DR REDDYS LABORATORIES LTD
Form 6-K
February 01, 2010

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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 January 2010
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 þ Form 40-F o

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): o

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): o

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 o No þ

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.
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Tel: 91 40 373 1946
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www.drreddys.com

Dr. Reddy s and Rheoscience announce headline results from First Phase III clinical trial of Balaglitazone (DRF 2593)

Significant reduction in HbA1c with Balaglitazone and improved safety profile

January 04, 2010, Hyderabad: Dr. Reddy s Laboratories Ltd. (NYSE: RDY) and Rheoscience, a subsidiary of Nordic Bioscience A/S, today announced the headline results from the first phase III study for their investigational agent, Balaglitazone. The study (Study 307) was a phase III, randomized, double blind, parallel-group placebo- and active comparator-controlled clinical study to determine the efficacy and safety of balaglitazone. **The study showed that the trial met its primary endpoint of reduction in HbA1c.**

The study explored the impact of adding placebo, Balaglitazone 10mg, Balaglitazone 20mg or Pioglitazone 45mg to a background treatment regimen of stable insulin therapy for a period of 26 weeks. The primary endpoint was HbA1c reduction, while several secondary endpoints including fasting plasma glucose, oedema, weight gain, and body composition were considered.

In all, 409 patients were randomized in roughly equal proportions across the four arms of the study. All three active arms (Balaglitazone 10mg, 20mg and Pioglitazone 45mg) showed similar levels of efficacy with respect to both HbA1c and fasting plasma glucose.

	Balaglitazone 10mg	**Balaglitazone 20mg**	**Pioglitazone 45mg**
HbA1c reduction against placebo	0.99%	1.11%	1.22%
FPG reduction against placebo	1.42 mmol/L	1.80 mmol/L	1.35 mmol/L

All three active arms showed good tolerability and adverse event profile, with Balaglitazone 10mg demonstrating less water retention, less fat accumulation, lower weight/BMI gain and less bone loss when compared to the Pioglitazone arm. Adverse events were numerically similar across the three active arms, with adverse events of special interest (bone fracture, hematuria, heart failure, cardiac ischemia, oedema, weight gain) being numerically under-represented in the Balaglitazone 10mg group compared to Pioglitazone 45mg.

These results offer the opportunity for a constructive series of dialogues with both potential partners as well as regulatory agencies. We look forward to working with Rheoscience to define the path forward for Balaglitazone , said GV Prasad, Vice Chairman & CEO, Dr. Reddy s.

Commenting on these results, Dr. Claus Christiansen, Chairman- Nordic Bioscience said We are encouraged by these results, which demonstrate the safety and efficacy of Balaglitazone, especially of the 10mg dose in relation to Pioglitazone. We intend to further seek guidance from regulatory agencies on additional studies needed to register Balaglitazone.

Data from the study will be submitted for presentation at upcoming international scientific meetings and to peer-reviewed journals.

Notes to the Editor

About Balaglitazone

Balaglitazone is a novel partial agonist of PPAR-gamma, which elicits only 52% of the PPAR-gamma activation observed with both pio- and rosiglitazone. Pre-clinical studies have indicated that besides robust glucose lowering ability, balaglitazone results in lower body fluid accumulation, lower fat accumulation, less heart enlargement and no

reduction of bone formation, indicating that Balaglitazone may be able to displace the balance between desired and side effects, and thus show a better safety profile than full agonists of PPAR-gamma.

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About the Balaglitazone programme

The Balaglitizone Phase III clinical trial programme is designed as multicenter, multi-country, randomized, controlled (active or placebo), double-blind and open studies.

About Diabetes

Type 2 diabetes is a major cause of morbidity and mortality in the industrialized world, with cardiovascular disease as the leading cause of death, accounting for almost 50% of all T2D deaths.

Furthermore, the number of T2D patients is increasing rapidly, and the number of patients is expected to reach between 300 and 380 million by 2025, thereby placing an enormous economical burden on global healthcare.

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

Established in 1984, Dr. Reddy s Laboratories (NYSE: RDY) is an emerging global pharmaceutical company. We fulfill our purpose of providing affordable and innovative medicines through three core businesses: Pharmaceutical Services and Active Ingredients, Global Generics and Proprietary Products. Our products are marketed globally, with a focus on India, US, UK, Germany and Russia. **www.drreddys.com**

About Rheoscience

Rheoscience is a Danish biopharmaceutical company focused on the discovery and development of novel pharmaceutical products for the treatment of metabolic diseases such as diabetes and obesity. Rheoscience has unparalleled experience in developing drugs for metabolic disorders and draws on this to advance its own pipeline of innovative compounds and to underpin its successful, profitable contract research business.

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Press Release

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Dr. Reddy s Q3 FY10 Financial Results
Revenues at Rs. 17,296 million
EBITDA at Rs. 3,666 million
Profits after Tax adjusted for impairment at Rs. 2,307 million

Hyderabad, India, January 20, 2010: Dr. Reddy s Laboratories Ltd. (NYSE: RDY) today announced its unaudited financial results for the third quarter ended December 31, 2009 under International Financial Reporting Standards (IFRS).

Key Highlights

Consolidated revenues at Rs. 17.3 billion ($373 million) in Q3 FY10 as against Rs. 18.4 billion ($397 million) in Q3 FY09, representing a decline of 6%. Excluding revenues from sumatriptan in the previous year, the 17% growth is largely driven by the key markets of India and Russia in Global Generics and PSAI.

Consolidated revenues for nine months FY10 at Rs. 53.9 billion ($1.2 billion); YoY growth of 9%. EBITDA at Rs. 3.7 billion ($79 million) in Q3 FY10. EBITDA for nine months FY10 at Rs. 11.8 billion ($255 million) represents a YoY growth of 31%. Adjusted PBT for the quarter is at Rs. 2.6 billion ($56 million).

During the quarter, many healthcare insurance providers in Germany announced their final tender results indicating a higher pace of transition to the tender based model in the German generics pharmaceutical market, with an associated significant deterioration in prices from the previous year s levels. As a result of this, the carrying value of betapharm s goodwill and intangibles were tested for impairment**. A non-cash write-down of intangible assets and beta brand amounting to Euro 48 million and a non-cash write-down of goodwill amounting to Euro 76 million were recorded for the quarter.** The overall net impact on Income Statement was Euro 109 million after a reversal of deferred tax liability relating to intangibles and beta brand.

Loss for the quarter is at Rs. 5.2 billion ($112 million) while Adjusted Profits after tax (PAT) for the quarter is at Rs. 2.3 billion ($50 million). Adjusted PAT* for nine months of this fiscal is at Rs. 7.3 billion ($158 million) as against adjusted PAT of Rs. 5.1 billion ($110 million) in the same period for previous year, representing a growth of 43%.

During the quarter, the company launched 27 new generic products, filed 16 new product registrations and filed 11 DMFs globally.

* *Note: Adjusted PAT represents PAT adjusted for one-time impacts like impairment (Q3 FY10), betapharm workforce restructure costs (Q1 FY10) and Atlanta facility closure costs (Q1 FY10)*

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All figures in millions, except EPS *All dollar figures based on convenience translation rate of 1USD = Rs 46.40*

Dr. Reddy s Laboratories Limited and Subsidiaries
Unaudited Condensed Consolidated Income Statement

	Q3 FY10			Q3 FY09			
Particulars	**($)**	**(Rs.)**	**%**	**($)**	**(Rs.)**	**%**	**Growth %**
Revenue	**373**	**17,296**	**100**	**397**	**18,401**	**100**	**(6)**
Cost of revenues	183	8,487	49	175	8,129	44	4
Gross profit	**190**	**8,809**	**51**	**221**	**10,272**	**56**	**(14)**
Operating Expenses							
Selling, general & administrative expenses[(a)]	117	5,431	31	116	5,382	29	1
Research and development expenses, net	19	892	5	22	1,027	6	(13)
Write down of intangible assets	74	3,456	20				
Write down of goodwill	111	5,147	30				
Other (income)/expenses, net	(4)	(171)	(1)	2	110	1	
Total Operating Expenses	**318**	**14,755**	**85**	**140**	**6,519**	**35**	
Results from operating activities	**(128)**	**(5,946)**	**(34)**	**81**	**3,753**	**20**	
Finance income [(b)]	(1)	(47)	(0)	(2)	(89)	(0)	
Finance expenses [(c)]	2	97	1	17	788	4	
Finance expenses, net	**1**	**50**	**0**	**15**	**699**	**4**	
Share of profit/(loss) of equity accounted investees	0	2	0	0	8	0	
Profit before income tax	**(129)**	**(5,994)**	**(35)**	**66**	**3,062**	**17**	
Income tax expense	17	777	4	(13)	(617)	(3)	
Profit for the period	**(112)**	**(5,217)**	**(30)**	**53**	**2,445**	**13**	
Attributable to:							
Equity holders of the company	(112)	(5,217)	(30)	53	2,445	13	
Minority interest							

Profit for the period	**(112)**	**(5,217)**	**(30)**	**53**	**2,445**	**13**
Diluted EPS	**(0.7)**	**(30.9)**		**0.3**	**14.5**	

Notes:

(a) Includes amortization charges of Rs. 374 million in Q3 FY10 and Rs. 340 million in Q3 FY09.

(b) Includes forex loss of Rs. 44 million in Q3 FY10.

(c) Includes forex loss of Rs. 493 million in Q3 FY09.

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Segmental Analysis

Global Generics

Revenues of Global Generics for the nine months at Rs. 37.4 billion ($807 million) represent a growth of 7%.Revenues from Global Generics business at Rs. 11.7 billion ($253 million) in Q3 FY10 as against Rs. 13.7 billion ($295 million) in Q3 FY09. Excluding the revenues from sumatriptan the growth is at 16% driven by the key markets of India and Russia.

Revenues from North America at Rs. 3.0 billion ($64 million) in Q3 FY10 as against Rs. 6.7 billion ($143 million) in Q3 FY09. Excluding the revenues from sumatriptan the growth is flat.

The total cumulative ANDA filings are 141. 62 ANDAs are pending approval at the USFDA of which 35 are Para IVs and 13 are FTFs.

Revenues from Europe at Rs. 2.6 billion ($56 million) in Q3 FY10 as against Rs. 2.5 billion ($54 million) in Q3 FY09, representing a growth of 3%.

Revenues from Germany increase by 2% to Rs. 2.0 billion ($44 million) in Q3 FY10.

Revenues from Rest of Europe grew by 6% to Rs. 534 million ($12 million) in Q3 FY10.

Revenues from Russia & Other CIS markets at Rs. 2.8 billion ($60 million) in Q3 FY10 as against Rs. 2.0 billion ($43 million) in Q3 FY09, representing a growth of 38%.

Revenues in Russia at Rs. 2.3 billion ($49 million) in Q3 FY10 as against Rs. 1.6 billion ($34 million) in Q3 FY09 representing a YoY growth of 45%.

The secondary prescription sales trend as per Pharmexpert for the eight months of April to November compared to same period last year indicates a dollar growth of 13% for Dr. Reddy s as against the industry s growth of 2%.

Revenues in Other CIS markets increase by 13% to Rs. 488 million ($11 million) in Q3 FY10 as against Rs. 434 million ($9 million) in Q3 FY09.

Revenues in India at Rs. 2.6 billion ($57 million) in Q3 FY10 from Rs. 2.0 billion ($42 million), representing a growth of 34% led by key brands of Omez, Nise, Stamlo Beta, Reditux & Stamlo.

The YoY growth of 34%, is largely driven by volume growth of 29% from existing portfolio and 7% by new product launches.

The secondary sales trend as per ORG IMS for the eight months April to November 2009 indicates a growth of 20% for Dr. Reddy s as against an industry growth of 16% and the Top 10 Companies growth of 19%.

18 new products launched during the quarter. 56 new products launched in the nine months FY10 contributed 4% to nine months sales.

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Pharmaceutical Services and Active Ingredients (PSAI)

Revenues from Pharmaceutical Services & Active Ingredients for the nine months at Rs. 15.5 billion ($334 million) represent a growth of 11%. Revenues from (PSAI) at Rs. 5.2 billion ($113 million) in Q3 FY10 as against Rs. 4.4 billion ($96 million) in Q3 FY09 ; YoY growth of 17% driven by the regions of India and RoW.

During the quarter, 11 DMFs were filed globally, with 3 in US and 8 in Europe. The cumulative DMF filings as of Dec 09 are 388.

Income Statement Highlights:

Gross profit at Rs. 8.8 billion ($190 million) in Q3 FY10 represents a margin of 51% to revenues as against 56% in Q3 FY09. This change in gross margins is on account of a favorable mix of high margin revenues from sumatriptan in the previous year.

Selling, General & Administration (SG&A) expenses excluding amortization for the quarter at Rs. 5.1 billion ($117 million), remained flat as compared to both previous year and sequentially.

Amortization expenses for the quarter at Rs. 374 million ($8 million) showed a modest growth from previous year of Rs. 340 million ($7 million).

Other operating income of Rs. 171 million in Q3 FY10 as against Other operating expenses of Rs. 110 million in Q3 FY09. The movement is largely on account of the fact that in Q3 FY09, a provision for damages payable of Rs. 224 million was recorded on account of the German court upholding the validity of the olanzapine patent of the innovator in Germany.

R&D expenses at Rs. 892 million in Q3 FY10 represent 5% of revenues.

Finance costs (net) are at Rs. 50 million in Q3 FY10 as against Rs. 699 million in Q3 FY09. The change is mainly on account of :

Net forex loss of Rs. 44 million in Q3 FY10 as against Rs. 493 million in Q3 FY09.

Net interest expense of Rs. 19 million in Q3 FY10 as against Rs. 215 million in Q3 FY09.

Loss for the quarter is at Rs. 5.2 billion ($112 million) and Adjusted PAT for the quarter is at Rs. 2.3 billion ($50 million). Adjusted PAT for nine months FY10 is at Rs. 7.3 billion ($158 million) as against adjusted PAT of Rs. 5.1 billion ($110 million) in the previous year, representing a growth of 43%.

The adjusted effective tax rate for the nine months is at 19%.

Adjusted diluted EPS is at Rs. 13.6 (29 cents) for the quarter and Rs. 43.3 (93 cents) for nine months FY10.

Capital expenditure for nine months FY10 is at Rs. 2.6 billion ($56 million).

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About Dr. Reddy s

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Notes

1. All the above analyses are based on consolidated IFRS financials.

2. Detailed analysis of the financials is available on the Company s website at www.drreddys.com.

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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)

By: /s/ V.S. Suresh
Name: V.S. Suresh
Title: Company Secretary

Date: February 1, 2010