

BUSINESS WITH ITALY FIRST SYMPOSIUM

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Good morning everyone,

Welcome and thank you for being here today at this important event, the first, I hope, of many many others to come and focusing on Italy and on opportunities of doing business between Italy and the State of New Jersey.

Let me very briefly **introduce myself and the organization** I work for: I am Valentina Petricciuolo and I head the Investments Desk of the Italian Trade Commission of NY. The Italian Trade Commission is the government agency promoting trade relations and industrial collaboration between Italian and foreign companies, as well as attract foreign direct investment into Italy.

It operates through 115 branch offices in 86 countries. In the Unites States we are present in New York, Los Angeles, Chicago, Atlanta, Houston and Miami. Our offices in the US are deeply committed toward tighter economic and political partnership between Italy and the US and one of our goals is to encourage US companies to intensify their activities in Italy as well as encourage Italian firms to establish in the US. Within the framework of our mission to promote business cooperation between Italy and the U.S., our New York and Los Angeles offices have Investments Desks which specifically carry out various programs aimed at positioning Italy as a desirable destination for American investment and provide a first assistance to US companies wanting to locate or expand their operations in Italy.

Having said that, let me also continue by saying that we depend directly from the Italian Ministry of Economic Development in Rome. I know that my colleagues ad the Ministry are looking with great interest at this event and I am sure that they will not hesitate to attend the next symposium the New Jersey / Italy Trade Council will organize.

As my “mandate” is to attract investments to Italy, today **I will talk to you about some of the opportunities a US investor might find in our country**, specifically in the **lifesciences sector**. A sector that has made huge strides in the last few years, growing at rapid pace and currently generating an overall 16.3 billion euros (24 billion dollars) in yearly revenues, of which 6.3 euros (9.2 dollars) come from strict biotech sales. It comprises **260 companies** - of which more than 190 are focused on the health care segment - whose R&D spending reached 1.5 billion euros (2.2 billion dollars) in 2008. The largest number of firms (at least 40) are focused on **Oncology**, a field in which Italy is ranked second only to the United States. Other fields such as **Vaccines, Gene Therapy, Neurosciences and Cardiovascular Diseases** have also been a longtime focus of leading-edge applied medical research. Italian biotech companies are also proving to be

exceptionally strong in product development, with 136 compounds in clinical trials and 73 at the preclinical phase by the end of 2008.

But potential investors – i.e. venture capitalists - might be attracted by the numerous early stage companies currently active or in the process of being formed in Italy within the numerous science parks, research centers, universities and incubators which host researchers, ideas, business plans and which could therefore be the target of a careful investigation by potential investors. In fact, an important source of start-ups and new business in the Life Sciences is the extensive network of **Science Parks and Business Incubators**, which, thanks to the dynamic interaction among companies, research, finance and the local governments, has contributed to the creation of a growth oriented business environment. In addition, **several public and private Research Institutes** are present throughout the country, highly specialized in molecular technologies, biomedical technologies, neurosciences, cell biology, molecular immunology, molecular genetics, oncology, gene therapy. At least 95 companies out of 260 are located in these types of infrastructures. Also, several of the universities and institutes have incubators or tech transfer capabilities and in 2008 they generated 44 spin-offs. Investors can find several start-ups and early stage companies inside these environments, and explore co-investment opportunities with existing financial backers.

The **high quality of the research** occurring in these infrastructures and the **strength of Italy's scientific community** is well known. The Aspen Institute Italia, which recently carried out an analysis measuring the strength of Italian biomedical research vis-à-vis the one conducted in France, the UK and Germany (measured by Italian publications' share of total output, growth rate and relative degree of specialization), found that **Italy is a leader** in most areas, particularly Oncology, Endocrinology, Gastroenterology, Urology.

To provide a glimpse of Italy's vibrant biotech entrepreneurial community the Investments Desk has **produced a report** - soon to be released - that will include brief profiles of several early stage biotech companies willing to attract investors as well as other sources of information – such as the NETVAL website (network per la valorizzazione della ricerca universitaria in Italia) www.netval.it . NETVAL is the association of Italian public universities (representing almost 50% of the total) whose goal is to enhance the value of its members' research activities by working with tech-transfer offices and developing collaborations with industry.

On Netval's site you will be able to find a list of **University spin-offs** searchable by University and soon by sector. Out of the roughly 600 spin offs generated by Italian public universities and research centers over the last 8 years that were identified by NETVAL, approximately 90 (15% of the total) belong to the Life Sciences sector. A quick search on the association's website reveals some examples, such as **BiosiLab**, a 2004 spin off of the **University of Padova**, which creates and sells highly automated micro-laboratory on chips in order to obtain an high throughput and quality research in cellular experiments; **Blue Print Biotech**, a 2006 biopharmaceutical spin off of **University of Milano Bicocca**, dedicated to neurodegenerative diseases; **Biosuma**, a 2006 spin off of **University of Siena**, which develops innovative materials for biomedical use; **Medicad**, a spin off of the **University of Palermo**, which develops CAD solutions for medical imaging.

Another important source of interesting opportunities in Italy is the **National Prize for Innovation - Premio Nazionale dell'Innovazione (PNI) website** – www.pni.it. The PNI is the competition that every year gathers the winners of the Italian “Start Cups” - the business plan competitions organized by the universities taking part to the “PNI”. The PNI is the **grand final** among the top 3 winners of each of the seventeen local contests for the best high-tech entrepreneurial ideas.

The report will also provide a selected list of **venture capitalists** in Italy. Italy is still experiencing a significant lack of VC activity and the industry is rather immature compared to several European neighbors. However, there are several active VC funds, both private and public or a combination thereof, with which prospective foreign players could co-invest in early stage companies.

Among these, I would just mention here to you:

- **Quantica** - an Asset Management Company specialized in closed-end funds for venture capital activities, investing in high-tech spin-offs and start-up stemming from scientific research, as well as early-stage financing. Quantica is the Venture Capital arm of CNR – the Centro Nazionale delle Ricerche - , enhancing the connection between investors and innovation. Quantica's Principia Fund is the first Italian venture Fund promoted by experienced managers and prestigious research and university institutions. Principia Fund selects and proposes scientific innovations on the technological frontier to be transferred with profit into market-driven products. www.quanticasgr.it
- **Innogest Capital** - Innogest Capital, with its 80 million euros is currently the largest Italian Venture Capital fund in the Seed and Early Stage segment. Set up in 2005, it is recognized as a reference investor for young, high-potential companies that intend to raise capital in order to sustain their growth plans. The goal of Innogest is to invest in and encourage the success of about twenty highly entrepreneurial and young companies with very strong technology and a distinctive and unique approach to the market. Among biotech and healthcare companies in its portfolio are Silicon Biosystems, Adriacell, Erydel and Igea. www.innogest.it
- **TT Venture** - TT Venture is the first Italian closed-end fund dedicated to Technology Transfer. The fund supports the development of high-potential entrepreneurial projects within the sectors of Biomedicine, New Materials, Agro-food and Energy/Environmental Technologies. An extensive established network facilitates the deal flow and a relevant contribution is provided by the Italian Banking Foundations, a key player in the private funding for research in Italy. The fund will also invest in international venture capital funds in order to strengthen its network and to gain access to the latest R&D developments overseas. www.ttventure.it
- **Z Cube** – Z-Cube was founded in 2003 to support young life-science start-up and spin-off companies with novel therapeutics to address significant unmet medical needs. Z-Cube has achieved the launch of 3 start-ups based on projects with the goal to develop highly innovative medicine. <http://www.z-cube.it>

Very active and also very important organizations/institutions to get in touch with if you want to invest in Italy, are **INVITALIA**, the Investment Promotion Agency supporting and attracting foreign investors TO Italy, the **Italian Business Angels Association (IBAN)** and the **Italian Venture Capital and Private Equity Association (AIFI)**, whose members follow and fund entrepreneurs and could therefore serve as insightful local partners for foreign investors.

Examples of additional **sources of funding** will also be provided in the REPORT. For example, **banking foundations**, a traditional source of funding for education and science in Italy, have started to actively back the biotech industry through several initiatives. Furthermore, some

regions most notably Lombardy, Emilia Romagna, Sardinia and Tuscany, have started **local private equity funds** dedicated to the support of young and innovative companies.

Among the most important ones:

- **Monte dei Paschi di Siena (Tuscany)** – Scientific research is the sector in which the Monte dei Paschi di Siena Foundation (MPS) is most directly involved. In addition to providing support to various universities and earmarking almost 12 million euros in 2007 for specific third-party projects in this field, the Foundation also supports Siena Biotech, an operational arm of the MPS Foundation. Furthermore, the MPS Foundation is part of “Toscana Life Sciences,” the science and technology park taking shape in Siena, having established an operational arm BioFund, a seed-capital company, to provide support for companies in their start-up phase.
- **The Compagnia di San Paolo (Piemonte)** – The Compagnia is one of the most important foundations in Europe, which devotes one third of its budget (€150 million in 2007) to the research and education sectors. It makes grants to organizations which propose projects in line with its programmes, and, through its “operating units”, the foundation works directly in various sectors of its activities. In the biomedical field Compagnia focuses on projects linked to pathologies with important social impact, like cardiology and oncology. One of the main biotechnology projects spearheaded by the Compagnia was the establishment in Turin in 2007 of the Human Genetics Foundation, together with the University of Turin and Politecnico of Turin, which covers activities in advanced training and cutting edge research in genomics and proteomics. <http://www.compagnia.torino.it>
- **NEXT Fund (Lombardia)** – NEXT is a closed-ended fund of funds, subscribed by institutional investors, created by Regione Lombardia with the aim of developing on the territory of the region a venture capital market focused on innovation and development of new technologies. NEXT can invest both in other closed-ended venture capital funds and directly in companies in partnerships with other investors. NEXT’s direct investments focus on start-up or early stage small and medium enterprises (SMEs), located in the Lombardy region, and belonging to innovative and technological sectors. <http://www.finlombardasgr.it/on-multi/en/Home/Funds/Next.html>
- **Ingenium (Emilia Romagna)**- Launched in 2005, Ingenium is the first public-private venture capital fund for financing innovative enterprises based in the Region of Emilia Romagna. It is managed by Zernike Meta Ventures, a joint venture between the Italian META Group and the Dutch Zernike Group, and it currently has €7 (\$10.2) million under management, of which €5.3 (\$7.7) are regional public funds and €1.7 (\$2.5) are provided by the managing companies. <http://www.meta-group.com/ingenium/ilfondo.html>
- **Intesa Sanpaolo Eurodesk**- Part of the Intesa SanPaolo bank, the EuroDesk offers technical support to companies engaged in research and innovation. Its services are designed to inform companies about the content and operation of EU funding programs and assist them in the application process. Companies making use of the Intesa Sanpaolo Eurodesk can also benefit from the banking and financial services offered by Intesa Sanpaolo, in view of their participation to the calls for proposals at the European level. <http://www.intesasanpaoloeurodesk.com/tiki-index.php>

The Italian government has been increasingly committed to the development of the Italian biotech industry. It has created ad hoc organizations like the National Committee for Biosafety and Life Sciences to coordinate and support Government and Ministries in their actions aimed at fostering the biotech sector. The **Ministry for University and Research (MIUR) is instrumental in the support of research in the Life Sciences**. Its ongoing actions include the establishment of public-private laboratories, the creation and strengthening of high-tech districts, and the support of major research programs. Since 2005 the Ministry of University and Research has funded with over 308 million euros (\$452 million) at least 50 research and training projects with significant scientific-technological impact in the fields of human health and new diagnostics

and biomedical applications, all areas identified as strategic in Italy's National Research Program (2005-2007).

The Italian government's flagship program to increase the competitiveness of the industrial system, which includes a specific focus on biotech, is "**Industria 2015**", promoted by the Ministry of Economic Development, and launched in 2006. The strategy followed with Industria 2015 is take advantage of the opportunities arising from the growth of private demand of highly innovative goods; to improve the capacity of the productive system to effectively fit the new needs characterizing an advanced society; to improve the competitiveness of traditional sectors by developing new synergies between technology producers and consumer goods producers.

Among the main actions planned within this program are the *Industrial Innovation Projects* (IIPs), which aim to stimulate and promote the development of innovative products and services in five strategic areas, namely Energy Efficiency, Sustainable Mobility, **Life Sciences and Biotechnology**, New Technologies for SME's Development, and Innovative Technologies for the Enhancement of Cultural Heritage.

Once a strategic plan is devised for each IIP and priority areas of funding are clearly defined, the Ministry will issue requests for bids through which entities can submit project proposals and be considered for funding. Proposal must: be detailed and represent innovative and technical scientific progress, while matching the technological objectives established in the strategic plan of the relevant IIP; lead to the concrete implementation of an innovative product or service prototype that has a positive impact on the industry; be the result of cooperation between research organizations and entrepreneurial companies; be competitive in economic terms.

While the Ministry has already closed the bidding processes and awarded funds for projects within 3 IIPs, the strategic plan for Life Sciences and Biotechnology is currently being finalized. The Chairman of the company Sigma-Tau, **Mr Claudio Cavazza**, a seasoned expert in biotechnologies, who was president of Farindustria from 1986 to 1992 and who also received accolades in the US for his R&D work in rare diseases, is the appointed Project Manager administering the Life Sciences and Biotechnology IIP.

Although the program is aimed at financing Italian companies and research centers, foreign entities are eligible to obtain funds when submitting proposals in partnership with Italian counterparts. Nonetheless, if the project is eligible to obtain funds, the amount the foreign entity will receive cannot exceed 15% of the total project amount.

The Report will finally contain a list of other **programs and initiatives promoted by the Italian Government** and aimed at spurring research initiatives including in the Life Sciences, such as:

- **Research Incentive Fund (FAC)** – Among the most important funding programs administered by the Ministry for University and Research is the Research Incentive Fund, which was created with Legislative Decree 297/99 and supports applied research programs for the development of new products, production processes and services and to promote existing technologies.
- **Fondo per gli Investimenti della Ricerca di Base (FIRB)** – The FIRB, also administered by the

MUIR, is the main instrument for funding of basic research, ie activities which aim to widen the scope of scientific and technical knowledge not linked to immediate and specific commercial and industrial objectives, with the aim of enhancing Italy's global competitiveness.

- **Fund for Scientific and Technological Research (FIRST)** – Through the FIRST, the MIUR earmarked €900 million since it was established in 2007 for research in high innovation industrial fields, which includes biotech.
- **Technological Innovation Fund** – Established by Law 46/82, the Fund seeks to finance programs in high to medium-high tech sectors, including the Life Sciences, supporting industrial research projects and the establishment of research centers or conversion and/or renovation of existing ones. A tender procedure has opened in July of 2009 to award €55 million (€35 from this Fund and €20 million from the PON Research and Competitiveness), which have been specifically earmarked to finance R&D activities and projects carried out by start-ups with less than 5 years of operations.
- **EUROTRANSBIO (ETB)** – EuroTransBio is a joint initiative of 11 European countries and regions (including Italy) working to support trans-national R&D private/private and private/public co-operations between companies, especially SMEs, and academic labs by coordinating their national or regional public funding programs. The goal is to allow economic and academic biotech players to share risks, costs and skills related to innovation in order to develop more efficiently new products and technologies that could reach the market in the short to medium term. Consortiums consisting of at least two SME partners from two different ETB member countries can bid for the joint calls for industry-driven trans-national R&D projects launched by the countries and regions involved. From 2004 to 2009 ETB has launched four calls and the next will open in October 2009 and close in February 2010. An entity from a non-member country can participate in the bidding consortium (at its own costs) as long as it is offering a significant technical scientific contribution and there are already at least 2 participating entities from 2 member countries; In some case it could also be included as a subcontractor and managed under the national/regional financing regulations of the eligible participant. www.eurotransbio.net
- **7th Framework Program** – The 7th Framework Program for research and technological development Program (FP7) is the European Union's primary tool for funding research for the 2007-2013 period. The Program is aimed at research centers, scientific or technological organizations, governments and companies. Any organization operating in one of the EU Member States may take part in the program, which provides a variety of grants that can cover up to 100% of eligible investment costs.

As a testament to the growing partnership between the scientific and entrepreneurial communities of Italy and the US, here is a selection of the most recent and relevant examples (**“success stories”**) of alliances, collaboration agreements and investments between Italian life sciences companies or Universities and American counterparts:

- **Genentech**, initially assisted by Italian Trade Commission of Los Angeles office, signed in 2008 an agreement with Nerviano Medical Sciences, the largest pharmaceutical R&D facility in Italy and one of the leading oncology-focused and integrated discovery companies in Europe, to collaborate in the research of small molecule inhibitors which may be developed as anticancer agents.
- **GALILEO ONCOLOGICS**, a company established in 2008 and originating from Abiogen Pharma S.p.A, with anti-neoplastic projects at different stages of development, has existing research partnerships with the **University of Texas Southwestern Medical School** and the **Wistar Institute in Philadelphia**.
- The science park **Insubrias Biopark in Gerezano** (in the region of Lombardy) signed an agreement in 2009 with **Texas University** to study possible cures of tuberculosis and malaria, pathologies which have

registered an increase in resistance cases. Texas University has acquired a copy of all of the 166.000 biological extracts of Insubrias Park's Foundation.

- A team led by Professor Saverio Minucci of the **Institute of Molecular Oncology / European Institute of Oncology in Milan**, in collaboration with **J Craig Venture Institute** in Maryland and **Sangamo Biosciences** in Virginia, has developed a new epigenetic screening technology that improves molecular-based disease diagnosis. The technology employs high-throughput DNA sequencing that enables doctor to determine patient's epigenetic profile in 3-4 days.
- The **Area Science Park** in Trieste and the **Case Western Reserve University of Cleveland** have entered into a partnership agreement in 2008 aimed at identifying common research activities capable of stimulating the development of both institutions; supporting and facilitating opportunities for technology transfer on the respective markets; promoting the program which allows Italian and American researchers to work in both institutions; sharing skills and experiences relating to the creation, development and management of scientific parks.
- **Microsoft**, in collaboration with the Italian Government, the University of Trento and the Province of Trento created the **Centre for Computational and Systems Biology at the University of Trento**, a cutting edge Science and Technology centre seeking to increase the understanding of fundamental biological processes at system level by using programming language theory to design new conceptual tools.
- The **University of Pittsburgh Medical Center** will create a 400 million dollars **Biomedical Research and Biotechnology Center near Palermo** by the year 2010, in partnership with the Italian government, the region of Sicily and Italy's National Research Council. The UPMC and the University of Pittsburgh School of Medicine are also creating a new medical simulation center in Palermo to be based at the Mediterranean Institute for Transplant and High Specialization Therapies (Istituto Mediterraneo per i Trapianti e Terapie ad Alta Specializzazione).
- **Bristol-Myers Squibb** announced in 2006 an agreement with **Nerviano Medical Sciences** according to which Nerviano will identify and conduct early stage development of active compounds against new oncology targets provided by Bristol-Myers Squibb. Terms of this collaboration include the potential for up to \$150 million in clinical and regulatory milestones in addition to royalty payments for each successful research program.
- **Schering-Plough Research Institute (SPRI)**, the human pharmaceutical research unit of Schering-Plough, established a research center within the San Raffaele Science Park in Milan.

These are all great examples – taken only from the biotech sector, as there would be many more to be mentioned in all other scientific and technological fields - of how Italy and the US can cooperate in order to achieve major results.

Coming back to my “mission” and role as the head of the Investments Desk in NY, I must say that that is to encourage and “address” the interest of US investors - venture capitalists and large corporates– towards Italian “opportunities” (university spin offs, start-ups). But also to encourage R&D investments in Italy carried out by large enterprises such as IBM or GE and such as Microsoft or Genentech already did. It is a difficult task, because economies like India and China are becoming so strong and powerful, but I am also positive that Italy has a lot to offer. Our scientists and researchers are among the best and this is what a foreign investor is ultimately looking for: talent.

What can we do in order to try to achieve this goal? As the Italian Trade Commission, we organize and **participate in several events**. For example, we participate along with a large representation of Italian companies and research centers to the annual **BIO Conference and Expo**, as well as to the **NSTI Nanotech Trade Show**, the most important nanotech conference and event in the world. Within the Nanotech trade Show we also aim at increasing the presence of Italian spin offs and start ups – as well as research centers which have a patent portfolio to sell and promote - to participate into the **TechConnect Summit**, an event taking place simultaneously with the Nanotech Show but that focuses specifically on “selling” and promoting technology.

We continuously work to produce **detailed reports** that will provide potential investors – and not only to them – a picture of the “state of the art” of Italian biotech, nanotech and cleantech research centers and University spin-offs. The first of these reports, which I already mentioned, titled - Locating and Funding Early Stage Biotech Companies and Spin-offs an overview of Italian excellences in red biotech - is going to be released soon and I encourage you to contact me in order to receive a copy of it.

As part of our activity I am also very proud to announce here our recent **commitment with the Italian Scientists and Scholars of North America Foundation, ISSNAF**. The ITC (NY) and ISSNAF very recently entered into a collaboration that I am sure will bring us a lot of visibility and will help achieve our goals. We both believe how important it is to support science and research in Italy as well as provide a “social forum” aimed at all those “talents” that we have “lost”, in a way, but that we should regard as an “opportunity”, instead. I encourage all of those interested in the activities of the ISSNAF foundation to become part of it.

This is all, for today. I hope you found my brief introduction useful and that you will look at Italy and at all the opportunities I mentioned to you with interest. My staff at the investments desk and myself are at your disposal for any further information you may require.

Thank you.

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