## **BIOSIDUS**

一家阿根廷生物技术公司,在过去的二十年中致力于高质量生物制药的供应,其商务领域覆盖亚洲、非洲、东欧和拉丁美洲。

该公司在阿根廷拥有两个生产中心,一个从事研发和活性药物成份的生产,另一家从事充填、和包装。公司计划开设第三个符合美国及欧洲药物管理局标准的生产中心。

公司主要产品包括干扰素 alpha 2a, alpha 2b, beta 1a、促生长激素、非格司亭、莱诺拉提等。此外,正在开发的一些治疗性蛋白质,也将陆续上市。

公司依靠自己的制造工艺专利及技术知识产权在生物仿制药方面有很大的竞争优势。

在基因治疗和转基因牛领域已建立了创新技术平台。BIOSIDUS 公司以研发出针对治疗心血管疾病的独有疗法,通过血管内皮生长因子使血管和肌肉再生。该技术平台已在美国和墨西哥获取专利,并正在申请欧洲及拉美的专利。转基因牛奶中的蛋白质重组技术用于生产药用蛋白质及保健食品。

BIOSIDUS 在此次来华有意提高其产品/服务/技术的出口量,并在基因治疗、治疗性蛋白质生产、转基因动物等生物科技领域寻找投资方/项目开发的战略合作伙伴。

Argentina based biotechnology company which over the past two decades has developed a global business in the supply of high quality biopharmaceuticals in the territories of Asia, Africa, Eastern Europe and Latin America.

Bio Sidus S.A. has two production sites. The Almagro Plant located in the city of Buenos Aires, devoted to R&D activities and to the production of APIs, equipped with bacterial fermentation capacities and also hosting mass cell culture areas. Filling, lyophilization and packaging operations are conducted in a separate facility, Planta Bernal, located in the outskirts of Buenos Aires. The company also counts on a suitable site to build a third manufacturing site to be fully FDA/EMA compliant.

Biosidus portfolio includes Eritropoyetin, Interferon alpha 2a, Interferon alpha 2b, Interferon Beta 1a, Human Growth Hormone, Filgrastim and Lenograstim

Bio Sidus S.A. counts on a robust pipeline of therapeutic proteins, in different stages of development. Parathormone (Teriparatide) will be launched during 2012 and Interferon beta 1b, Agalsidase, Peg Intereron and Peg Filgrastim are at advanced stages of development.

Bio Sidus proprietary manufacturing processes and technologies rely on a solid IP policy which constitutes a competitive advantage in the scenario of biosimilars.

The company has built innovative technological platforms in the field of Gene Therapy, Transgenic Bovines, as an alternative for the efficient production of biomolecules, Genomics and

Proteomics for the characterization of novel cold enzymes.

## Gene Therapy

Biosidus has developed a proprietary treatment for the treatment of cardiovascular diseases based con the administration of the Vascular Endothelial Growth Factor (VEGF) gene into cardiac tissue as well as skeletal muscle. We demonstrated that the use of high doses of naked plasmid DNA harbouring the VEGF gene produced, besides angiogenesis, arteriogenesis and muscle regeneration. Patents were granted in USA and Mexico and at present is under evaluation process in Europe and other countries of Latin America. After several preclinical studies in pigs, sheeps, rabbits and rodents a Phase I Clinical Study was successfully conducted. New Phase II Clinical Studies are plan to start in 2012 for two different indications: Heart Failure and Periferic Ischemia. All the results have been published in relevant scientific international publications.

## Transgenic Bovines

Biosdius has developed a technological platform based in the efficient expression of recombinant proteins in the milk of genetically modified bovines. This technology is directed to the production of proteins of pharmaceutical use as well as for the generation of functional food. In 2012 a comparative efficacy study of Human Growth Hormone obtained by using this methodology (Biohormon®) against the innovative product is to be started and it is expected to get the approval for commercialization in about two years. In doing so Biohormon® is going to be the third approved product in the world by using this innovative technology. Other molecules such as Insulin and Etanercept are in early phases of development. Besides, a functional milk containing nanoantibodies VHH against a Rotavirus conserved protein is under development. This virus is the major cause of diarrhea in children all over the world and the nanoantibodies produced in this way have the capacity to neutralize its infection. Biosidus is generating genetically modified cows producing these specific antibodies. The production of nanoantibodies in milk of transgenic bovines is an innovative approach for the generation of functional milks for the prevention of different infections.