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Licensing Agreement for a Nasal Drug Delivery Technology
“New Hopes for Infertility and Osteoporosis; Countermeasures to Address
the Declining Birthrate and the Aging Population”

Translational Research, Ltd. (TRL), a 100% subsidiary company of SNBL, has signed an agreement with Tokai Pharmaceuticals, Inc., for the license to use TRL's nasal drug delivery technology. The license is for Tokai's exclusive use of TRL's technology to research, develop, manufacture, and market products of specific pharmaceutical compounds, including Follicle Stimulating Hormone (FSH), Parathyroid Hormone (PTH), Parathyroid-related Protein (PTHrP), and Growth Hormone Releasing Peptide (GHRP).

In the recent years, there is an increasing trend in cases of infertility. Around 15% of all couples in the conceivable age are being treated after 2 years of infertility. The current infertility treatment market in the USA is reported to reach as high as US\$20 Billion. FSH is an effective drug to treat infertility; however it requires about 2 weeks of going to the hospital daily for subcutaneous or intramuscular injections of FSH until the ovum become mature. Also, there is a considerable amount of discomfort felt by the patient, because the location of the injections must be changed each time due to possible irritation and infections. Also, cases of osteoporosis have also been increasing each year. In the year 2000, the number of patients in major countries was reported to be around 35 million. The market size, in the USA alone, was reported to be US\$8.5 Billion in the year 2003 and is expected to increase to around US\$200 Billion by the year 2014. PTH and PTHrP are both known to effectively induce bone formation; however, the treatment currently requires a patient to take injections for an extended period. For these reasons, an alternate drug delivery method has been sought after for the treatment of infertility and osteoporosis without needle injections... one that is painless and more convenient to use.

Through this partnership, Tokai aims to apply TRL's nasal delivery technology to pharmaceutical compounds, including FSH, PTH, PTHrP and GHRP, for future manufacturing and marketing. The application of these pharmaceutical compounds using nasal delivery will add therapeutic value to the patients, by relieving them of the pain felt with injections and, ultimately, contributing the increase in their quality of life. According to this agreement, TRL has received an initial licensing fee of US\$50,000 and will receive additional total licensing fee of US\$475,000 over the next 4 years. TRL will also receive royalty fees according to the sales of Tokai's products.

Other than this partnership with Tokai, TRL is currently developing nasal delivery formulations of morphine (pain reliever) and granisetron (anti-emetics) in-house and, at the same time, proceeding to aggressively research/develop applications of the nasal delivery technology to other therapeutic compounds, as well as negotiating other licensing agreements.

The effect of this partnership on the performance of SNBL group in this fiscal year is minimal.