The recent completion of our agreement with Dr. Reddy's Laboratories and the participation of G.V. Prasad on our Board is a significant milestone in the growth of Leiner's OTC business, said Gale Bensussen, President of Leiner Health Products. "This strategic partnership has the potential to create enormous value for our retail partners and accelerate our growth as a leading supplier of OTC products. The alliance is a means of linking Dr. Reddy's product development



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capabilities with Leiner's private label sales expertise in servicing the nation's leading retailers, Bensussen added.

**About Dr. Reddy's Laboratories**

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.

**About Leiner Health Products**

Leiner Health Products is a leading private label supplier of self-care solutions to mass-market retailers. Headquartered in Carson, Calif., Leiner is the nation's largest private label vitamin manufacturer and a leading private label manufacturer of OTC products. The company provides the nation's leading retailers with more than 3,000 private label products.

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 files lawsuit against Pfizer regarding Sertraline ANDA**

Hyderabad, India, February 24, 2003:

Dr. Reddy s Laboratories (NYSE: RDY) today announced that the Company had filed a lawsuit seeking declaratory judgement against Pfizer in the United States District Court for the District of New Jersey regarding its Abbreviated New Drug Application (ANDA) for Sertraline HCl. The lawsuit seeks a declaratory judgement that the claims of certain Pfizer patents are invalid and/or not infringed.

The Company had filed an ANDA with the U.S. Food and Drug Administration (USFDA) for Sertraline HCl tablets, equivalent to 25, 50 and 100 mg base, with a Paragraph IV certification on four of the five patents listed on the Orange Book. Dr. Reddy s notified Pfizer of the filing. Pfizer did not file a lawsuit against Dr. Reddy s within the forty-five (45) day period prescribed by the Hatch-Waxman Act.

Sertraline HCl is the generic version of Pfizer s Zoloft®. It is indicated for use in the treatment of major depressive disorder, obsessive-compulsive disorder, panic disorder, post-traumatic stress disorder and premenstrual dysphoric disorder. The product had US brand sales of \$2.4 billion in the year 2002 (Source: Verispan)

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**Notes to the Editor:**

As of quarter ended December 31, 2002, Dr. Reddy s has filed 30 ANDAs with the United States Food and Drug Administration (USFDA), of which 17 are Para IV filings. Nineteen ANDAs are currently pending approval with the USFDA. Fourteen of these are Para IV filings which address

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a total market value of US \$ 12.7 billion (IMS 2002).

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**COMMUNICATION SENT TO STOCK EXCHANGES**

**Sub: Disclosure of shareholding**

February 10, 2003: Pursuant to Sub Regulation (3) of Regulation 7 of the SEBI (Substantial Acquisition of Shares and Takeover) Regulations, 1997, we hereby intimate you that Fidelity Investments has acquired 80,000 shares in the Company which taken together with the shares and voting rights held by it, would entitle it to more than 5% shares or voting rights in the Company.

Fidelity Investments has informed the Company vide its letter dated January 31, 2003 that their shareholding in the Company taken together with the ADRs is 3,869,838 which is equivalent to 5.06% of the paid up capital of the Company. The letter received from Fidelity Investments is enclosed.

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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**

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(Registrant)

Date:  
March 5,  
2003

By: /s/ Santosh Kumar Nair

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(Signature)\*  
**Santosh Kumar Nair**  
**Company Secretary**

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