

NASAL DRUG DELIVERY TECHNOLOGY LICENSE TRANSFER OF TRANSLATIONAL RESEARCH, LTD. AND NASAL DEVICE SUPPLY AGREEMENT OF BIOACTIS, LTD.

Translational Research, Ltd. (100% owned subsidiary) and Bioactis, Ltd. (92% owned subsidiary), both child companies of SNBL, Ltd., have signed general terms of agreement for the licensing and supplying of their patented nasal drug delivery technology in the field of endocrinology to Tokai Pharmaceuticals, Inc., a state of Massachusetts company in the USA.

Translational Research, Ltd. ("TRL"; CEO, Ryoichi Nagata, MD, PhD) is a branch of SNBL Group that is in charge of the translational research operation, which is one of the strategic operations of the Group. TRL has been developing nasal drug formulation technology that enables drugs that have, traditionally, been effective in treatment only using needle injections, to be delivered effectively through the nasal membrane, such as insulin for diabetes, morphine for pain killing, anti-emetics drugs (effective against emesis induced by anticancer-drugs), and etc. TRL's technology has attracted attention for its high degrees of safety, not using any irritation causing absorption enhancers to achieve the effective levels of drug absorption.

Bioactis, Ltd. ("Bioactis"; CEO, Ryoichi Nagata, MD, PhD) has been developing nasal devices, which are medical devices that deliver drugs to the nose. Bioactis's nasal device (Fit-lizer[®]) is a self administering, manual device that is pocket-size, is user friendly to patients, and has highly effective spraying performance.

Paired with TRL's nasal formulation technology, the combined nasal delivery system of TRL's nasal formulation technology and Bioactis's delivery device incorporates an effective therapeutic value in an easy-to-use package and is highly expected to improve the patients' quality of life. Already, the developments of insulin and morphine using this system are in the advanced clinical stages, and other hormone compounds are being considered to strengthen the product pipeline.

Tokai Pharmaceuticals, Inc. ("Tokai"; CEO, Joseph A. Yanchik III; Cambridge, Massachusetts) specializes in development and commercialization of therapeutic biopharmaceutical compounds focusing in the endocrine therapeutic area, especially in women's reproductive disease and anti-aging area. Tokai is acquiring several types of compounds from large pharmaceutical companies and research facilities and is preparing to conduct clinical trials. Tokai is a bio-venture company that has Apple Tree Partners (Managing General Partner, Seth L. Harrison, MD, www.appletreepartners.com) as a majority shareholder.

Tokai pharmaceuticals, by in-licensing the technology of the nasal delivery system owned by TRL and using the suited device supplied by Bioactis, decided to expand their endocrine therapeutic compounds that are planned for development using needle injections to nasal delivery.

The technology transfer to Tokai does not include contents related to other drugs under development by TRL such as insulin or morphine. Also, this agreement is centered around an earning based royalty of Tokai's products; therefore, the effect of this agreement on the earnings of SNBL's current term is minimal.