Oligonucleotide Service
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"Comments and suggestions regarding the planned implementation of the 'Advanced Therapies' Regulation (EC) No 1394/2007"

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BioSpring is a privately owned company which is located in Frankfurt am Main Germany. We currently employ 26 people. Our young innovative company produces synthetic nucleic acids (oligonucleotides) since 1997. We are exclusively specialized on the production of oligonucleotides. The olignucleotides we produce are all generated fully synthetically. Within the scope of oligonucleotides we produce DNA and RNA polymers with modified and unmodified components. The oligonucleotide production as such is a well known and well described process that is comparable to the synthesis of peptides. Since 2007 BioSpring is the only European company that holds a GMP certificate for the production of synthetic nucleic acids for use as APIs in clinical trials and for commercialization. Of our four worldwide competitors three are well established companies having a production site in the U.S. exclusively and one company having a productions site in Korea,

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To our knowledge there is no evidence that short synthetic oligonucleotides do interact with the genetic material (DNA within the nucleus and mitochondria) of cells. On the contrary, the effect of oligonucleotides is based on the interaction with a) cell based proteins (for example receptors in the case of aptamers or CpG oligonucleotides) or b) RNA. The interaction with RNA either leads to the direct degradation of for example mRNA (for example as antisense or siRNA) or to the specific repression of protein expression. A few nucleic acid based APIs have already been approved and are on the market.

For our company the present draft „PROPOSALS TO AMEND ANNEX I TO DIRECTIVE 2001/83/EC AS REGARDS ADVANCED THERAPY MEDICINAL PRODUCTS“ and in particular the article „*Gene therapy medicinal product“* constitutes an extremely disadvantageous framework to further operate in Europe. Classifying synthetic oligonucleotides as potential gene therapy products would lead to a significant increase in production costs. This would mean a clear disadvantage for the development of such products in Europe. As most of our clients currently perform their research and clinical trials in Europe it would also have a negative impact on the technology and the development of our business.

Oligonucleotides have a great potential of becoming a very important medicinal product within the next years.