



Invest *in* Tuscany

# **Investment opportunities** in the Life Sciences sector in Tuscany

Short List

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#### ELECTRO-MEDICAL DEVICES

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- ID: IO#02**      **Commercialization of an innovative PET Animal Scanner**
- ID: IO#03**      **Industrial production of 2 innovative solutions in electrospinning and cell culture bioreactors**

#### BIOMEDICAL-BIOTECH

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#### PHARMACEUTICAL

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New aesthetic machine based  
on radiofrequency and plasma energy

ID: IO#01 - Electro-medical devices 1/3

## NEW AESTHETIC MACHINE BASED ON RADIOFREQUENCY AND PLASMA ENERGY

- **Description:** The new aesthetic machine is based on radiofrequency and plasma energy for a good performance and low risk/cost.
- **Development phase (2008):** Preclinical trials performed; Clinical trials started on 2009; Manufacturing activity planned for the first half of 2009; Marketing plan finalized by March 2009. In the process to obtain the approval by Food and Drug Administration and CE.
- **Expected investment:** 2 mln € for project start up and obtain FDA approval
- **Project proposed by:** Company # 1



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Commercialization of an  
innovative PET animal scanner

ID: IO#02 - Electro-medical devices 2/3

## COMMERCIALIZATION OF AN INNOVATIVE PET ANIMAL SCANNER

- **Description:** The new product was developed on the basis of a simpler and cost-effective architecture in comparison to products of the same type, and ensures similar performance in most situations, with a price that is < 50% vs. traditional equipment.
- **Development phase (2008):** Development and validation was conducted through year 2008, and the product was successfully tested and installed at various company's locations in Italy and abroad (among them S.Raffaele Hospital, Ivrea Biopark, Geneve HUG etc..). The parent company does not have the visibility and skills to go global in the field of life sciences and molecular imaging, but expected market growth is promising.
- **Expected investment:** 200 k €, to be employed for increasing equity & assets (160 k) and reimbursing the initial founders contribution (40 k).
- **Project proposed by:** Company # 2



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Industrial production of 2 innovative solutions in electrospinning and cell culture bioreactors

ID: IO#03 - Electro-medical devices 3/3

## INDUSTRIAL PRODUCTION OF 2 INNOVATIVE SOLUTIONS IN ELECTROSPINNING AND CELL CULTURE BIOREACTORS

Company # 3 is working in two main areas, electrospinning and cell culture:

**1) Electrospinning** is a spinning technique from polymer solutions or melts by using the electrostatic force. The electrical charge is used to draw very fine (typically on the micro or nano scale) fibers from a liquid. ---- Company # 3 has developed a reliable and ready for use Electrospinning starting kit, with a Roto Translating (RT) Collector that guarantees high performance in terms of velocity and accuracy. Future application is the development of textile microfiber starting from spun of hundreds of aligned nanofibers with related machines for industrial production.

**2) Bioreactors** are devices or systems needed to grow cells or tissues in the context of cell culture. ---- Company # 3's cell culture bioreactors have high operative flexibility, due to several possible configurations of the nutrients flux, high automation with PC-based control, absence of dimensional constraints with modular design.

- **Project proposed by:** Company # 3



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A new approach to the  
analysis of serum GGT

ID: IO#04 - Biomed-Biotech 1/4

## A NEW APPROACH TO THE ANALYSIS OF SERUM GGT

- **Description:** Company's innovative approach to serum GGT breaks the parameter into four distinct sub-components, with considerable insights in diagnosis of cardiovascular as well as other diffuse diseases. The method is presently under validation within the frame of the world-reknown Framingham Heart Study.
- **Development phase (2009):** Patent registered. Manufacturing, marketing and sales will be performed by partner company Oxford Biochemical Res. Inc. (USA).
- **Project proposed by:** Company # 4
- **Additional info:** Patent coverage: Yes



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## Quantitative determination of S-nitrosoglutathione in biological fluids

ID: IO#05 - Biomed-Biotech 2/4

### QUANTITATIVE DETERMINATION OF S-NITROSOGLUTATHIONE IN BIOLOGICAL FLUIDS

- **Description:** The company's new procedure allows to overcome specificity, reproducibility and toxicity issues.
- **Development phase (2009):** Patent registered. Manufacturing, marketing and sales presently performed by a Licensee, the partner company Oxford Biochemical Res. Inc. (USA).
- **Expected investment:** 290 k € to keep both patents alive, foster corporate structure, improve equipment and carry out R&D activities
- **Project proposed by:** Company # 4
- **Additional info:** Patent coverage: Yes



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Capital participation in of one of the few players in the  
European musculo-skeletal market

ID: IO#06 - Biomed-Biotech 3/4

## CAPITAL PARTICIPATION IN ONE OF THE FEW PLAYERS IN THE EUROPEAN MUSCULO-SKELETAL TISSUE MARKET

- **Description:** Company #5 is one of the few players in the European musculoskeletal market. It aims at integrating its current shareholder structure and at improving the commercial strenghts in Italy and also in Europe.

**Project proposed by:** Company # 5



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Commercial exploitation of patents  
in hydrogels and biomaterials

ID: IO#07 - Biomed-Biotech 4/4

## COMMERCIAL EXPLOITATION OF PATENTS IN HYDROGELS AND BIOMATERIALS

- **Description:** Company # 6 is searching for industrial and financial partners to expand and commercially exploit 2 patents in hydrogels and biomaterials. The following solutions are being considered:
  - joint ventures for industrial production-commercialization-marketing
  - capital participation
  - partnership for R&D nad/or new product development
  - finance for laboratories
  - acquisition
- **Project proposed by:** Company # 6
- **Additional info:** Patent coverage: Yes



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Support for the development  
of 4 molecules up to clinical phases

ID: IO#08 - Pharmaceutical 1/8

## SUPPORT FOR THE DEVELOPMENT OF 4 MOLECULES UP TO CLINICAL PHASES

- **Description:** The support will help finalizing the pre-clinical phase for 4 synthetic molecules aimed at covering 4 different markets:
  - skin care (antiaging products)
  - oral care (enamel damaging)
  - oncology (pancreatic cancer treatment)
  - dry eye syndrome.
- **Development phase (2008):** all molecules are in a early drug development phase and the company has already registered two patents.
- **Expected investment:** 5 mln €
- **Project proposed by:** Company # 7
- **Additional info:** Patent coverage: Yes



ABIO 08/01

- **Description:** ABIO 08/01 is the first in a new chemical class of non-sedating, non-addictive drugs to treat anxiety. ABIO 08/01 has an innovative mechanism of action, and does not induce tolerance, even after chronic treatment, or withdrawal symptoms, even in case of sudden interruption of treatment. The results of the Phase I clinical trials indicate that the compound is perfectly tolerated and has a good PK profile.
- **Project Status:** Phase II trials are under way in GAD (Vienna, final report December 2009) and panic disorder (Italy, multicenter study, final report December 2010)
- **Project proposed by:** Company # 8



ABIO 09/01

- **Description:** ABIO 09/01 belongs to a new chemical class of drugs for the treatment of anxiety and depression. ABIO 09/01 has a new mechanism of action, which is under deeper investigation. This compound has demonstrated a clear anti-depressive activity in various non-clinical pharmacological models. ABIO 09/01 is devoid of typical side effects caused by the use of antidepressants (SSRI, SNRI...), such as sexual dysfunction or changes in appetite, and does not induce tolerance, even after chronic treatment or withdrawal symptoms, even in case of sudden interruption of treatment.
- **Project Status:** ABIO 09/01 has completed the regulatory studies required for the IND
- **Project proposed by:** Company # 8



## NEUROPROTECTANTS

- **Description:** Company # 8 has a library of new small chemical entities with high antioxidant activity and the property to cross the Blood Brain Barrier. Cerebral ischemia (stroke) has been selected as the first therapeutic target, since it is one of the first 3 causes of death, with an increasing incidence also in the younger population, therefore representing a need medically unmet. Moreover, the economical impact of hospitalization and regenerative therapies is extremely high.
- **Project Status:** the library has been screened and a lead compound has been identified: lead optimization is now starting
- **Project proposed by:** Company # 8



TALL-104

• **Description:** TALL-104, as a heterologous cell therapy, are a clonal human leukemic T-cell line endowed with potent MHC non-restricted cytotoxic and cytostatic activity against a broad range of tumor cells in animals and in humans, while sparing cells from normal tissues. TALL-104 represent a universal donor system and provide an unlimited and reliable source of tumoricidal cells with stable cytotoxic activity. In comparison to autologous cell therapy, in vivo co-administration of IL2 is not needed for TALL-104 cell killing activity; thus, the severe adverse effects (i.e. VLS) associated with IL2 are eliminated. A large-scale production procedure has been developed and patented and the final product is formulated and frozen in bags ready for cryopreservation and infusion. cGMP production of clinical supply occurs at ARETA INTERNATIONAL (Gerenzano, Varese, Italy). Two phase I trials have been conducted to determine toxicity of TALL-104 cell therapy in women with metastatic refractory breast cancer and in paediatric patients with a variety of solid tumours or leukaemia. TALL-104 cells were well tolerated by both patient populations. Circulating TALL-104 cells were detectable in the peripheral blood of the patients during the 5-day induction treatment but could no longer be detected 7 days after the last infusion.

• **Project Status:** a Phase IIa clinical trial has recently been concluded in patients with peritoneal carcinogenesis induced by different primary tumours. Tall 104 are under investigation from EMEA in order to achieve the orphan drug status designation in ovarian cancer.

• **Project proposed by:** Company # 8



### Monoclonal Antibodies – Immunotoxins (IMTOX 22 – COMBOTOX)

- **Description:** Immunoconjugates are becoming a significant component of anticancer treatment, because the unmodified MAbs, although they may show some therapeutic effect, are ultimately not curative. Immunotoxins are hybrid molecules composed of a monoclonal antibody chemically or genetically conjugated to a toxin, derived from plants, bacteria or fungi. Immunotoxins target to the cancer cell throughout its MAb moiety (anti CD-22 or anti CD-19) and, after binding of the MAb to its specific antigen, the product is internalized into the cell, where the toxin (Deglycosylated Ricin Toxin A-chain or dgRTA) is released and induces cytotoxicity by inhibiting protein synthesis. IMTOX 22 is an immunotoxin monoclonal antibody selectively projected for the treatment of specific forms of Non-Hodgkin's Lymphomas (NHL) (CD22 positive B-cell NHL). COMBOTOX is a 1:1 mixture of two Immunotoxins and it has been proposed for the therapy of various B-lineage NHL and leukemia cell lines.
- **Project Status:** Both of them present clinical proof of concepts and an IND pending in the USA. In order to enhance the tolerability, the two immunotoxins have been submitted to the original toxin replacement with the new mutant recombinant one. So the two compounds need to perform the completion of process development with the toxin modification and a further assessment of the new MTD and toxicity profile before the Ph. II clinical trial.
- **Project proposed by:** Company # 8



### Monoclonal Antibodies – cUV3

- **Description:** Despite new treatment options, including autologous and allogeneic stem cell transplants, multiple myeloma (MM) remains an incurable disease. ICAM-1 (CD54) is a cellular adhesion molecule which is involved in the homing of myeloma cells to the bone marrow stroma and participates in the regulation of myeloma cells growth and differentiation. cUV3 is a chimeric monoclonal antibody specific for ICAM-1 that inhibits the disseminated growth of myeloma cells. In SCID mice xenografted with human multiple myeloma, lymphoma, and melanoma cell lines, cUV3 is highly effective at slowing the growth of tumors and/or prolonging survival. Recent investigations indicate that cUV3 may also slow the growth of human uveal melanoma, pancreatic, non-small cell lung, breast and prostate tumors in SCID mice.
- **Project Status:** Advanced preclinical stage. cUV3 needs to complete the non-clinical pharmacology (toxicology and ADME). From the technical side, the compound needs to carry out the process development and clinical scale production.
- **Project proposed by:** Company # 8



Technology platforms – Homodimers (tetravalent antibodies) – N97A

- **Description:**

1) Monoclonal antibodies which have little or no signaling activity as monomers become potent anti-tumor agents when they are converted into homodimers, due to increased avidity. Homodimers exert antitumor activity by induction of apoptosis or growth arrest, depending upon their molecular target. The mechanism of action of homodimers does not necessarily involve the Fc portion. Homodimerization can be achieved by chemical conjugation or by genetic engineering. The genetically engineered tetravalent antibodies have a construct that does not induce unwanted immunological side effects and displays better bioavailability.

2) N97A is the recombinant toxin used in the preparation of our ITs. This technology can also be applied to other products, when the poor success in the clinical setting is related to the aspecific side effects of the toxin.

- **Project Status:** The strategy in order to further expand the application of this technology would be to identify companies or research groups that are currently involved in the use of these macromolecules and propose them to shift to this mutant protein in order to overcome the non-optimal properties of their products

- **Project proposed by:** Company # 8



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## Promoter

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