Generex Announces Amendment of Form S-1

WORCESTER, Mass. and TORONTO, July 3, 2013 /PRNewswire/ -- Generex Biotechnology Corporation (www.generex.com) (OTCBB: GNBT) today announced that it will be filing an amendment to the Form S-1 Registration Statement it filed with the United States Securities and Exchange Commission yesterday, July 2, 2013 (file number 333-189766).

The Form S-1 filed yesterday contained the following disclosure in respect of the filing with the Indian government by Shreya Life Sciences Pvt. Ltd. of the dossier for Oral Recosulin™ (the Indian name for Generex Oral-lyn™, Generex's proprietary buccal insulin spray product):

"Per the requirements of the regulatory approval in India, an in-country clinical study must be completed in India with Oral Recosulin™ before commercial sales can commence. The field portion of the study was completed in the third calendar quarter of 2012. The marketing acceptance dossier has been submitted to the Indian regulatory authority and a response is expected during the early part of 2014."

The Form S-1 will be amended to delete the last sentence of the foregoing disclosure and replace it with the following:

"Shreya has advised Generex that the dossier was submitted in December of 2012 to the Drugs Controller General (India) (DCGI), Central Drugs Standard Control Organization, Director General of Health Services, Ministry of Health and Family Welfare, Government of India. Generex has also been advised that Shreya anticipates receiving government approval for the marketing and commercial distribution of the product in 2013."

About Generex Biotechnology Corporation

Generex is engaged in the research, development, and commercialization of drug delivery systems and technologies. Generex has developed a proprietary platform technology for the delivery of drugs into the human body through the oral cavity (with no deposit in the lungs). The Company's proprietary liquid

formulations allow drugs typically administered by injection to be absorbed into the body by the lining of the inner mouth using the Company's proprietary RapidMist™ device. Antigen Express, Inc. is a wholly owned subsidiary of Generex. The core platform technologies of Antigen Express comprise immunotherapeutic vaccines for the treatment of malignant, infectious, allergic, and autoimmune diseases. Antigen Express has pioneered the use of specific CD4+ T-helper stimulation technologies in immunotherapy. One focuses on modification of peptides with Ii-Key to increase potency, while a second relies on inhibition of expression of the Ii protein. Antigen Express scientists, and others, have shown clearly that suppression of expression of the Ii protein in cancer cells allows for potent stimulation of T-helper cells and prevents the further growth of cancer cells. For more information, visit the Generex website at www.generex.com or the Antigen Express website at www.antigenexpress.com.

Cautionary Note Regarding Forward-Looking Statements

This release and oral statements made from time to time by Generex representatives in respect of the same subject matter may contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. These statements can be identified by introductory words such as "expects," "plan," "believes," "will," "achieve," "anticipate," "would," "should," "subject to" or words of similar meaning, and by the fact that they do not relate strictly to historical or current facts. Forward-looking statements frequently are used in discussing potential product applications, potential collaborations, product development activities, clinical studies, regulatory submissions and approvals, and similar operating matters. Many factors may cause actual results to differ from forward-looking statements, including inaccurate assumptions and a broad variety of risks and uncertainties, some of which are known and others of which are not. Known risks and uncertainties include those identified from time to time in the reports filed by Generex with the Securities and Exchange Commission, which should be considered together with any forward-looking statement. No forward-looking statement is a guarantee of future results or events, and one should avoid placing undue reliance on such statements. Generex undertakes no obligation to update publicly any forward-looking statements, whether as a result of new information, future events or otherwise. Generex cannot be sure when or if it will be permitted by regulatory agencies to undertake additional clinical trials or to commence any particular phase of clinical trials. Because of this, statements regarding the expected timing of clinical trials or ultimate regulatory approval cannot be regarded as actual predictions of when Generex will obtain regulatory approval for any "phase" of clinical trials or when it will obtain ultimate regulatory approval by a particular regulatory agency. Generex claims the protection of the safe harbor for forward-looking statements that is contained in the Private Securities Litigation Reform Act.

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