DR REDDYS LABORATORIES LTD
Form 6-K
February 03, 2015
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SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

Report of Foreign Private Issuer

Pursuant to Rule 13a-16 or 15d-16

of the Securities Exchange Act of 1934

Month of January 2015

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)

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 x 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 x

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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FOR IMMEDIATE RELEASE

Curis and Aurigene Announce Collaboration, License and Option Agreement to Discover, Develop and Commercialize Small Molecule Antagonists for Immuno-oncology and Precision Oncology Targets

Agreement Provides Curis with Option to Exclusively License Aurigene s Antagonists for Immuno-Oncology, Including an Antagonist of T-cell Checkpoint Target PD-L1 and Selected Precision Oncology Targets, Including an IRAK4 Kinase Inhibitor

Investigation New Drug (IND) Application Filings for Both Lead Programs Expected in 2015

Curis to issue 17.1M shares of its Common Stock as Up-front Consideration

Management to Host Conference Call Today at 8:00 a.m. EST

LEXINGTON, Mass. and Bangalore, India, January 21, 2015 (GLOBENEWSWIRE) Curis, Inc. (NASDAQ:CRIS), a biotechnology company focused on the development and commercialization of innovative drug candidates for the treatment of human cancers, and Aurigene, a specialized, discovery stage biotechnology company developing novel therapies to treat cancer and inflammatory diseases, today announced that they have entered into an exclusive collaboration agreement focused on immuno-oncology and selected precision oncology targets. The collaboration provides for inclusion of multiple programs and Curis retains the option to license compounds once a development candidate is nominated within each respective program. The partnership draws from each company s respective areas of expertise, with Aurigene having the responsibility for conducting all discovery and preclinical activities, including IND-enabling studies and providing Phase 1 clinical trial supply, and Curis responsible for all clinical development, regulatory and commercialization efforts worldwide, excluding India and Russia.

The first two programs under the collaboration are an orally available small molecule antagonist of programmed death ligand-1 (PD-L1) in the immuno-oncology field, and an orally available, small molecule inhibitor of Interleukin-1 receptor-associated kinase 4 (IRAK4) in the precision oncology field. Curis expects to exercise its option to obtain exclusive licenses to both programs and file IND applications for a development candidate from each in 2015.

We are thrilled to partner with Aurigene to discover, develop and commercialize small molecule drug candidates generated from Aurigene s novel technology and believe that this collaboration represents a true transformation for Curis that positions the company for continued growth in the development and eventual commercialization of cancer drugs. The multi-year nature of our collaboration has the potential to generate a steady pipeline of novel drug candidates in the coming years, said Ali Fattaey, Ph.D., President and Chief Executive Officer of Curis. Addressing immune checkpoint pathways is now a well validated strategy to treat human cancers and the ability to target PD-1/PD-L1 and other immune checkpoints with orally available small molecule drugs has the potential to be a distinct and major advancement for patients. Recent studies have also shown that alterations of the MYD88 gene lead to dysregulation of its downstream target IRAK4 in a number of hematologic malignancies, including Waldenstrom s Macroglobulinemias and a subset of diffuse large B-cell lymphomas, making IRAK4 an attractive target for the treatment of these cancers. We look forward to advancing these programs into clinical development later this year.

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Dr. Fattaey continued, Aurigene has a long and well-established track record of generating targeted small molecule drug candidates with bio-pharmaceutical collaborators and we have significantly expanded our drug development capabilities as we advance our proprietary drug candidates in currently ongoing clinical studies. We are now well-positioned to advance compounds from this collaboration into clinical development.

We are excited to enter into this exclusive collaboration with Curis under which we intend to discover and develop a number of drug candidates from our chemistry innovations in the most exciting fields of cancer therapy. This unique collaboration is an opportunity for Aurigene to participate in advancing our discoveries into clinical development and beyond, and mutually align interests as provided for in our agreement, said CSN Murthy, Chief Executive Officer of Aurigene. Our scientists at Aurigene have established a novel strategy to address immune checkpoint targets using small molecule chemical approaches, and have discovered a number of candidates that modulate these checkpoint pathways, including PD-1/PD-L1. We have established a large panel of preclinical tumor models in immunocompetent mice and can show significant *in vivo* anti-tumor activity using our small molecule antagonists. We are also in the late stages of selecting a candidate that is a potent and selective inhibitor of the IRAK4 kinase, demonstrating excellent *in vivo* activity in preclinical tumor models .

In connection with the transaction, Curis has agreed to issue to Aurigene approximately 17.1 million shares of its common stock, or 19.9% of its outstanding common stock immediately prior to the transaction, in partial consideration for the rights granted to Curis under the collaboration agreement. The shares to be issued to Aurigene will be subject to a lock-up agreement until January 18, 2017, with a portion of the shares being released from such lock-up in equal installments between now and such date.

The agreement provides that the parties will collaborate exclusively in immuno-oncology for an initial period of approximately two years, with the option for Curis to extend the broad immuno-oncology exclusivity.

In addition Curis has agreed to make payments to Aurigene as follows

- for the first two programs: up to $52.5 million per program, including $42.5 million for approval and commercial milestones, plus pre-specified approval milestone payments for additional indications, if any;
- for the third and fourth programs: up to $50 million per program, including $42.5 million for approval and commercial milestones, plus pre-specified approval milestone payments for additional indications, if any; and
- for any program thereafter: up to $140.5 million per program, including $87.5 million in approval and commercial milestones, plus pre-specified approval milestone payments for additional indications, if any.

Curis has agreed to pay Aurigene royalties on its net sales ranging between high single digits to 10% in territories where it commercializes products and will also share in amounts that it receives from sublicensees depending upon the stage of development of the respective molecule.

For more information, please refer to the Current Report on Form 8-K filed with the U.S. Securities & Exchange Commission on January 21, 2015.

Conference Call Information

Curis management will host a conference call today, January 20, 2015, at 8:00 a.m. EST, to discuss the Curis-Aurigene agreement. To access the live conference call, please dial (877) 868-1829 from the U.S. or (253) 237-1135 from other locations, shortly before 8:00 a.m. EST. The conference ID number is 70465692. The conference call can also be accessed on the Curis website at www.curis.com in the Investors section.

About Immune Checkpoint Modulation and Programmed Death 1 Pathway

Modulation of immune checkpoint pathways has emerged as a highly promising therapeutic approach to augment anti-tumor immunity in a wide range of human cancers. Immune checkpoints are critical for the maintenance of self-tolerance as well as for the protection of tissues from excessive immune response generated during infections. However, cancer cells have the ability to modulate certain immune checkpoint pathways as a mechanism to evade the immune system.

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Certain immune checkpoint receptors or ligands are expressed by various cancer cells, targeting of which may be an effective strategy for generating anti-tumor immunity. Some immune-checkpoint modulators, such as programmed death protein 1 (PD1), specifically regulate immune cell effector functions within tissues. One of the mechanisms by which tumor cells block anti-tumor responses in the tumor microenvironment is by upregulating ligands for PD1, such as PD-L1. Hence, targeting of PD1 and/or PD-L1 has been shown to lead to the generation of effective anti-tumor responses.

About IRAK4:

Interleukin-1 receptor-associated kinase 4, or IRAK4 is a signaling kinase that becomes inappropriately activated in certain cancers including activated B cell-diffuse large B cell lymphoma (ABC-DLBCL), an aggressive form of lymphoma with poor prognosis. There appears to be a mechanistic link with IRAK4 in ABC-DLBCL where these tumors from approximately 35% of patients harbor oncogenic mutations in MYD88, an adaptor protein that interacts directly with IRAK4. MYD88 mutations appear to constitutively activate the IRAK4 kinase complex, driving pro-survival pathways in ABC-DLBCL disease. Oncogenic MYD88 mutations have also been identified in other cancers, including in over 90% of patients with Waldenström s Macroglobulinemia as well as in a subset of patients with chronic lymphocytic leukemia (CLL).

About Curis, Inc.

Curis is a biotechnology company focused on the development and commercialization of novel drug candidates for the treatment of human cancers. Curis pipeline of drug candidates includes CUDC-907, a dual HDAC and PI3K inhibitor, CUDC-427, a small molecule antagonist of IAP proteins, and Debio 0932, an oral HSP90 inhibitor. Curis is also engaged in a collaboration with Genentech, a member of the Roche Group, under which Genentech and Roche are developing and commercializing Erivedge®, the first and only FDA-approved medicine for the treatment of advanced basal cell carcinoma. For more information, visit Curis website at www.curis.com.

About Aurigene

Aurigene is a specialized, discovery stage biotechnology company, developing novel and best- in-class therapies to treat cancer and inflammatory diseases. Aurigene s Programmed Death pathway program is the first of several immune checkpoint programs that are at different stages of discovery and preclinical development. Aurigene has partnered with several large- and mid- pharma companies in the United States and Europe and has delivered multiple clinical compounds through these partnerships. With over 500 scientists, Aurigene has collaborated with 6 of the top 10 pharma companies. Aurigene is an independent, wholly owned subsidiary of Dr. Reddy s Laboratories Ltd. (NYSE: RDY). For more information, please visit Aurigene s website at http://aurigene.com/.

Cautionary Note Regarding Forward-Looking Statements:

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation: Curis expectations regarding its plans to file two INDs in 2015 for drug candidates under the collaboration with Aurigene; Curis collaboration with Aurigene will have the potential to generate a steady pipeline of novel drug candidates in the coming years; the expected benefits of the collaboration for Curis, including positioning Curis for competitive growth; Curis ability to advance molecules from the collaboration into clinical development; and any other statements about Curis regarding clinical developments within the meaning of the Private Security Litigation Reform Act. Forward- looking statements used in this press release may contain the words believes, expects, anticipates, plans, seeks, estimates, assumes, will, may, could or similar expressions. These forward-looking statements are not guarantees of future performance and involve risks,

uncertainties, assumptions and other important factors that may cause actual results to be materially different from those indicated by such forward-looking statements. For example, there can be no guarantee that the collaboration agreement will continue for its full term, that Curis or Aurigene will maintain the financial resources necessary to continue financing its portion of research, development and commercialization costs or that the parties will successfully discover, develop or commercialize drug candidates under the collaboration. Curisls expectations could also be affected by risks and uncertainties relating to a failure of Curis or Aurigene to fully perform under the collaboration agreement and/or any early termination of the collaboration agreement, adverse results of clinical trials and preclinical studies that are the subject of the collaboration, including subsequent analysis of existing data and new data received from ongoing and future studies, the content and timing of decisions made by the U.S. Food & Drug Administration and other regulatory

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authorities, investigational review boards at clinical trial sites, and publication review bodies, and Curis ability to enroll patients in clinical trials that may be initiated under the collaboration. Furthermore, Curis [and Aurigene] may not obtain or maintain necessary patent protection for the programs that are the subject of the collaboration and could become involved in expensive and time consuming patent litigation and interference proceedings. Curis faces substantial competition from other companies developing cancer therapeutics. Unstable market and economic conditions and developments relating to Curis s business may adversely affect Curis financial condition and its ability to access capital to fund the growth of its business. Curis also faces other important risks relating to its business, operations, financial condition and future prospects that are discussed in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2014 and other filings that it periodically makes with the Securities and Exchange Commission.

In addition, any forward-looking statements represent the views of Curis only as of today and should not be relied upon as representing Curis views as of any subsequent date. Curis disclaims any intention or obligation to update any of the forward-looking statements after the date of this press release whether as a result of new information, future events or otherwise, except as may be required by law.

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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)

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

Date: February 3, 2015