

DR REDDYS LABORATORIES LTD

Form 6-K

April 08, 2013

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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**

Month of March 2013

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

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(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 Laboratories Ltd.  
8-2-337, Road No. 3  
Banjara Hills, Hyderabad - 500 034  
Andhra Pradesh, India  
  
Tel: 91-40-4900-2900  
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[www.drreddys.com](http://www.drreddys.com)

**Dr. Reddy s Announces the Launch of Zoledronic Acid Injection**

*Hyderabad, India, March 05, 2013*

Dr. Reddy s Laboratories (NYSE: RDY) announced today that it has launched Zoledronic Acid Injection (4 mg/5 mL), a bioequivalent generic version of Zometa® (zoledronic acid) 4 mg/5 mL Injection in the US market on March 4, 2013, following the approval by the United States Food & Drug Administration (USFDA) of Dr. Reddy s ANDA for Zoledronic Acid Injection (4 mg/5 mL).

Dr. Reddy s Zoledronic Acid Injection 4 mg/5mL is available in a single use vial of concentrate.

**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)

Zometa® is a registered trademark of Novartis AG

**For more information, please contact:**

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Milan Kalawadia (USA) at [mkalawadia@drreddys.com](mailto:mkalawadia@drreddys.com) /+1 908-203-4931

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**Dr. K. Anji Reddy is no more**

***Hyderabad, India, March 15, 2013***

Dr. K. Anji Reddy, Founder & Chairman of Dr. Reddy s Laboratories Ltd., passed away this evening in Hyderabad. He was ailing for some time.

Dr. Reddy s mission in life was to provide innovative new medicines at a price that the common man could afford. His passion for research became legendary when Dr. Reddy s Laboratories Ltd. became the first pharmaceutical company of India to initiate basic drug discovery research in 1993. A B.Sc graduate from Bombay University with specialization in Pharmaceutical Science and Fine Chemicals, Dr. Reddy obtained his Ph.D in Chemical Engineering from National Chemical Laboratory, Pune. Soon after his studies, he served in the state-owned IDPL before he founded the company in 1984.

Under his leadership, the company became a pioneer and trendsetter in the Indian pharmaceutical industry. Dr. Reddy also set-up the Institute of Life Sciences at Hyderabad, which is a public-private partnership with the Government of Andhra Pradesh for carrying out cutting edge research in Life Sciences. Critically aware of his own responsibility to society, Dr. Reddy in the last decade was renowned for his outcome based institutionalized philanthropy that positively impacted the lives of nearly 5 million underprivileged citizens, mainly children and youth.

In 1998, Dr. Reddy set up the Naandi Foundation as a Public Charitable Trust. Naandi is probably India s largest rural safe drinking water provider, and gives midday meals to 1.3 million government school-going children and farmers. Dr. Reddy took up the cause of safe motherhood and newborn care, thereby reducing maternal and neo-natal care in India. He also spearheaded and founded the Neo Natal Intensive Care and Emergencies called NICE Foundation , the only institute for newborns in Asia that also does large scale community outreach programs, saving a number of lives on a daily basis.

Satish Reddy, MD and COO of Dr. Reddy s Laboratories Ltd and son to Dr. Reddy said: *Dr. Reddy touched millions of lives through his contribution to the Pharmaceutical industry and his Philanthropic efforts. In improving access to affordable, high quality medicines and in innovation, his contributions have been extraordinary. His philanthropic initiatives made a difference in the lives of so many Indians in the areas of livelihood, education, clean drinking water and healthcare. A nation is grateful to a man who paved a way for the delivery of affordable medicines to the masses and made us believe and take pride in innovation as a means to prosperity.*

Dr. Reddy served as a Member of the Prime Minister s Council on Trade & Industry, Government of India. He was the Chairman of Andhra Pradesh Industrial Development Corporation (APIDC), and President of The Indian Pharmaceutical Alliance. He served as a Board Member of GAIN, Switzerland (Global Alliance for Improved Nutrition) and also was on the Board of Directors for TB Alliance, New York (Global Alliance for TB Drug Development).

In April 2011, he was honored by the Government of India with the Padma Bhushan, one of the highest Civilian Awards in India, recognizing his distinguished service of high order in the field of Trade and Industry. In 2012, CNBC TV18 conferred the Lifetime Achievement Award (IBLA) on him for being a visionary who had spent a lifetime building up his company into a colossus with a global reach putting Indian industry on the world map.

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**Dr. Reddy s and Nordion Inc. (formerly MDS Inc.) settle claims**

***Hyderabad, India, March 22, 2013***

Dr. Reddy s Laboratories (NYSE: RDY) announced today that it had settled its claims against Nordion Inc. (formerly MDS Inc.), headquartered in Ottawa, Canada, in a case pending in the United States District Court for the District of New Jersey, for a cash payment of USD 22.5 Million by Nordion to Dr. Reddy s. The settlement was concluded on 20 March 2013, with the receipt of the settlement funds by Dr. Reddy s.

The case was brought by Dr. Reddy s in April 2009 seeking damages sustained by the company caused by a claimed breach by Nordion (then MDS) of its Laboratory Services Agreement with Dr. Reddy s. Nordion, as a contract research organization, provided laboratory services to Dr. Reddy s, including bio-equivalency studies, to support Dr. Reddy s regulatory applications for approval of generic drugs, including Abbreviated New Drug Applications (ANDAs) filed with the United States Food and Drug Administration (the USFDA) for approval to market generic drugs in the United States.

The case arose after the USFDA cited MDS with violations of good laboratory practices which caused the USFDA not to accept, without further substantiation, MDS s laboratory reports performed during the period 2000-2004.

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**About Dr. Reddy s**

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**Dr. Reddy's announces the launch of Zenatane (Isotretinoin Capsules USP)**

*Hyderabad, India, March 29, 2013*

Dr. Reddy's Laboratories (NYSE: RDY) announced today that it has launched Zenatane (Isotretinoin Capsules USP) in 20 mg and 40 mg, a therapeutically equivalent generic version of Accutane® (Isotretinoin Capsules USP) in the US market on March 28, 2013 following the approval by the United States Food & Drug Administration (USFDA) of Dr. Reddy's ANDA for Zenatane 10 mg, 20 mg and 40 mg.

The total market had U.S. sales of approximately \$309 Million for the most recent twelve months ending January 2013 according to IMS Health\*.

Dr. Reddy's Zenatane Capsules 10 mg, 20 mg, & 40 mg will be available in boxes of 30 (3 prescription packs of 10 capsules), as unit dose blisters.

**CONTRAINDICATIONS AND WARNINGS**

**Zenatane must not be used by female patients who are or may become pregnant. There is an extremely high risk that severe birth defects will result if pregnancy occurs while taking Zenatane in any amount, even for short periods of time. Potentially any fetus exposed during pregnancy can be affected. There are no accurate means of determining whether an exposed fetus has been affected.**

**Birth defects which have been documented following Zenatane exposure include abnormalities of the face, eyes, ears, skull, central nervous system, cardiovascular system, and thymus and parathyroid glands. Cases of IQ scores less than 85 with or without other abnormalities have been reported. There is an increased risk of spontaneous abortion, and premature births have been reported. Documented external abnormalities include: skull abnormality; ear abnormalities (including anotia, micropinna, small or absent external auditory canals); eye abnormalities (including microphthalmia); facial dysmorphism; cleft palate. Documented internal abnormalities include: CNS abnormalities (including cerebral abnormalities, cerebellar malformation, hydrocephalus, microcephaly, cranial nerve deficit); cardiovascular abnormalities; thymus gland abnormality; parathyroid hormone deficiency. In some cases death has occurred with certain of the abnormalities previously noted.**

**If pregnancy does occur during treatment of a female patient who is taking Zenatane, Zenatane must be discontinued immediately and she should be referred to an Obstetrician-Gynecologist experienced in reproductive toxicity for further evaluation and counseling.**

**Special Prescribing Requirements**

**Because of Zenatane teratogenicity and to minimize fetal exposure, Zenatane is approved for marketing only under a special restricted distribution program approved by the Food and Drug Administration. This program is called iPLEDGE. Zenatane must only be prescribed by prescribers who are registered and activated with the iPLEDGE program. Isotretinoin capsules must only be dispensed by a pharmacy registered and activated with iPLEDGE, and must only be dispensed to patients who are registered and meet all the requirements of iPLEDGE (see PRECAUTIONS).**

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Zenatane is a trademark of Dr. Reddy s Laboratories and or its affiliates.

Accutane® is a trademark of Hoffman- La Roche Inc.

iPLEDGE is a trademark of Covance, Inc.

\* IMS National Sales Perspectives: Retail and Non-Retail MAT January 2013

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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: April 8, 2013

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