Bonus BioGroup Ltd. (TASE: BONS.TA)

Bonus BioGroup Ltd. is an Israeli biotechnology company engaged in personalized tissue engineering and cell therapy, and developing, *inter alia*, proprietary technology for growing live human bone grafts for transplant in human patients.

Bonus BioGroup achieved a revolutionary breakthrough in safe, rapid and efficient bone rehabilitation, through a single injection of live human bone graft, manufactured by the Company, which was successfully demonstrated in all of the participants in the Company's first clinical trial for repairing maxillofacial bone deficiencies in the upper or lower jaw, regardless of sex, age and medical background, recording a significance level of 95%.

Such extraordinary safety and efficacy results are not guaranteed by any other medical treatment. Demonstrating such high levels of statistical significance, even with a small sampling, means the success achieved is not coincidental, but rather is steadfast and repeatable, and therefore is expected to repeat itself also with a larger population.

Concurrently to conducting the first clinical trial, Bonus BioGroup has developed a second generation of injectable bone graft, which is more advanced, reduces manufacturing time, with less human involving, at a reduced cost and with suitability for mass production.

At this time, Bonus BioGroup is conducting two clinical trials for the second generation of its injectable bone graft, both defined Phase I/II, with the clinical objectives of evaluating safety and efficacy of using its injectable bone graft, as follows:

1. In September 2016, a second clinical trial began for filling bone void in the upper or lower jawbone, administered by Dr. Ephraim Tzur;
2. In August 2017, a clinical trial began for filling critical bone defects in limbs – arms or legs, administered by Prof. Nimrod Rozen.

Bonus BioGroup strives to be the first company in the world to introduce to the global bone rehabilitation market, estimated at approximately US$7.5b per annum in 2017, a safe and rapid solution for filling bone deficiencies, through a single injection of live bone graft, manufactured by the Company after having been grown in the laboratory from cells sampled from the patient.

Alternate treatments to the Company's solutions are either surgery for harvesting bone and its peripheral blood vessels to be implanted in the area of the defect, or using artificial bone substitute that shall not induce healing and not enable the patient to return to normal activity due to failure of artificial bone substitute to integrate with the human body.

All patients desiring to participate in Bonus BioGroup's clinical trials are required to undergo examinations to verify their suitability. Having been verified, patients undergo biopsy of fat tissue for deriving the cells necessary for manufacturing a personalized live human bone graft. The manufacturing procedure takes place at Bonus BioGroup's manufacturing facility in Haifa, under controlled sterile conditions, on a three-dimensional, biodegradable scaffold, in a unique environment simulating the conditions necessary for *in vivo* growth of human bone.

Within two weeks of sampling the patient's fat tissue, an injectable bone graft made of tiny bone particles, ready to be implanted in the patient's body. Once the bone graft is injected, the tiny particles unite and form a solid human bone for complete healing of the implant area.

Up to 20 patients, male and female ages 18-70, are expected to participate in the second clinical trial for filling jawbone void.

The clinical trial for filling orthopedic bone void shall be conducted for two indications: (1) extensive critical bone defect of long limb bones failing to mend, whether due to failure of the body's natural rehabilitation process without medical intervention, or in the event of failure of orthopedic procedure to mend the limb; and (2) long limb bone extra-articular comminuted fractures.

The clinical trial for filling orthopedic bone defect is planned to include 30-40 participants, male and female ages 18-75. Initially, 10 participants shall be recruited for both clinical indications; in the second part, at least 10 more participants shall be recruited for each of the two clinical indications and up to 30 additional participants for both clinical indications together.

Medical observation of every clinical trial participant shall last six months from the date of implant.

Bonus BioGroup holds exclusive rights of use in six families of patents, which include two patents and ten patent applications. Bonus BioGroup is acting to register additional patents and patent applications, for realizing the revolutionary breakthrough in additional indications.

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