# BIO 2013 ITALIAN PAVILION

McCormick Place - Chicago, Illinois U.S.A. / April 22nd - 25th

**BOOTH 4217** 















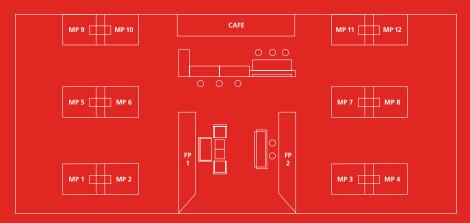






# BIO 2013 ITALIAN PAVILION

### Italian Pavilion Exhibitor Map – Booth 4217



### **FOCAL POINTS**

**FP 01: ITALIAN TRADE COMMISSION** 

FP 02: TOSCANA PROMOZIONE - INVEST IN TUSCANY
PROMOSIENA
EXOSOMICS SIENA
PHILOGEN
TUSCANY LIFE SCIENCE CLUSTER
VISMEDERI

### **MEETING POINTS**

MP 01: PHARMA & BIOTECH ADVISORS
MP 02: BIOINDUSTRY PARK SILVANO FUMERO
MP 03: STUDIO TORTA
MP 04: NUOVA OMPI STEVANATO GROUP
MP 05: ISTITUTO BIOCHIMICO ITALIANO
G. LORENZINI
MP 06: BIOCELL CENTER
MP 07: TECHNAPOLI
MP 08: CYANAGEN

MP 11: XEPTAGEN
MP 12: ARETA INTERNATIONAL

MP 10: A. MENARINI I.F.R.

MP 09: MOLMED



### The Italian Trade Commission

The Italian Trade Commission ITC is the Government agency that supports the globalization of Italian firms, under the strategies of the Ministry of Economic Development.

ICE helps to develop, facilitate and promote Italian economic and trade relations with foreign countries, focusing on the needs of SME, their associations and partnerships.

ICE sustains Italian firms in their internationalization processes and promotes worldwide the marketing of Italian goods and services, Italian investments, as well as the image of "Made in Italy" products around the world.

ICE provides information, support and consultancy to Italian companies on foreign markets, promoting and fostering export and cooperation in all areas - industry, agricultural and agri-food, services, etc. - with the target of increasing and make more effective their presence on international markets.

ICE works closely with the Italian Regions, the network of the Italian Chambers of Commerce, business organizations and other public and private entities.

ICE headquarters are in Rome, with a large network of offices and commissions around the world that act as "Trade Promotion Sections" of the Italian Embassies or Consulates.

I.C.E. / Agenzia per la Promozione all'Estero e l'internazionalizzazione delle Imprese Italiane

Via Liszt, 21, 00144 Rome, Italy Tel: +39 06 59926678

Fax: +39 06 59926678

www.ice.gov.it / www.biotechinitaly.com beni.strumentali@ice.it

Italian Trade Commission 1801 Avenue of the Stars, Suite 700 Los Angeles, CA 90067 Tel: (323) 879-0950 / Fax: (310) 203-8335 www.italtrade.com / losangeles@ice.it

### Message From H.E. Ambassador Claudio Bisogniero



Dear Friends and Colleagues,

Welcome to BIO 2013 in Chicago.

This is a special year, as many of you already know. We celebrate the Year of the Italian Culture in the US and we could have identified no better place the BIO 2013 and Chicago to promote our centers of excellence in biotechnologies with such a qualified and diversified audience.

The science and technology parks are an innovative organizational arrangement with industrial, academic, research and development components. It is in their incubators that young scientists meet the challenges of applied research and develop new tools in areas only partially explored or totally new.

Biotechnologies will be the key resource in the quest for better diagnostics and treatments leading to the no longer utopist dream of personalized medicine. With the ageing of our populations, with communicable diseases and diseases caused by poverty around the world, we need new and better tools that minimize risks and adapt to individual patients' profiles to defeat chronic diseases and improve the quality of our lives.

Biotechnologies keep the promise for sustainable development. The sector is expanding rapidly, thanks to small and medium enterprises, a traditional feature of the Italian industrial culture, renowned for their innovation capacity and their ingenuity. The Italian scientific community in the U.S. is increasingly connected with companies, hospitals, doctors based in Italy, especially in the science and technology parks. I therefore consider this a great opportunity to further strengthen these collaborative links and generate more opportunities for scientific cooperation between Italy and the US.

I wish to thank the Italian Trade Commission, which supports the Italian pavilion, the Parks, the companies and their national association, Assobiotech, the Italian S&T Parks Association, and our sponsors who are supporting the Year of the Italian Culture in the US, for having made this event possible.

# Message From Riccardo Maria Monti, Chairman Italian Trade Commission



Dear Friends of the Bio world,

I would like to extend to all of you a warm welcome to the 2013 BIO International Convention, which will take place this year in the beautiful and scenic city of Chicago, IL.

The Italian Trade Commission is honored to participate in the BIO Convention again with a selection of 20 leading biotech firms and organizations, that represent a rapidly growing sector in the last ten years - now firmly established: a dynamic and growing player in the world biotechnology industry with a more than 50,000-person strong workforce and 400 companies, with nearly 400 clinical-stage products in development (+ 30% in comparison to 2012).

In spite of the difficult moment, Italian biotech is eager to establish new relationships around the world and our task is to help facilitate these connections fostering scientific and commercial collaboration among Italian and American companies and institutions to bring new Italian products and services to commercial success.

Italy now ranks third in Europe in number of pure biotech companies and this has gained the attention of investors and venture capital firms in the U.S. and globally: Italy's excellent academic & research base, with more than 40 universities with dedicated biotech courses and 20 science parks in all the Italian Regions is a strong weapon to attract foreign investments.

Finally, for the importance of this aspect, I want to warmly thank Ambassador Bisogniero whose interpretation of "The Year of the Italian Culture in the US 2013" was intended - since the beginning - to be also a year of trade and reciprocal investments as we can witness with this effective collaboration at Bio 2013.



### MINISTERO DELLO SVILUPPO ECONOMICO

Viale Boston, 25 00144 Rome, Italy

Tel: +39 06 59931 - 59932602 - 59922603

www.mincomes.it

interpromo.seg@sviluppoeconomico.gov.it

The Ministry of Economic Development (Ministero dello Sviluppo Economico) coordinates all public entities supporting the internationalization process of Italian small and medium enterprises and the diffusion of Made in Italy in the world markets.

The Ministry of Economic Development establishes directives and has a supervisory role on the activities of ICE.



### NATIONAL COMMITTEE FOR BIOSAFETY, **BIOTECHNOLOGY AND LIFE SCIENCES**

(Presidency of the Council of Ministers) Via della Mercede, 96 00187 Rome, Italy

Tel: +39 06 67795432 Fax: +39 06 67795434 www.governo.it/biotecnologie CNBBSV@palazzochigi.it

The Committee provides direct support to the President of the Council of Ministers. The Committee's aim is to advise the Government on specific measures in scientific, economic and social fields at a national and communitarian level.

The Committee is composed of experts in microbiology, molecular biology, genetics, chemical engineering, occupational medicine, agronomy, pharmacological ecology and hygiene and by representatives of the relevant ministries and public and private institutions involved in the biotechnology sector.



### **ASSOBIOTEC**

Via Giovanni da Procida, 11 20149 Milan, Italy

Tel: +39 02 34565306 Fax: +39 02 34565284 www.assobiotec.it assobiotec@federchimica.it

Assobiotec is the Italian Association for the Development of Biotechnology, representing more than 130 companies and science & technology parks operating in Italy in all fields of biotechnology such as pharmaceuticals, diagnostics, agro-food, fine chemicals, environment, processing industry, and equipment.

The mission of Assobiotec is to be the reference for Italian companies involved in R&D, production, and marketing of products/services derived from biotech applications.

Assobiotec also represents the Italian bioindustry at National and International levels through close interactions with various institutions, trade, and scientific organizations.



### **BIOTECHINITALY.COM**

Via Liszt, 21 00144 Rome, Italy Tel: +39 06 59926755 www.biotechinitaly.com biotech@ice.it

**BiotechInItaly.com** is the virtual showroom dedicated to life sciences that will help you promote your business, find partners and be always updated on commercial opportunities in Italy.

**BiotechInItaly.com** is a website made available to you by the Italian Trade Promotion Agency.

Search the online database of Italian and international biotech companies; explore business opportunities; navigate through an extensive and detailed archive of European laws and regulations; discover important events and find the hottest topics of the moment.

**BiotechInItaly.com** Come and see what Italy has to offer!

# THE BIOTECH SECTOR IN ITALY: A GROWING AND PROMISING REALITY

Vigorous growth and an excellent innovation capacity. These are the principal characteristics of the Italian biotech sector. In view of the tender age of this industry such characteristics are, in some respects, very surprising. Thanks to them, Italy has managed to meet a challenge that would have been unthinkable a few years ago: to finally appear on the radar screens of the major biopharmaceutical and biotechnological companies and venture capital operators. There are tangible facts behind this phenomenon: new enterprises emerging at a progressively faster rate, companies reaching maturity and consolidating themselves, but first and foremost, major R&D investments being made, which a very significant growth rate in the last few years.

### **BIOINITALY REPORT 2013**

The data highlighted by the BioInItaly Report 2013, by Assobiotec and Ernst & Young, in cooperation with Farmindustria and the Italian Trade Commission, are very exciting: the Italian biotech industry is composed of 407 companies, mostly small, employing less than 50 employees. With 235 companies operating in the health-care field, the "Red Biotech" is the prevalent sector.

Total turnover equals € 7,152 million, with a 6% increase compared to the previous year, whilst R&D investments have grown to € 1,832 million, with a further 2.9% increase.

### The therapeutic pipeline of the Italian red biotech companies

Human health care is the spearhead segment of Italian biotechnologies, with a significant number of companies engaged in the development of highly innovative drugs and therapies.

Overall the Italian pipeline boasts a total of 359 products, of which 97 are in preclinical phase, 50 in Phase I, 107 in Phase II and 105 in Phase III clinical trials. If the number of products under development grows by 12%, the number of molecules that have reached Phase I (+13%), Phase II (+9%) and Phase III (+7) of clinical development has increased too. With regards to their origin, approximately 52% of the projects derive from foreign capital companies – notably multinationals' subsidiaries in Italy – and 48% from Italian capital companies, including Italian pharmaceutical companies.

Focusing our attention on the pipeline deriving from the Italian biotech companies alone, there are 136 products under development, of which 77 are in preclinical phase (56%), 17 in Phase I (13%), 32 in Phase II (24%) and 10 in Phase III (7%) of clinical development. In addition to these there are 67 research projects in the early stage or discovery phase.

Overall, approximately 46% of the projects of the Italian pipeline are biotech drugs, or biopharmaceuticals that include, by definition, monoclonal antibodies (25%), recombinant proteins (13%) and Advanced Therapies (AT) (8%).

Once again, oncology remains the therapeutic area with the largest number of projects (40%, considering also discovery activities). This percentage reflects the fact that the Italian red biotech companies' investments are clearly oriented to key medical needs, namely to those disease, such as cancer, which still lack adequate treatments. In addition to oncology, the Italian biotechnology pipeline also includes a number of projects in neurology (13%), as well as in the areas of infectivology (11%) and inflammation-autoimmune disease (10%).

The Italian biotech companies are strongly committed and perform at very excellent levels in the areas of Orphan Drugs and AT.

Indeed, out of the 49 projects currently managed by the 23 companies in our survey, which are active in the field of Rare Disease, 10 have received an Orphan Drug Designation by the EMA, 5 by the FDA and, 34 by both regulatory agencies. Within the 49 aforesaid projects, 17 originate from pure biotech companies, 6 from Italian pharmaceutical companies and 26 from the Italian subsidiaries of multinational corporations.

As regards AT, out of a total of 32 projects - 4 of which have also received Orphan Drug Designation - 17 are based on cell therapy, 8 on gene therapy while 7 apply to Regenerative Medicine. Whilst 17 of them are in preclinical phase, 6 are in Phase II and 4 are in Phase III of clinical development.

All of the above figures provide a clear evidence of the dynamic pace of the Life Sciences industry in Italy, are even more relevant if we take into account the fact that our analysis was limited only to those projects that are the result of Italian research. Indeed, even in the case of pharmaceutical companies with foreign capital, we only considered those projects which originate from R&D activities mainly conducted in Italy.

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Once again we are in front of a clear division and a complementarity of roles between pure biotech companies, which are more focused on early-stage research and preclinical development - with almost 70% of their projects ranging from discovery to Phase I, and foreign-capital pharmaceutical companies which are almost exclusively involved in late-stage clinical and regulatory development activities - with 82% of their projects concerning Phase II and III trials. This latter finding further confirms the level of excellence and competitiveness achieved by Italy in the conduct of clinical trials.

However, despite Italy represents today, at the European level, a point of reference to carry out Phase II and III clinical trials, we still need to strengthen our competitiveness particularly with regard to Phase I, whose timely management is still conditioned by a number of cultural, regulatory and administrative hurdles.

At this purpose Assobiotec has signed an agreement with the Italian Medicines Agency – AIFA and the National Institute of Health – ISS, aimed at increasing knowledge and scientific competences in the specific area of Phase I studies, as well as at stimulating biopharmaceutical companies to carry out early stage clinical activities in Italy.

### **KEY STRENGTHS OF ITALIAN BIOTECH**

Once again, this year, the biotechnology industry shows consistent dynamism and promising results, despite the continuing difficult economic situation which our companies have been struggling with, since long.

Despite a marginal decrease in the number of the companies, the Italian biotech industry ranks third in Europe after Germany and the United Kingdom as number of pure biotech companies, thus representing an extremely competitive reality, able to overcome the cyclic nature which is typical of other industrial sectors.

This development is a strong index of the Italian biotech industry's capacity of innovation, which even in an international context characterised by a little growth of investments and doubtful forecasts, has shown itself able to forge ahead, and confidently project itself towards the future.

Therefore, the research commitment is growing and in this scenario agreements between Italian companies and international partners are multiplying.

Another key factor is the excellent academic & research background present in Italy, with a strong commitment towards education and training of biotech scientists & technicians: for instance, although our country ranks 13th in terms of R&D investments in proportion to GDP (1.2%), Italian research ranks among the best in terms of quality, with a trend indicating steady growth.

In fact, Italy is one of the top three countries worldwide in the number of publications per researcher, and among the first ten countries in terms of citations per scientific article, showing a great capability of improving the research value through patents- Italy ranks third in Europe for patents per 1000 researchers.

Specifically, the growth of the emerging life sciences industry in recent years has been accelerated by the Government's commitment to develop the biotech sector. For instance, foreign investors are greeted with a variety of incentives and there are no restrictions on foreign ownership. Moreover several regional authorities, too, are actively involved in promoting biotech, through funding technology transfer agencies, incubators and seed funds.

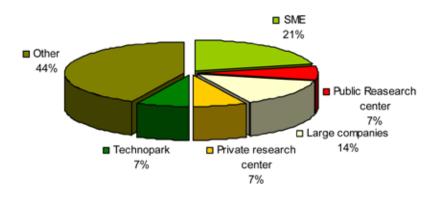
Over the last few years, biotechnology in Italy has become an established industrial reality in all fields of application, including health, agro-food, industry. The path has been difficult, but even so the biotech sector has advanced enormously, resulting in well-earned respect on an international level – an unimaginable achievement just a few years ago.

Italy is now an attractive and competitive place for entrepreneurs and investors in the biotech field. With a strong portfolio of potentialities, the country is pursuing its own path towards a level of maturity that will certainly generate further innovation and economic growth, thus reinforcing the country's role as an international player.

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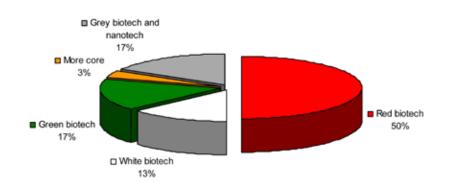
### THE ITALIAN DELEGATION AT A GLANCE

### **COMPANY STRUCTURE**



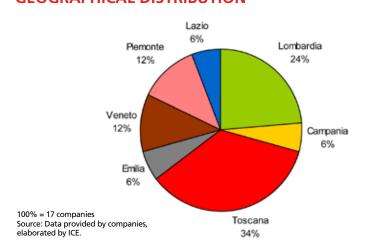
100% = 17 companies Source: Data provided by companies, elaborated by ICE.

### **SECTOR OF ACTIVITY**

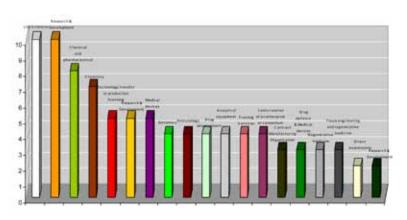


Multiple percentages (each company can declare more than one sector of activity). Source: Data provided by companies, elaborated by ICE.

### **GEOGRAPHICAL DISTRIBUTION**

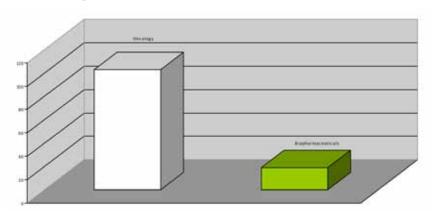


### **FOCUS**



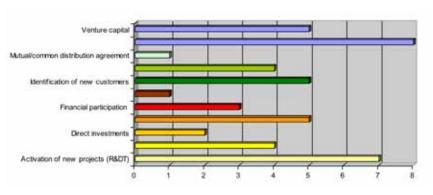
Multiple percentages (each company can declare more than one sector of activity). Source: Data provided by companies, elaborated by ICE.

### **PATENTS FILED**



Multiple percentages Source: Data provided by companies, elaborated by ICE.

### **PARTNERSHIP OBJECTIVES**



Multiple percentages Source: Data provided by companies, elaborated by ICE. **BIO 2013 ITALIAN PAVILION - ITALY AT A GLANCE** 



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### **ARETA INTERNATIONAL**

Via Roberto Lepetit, 34 21040 Gerenzano (Varese), Italy

Tel: +39 02 96474804 Fax: +39 02 96474800 www.aretaint.com Contact: Luca Romagnoli (Business Development Manager) areta@aretaint.com

### **MAIN ACTIVITY**

Areta International is a biotech company recently affiliated to Holding F.I.S., the parent company controlling F.I.S. – Fabbrica Italiana Sintetici S.p.A., the largest Italian API manufacturer.

Areta is involved in the development and manufacturing of investigational biotechnology and cell-based medicinal products. Areta holds an extensive experience in process optimization, cGMP manufacturing, aseptic filling, development of new analytical methods, quality control analysis, batch release, stability studies and regulatory affairs.

### **COMPANY STRENGTHS**

### PATENTS/LICENSES/TRADE MARKS/QUALITY CERTIFICATIONS:

Patents for anti-HMGA1 monoclonal antibodies, process for their preparation and their use for the quantitative determination of HMGA1 - Idiotypic vaccine. GMP certification by Italian Drug Agency and ISO:9001: 2008 certification.

**INNOVATIVE PROCESSES/SERVICES/PRODUCTS:** Single-use bioreactor process development and manufacturing for biotechnology products and cell-based medicines.

**NETWORKING:** Areta is member of Assobiotec, the Italian association of biotech companies and it is corporate member of EuropaBio, the European Association for Bioindustries.

**R&D:** Areta is active in the field of generation and production of customized monoclonal antibodies and recombinant proteins both from mammalian and E.coli cells. Moreover, it has developed an extensive experience in the set-up and optimisation of customized potency assays and cell-based tests.

**EXPERTISE:** Areta has 14 years of experience in the field of cell culture and in the translation of drug candidates from the preclinical to the clinical stage, through process optimization, validation and GMP-manufacturing for clinical trials.



### **BIOCELL CENTER**

Viale Stelvio, 125 21052 Busto Arsizio, VA - Italy Tel: +39 0331 386 028

Fax: +39 0331 367 321 www.biocellcenter.it Contact: Edoardo Borgo

(Vice President and Business Development)

info@biocellcenter.it

### **MAIN ACTIVITY**

Biocell Center is a biotech company focused on fetal stem cells - Amniotic Fluid and Chronic Villi derived stem cells - both on cryopreservation and R&D activities. Biocell Centerwas founded in Europein 2006 by distinguished scientists, following the discovery that amniotic stem cells possess unique characteristics compared to the cells derived from other sources. The company developed and patented an innovative technology for processing in GMP conditions amniotic fluid and chorionic villi containing stem cells. Amniotic stem cells have proven to be the richest source for Mesenchymal Stem Cells, which are the progenitors of Muscles, Bones, Cartilages, Neurons, Liver cells, Renal Cells and hemopoietic cells. The service of cryopreservation is available for private banking.

Biocell Center Headquarter is in Milan, North of Italy, and the US branch of the group is located in Medford, Massachusetts, in the Boston area biotech cluster. Biocell Center has been successfully collaborating with many leading hospitals, Ob/Gyn, maternal-fetal health groups and stem cell research laboratories worldwide.

### **COMPANY STRENGTHS**

**HIGH END PRODUCTS:** Service of cryopreservation of Amniotic Fluid and Chorionic Villi containing stem cells.

**PATENTS/LICENSES/TRADE MARKS/QUALITY CERTIFICATIONS:** Biocell Center owns two patents on processing and cryopreservation in GMP conditions of Amniotic Fluid and Chorionic Villi. Certification quality ISO 9001.

**INNOVATIVE PROCESSES/SERVICES/PRODUCTS:** The only company in the world offering the service of cryopreservation of Amniotic Fluid and Chorionic Villi containing stem cells.

**NETWORKING:** Worldwide network, with specific partnerships in Europe and Boston area.

**R&D:** Basic and Clinical research on Amniotic Fluid and Chorionic Villi stem cells.

**EXPERTISE:** Fetal stem cells optimized protocols for cell processing (expan sion, differentiation, characterization, cryopreservation)



### **BIOINDUSTRY PARK SILVANO FUMERO**

Via Ribes, 5

10010 Colleretto Giacosa (TO), Italy

Tel: +39 0125 561311 Fax: +39 0125 538350

www.bioindustrypark.eu; www.biopmed.eu

Contact: Fabrizio Conicella

(Director of Business Development and International Projects)

info@bioindustrypark.it

### **MAIN ACTIVITY**

Bioindustry Park is a science park focused on life sciences. Through the ABLE initiative it is offering scientific services at GLP level for biotech, med-tech, pharma and diagnostic companies. Through the ForLab initiative it proposes custom synthesis services. At the same time Bioindustry Park acts as a modern science park, hosting companies, offering lab and pilot plant spaces and supporting start-ups through incubation services. Finally, it is also managing bioPmed, the regional (Piemonte Region, north-west of Italy) cluster initiative, representing the local community of companies, R&D centers and Universities working in the field of healthcare.

### **COMPANY STRENGTHS**

**HIGH END PRODUCTS:** Scientific services.

**INNOVATIVE PROCESSES/SERVICES/PRODUCTS:** GLP services through ABLE BIOSCIENCES initiative.

**NETWORKING:** Cluster managing company of bioPmed, a community of more than 350 companies and 3500 scientist localized in Piemonte region (N.W. Italy).

**R&D:** Molecular and cellular biology, mass spectrometry, bioanalytics, proteomics and custom syntesis platforms. Different R&D projects realised and ongoing.

**EXPERTISE:** Know how in bioanalytics, custom synthesis, cell and molecular biology. Expertise in business development, networking/clustering, biomanagement, science park management, coaching to start-ups, project management.



### Reagents for Genomics and Proteomics

### **CYANAGEN**

Via degli Stradelli Guelfi, 40/c 40138 Bologna (BO) - Italy

Tel: +39 051 534063 Fax: +39 051 534063 www.cyanagen.it

Contact: Ing. Gabriele Gabrielli (CEO)

mail@cyanagen.it

### **MAIN ACTIVITY**

Cyanagen is a biotech company established in Bologna, Italy, in May 2003. Cyanagen is dedicated to research, development and production of chemical reagents, optical and fluorescent markers.

In detail, synthesis, development and production of chemiluminescent and fluorescent reagents for biological analysis, with particular reference to proteomics and genomics, as well as chemical sensors. Due to its continuous innovative research programs and also thanks to its patenting policy, Cyanagen is recognized as one of the world leaders in the field of immunoassays, in particular chemiluminescent Western Blot and ELISA.

Cyanagen provides technological support to clients and carries out customized R&D programs and problem solving solutions.

### **COMPANY STRENGTHS**

**HIGH END PRODUCTS:** Reagents for protein modification and labeling, crosslinkers and biotinylation reagents; Highly sensitive chemiluminescent substrates (WESTAR) for the detection of horseradish peroxidase in Western Blot and ELISA immunoassays; Fluorescent labeling dyes (CHROMIS) with superior stability and brightness, covering the entire visible and near-infrared spectrum. Application include Proteomics, from immunoassays to gel electrophoresis and genomics, such as DNA analysis and sequencing.

### PATENTS/LICENSES/TRADE MARKS/QUALITY CERTIFICATIONS:

Preparation of high purity phenothiazine N-alkylsulfonates and their use in chemiluminescent assays for the measurement of peroxidase activity (Publication date: 2007-01-24) Method for increasing light emission from a chemiluminescent reaction (Publication date: 2007-02-23) Kit and method for the labeling of biomolecules (Publication date: 2009-10-21) Active particles for bio-analytical applications and methods for preparation thereof (Publication date: 2008-07-31) Certification: ISO 9001 2008 since 2010

**INNOVATIVE PROCESSES/SERVICES/PRODUCTS:** WESTAR enhanced chemiluminescent substrates for Western blot. CHROMIS fluorescent dyes for genomics and proteomics. Preparation of high purity phenothiazine N-alkylsulfonates.



### **EXOSOMICS SIENA**

Via Fiorentina 1 53100 Siena, Italy

Tel: +39 345 3065144 Fax: +39 045 7112533 www.exosomics.eu

Contact: Antonio Chiesi (CEO)

achiesi@exosomics.eu

### **MAIN ACTIVITY**

Development of exosomes based immunometric diagnostic assays for cancer with proprietary technologies.

### **COMPANY STRENGTHS**

**HIGH END PRODUCTS:** Proprietary technologies to quantify and characterize exosomes from body fluids and tumor markers.

**PATENTS/LICENSES/TRADE MARKS/QUALITY CERTIFICATIONS:** Patents on proprietary technologies and tumor markers; trade mark on EXOTEST.

**INNOVATIVE PROCESSES/SERVICES/PRODUCTS:** Tools and assays for exosome research; exosome based immunometric diagnostic assays for cancer.

**NETWORKING:** Company scientists are collaborating with several Academic groups in Europe (i.e. Italian National Institute of Health, Karolinska Institutet, University of Riga, University of Ulm), USA (Yale and Harvard Universities) and Asia (A\*Star University in Singapore).

**R&D:** Exosomics Siena is an R&D performing company with a strong focus on exosome based immunometric assays for human diagnostics.

**EXPERTISE:** Exosomics Siena team includes some profiles who are among the more experienced and world leading scientists in the exosome field (Stefano Fais, Antonella Logozzi, Francesco Lozupone, Antonio Chiesi and Natasa Zarovni).



### ISTITUTO BIOCHIMICO ITALIANO G. LORENZINI

Via Fossignano, 2 04011 Aprilia (LT) - Italy

Tel: +39 06921501 Fax: +39 0692150338 www.ibi-lorenzini.com

Contact: Renzo Balconi (Business Development Director)

rbalconi@ibi-lorenzini.com

### **MAIN ACTIVITY**

Istituto Biochimico Italiano (IBI) is a privately owned bio-pharmaceutical company, founded in 1918. IBI has a long tradition in Biotechnology and Chemical Synthesis, which, combined with state-of-the-art technologies has enabled it to become internationally as synonymous with reliability and high quality guarantee. Certified by FDA and AIFA, IBI has 18,000 square meters of production area for parenteral, topical, oral forms and segregated plants for production of antibiotics and biologicals.

In 2006 IBI has set up a new biotech plant, for production of recombinant proteins from mammalian cells, using the latest technologies (disposable devices) for upstream and downstream processes, supported by a dedicated department for aseptic filling and lyophilization. The Company offers tailor -made contract development and manufacturing services, providing the entire production cycle: from cell line development to up-stream and down-stream development up to aseptic filling. All the development and manufacturing phases are based on QbD and are supported by validated state-of-the-art Analytical methodologies. IBI is capable to produce therapeutic proteins and sterile finished products as solutions or freeze-dried powders, also based on innovative delivery systems (nano or microparticles) to support Phase I to III clinical trials.

### **COMPANY STRENGTHS**

**PATENTS/LICENSES/TRADE MARKS/QUALITY CERTIFICATIONS:** IBI has many process patents for beta-lactams production and fermentation. It is certified by AIFA and FDA from 1987.

**INNOVATIVE PROCESSES/SERVICES/PRODUCTS:** The Company has a biotech cGMP plant for production of rec-proteins using mammalian cells platforms involving principally disposable technology (stirred and wave bioreactors). The APIs can be formulated as sterile solution or freeze-dried powders, also using innovative delivery systems based on nano or microparticles.

**NETWORKING:** In the R&D laboratories the researchers carry out their studies in co-operation with several scientific institutions (Universities, public research centres, hospitals) and the Company offers services as contract-development manufacturing organization for clients in Europe and in USA.



### A. MENARINI I.F.R.

Via Sette Santi, 3 50131 Firenze - Italy

Tel: +39 055 5680658 Fax: +39 055 56809991 www.menarini.com

Contact: Cristiano Musso (Licensing Director)

cmusso@menarini.it



Menarini is characterized by its world-class research and marketing skills. It has consolidated licensing and co-marketing agreements with the main European, American and Japanese companies, characterized by continuous exchange of know-how and experience with partners. Currently, it has full coverage of the entire European territory and is also present in Latin America, Middle East, Africa and Asia.

Menarini has strong Field Force presence throughout our territories. Its long-term successful experience in marketing and sales of products in different therapeutic areas, best geared to country/region characteristics, makes Menarini a preferred partner for new drug originators.

It has excellent know-how and performances in regulatory affairs, with expert management and implementation of specific local requirements in any country/region.

Menarini focuses its research efforts mainly on cancer, inflammation and GI in its six Research Centres in Europe. The largest of these Centres, the Campus based in Pomezia (Rome), includes separate facilities for Chemistry, Pharmacology, Toxicology, and Biotechnology.

Partnering with innovative Companies is an integral part of its long-term research and business strategy. Menarini's aim is to pursue the best scientific opportunities and build strong relationships with its partners based on a shared vision.



### **MOLMED**

Via Olgettina, 58 20132 Milan, Italy Tel: +39 02 212771

Fax: +39 02 21277325 www.molmed.com Contact: Holger Neecke

(Business Development Director) elena.candossin@molmed.com

### **MAIN ACTIVITY**

MolMed is a medical biotechnology company focused on discovery, R&D and clinical validation of innovative therapies for the treatment of cancer.

### **COMPANY STRENGTHS**

**HIGH END PRODUCTS:** TK - a cell therapy enabling bone marrow transplants from partially compatible donors, in Phase III for high-risk leukemia. NGR-hTNF – a novel VTA, in Phase III in mesothelioma and in Phase II in six indications (colorectal, liver, ovarian, Small-Cell and Non-Small-Cell lung cancers, and soft tissue sarcomas).

**PATENTS/LICENSES/TRADE MARKS/QUALITY CERTIFICATIONS:** Patent portfolio - assignee/applicant or licensee of 44 patent families, with 102 granted patents and 141 pending applications in EU, US and JP.

**INNOVATIVE PROCESSES/SERVICES/PRODUCTS:** Design and development of novel vascular targeting agents; cell and gene therapy: individual-specific cell modification for insertion of genes with therapeutic functions.

**R&D:** MolMed focuses its efforts particularly on the development of novel cell and gene therapies, and vascular targeting agents, thanks to outstanding know-how and expertise in related technologies.

**EXPERTISE:** Viral vectors, master cell banks, GMP production of cell/gene therapy, regulatory support and QA.

### **NUOVA OMPI - STEVANATO GROUP**

Via Molinella, 17

35017 Piombino Dese (Padova), Italy

Tel: +39 049 9318111 Fax: +39 049 9366151 www.stervanatogroup.com

Contact: Gabriele Peron (Marketing Manager)

info@stevanatogroup.com

### **MAIN ACTIVITY**

**Nuova Ompi – Stevanato Group** together with **Alfamatic, Medical Glass** and **Ompi of America** - comprise the **Glass Division** of the **Stevanato Group**, which is among leading suppliers of glass primary packaging for the global pharmaceutical industry.

Nuova Ompi was founded in 1949 by Cav. Giovanni Stevanato in the Venice region of Italy. Since the beginning we have been self-sufficient in developing the technology and producing the machinery to produce and control containers converted from glass tubing. The Glass Division is strongly connected to the Engineering Division, consisting of **S.P.A.M.I** and **Optrel**, the inspection system division.

These companies specialized in the design, manufacture, installation and after-sales support of high speed precision machinery for the production and control of glass containers as well as vision inspection systems.

The Glass Division sites are located throughout Europe (Italy-Venice & Rome, Slovak Republic-Bratislava). The most recent phase in Stevanato Group's expansion is the construction of a new manufacturing facility for glass containers at a site in Mexico, near Monterrey and the new greenfield state of the art plant in Shanghai.

We produce a full range of glass packaging including important traditional products such as vials and ampoules and also strong growth products like cartridges for pen-injection systems and auto-injectors as well as prefillable syringes.

Nuova Ompi supplies syringes, vials and cartridges in EZ-fillTM clean, sterile and ready to fill formats (www.ez-fill.com). This allows clients to continue the trend of delegating services to partner suppliers while improving operational efficiency. Today the ready-to-fill syringes are gradually replacing all the "bulk" formats. The reasons of this success, actually a break through in the pharmaceutical processing, are related to the following aspects:

- the significant reduction of TCO (Total Cost of Ownership) in terms of the capital investments and costs associated to acquisition, validation and maintenance of traditional lines for the treatment of bulk
- the overall mitigation of the risk of phenomena that can impact on the quality and safety of the final glass products.



### **PHARMA & BIOTECH ADVISORS**

Via Placido Riccardi, 19 20132 Milan, Italy

Tel: +39 02 45409122
Fax: +39 02 27203492
www.pharmaebiotech.com
Contact: Paolo Barbanti
(Chief Executive Officer)
barbanti@pharmaebiotech.com

### MAIN ACTIVITY

Pharma & Biotech Advisors is a management consulting firm that helps clients to solve their toughest problems in strategy, operations, organization and change.

Its work is helping life sciences and medtech companies drive an industry evolution through improved R&D productivity and drug safety, sales and marketing excellence, and growth in increasingly large, complex organizations.

Pharma & Biotech Advisors invests significant resources in building knowledge. It is the company's mission to bring this knowledge to its clients, in order to help build internal support and to inform its customers on opportunities in licensing and alliances, portfolio management and emerging therapeutic areas and technologies.

As R&D pipelines and the search for the next blockbuster are essential to continued strong performance, Pharma & Biotech Advisors helps clients develop sound R&D strategies.

### **COMPANY STRENGTHS**

**HIGH END PRODUCTS:** Pharma & Biotech Advisors helps make big decisions: on strategy, organization, operations, technology and mergers & acquisitions. Its work is helping life sciences companies drive an industry evolution through improved R&D productivity and drug safety, sales and marketing excellence and growth in increasingly large, complex organizations. It has been working with for-profit, non-profit, government and academic organizations.

**INNOVATIVE PROCESSES/SERVICES/PRODUCTS:** Pharma & Biotech Advisors helps clients manage R&D, enter new markets and improve operations. It has been helping companies address their greatest challenges, from reorganizing for long-term growth to improving business performance, creating value and maximizing revenue.

# Philogen innovating targeting



### **PHILOGEN**

Via Bellaria, 35 53018 Sovicille (Siena), Italy

Tel: +39 0577 1781605 Fax: +39 0577 1781680

www.philogen.it

Contact: Jane Wilton (Director of Business Development)

jane.wilton@philogen.it

### **MAIN ACTIVITY**

Philogen is a fully integrated biotechnology company engaged in the discovery and development of biopharmaceutical products for the treatment of diseases that are characterized by angiogenesis. Philogen's strategy is to deliver bioactive agents (for example cytokines or radioactivity) to the site of disease, using antibodies that specifically target the new blood vessels.

Philogen helped pioneer this strategy, having participated in more than 200 publications in leading scientific journals. This technology has generated a strong pipeline of five bio-pharmaceutical products that are undergoing Phase I/II clinical trials in cancer and chronic inflammation indications.

Philogen also has established discovery technologies, including human antibody technology, antibody drug conjugates, chemical proteomics for the discovery of vascular markers and DNA-encoded libraries for the isolation of chemical entities. Philogen is based in Siena, Italy and in Zurich, Switzerland and has R&D facilities and an EMA-certified GMP production facility that accelerates transition of its 'armed antibodies' to the clinic.

### **COMPANY STRENGTHS**

**HIGH END PRODUCTS:** Pipeline of immunocytokines and radiopharmaceuticals at advanced clinical development stages.

**PATENTS/LICENSES/TRADE MARKS/QUALITY CERTIFICATIONS:** All of Philogen's technologies and products are protected by international patent filings.

**INNOVATIVE PROCESSES/SERVICES/PRODUCTS:** World-leading technology platform in antibody and small molecule discovery.

**NETWORKING:** Established long-term contracts with large pharmaceutical companies, and extremely active academic and biotechnology contacts and projects.

**R&D:** Integrated discovery and development capabilities.

**EXPERTISE:** Antibody engineering, small molecule discovery, biologics product manufacture and clinical development.



### **STUDIO TORTA**

Via Viotti, 9

10121 Torino (TO) - Italy Tel: +39 011 5611320 Fax: +39 011 5622102 www.studiotorta.it

Contact: Francesco Fiussello

info@studiotorta.it

### **MAIN ACTIVITY**

Studio Torta is one of the most outstanding Italian Intellectual Property firms and provides a broad range of services to assist clients in establishing, managing and defending their patent/trademark portfolio.

### **BUSINESS PROPOSAL**

Studio Torta's primary focus is assisting companies obtain protection for their innovative technologies worldwide.

Studio Torta has a team of professionals specialized in the biotech and pharma field.

Studio Torta would like to take this opportunity to present its services to new clients, giving information on protection of inventions in Europe.





# TECHNAPOLI – SCIENCE & TECHNOLOGY PARK OF NAPLES METROPOLITAN AREA

Via A. Olivetti, 1

80078 Pozzuoli (Naples) - Italy

Tel: +39 081 8046040 Fax: +39 081 5255184 www.technapoli.it

Contact: Emanuela Flora (International Relations & Partnerships)

constec@technapoli.it

### **MAIN ACTIVITY**

Technapoli Consortium is the Science and Technology Park (STP) located in Naples area (south Italy). It's a territorial innovative system organizing and integrating actions that foster innovative processes also strengthening and developing cooperation networks among entities working on R&D, technology and innovation (universities, research, training and services centres, innovative enterprises). Technapoli STP detects suitable cooperation models leading to a high qualified service supply enhancing competitiveness and national/international partnership capability of the local system actors. Technapoli is a multidisciplinary STP covering various sectors such as Biotech, ICT, New materials, Tourism, Environment, Transports and Aerospace.

Technapoli STP is a facilitator within the biocommunity sharing networks such as CEBR (Council of the European BioRegions) and Italian Bio Parks and common facilities and tools such as the PAT-LIB European Patent office (in Technapoli since 1998), APRE European Research Promoting Agency (supporting the participation to EC Framework Programs on R&D, in Technapoli since 1996), IDEAM webportal (the open marketplace for innovation) and BioStarNet project (for the promotion and technical support to set up and early development of new biotech-companies).

### **COMPANY STRENGTHS**

**HIGH END PRODUCTS:** Technapoli, as regional facilitator and member of the Campania Bioscience consortium, is involved in biotechnology projects (mainly focusing on technology transfer) supporting and promoting the cooperation among companies and major research centers while approaching policy makers and stakeholders to foster, under a smart specialization strategy, the development of the biotechnologies in the Region as a key element of socio-economic growth.

**INNOVATIVE PROCESSES/SERVICES/PRODUCTS:** The regional biocommunity provides facilities for study of molecular and cellular biology; bank and biological samples and stem cells for regenerative medicine; platforms for drug screening (HTS), development of industrial fermentation processes, proteomics and genomics, bioinformatics, imaging, drug design and NMR spectrometry and for study of animal models. A Euro-Mediterranean platform in biotechnologies applied to agri-food is available towards the Expo Milano 2015 "Feeding the Planet" theme.



## Invest in Tuscany

### **TOSCANA PROMOZIONE – INVEST IN TUSCANY**

Via Vittorio Emanuele II, 62-64

50134 Florence, Italy

Tel: +39 055 4628096 Fax: +39 055 4628025

www.toscanapromozione.it/www.investintuscany.com Contact: Marco Perrone (Key Account Life Sciences Sector) m.perrone@toscanapromozione.it / info@toscanapromozione.it

### **MAIN ACTIVITY**

Toscana Promozione is the regional agency for economic promotion of the Tuscan economy worldwide. Invest in Tuscany is the service of Toscana Promozione focused on the attraction of foreign direct investment in the Region through marketing and communication activities.

Invest in Tuscany also provides assistance and guidance to investors, both financial and industrial, willing to invest in Tuscany, a region highly dedicated and open towards foreign investors. It aids investors in creating and developing networks with Tuscan partners and it facilitates the relations with local authorities, private and public bodies – all while guaranteeing maximum confidentiality.

# **BIO 2013 ITALIAN PAVILION**









### **TUSCANY LIFE SCIENCE CLUSTER**

Via Fiorentina, 1 53100 Siena, Italy

Tel: +39 0577 231204 Fax: +39 0577 43444

 $www.to scanalife sciences.org \ / \ www.scienze dellavita.it$ 

Contact: Francesco Maria Senatore

(Business Development, Communication & Projects)

f.senatore@toscanalifesciences.org

### **MAIN ACTIVITY**

The Toscana Life Sciences Foundation (TLS) is a non-profit organization founded in 2004 by a group of public and private institutions in Tuscany, with the mission to support research activities in the field of Life Sciences and in particular to foster the development of projects from basic research to industrial application.

The main project of the Foundation has been the development of the Science and Technology Park (STP) that offers equipped buildings, services and financing opportunities, thus creating a fertile ground for the development of new biotech companies focused on pharmaceutical, biotech, diagnostic and innovative biomedical technologies. TLS is today the third STP in Italy in terms of number of companies located, investment attracted and number of specialized employees.

On top of the incubation activities TLS is committed to the development of new therapies for orphan diseases and technology transfer from Tuscany Universities in the red biotech sector.

According to its mission in the technology transfer support, TLS will manage the centralized activities of the new born Life Sciences Regional Cluster putting together over 200 companies in the field and 6 Universities, representing one of the most active and interesting biotech hub in Italy.

### **COMPANY STRENGTHS**

**NETWORKING:** The Toscana Life Sciences Foundation is part of the national and international network of Science Parks and technology transfer organization.

**EXPERTISE:** Technology transfer and business development.

### VISMEDERI

Via Fiorentina, 1

53100 Siena (SI) - Italy Tel: +39 0577231253 Fax: +39 057743444 www.vismederi.com

Contact: Emanuele Montomoli (Chief Scientific Officer)

administrator@vismederi.com

### **MAIN ACTIVITY**

VisMederi is a private SME established in 2009 and located in Siena (Italy) in the scientific park "Toscana Life Sciences", which is part of the Innovation Life Sciences Italian Clusters.

The company is involved in the development and management of protocols of basic, applicative and clinical research. The company is focused on the validation of serological assays associated with immunogenicity and cell-mediated immunity and experimental animal models. The company has been involved in several clinical studies (phase I, II and III) for vaccine licensing in order to provide functional and non functional serological testing. All assays performed by VisMederi's staff are ISO9001:2008 certificated and in compliance with GLP. The company has available BSL2 and BSL3 facilities that allow to develop and to carry out several kind of assays which require the handling of wild type live viruses. VisMederi provides analytical assays to several vaccines manufactures in worldwide.

### **COMPANY STRENGTHS**

**HIGH END PRODUCTS:** Analytical assays in Life Science Field (e.g. serology, microbiology, drug delivery).

PATENTS/LICENSES/TRADE MARKS/QUALITY CERTIFICATIONS: ISO 9001:2008.

**INNOVATIVE PROCESSES/SERVICES/PRODUCTS:** Validated assays and Validation process of analytical methods.

**NETWORKING:** Big Pharma and Academies involved in vaccine licencing assays performance.

**R&D:** Development of Analytical assays for Biological samples.

**EXPERTISE:** Serology, Microbiology, and Consultancy for Vaccine licencing process in collaboration with Regulatory Agencies.



### **XEPTAGEN**

Via delle Industrie, 9 30175 Marghera (VE) - Italy Tel: +39 041-5093910

Fax: +39 041-5093884 www.xeptagen.com

Contact: Giorgio Fassina (Chief Executive Officer)

info@xeptagen.com

### **MAIN ACTIVITY**

XEPTAGEN SpA is engaged in the discovery and validation of novel molecular markers in order to produce innovative diagnostic devices for the early detection, monitoring, and screening of cancerous cells. By exploiting the natural immune response to early stage cancer and the proprietary platform technology Combinatorial Proteomic®, XEPTAGEN has discovered specific tumor markers that lead to an earlier and much more accurate detection of developing carcinomas. XEPTAGEN intends to transfer its proprietary biomarkers on a specially designed Biochip the size of a coin (CompleXima®) in order to facilitate and increase the availability of devices for diagnosing cancer at the early stage. Our mission includes creating innovative tools that improve the diagnostic accuracy for cancer and the clinical management of cancer patients.

### **COMPANY STRENGTHS**

**HIGH END PRODUCTS:** Hepa-IC: a highly specific and sensitive ELISA assay designed for hepatocellular carcinoma (HCC) diagnosis, assessment of HCC risk ,assessment of the evolution of liver disease in HCV infected patients, prediction of therapeutic outcome in HCV treatments, prognosis of HCC patients:

Prostate-IC: a highly specific and sensitive ELISA assay designed to reduce up to 60% the number of negative prostatic mappings in PCa suspected patients constituting a novel diagnostic procedure to determine the probability of having prostate cancer thus helping physicians to better determine if a man, suspected of having prostate cancer should be recommended for a prostate biopsy. It is not intended to replace PSA for cancer screening.

Colon-IC: a highly specific and sensitive ELISA assay designed to measure in patients sera CEA-IgM, a novel proprietary biomarker of colon-rectal cancer (CRC), significantly higher since the early stage of the disease (Duke A), improving in particular the diagnosis of the early forms of colon cancer.

### PATENTS/LICENSES/TRADE MARKS/QUALITY CERTIFICATIONS:

More than 7 patents

**INNOVATIVE PROCESSES/SERVICES/PRODUCTS:** Combinatorial Proteomic

**NETWORKING:** University of Padova, Mayo Clinic

**R&D:** Development of biochips for multimarker detection

### **BIO 2013 NOTES / APPOINTMENTS**





### **Italian Trade Commission USA Locations**

- 1. Italian Trade Commission Los Angeles 1801 Avenue of the Stars, #700 Los Angeles, CA 90067 (323) 879-0950 • Fax: (310) 203-8335 email: losangeles@ice.it
- 2. Italian Trade Commission New York 33 East 67th Street New York, NY 10021 (212) 980-1500 • Fax: (212) 758-1050 email: newyork@ice.it
- 3. Italian Trade Commission Chicago 401 N. Michigan Avenue, #3030 Chicago, IL 60611 (312) 670-4360 • Fax: (312) 670-5147 email: chicago@ice.it
- 4. Italian Trade Commission Atlanta 2301 Peachtree Center – Harris Tower 233 Peachtree Street NE Atlanta, GA 30343 (404) 525-0660 • Fax: (404) 525-5112 email: atlanta@ice.it
- 5. Italian Trade Commission Miami 4000 Ponce de Leon – Suite 590 Coral Gables, FL 33146 (305) 461-3896 • Fax: (786) 497-8900 email: miami@ice.it















