TARSA THERAPEUTICS TARGETS 2012 NDA SUBMISSION FOR ITS OSTORA™ ORAL CALCITONIN

PHILADELPHIA, PA – December 13, 2011 —Tarsa Therapeutics today confirmed that it is planning to submit a New Drug Application (NDA) to the Food and Drug Administration (FDA) in the second half of 2012 for OSTORA™, the company's oral recombinant salmon calcitonin tablet for the treatment of postmenopausal osteoporosis. This follows a formal pre-NDA dialogue with the FDA that verified the results from Tarsa's Phase III ORACAL trial and the requirements for regulatory approval, including agreement on key elements of the submission. The study design and specific endpoints had previously been agreed in a Special Protocol Assessment with the FDA.

"Our recent dialogue with the FDA was very productive and we are on track to submit an NDA for OSTORA as a treatment for postmenopausal osteoporosis in the second half of 2012," noted David Brand, Chief Executive Officer of Tarsa, "Our revised timeline for filing the NDA partly reflects Emisphere Technologies' recent report of negative Phase III trial results for their oral calcitonin product. This development affords us the time to ensure that we assemble the highest quality NDA submission with the goal of maximizing our chances for timely regulatory review and approval."

At the 2011 Annual Meeting of the American Society for Bone and Mineral Research earlier this year, Tarsa reported positive efficacy and safety results from its year-long Phase III ORACAL trial showing that OSTORA achieved all of the trial's efficacy endpoints and demonstrated statistically significant superiority to both placebo and nasal calcitonin spray in increasing bone mass density at the lumbar spine. In this trial, the safety profile of OSTORA did not substantially differ from nasal calcitonin or placebo and the majority of adverse events were mild or moderate.

Tarsa's oral calcitonin is also being assessed in a one-year double-blind Phase II study comparing the OSTORA tablet to placebo in postmenopausal women who have low bone mass (osteopenia) and are at increased risk of fracture. The study is evaluating the ability of oral calcitonin to prevent osteoporosis and maintain bone mass in this population.

Tarsa is developing its OSTORA oral calcitonin under a licensing agreement with Unigene Laboratories that provides Tarsa with exclusive development and worldwide commercialization rights to Unigene's oral calcitonin product, with the exception of China.

About Tarsa Therapeutics

Tarsa Therapeutics is a venture-backed clinical stage biotechnology company developing OSTORA™, an oral formulation of calcitonin for the treatment and prevention of postmenopausal osteoporosis. Calcitonin has a long history of safety and efficacy and availability of an oral form is expected to generate wider use. Tarsa has reported positive efficacy and safety results from the Phase III ORACAL trial of its oral calcitonin tablet in the treatment of postmenopausal osteoporosis, and a Phase II osteoporosis prevention trial is underway. Tarsa is based in Philadelphia, PA. For more information, visit www.tarsatherapeutics.com.

Contact:

GendeLLindheim BioCom Partners
Barbara Lindheim
212-584-2276