ITALY AT BIO
INTERNATIONAL CONVENTION
June 3-6, 2019 - PHILADELPHIA

Business opportunities in Italian Life Sciences
PROJECTS AND CLUSTERS

In collaboration with
Business opportunities in Italian Life Sciences
PROJECTS AND CLUSTERS
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**LIFE SCIENCES IN ITALY: FACTS & FIGURES**

1. With a production value of € 32 bn in 2018, pharmaceutical companies in Italy have a role of leadership in the EU, also thanks to the quality of the supply and service chain.

2. Largest pharma export growth in Europe: from 2008 to 2018 +117% (vs +58% big EU Countries average).

3. € 1.5 bn pharma R&D investments, grown by 22% over the last 5 years (vs +16% the European average), with an ever increasing synergy between companies and public bodies.

4. € 700 m invested yearly in clinical trials by pharma companies, rising to € 1 bn if we include medical devices companies.

5. 66,000 highly qualified employees (90% with secondary school certification or university degree) +8.6% over the last 5 years. A skilled and flexible workforce is considered a crucial factor by foreign companies who have already located in Italy.

6. Top destination for life sciences FDIs in Europe: 60% of pharma companies based in Italy are foreign-owned companies.

7. Vibrant pharma national industry, doubling its export value over the last 10 years.

8. Robust medical devices sector, accounting for over 3,800 companies and hosting the “Mirandola district”, one of the top biomedical clusters in the world.

9. 3 out of 9 advanced therapy medicinal products currently authorized for the EU market are the result of Italian R&D.

10. Therapeutic pipeline of more than 300 biotech projects, of which 90 in clinical development.

11. World-class R&D in a wide range of areas, including vaccines, oncology, neurological and degenerative diseases, immunology, rare diseases, plasma derivatives, respiratory and cardiovascular diseases.

12. World-renowned National Healthcare System with universal coverage, including a broad variety of excellent institutes as potential partners (the overall healthcare sector accounts for 11% GDP).

* PROVIDED BY FARMINDUSTRIA AND FEDERCHIMICA/ASSOBIOTEC
Italian Trade Agency -
Invest In Italy

The Italian Trade Agency (ITA) is the governmental body in charge of the international development of the Italian economy. ITA supports the internationalization of Italian firms and through the Foreign Direct Investment Unit facilitates the establishment and development of foreign companies in Italy. Inward investment attraction is carried on through the “Invest in Italy” program along with the support of Invitalia spa, the state-owned company for economic development. “Invest in Italy” provides several facilities:

• promoting business opportunities;
• helping foreign investors to establish or expand their operations;
• supporting investors throughout the investment life cycle with sector-specific experts;
• offering high-level tutoring services for existing strategic investments.

“Invest In Italy” provides information, support and advisory services to foreign companies on the Italian domestic markets, encouraging and facilitating investments and cooperation in different areas such as: real estate, tourism, infrastructures and logistics, biotechnologies, smart manufacturing and technologies.

To achieve its goals ITA, with its headquarter in Rome, can rely on a worldwide network of 78 branches in 66 countries and 12 Foreign Direct Investment dedicated Desks (Istanbul, London, New York, Tokyo, Dubai, San Francisco, Beijing, Bern, Stockholm, Doha, Toronto, Paris), so as to ensure a worldwide coverage and customized services.

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LIFE SCIENCES PROJECTS
IVIS SUITE:
Integrated Platform For Customized, Remotely Controllable, Refractive And Therapeutic Corneal Surgery

**DESCRIPTION**

The iVis Suite™ is an in-house fully developed platform for customized corneal surgery, with remote close loop control, conceived to carry out cTen™, an iVis Technologies’ proprietary, fully automated, no-touch surgical technique. cTen™ carries out the treatment for any refractive disease and complex corneal therapeutic cases, based on to the patient’s real needs, optimizing the quality of vision and minimizing surgical invasiveness. The cTen™ no-touch, remote controlled process maximizes surgical performances even in remote areas, where the presence of skilled surgeons may not be possible. The iVis Suite™ consists of Precisio™, a surgical corneal tomographer, pMetrics™, a dynamic pupillometer, Cipta™ and Clat™, planning software and iRes™, a full automated excimer laser. iVis Suite™ data analysis and process verification are remotely managed by means of iVerify™, an iVis Technologies’ proprietary WEB app allowing data exchange and interaction among all worldwide installed platforms.

The iVis Suite™ is a pluri-patented technological platform which has been developed on the basis of 13 patents (3 Italian patents, 7 European patents and 3 pending patents).

The iVis Suite™ is a fully developed ensemble of medical devices CE, Australian and Canadian approved, currently undergoing KFDA approval.

iVis Technologies’ R&D team is currently developing TES™, an innovative biomaterial to temporarily replace the corneal epithelium aimed to eliminate post-operative pain and to improve the quality of vision in the immediate post-op and a second generation of the iVis Suite™ to furthermore enhance its technological market leadership.

iVis Technologies is presently a privately owned company, without any external shareholders.

**BUSINESS PROPOSAL**

The iVis Suite™ is the only technological platform available in the international market, granting high levels of performance in corneal surgery even in remote geographic areas. An Industrial Partner with a consolidated worldwide presence is required to build up our new sales model, based on the creation of iVis Centers™ which will be directly managed by the Company in order to optimise revenue from the patient’s treatment fees. Based on the latest business plan to support iVis Suite™ large scale production and to start running the iVis Centers™, an investment of €20M is required.

**Key advantages**

The iVis Suite™ is the only technological platform for corneal surgery on the market, totally designed, developed and manufactured inside iVis Technologies to meet patient’s needs by optimizing the quality of vision and minimizing invasiveness for refractive surgery and for otherwise untreatable therapeutic pathologies. Thanks to its own proprietary cTen™, no-touch, remote controlled, surgical technique, it allows high performance even in remote geographic areas. It may be easily installed within basic-level surgical ophthalmic iVis Centers™.
PLENITY (GELESIS100)
Superabsorbent hydrogel for GI-related chronic diseases

DESCRIPTION
Gelesis is developing a novel hydrogel platform technology to treat overweight and obesity and chronic diseases related to the GI pathway. Gelesis’ proprietary approach is designed to act mechanically in the GI pathway to potentially alter the course of chronic diseases. In April 2019, Gelesis received FDA clearance for its lead product candidate, PLENITY™ (Gelesis 100), as an aid for weight management in overweight and obese adults with a Body Mass Index (BMI) of 25-40 kg/m², when used in conjunction with diet and exercise. Gelesis is preparing to initiate a targeted U.S. launch of PLENITY in the second half of 2019 and anticipates PLENITY will be broadly available by prescription in the U.S. in 2020. Plenity will initially be manufactured for commercial distribution by Gelesis S.r.l. at its clinical manufacturing facility in Calimera Italy. Gelesis also plans a new commercial-scale manufacturing facility in the region to support anticipated future demand for Plenity in the US, EU and other markets. Additionally, Gelesis is developing its second investigational candidate, Gelesis200, a hydrogel optimized for weight loss and glycemic control in patients with type 2 diabetes and prediabetes. Novel hydrogel mechanotherapeutics based on the Gelesis platform technology are also being advanced through a pipeline in other GI inflammatory conditions where gut barrier and gut permeability potentially play a role, such as non-alcoholic steatohepatitis (NASH), inflammatory bowel disease (IBD) and chronic idiopathic constipation (CIC). The Gelesis executive and advisory team includes some of the world’s leading experts in obesity, materials science, chronic disease research and commercialization.

BUSINESS PROPOSAL
The iVis Suite™ is the only technological platform available in the Our proposal is directed to financial partners interested in collaborating with Gelesis in the industrial start-up of its product. Plenity (Gelesis100) PLENITY™ is an orally administered, non-stimulant, non-systemic aid to weight management with a highly favorable safety and efficacy profile demonstrated in clinical studies. Plenity is FDA cleared, in conjunction with diet and exercise, for the largest number of adults struggling with overweight and obesity (BMI 25-40 kg/m²) of any prescription weight-management aid. More than half of the 150 million adults in the U.S. with a BMI ranging from 25 kg/m² to 40 kg/m² are classified as overweight (BMI 25-30 kg/m²). Until now, many of them have not had any prescription treatment options. The safety and efficacy profile of PLENITY makes it well-suited for these individuals. It is the only prescription weight management product to be cleared for use by overweight adults with a BMI as low as 25 kg/m², with and also without comorbidities such as hypertension, type 2 diabetes or dyslipidemia. There is no restriction on how long PLENITY can be used to assist in weight management. The eligible partners are: pharma companies, banks, venture capitals, funds, institutional and non-institutional investors.

Key advantages
• Significant market opportunity for approved product
• Robust clinical and preclinical pipeline leveraging proprietary hydrogel platform targeting large, unmet medical needs including Gelesis200 (weight loss and glycemic control), GS300 (NAFLD/NASH), GS400 (Mucositis/IBD) and GS500 (Chronic Idiopathic Constipation).
• Ongoing investment focused on preparation for US commercial launch and manufacturing scale-up of Plenity™ (Gelesis100) to commercial-scale levels.
• Specialized team covering all the Company activities (from R&D to management and finance).
DESCRIPTION

The main objective is the realization of a Network, for the development of new radiopharmaceuticals, in order to identify a new radiopharmaceutical useful for the diagnosis of ovarian cancer and preclinical experimentation, of the molecule PDL-1 Affibody marked with Zr-89 for the diagnosis of malignant tumors, characterized by the over-expression of the transmembrane protein PDL1 (Programmed Death Ligand).

The research results, intellectual and industrial property, rights will be provided, and will be the subject of agreements between the partners. The research outputs will have undoubted repercussions on the area of specialization as new radiopharmaceuticals will be available that are more selective, innovative and with a longer half-life. Unfortunately, the market demand is constantly increasing, as is the demand for radiopharmaceuticals for the diagnosis and treatment of cancer. From the point of view of the reference market, in 2016 there were 225,000 new cases in the world of ovarian cancer, 61,000 in Europe and 5,000 in Italy. From a histological point of view, there are different histotypes and high-grade serous ovarian cancer accounts for about 70% of all ovarian tumors diagnosed. The use of radiometers for the marking of biomolecules in recent years is on the rise (think of 68Ga-DOTA-peptides, 68Ga-PSMA, 64Cu-DOTA-peptide, 89Zr-monoclonal antibodies, etc). The creation of the Network will give the possibility to generate further patents for new products and processes subject to experimentation.

BUSINESS PROPOSAL

The focal point of the project is the realization of a Network, for the development of new radiopharmaceuticals through the aggregation between public and private subjects, which can guarantee the carrying out of all the research and development phases: from the conception of a new molecule (New Chemical Entity), in vitro studies, ex vivo and in vivo (preclinical experimentation), up to clinical trials in humans. This business has a good Ebitda and the average investment for building and technology is around 10M USD. In our business plan we estimate to have a ROI in 3 years. According to this, we are looking for investors such Private Equity and Big Pharma company to build a facility and a pharmaceutical network for the development.

Key advantages

The initiative provides for the transfer of know-how and expertise from primary companies operating in the radiopharmaceutical production sector through experimentation and subsequent collaboration in the production and use of new radiotracers.

- The collaboration with large companies and multinationals will be able to provide agreements for the on-site production of radiopharmaceuticals.
- The realization of the Network will allow the formalization of the know-how transfer processes towards the Southern Regions.
- The initiative sees the main area of interest as Puglia but the partners have already activated research units located in other areas of Southern Italy, Sicily.
BREATHLESS
Micrornas as biomarkers for the diagnosis of lung diseases caused by exposure to environmental pollutants

DESCRIPTION
Breathless is a method for screening and assessing lung damage through the rapid and accurate detection of the microRNA pattern from all biological fluids in subjects exposed to environmental pollutants. It has been developed and experimented at the Magna Graecia University of Catanzaro in partnership with Biotecnomed S.CaRL.

Breathless can be used to monitor working and living conditions and helps preventing respiratory diseases, thus avoiding/reducing NHS costs due to treatments and assistance.

It can be implemented as an analysis sequence or as a portable diagnostic kit.

The screening method is patent pending (Italian Patent application no. IT20170034619, PCT application WO/2018/178917).

BUSINESS PROPOSAL
- A screening method and RNA sequence for easy assessment of lung damage and working/living conditions
- Target investor can be a licensee interested in acquiring an exclusive license for the exploitation of the invention OR a financial partner able to support us in developing a diagnostic kit. Alternatively, we can sell the patent to pharma companies.

Key advantages
• Can be implemented as analysis sequence or as device kit (digital reader + sample stick)
• Low-cost test for self-diagnosis
• Easy monitoring of health and air quality in working environments
• Helps avoiding prescription of inappropriate drugs
• It can reduce NHS costs due to treatment of lung and respiratory diseases due to working/living conditions.

Region: Calabria Region

Proposer:
Biotecnomed S.CaRL – Innovation Cluster for Life Sciences

Areas of Activity:
Biotecnologies (Pharma & Medical Devices), Consulting Services, Life Sciences related activities

Investment Type:
R&D Industrial/technological partnership Funding

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μEMG – TREMOR ANALYZER

DESCRIPTION
μEMG – Tremor analyzer is an innovative wearable device for automatic characterization of tremor symptoms. It allows early screening and reliable diagnosis of neurodegenerative disorder based on tremor analysis and can identify Parkinson’s Disease tremor. It can also be used to monitor and assess efficacy of therapies. It is worn like a watch and has two tiny satellites that are stuck to antagonist muscles using pre-gelled clip electrodes. It can be used even by a non-specialist (e.g. general practitioner) and can reliably distinguish parkinsonian tremor from essential (benign) tremor. Can easily be implemented as a wearable armband and is suitable for diagnostic applications in presence of tremor symptoms, thus avoiding expensive and invasive examinations like MIBG, DAT-SPECT, EMG.

The wearable device and analysis method are patent pending (Italian Patent Application no. 102019000002559 “Metodo e kit per la classificazione dei tremori muscolari”). A first prototype is being experimented.

Bibliography:

BUSINESS PROPOSAL
A low cost digital device for outpatient use + mobile app + (optional) web application. The analysis method can also be implemented to extend functions of classical EMG.

Target investors: licensee (annual fee+royalties%) or patent buyer

Key advantages
• Low cost (high margin) and easily adoptable by physicians and GPs for capillary diffusion
• Reliable diagnosis of neurodegenerative disease (PD tremor vs essential tremor)
• Can positively impact on costs for NHS
• Sound scientific background.
UTERINE CANCER DETECTOR (UCD)

DESCRIPTION
UCD is a method for uterine cancer detection. This diagnostic method allows to discriminate between uterine sarcoma (malignant) and fibroma (benign); in particular, the in vitro method includes some steps:

a) Determine LDHTOT total lactate dehydrogenase expression and LDH5, LDH1 and LDH3 isoforms from a sample of a subject;

b) Compare the values obtained to reference values;

c) Assign this sample to a risk class.

It can be implemented as a kit for automatic diagnosis and/or self-diagnosis.

For this screening method a patent application has been submitted (Italian Patent Pending No.102019000004155).

BUSINESS PROPOSAL

- A new method and a diagnostic kit for the reliable detection of uterine cancer
- Target investor can be a licensee interested in acquiring an exclusive license for the exploitation of the invention OR a financial partner able to support us in developing the diagnostic kit. Alternatively, we can sell the patent to pharma companies.

Key advantages

- It allows to make accurate diagnosis avoiding invasive (and very harmful) surgery
- Can be implemented as a device/kit for fast automatic analysis of biological fluids
- Early detection highly enhances life expectancy.
THE “BIG DATA TECHNOPOLE – BOLOGNA HUB”

**Region:** Emilia Romagna

**Proposer:** Emilia-Romagna Region

**Areas of Activity:** Bioinformatics, Big data analytics eHealth, mHealth, telemedicine Software, ICT applications, system integration

**Investment Type:** Greenfield manufacturing (new research facilities and/or services) Brownfield (expansion/renovation) R&D Industrial/technological partnership

**Key advantages**
1. Outstanding business environment in the same area (facility) including top world HPC computers, Bio-banks of the Rizzoli Institute of Bologna, the “Bi-Rex” Competence Center (that includes companies connected to the Health Cluster), and many other organizations related to energy and environment (e.g.: Enea, Arpae);
2. Strong link with the regional Health Cluster including biomedical, pharmaceutical and wellness sub-clusters with a widespread network of universities and research institutions and excellent health care services;
3. Collaboration with the regional “Clust-ER Health”, PPP involving companies and R&D and training institutes;
4. Strategic location with excellent logistics position and transport and ICT infrastructures;
5. Clear procedures and certain times.

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**Business Proposal**
The “Big Data Technopole - Bologna Hub” provides an area of about 40,000 sq.m available for new investments of which:
- 30,000 sq.m available through renovation of the “Ballette – Research and Innovation Centre”
- 10,000 sq.m for new facilities to be built

Targeted investors are companies and organizations (including also R&D Centre, Training institutes, etc.) related to big data analytics and industry 4.0, also focused on health industries.

**Note:** investment opportunities (including the amount) will be directly managed by Emilia-Romagna Regional Government through public tender or other forms of negotiation.

**Description**
The Technopoles are a network of 10 infrastructures located in 20 locations throughout the Emilia-Romagna region (www.retealtatecnologia.it/en/technopoles), hosting and organizing activities and services for industrial research, experimental development and technology transfer.

The main objective is to make the Big Data Technopole a global benchmark for computing capacity and data management for the industrial ecosystem. The “Big Data Technopole - Bologna Hub” is a new space for Digital Economy with an area of about 120,000 sq.m of which 40,000 sq.m available for new investments in an outstanding business environment.

By 2019, the Hub will host the European Centre for Medium-Range Weather Forecasts (ECMWF) data centre, and by 2020 will host Interuniversity Consortium (CINECA) with one of the top 20 world most powerful HPC computers, the Competence Center Industry 4.0 “Bi-REX”, INFN complex (National Institute of Nuclear Physics), the Bio-banks of the Rizzoli Institute of Bologna, Arpae Emilia-Romagna, ENEA, and other small and large companies and organizations also related to health industries.

Emilia-Romagna region is strongly investing on the development of an innovative ecosystem based on Big Data management/exploitation: the Bologna Technopole for Big Data and artificial intelligence calls for an investment of over €350 million. The investment plan includes taking part in a European tender to host a world class pre-exascale HPC supercomputer acquired by the Joint Undertaking EuroHPC at the Bologna Technopole, at a cost of €120 million that the Region intends to fund in close collaboration with the national government. The Region is also working on a new regional law to create a Foundation to consolidate, enhance and promote scientific research and its interdisciplinary implications with a particular focus on Big Data and artificial intelligence.
REGENERATIVE MEDICINE INNOVATION HUB OF EMILIA-ROMAGNA

Region:
Emilia Romagna

Proposer:
Clust-ER Health and Wellbeing

Areas of Activity:
Biotechnologies (Pharma&MedicalDevices); Genetics&Genomics; Life Sciences related activities

Investment Type:
R&D Industrial/technological partnership Funding

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DESCRIPTION
The regenerative Medicine Innovation Hub of the Emilia Romagna Region is a combination of research centres, companies, facilities and innovative projects focused on regenerative and restorative medicine. It can rely on several strategical assets that are looking for new partners and investors, such as:

1. CMR “Stefano Ferrari”: the Centre is focused on basic and translational research of epithelial stem cells. CMR is run by Holostem, a biotech company founded as a spin-off of the University of Modena along with the big enterprise Chiesi. In 2015, Holostem obtained from the EU Commission the first European marketing authorization for an ATMP (Holoclar®). CMR has a 2000sqm GMP facility containing 17 Class B rooms.

2. Multiparametric platform for patient and cells profiling: this platform is the fruit of a partnership among regional partners of the IRMI project (University of Bologna, Rizzoli Orthopaedic Institute, IRET Foundation, Chiesi Group, IGEA, CIDSTEM). The platform is focused on markers for cell and patient selection, genotype and phenotype profiling of patient-derived cells with the power of predicting cell therapy efficacy.

3. HPC Infrastructure for Big Data Analytics in the life sciences: This project will exploit the potential of the HPC infrastructure in order to develop multivariate analysis techniques of personal, demographic, clinical, bio-temporal, genetic and neurobiological characteristics of patients. Investment required: 6M€.

4. Advanced centres for biomaterials for regenerative medicine: involved research and innovation centres are ISTEC-CNR, CNR-BO, University of Bologna and others. Available for partnership and research project.

5. Epidermolysis Bullosa Hub: It aims to develop an international network for Epidermolysis Bullosa studies.


BUSINESS PROPOSAL
The Regenerative Medicine Innovation Hub of the Emilia-Romagna Region is ready to establish Industrial and technological partnership with:

- Pharma companies interested in investigating the potential of regenerative medicine
- Research centres interested in activating joint labs
- Investors interested in startups operating in the regenerative and restorative medicine.

Key advantages
- Emilia-Romagna is cutting edge region in regenerative medicine
- Ecosystem is already in place and it covers all the Value Chain of the regenerative medicine (materials, equipment, research laboratories, startups, pharma companies, technology provider, certification authorities)
- Regenerative Medicine is a very strategic area (regional S3 Strategy) for the Emilia Romagna region: further public investment are planned in this sector
- The global regenerative medicine market was valued at $5,444 million in 2016, and is estimated to reach $39,325 million by 2023.

Big Data Technopole
Bologna Hub
10,000 sq.m for new facilities to be built
30,000 sq.m available through renovation
STREAMED.AI – ANTICIPATE TREATMENT DECISION

**REGION:**
Friuli Venezia Giulia

**PROPOSER:**
Biovalley Investments spa

**AREAS OF ACTIVITY:**
Medical devices

**INVESTMENT TYPE:**
Funding

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**DESCRIPTION**
StreaMED.ai is a SaaS platform designed to support effective patient flow management in surgery units of public and private healthcare providers. Based on integrated medical data collection systems - including sensors, monitoring machines and other hardware - and driven by its Artificial Intelligence engine, it helps hospital professionals deliver excellent service to patients, reduce surgery-related risks by anticipating the onset of critical issues and optimizing resources. Compared to available solutions on the market, streaMED.ai offers a unique combination of the clinical and real-time data integration and standardization with the prediction and scheduling capabilities designed for the surgery patient flow.

Key partners are four private companies plus one University: the streaMED.ai team (to be founded as spin-off of University of Trieste), Biovalley Investments spa (contributing with fundraising and advisory support), ServerNET srl (as technology partner providing multi-year industry expertise and hardware and middleware medical technology in use in surgery units across the world), OSSi Intl. (technology partner providing software), and University of Trieste (R&D and scientific support). In order to produce a deliverable prototype, an estimated investment of € 900,000 is required to cover the development costs for the first three years. Based on current negotiations with two research hospitals, the team expects to receive from these institutions € 300,000 in the 3 years; a portion of this funding will be received upfront to develop the prototype.

The project is in its early stage: the streaMED.ai company is expected to be founded by the end of 2019; the business model and revenue/cost streams have been finalized: hospitals will benefit from cost savings up to 10% on average operating room costs, produced by reduced risk and increased efficiency; the break-even point is expected to be achieved at the beginning of the fifth year. The core team has been working on the project for one year and is looking for additional resources to expand; the team is now focused on fundraising efforts targeting regional, European and international private and public financing.

**BUSINESS PROPOSAL**
The team offers to investors a remuneration of 5-10% based on the amount of the investment and on the investors’ to be involved in the project as a company shareholder and/or scientific advisor or commercial partner. The team is looking for pure investors and/or commercial partners.

**Key advantages**
- The project aims at solving a problem experienced by surgery units for years, producing relevant cost savings with AI technology developed in collaboration with a specialized center of the University of Trieste.
- As of today, there are no comparable solutions available in terms of integration of technologies and clinical data management.
- The consortium of partners gathers skills, expertise, and technology acquired during 20 years of direct professional experience in developing middleware, connectivity and integration of clinical, laboratory and medical image data for hospital organization.
HTMark
(Hepato-toxicity biomarker)

**Region:**
Lazio Region

**Proposer:**
Genechron S.r.l.

**Areas of Activity:**
Diagnostics IVD, Biotechnologies (Pharma&Medical Devices), Genetics & Genomics

**Investment Type:**
R&D Industrial/technological partnership Funding

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**DESCRIPTION**
Genechron Srl is a biotechnological company: it focuses on the development and production of new diagnostic assays based on biomarkers (miRNA). Genechron has strong competences in molecular biology, a motivated and highly professional researchers team, an international Business Development, a relevant scientific network embracing Academia, General Hospital and Medical Research Centre, a good track record showing its capability of attracting public funds for R&D. In the first 2 years of activity it has collected €700k from investors and €700k from public grants. To date it has an exclusive licence of a miRNA patent for DMD and the exclusive distribution licence in Italy of a liquid biopsy assay for prostate cancer. The HTMark project aims at realizing a new biomarker-based assays for testing drug hepato-toxicity to be used either in pre-clinical and Phase 1 clinical trials (in its GLP formulation) and, more widely, in the hepatology diagnostics, when dealing with DILI (Drug-Induced Liver Injury) and other types of diseases related to hepatic damages. Genechron aims at completing the R&D phases consisting in the realization of a CE-IVD RT-qPCR assays based on three different miRNA which, together, could provide a sensitive and specific test for identifying a liver pathological state. The three miRNAs have been identified: among them, the most known is miRNA122 which is highly liver-tissue specific; there is a large scientific literature showing that this biomarker can also be used to differentiate among different liver damages. Other miRNAs, which have been object of investigations by Genechron Srl, will be used to improve even further the assay specificity and to allow a better differentiation among different pathological causes which could produce similar miRNA122 outcomes. Assay will be also validated in GLP in a way to be deployable as toxicological end-point in pharmaceutical pre-clinical and phase 1 clinical trials. Project will also forecast the industrial design of the assay (in terms of components) and the identification of a kit production company.

**BUSINESS PROPOSAL**
Our target Investor is a financial organization aiming at investing on such specific project and enabling its completion in the time span of 18 months. A further investor type could be a biotechnological Company acting in the area of production of new biomarkers assays. To the first we offer a relevant ROI, to the second the possibility of producing and selling (royalty mechanism) a kit with a very large basin of use (hepatic problems are largely diffused in the western countries with a large use of drugs).

**Key advantages**
- Genechron has a proprietary miRNA “absolute quantification method” relevant in the GLP formulation of the assay and suited to be implemented in the assay application in pharmacological trials.
- Hepatic problems are largely diffused in western countries due to an extensive use of drugs and other medical supports.
- Return of Investments can be important as the assay, due to its relevance as early diagnostics, can be particularly appealing for Pharmaceutical Companies that are developing new drugs in preclinical and Phase I clinical trial and for National Health Services as it can produce significant costs reduction.
HAPPYSALUS

DESCRIPTION
HappySalus is a Mobile-Health system that, starting from the monitoring of physiological parameters carried out through medical and wearable instruments, guides users towards wellbeing and longevity. HappySalus, using a proprietary algorithm (which also includes an artificial intelligence engine to interpret medical Big Data) is able to provide the user with alerts, tips and health paths.

The HappySalus system consists of the following elements:
1. The monitoring of physiological parameters operated with medical and wearable devices and an intuitive APP,
2. The algorithm for the analysis of the data received and the management of big data
3. an engagement system with the end user, with the aim of maintaining a lasting and proactive relationship.
4. an Ecommerce platform (Happymarket) where the customer can buy products related to his health based on targeted and ad hoc (customized) indications.

With offices in Rome, Bologna, and Benevento, Healthia can boast a Scientific Committee made up of internationally renowned medical professors from all over the world, technical collaborations with research centers (Inuit University Foundation of Tor Vergata and Scientific Research Center Sannio Tech), commercial partners (Gima Spa, Nital Spa), institutional partners (Regione Lazio, IUC) and the support of Banca Intesa San Paolo.

Happysalus has already been created and integrated with other services: video-visits, remote health management, virtual clinic, blockchain permissioned technology. We are awaiting patenting and have already completed the first financing phase; we are looking for financial investors, university scientific partnerships and business partners.

BUSINESS PROPOSAL
We are looking for investors, university and technology partners to:
1. Develop our interpretative algorithm and in particular that based on medical artificial intelligence engines
2. Develop our IT platforms, our APPs VS customers and our market place
3. Internationalize as quickly as possible
4. Create digital and social marketing campaigns for the B2C market in order to acquire customers.

In particular we want to attract investors for the following two steps:
1) 1,500,000 euros for the development of new algorithms based on medical artificial intelligence engines,
2) an additional 3,500,000 euros for internationalization investments (opening foreign offices), commercial development and digital marketing (consumers customer base development).

Key advantages
• It has a very high potential market: remote monitoring based on AI, telemedicine for all, video visits,
• HappySalus can use any type of medical and wearable device
• Is the only system that provides an interpretation of multi-factorial medical data based on objective and non-perceived data,
• The ROI of the investment is extremely high and the business model is extremely replicable,
• It is suitable for both the B2B2C market and the B2C market.
TK-NEO: a Cancer Vaccine targeting NeoAntigens

**Region:**
Lazio Region

**Proposer:**
Takis Biotech

**Areas of Activity:**
Vaccines
Manufacturing & process engineering
Biotechnologies
(Pharma&MedicalDevices)

**Investment Type:**
Funding
Industrial/technological partnership

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**DESCRIPTION**

Takis is a Biotechnology Company founded in 2009 from a research group formerly in Merck Research Laboratories. The company currently includes 20 scientists/technicians, turnover 1.8M€, providing services and collaborating with key cancer R&D centres in Europe and USA.

The new frontier in Oncology is Cancer Immunotherapy. Cancer is caused by specific genomic mutations which are masked from the control of the immune system. Therapies based on PD-1 inhibitors have been approved and commercialized with good results for many different cancers. However, de-novo and acquired resistance is still seen in a large proportion of patients, due to patient-specific mutations and tumor heterogenicity. Neoantigen Cancer Vaccines (NCVs) based on patient-specific tumor genomes have recently entered the arena of immune therapy, raising great expectations. NCVs represent a new form of precision medicine and are a perfect clinical approach for highly heterogeneous tumors, providing the best balance/ratio between targeting tumors (specificity) while sparing normal tissue (toxicity). Takis has developed and patented a unique method for production and delivery of plasmid DNA-based patient-specific NCVs named TK-NEO, an individualized therapeutic cancer vaccine. TK-NEO is intended for use as therapeutic vaccination in patients with locally advanced or metastatic solid tumours. The whole process is based on 3 steps and requires 8 weeks from tumor sampling to vaccine delivery.

**BUSINESS PROPOSAL**

The strategy to reach the market for TK-NEO is to license the IP of TK-NEO to pharma company, once safety, regulatory and clinical validation is demonstrated in melanoma cancer patients. The financing needs in the next three years are about 7.5 million$. Takis has invested so far 500 k Euro in the development of TK-NEO and requires this investment to reach completion of a phase I, when the licensing will be targeted. Takis is looking for a Financial Partner (e.g. VC).

**Key advantages**

- TK-NEO is designed to act against the specific tumor/metastasis of the patient while current immunotherapies are not
- TK-NEO is 45% cheaper
- Takis would reach revenues of 25M€ in 2026 and cumulated cash flow of > 40 M€
- Target market: 5000 patients per year. In the 3 years after market launch, TK-NEO would produce a turnover of 250 million Euro per year to the pharma company.
KITHER BIOTECH:
Innovative drugs to treat Cystic Fibrosis and other Pulmonary Diseases

DESCRIPTION
PROJECT OVERVIEW: Kither Biotech is a biotech company that developed and patented a peptide (small molecule) to be administered through inhalation that claims superior efficacy vs. current standard of care in most of Cystic Fibrosis patients (class II-III-IV-V), carrying long lasting effects as a CFTR potentiator and corrector, as a bronchodilator and as an anti-inflammatory agent, with strong safety.

MARKET POTENTIAL: Cystic Fibrosis (CF) is a genetic disorder caused by mutations in the gene coding for CFTR protein, affecting over 75k patients worldwide whose life expectancy does not exceed 40 years old, mostly due to lung problems. The only approved treatments in the market are Kalidaco, indicated for around 5% of CF patients carrying a G551D mutation (and few others), Orkambi and Symdeko, indicated for around 85% of CF patients carrying F508del mutation (and few others), all of which developed by Vertex (NASDAQ:VRTX), providing limited efficacy and relevant side effects. High reimbursement price (> $250k/year), lack of competition and large pool of target patients (50k treated by 2025) made Vertex a $50bn company with around $3bn annual revenues in 2018 in CF only.

PROJECT STAGE: Kither Biotech was founded in Turin (Italy) by Prof. Hirsch, together with Prof. Bardelli (founder of Horizon Discovery, listed at London stock market - £330m), advised by Prof. Pandolfi (Harvard, Director of Beth Israel Cancer Center). Ex vivo (CF patients tissue organoids) and animal data collected so far support strong efficacy with no safety issues, making the compound a promising candidate for a Phase I study. Kither Biotech raised a Series A round in Q2 2019 to finance its development plan up to the completion of a Phase I study and will soon be fundraising again to support further Phase II studies and pursue trade sale or IPO opportunities.

BUSINESS PROPOSAL
Kither Biotech raised a Series A round in Q2 2019 to finance its development plan up to the completion of a Phase I study and will soon be fundraising again to support further Phase II studies and pursue trade sale or IPO opportunities. The company is open to discuss with possible investors or pharma/biotech companies interested in future licensing opportunities.

1. Institutional investors (PE/VE funds) with focus on life sciences ventures
2. Private investors with relevant experience in pharmaceutical industry
3. Pharma/Biotech companies

Key advantages
• High return opportunities (strong clinical need in CF), with short time to exit
• Promising pre-clinical data in CF, fully funded development path up to Phase I study completion;
• Experienced founding team
• Top tier biotech entrepreneur and investor among current shareholders
• Risk mitigation provided by pipeline programs currently going on in COPD, Asthma and IPF.

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PHARMA AND MEDTECH
DIGITAL-LOGISTICS HUB

DESCRIPTION
A digital logistical platform to support life sciences-based companies, which will optimize the supply chain of medicines produced in Tuscany, and in central Italy. The investment is aimed at equipping an area of 125,000 sqm, half of which to be used for new buildings, including a 21,000 sqm fully-automated warehouse with temperature-controlled environments, suitable to storage pharmaceutical products, 8 loading areas for shipment of goods, as well as about offices spaces of about 6,000 sqm.

It is a platform designed to have high expansion capacity, to serve any other interested companies operating in life sciences industry, since other warehouses can be built for an additional 20,000 sqm. The storage capacity, according to a feasibility analysis, is estimated at 38,000 initial pallet places, three quarters of which can hold temperatures between 15°C and 25°C and one quarter between 2°C and 8°C. 70% of stocks will be assigned to raw materials and packaging, 30% to finished products, handled at a rate of 52,000 pallets per year. 80% are intended to be exported and 20% for the domestic market.

PARTNERS INVOLVED: 4 Pharma Companies already operating in Tuscany
INVESTMENT REQUIRED: €100 Mln
PROJECT PHASE: feasibility study phase. A MoU between all partners to develop the logistics hub has been signed in 2018 between Italian National Government, Tuscany Region, Companies and other local Partners. The 4 Companies (future customers of the platform) signed a Network Agreement to collaborate and to speed-up the realization of the next phases of the project. The project is under evaluation to be proposed to regional and national incentives measures.

BUSINESS PROPOSAL
TARGET INVESTOR: Specialized financial or industrial Investor, operating in pharma/medtech and/or in pharma-logistics.

The investor will enter a fully developed pharma/medtech market, ready-to-buy innovative logistics services to internationally shipping medicines and medtechs from Italy

Key advantages
• the project is fully supported by the regional government and also received the commitment from the national level;
• the feasibility study has been strongly supported by the partners, together with a big specialized consultancy company;
• the logistics hub will be built on a strategic freight area, close to the Pisa’s cargo airport area, next to the highway, fully served by railway services and right behind the Livorno commercial harbour area;
• 4 big future customers already “on board”, with a high potentiality to attract many other big players from central Italy;
• the project is eligible to be presented to regional and national incentives measures.
EXOSOMICS: from Exosomes to Insight™

**Region:** Tuscany Region

**Proposer:** Exosomics SpA

**Areas of Activity:**
- Cancer Screening and Diagnostics
- Cancer Drug Development

**Investment Type:**
- R&D
- Funding

**Contact Info**

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**DESCRIPTION**

Exosomes develop breakthrough sample preparation technology for the isolation of tumor-derived exosomes for Precision Medicine. We serve both diagnostic providers and pharma so that they can extract more relevant information from liquid biopsy and improve patient outcomes.

Our business is made of Products and Services and we are opening our Round A of investments to help grow the business.

For Products, we have launched the first CE-IVD products for Cancer Diagnostics which allow to detect Cancer earlier from a blood draw. We are raising money to expand our clinical validation efforts and commercial infrastructure.

For Services, we secured the first services for Big Pharma and Biotech companies that are using our proprietary platform to analyze the genetic content of exosomes in cancer patients. This helps them to better stratify patients and therefore reduce the time and cost of the clinical trials. We have more request for services than we can currently sustain, and we are raising money to expand our capacity.

The fact that we are the first and only company in the world focussed exclusively on products and services on exosomes puts us in an extremely strong position for both disruptive growth or a big exit.

**BUSINESS PROPOSAL**

We have already raised $10M. We now offer a stake in our company and we would like to hear from private or corporate investors for our Round A (between 10 and USD15$M).

**Key advantages**

- Unique leadership position in the exosome field.
- Proprietary IP on technology to selectively isolate tumor-derived exosomes.
- Already on the market with CE-IVD approved products for clinicians and diagnostics providers.
- Secured big contracts from several Big Pharma.
- Lonza is a key strategic investor.
TOSCANANA LIFE SCIENCES FOUNDATION

DESCRIPTION

Toscanana Region counts more than 350 life science companies with 8.6 billion overall turnover and 16,000 employees, thanks to this dynamic business environment TLS has generated and attracted almost 180 million euros from 2007, created more than 340 new jobs mostly in R&D and provides services and lab space to 42 among spin-off, start-up, mature companies and research groups. TLS is one of the few certified incubators on the national scene dedicated exclusively to supporting the start-up of businesses in the Life Sciences sector.

The bio-incubator

The bio-incubator is a point of reference for companies that need to give legs to their ideas through spaces, technological facilities and services. “Basic” tools to grow and be able to compete on the market, with all its risks and opportunities. TLS provides the companies of the future with a team of professionals with experience in the scientific and industrial world who are specialized in technology transfer processes.

Research Services

Starting from this mix of skills, spaces and services the bio-incubator offers support to companies at every stage of their development, also providing a consolidated network of experts and consultants. TLS provides incubated and affiliated companies and third parties with analytical instruments and equipment for molecular biology research. In addition to direct access by users, TLS makes available its own technical staff to support researchers in the development of analytical methods or to directly conduct both in vivo and in vitro experimental activities.

• Equipment
• Mass Spectrometry Facility
• Animal Facility
• Level 3 pathogen containment laboratory (BSL3)
• Third-party services.

Intellectual Property Protection

The TLS staff provides assistance and advice in assessing and exploiting the assets represented by research results, in addition to accompanying and supporting companies in the contact phase with development and licensing partners for research projects and patent applications. To support the patenting and marketing activities of incubated or affiliated companies and research groups, TLS performs patent due diligence, offers monitoring and support for the management of filed patent applications and performs business intelligence and technology transfer activities.

BUSINESS PROPOSAL

1. Companies willing to establish R&D, Production and Commercial facilities in Italy
2. Companies looking for licensing opportunities in a broad range of Healthcare technologies
3. Investors searching for new technologies already validated on the Italian market
4. Investors searching for first and second round financing opportunities
5. International R&D companies searching for Clinical Development sites

Key advantages

• High Tech Facilities ready to start and implement your R&D project with top level experts
• Access to Intellectual Property protection, technology assessment and valorisation competences
• Introduction to the Italian market, soft-landing schemes and EU regulations compliance
• Access to Regional, National and European funding
• Networking activities at National and International level.

Contact Info

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**BIOTECH ECOSYSTEM IN TRENTO**

**Region:**
Autonomous Province of Trento

**Proposer:**
HIT-Hub Innovazione Trentino, Trentino Sviluppo and CIBIO - University of Trento

**Areas of Activity:**
Biotechnology for pharma Diagnostics IVD Genetics and genomics Peptides and proteins preparation

**Investment Type:**
R&D Industrial/technological partnership

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**DESCRIPTION**
The project consists in leveraging the potentiality of the Trentino Biotech ecosystem. After ten years since the creation of CIBIO, the department of the University of Trento dedicated to biology and biotechnology with more than 300 researchers operating there is a strong effort (public and private players) for the creation of an innovation environment that can facilitate the set up and development of a new generation of biotech companies and the localization of R&D centres of existing pharma companies.

The factors enhancing these possibilities are related to:

a) a number of biotech startups born in the last two years;
b) the excellence of the research competences and of the platform technologies in the CIBIO department;
c) local actors and experts facilitating the soft landing in Trentino: - Trentino Sviluppo (Development Agency), HIT-Hub Innovazione Trentino (innovation and technology transfer agency), Bio4Dreams (the first private biotech incubator), bank foundations, association and companies;
d) the possibility of the use of local incentives due to the autonomous status of the Trento Province for supporting R&D projects;
e) Access to clinical patients through the local Hospital (the public sanitary system is recognized of one of the excellences in the region);

Examples of the technology platforms available for biotechnology:

- High Throughput Screening (HTS)
- Next Generation Sequencing (NGS)
- Cell Analysis and Separation
- Advanced Imaging
- Mass Spectrometry (MS)
- Protein Technology
- Cell Technology
- Model Organism
- Bioinformatics
- Advanced molecular diagnostics

**BUSINESS PROPOSAL**
The primary target are pharmaceuticals companies and small/medium biotech that are looking for establishing or expanding R&D facilities looking for high knowledge intensive areas.

The proposals are to start R&D collaborations and technology partnership with the scope of setting up business locations for pharma and biotech companies.

**Key advantages**
- Research excellence
- Highly qualified workforce available
- Platform technologies
- R&D incentives
- Fiscal and tax credits
**CMP³ VDA**
Research center supporting personalized, preventive and predictive medicine

**Region:**
Valle d’Aosta

**Proposer:**
Regione Autonoma Valle d’Aosta

**Areas of Activity:**
Genetics & Genomics - Bioinformatics, Big data analytics - Biotechnologies (Pharma&MedicalDevices)

**Investment Type:**
R&D Industrial/technological partnership

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**DESCRIPTION**
The Aosta Valley region is creating a research center supporting personalized, preventive and predictive medicine, on a scale appropriate to the size of Valle d’Aosta, to boost the region’s research and health sector in an innovative way, implementing the specialization zones and technology transfer model set out in the Valle d’Aosta regional Research and innovation strategy for smart specialization for the period 2014/2020.

The main objective is to improve health, with particular reference to various neurodegenerative and oncological diseases. The research will also focus on building the genome profiles of samples of the population in order to establish a regional bioinformatics database.

The research activities are carried out by a partnership composed of research body and enterprises.

The project has available a total funding amount of 15,000,000 Euros for 5 years.

The proposals presented in response to the call are being evaluated. The activities are expected to begin on 1 July 2019 and the center will be fully operational on 1 January 2020.

The operation aims to establish technology transfer and create start-up and spin-off businesses. For example, it could be possible to support the creation of businesses which would focus their activity on identification of the diagnostic bio-markers which are needed for the development of new diagnostic kits which could be used by medical analysis laboratories, hospitals, clinics and care home.

Examples of the technology platforms available for biotechnology:
- High Throughput Screening (HTS)
- Next Generation Sequencing (NGS)
- Cell Analysis and Separation
- Advanced Imaging
- Mass Spectrometry (MS)
- Protein Technology
- Cell Technology
- Model Organism
- Bioinformatics
- Advanced molecular diagnostics

**BUSINESS PROPOSAL**
We are looking for companies, start-ups or consolidated companies, which intend to establish in the Aosta Valley region to benefit from the transfer of technology from the research center, to be supported with regional incentives for research and development, which provides grants to companies.

We are looking for researchers in biotechnologies or information technologies who want to come to work in a cutting-edge scientific context and in an environmental and natural context of excellence.

**Key advantages**
To acquire state-of-the-art of technologies that allow the development of the business of the companies in an advanced scientific context.

To operate in an administrative context favorable to business development, also thanks to the attention of the public administration and the availability of financial aid.

To operate between the highest peaks of the Alps, with important ski resort and Natural Parks, in a land of conjuncture between Italy, France and Switzerland.
LIFE SCIENCES CLUSTERS
Apulia

Infrastructures and connections

- 2 international airports (Bari and Brindisi), serving over 40 international destinations
- 1 industrial cargo airport (Taranto-Grottaglie), recently adopted as a test-bed for remotely piloted aircraft and designated as the first spaceport in Italy for the development of sub-orbital flights
- 1 local airport (Foggia), with connections to Tremiti Islands
- 3 major ports: Taranto (container shipping; the 3rd largest commercial port in Italy for cargo traffic); Bari (passenger and container traffic); Brindisi (passenger traffic)

Extensive road and railway networks, linking the region to major north-south corridors and high-speed rail network

1 logistics Interport located in Bari.

Industrial base

Apulia plays a leading role in the pharmaceutical sector in Italy and is one of the main regions for exports, thanks to the presence of multinational companies, including Sanofi and Merck which have located manufacturing plants and research facilities in the region.

The region has also gained recognition as a center of excellence for precision medicine, with the recent creation of the national Hub for precision medicine, TecnoMED, which carries out innovative research into tumors and neurodegenerative diseases, based on nanotechnologies.

Synergy between private and public research institutes aims at advancing research and encouraging the creation of local hi-tech businesses that can industrialize research results and bring patents to markets in areas such as biotechnology drugs, gene therapy, somatic cell therapy, tissue engineering, biomarkers, drug discovery and drug delivery, advanced diagnostics, bioinformatics.

H-BIO - Apulian Biotech Cluster (11 public and 25 private partners) is a key player in this area and brings together the interests and activities of both regional universities and research centers and private companies operating in the fields of healthcare and biotech-drugs, focusing on 4 strategic sectors: Personalized medicine; Advanced Therapy; Molecular and advanced diagnostics; New manufacturing processes.

R&D network

3 major Universities (Bari, Foggia, Salento) and 1 Polytechnic University (Bari)
3 specialised Hospital Research Institutes
- IRCCS Istituto Tumori “Giovanni Paolo II” (specialised in cancer research)
- IRCCS “Casa Sollievo della Sofferenza” (specialised in genetic diseases)
- IRCCS “Saverio de Bellis” (specialised in molecular biology and degenerative diseases)
2 National Research Centres
- National Research Council (CNR), present in Apulia with 6 research institutes, including NANOTEC – Institute of Nanotechnology which hosts TecnoMED
- National Institute for Nuclear Physics (INFN)
CVBF - Biological and Pharmacological Evaluation Consortium for research and product testing.
C.A.R.S.O. Consortium for post-doc training in biomolecular and oncological research and treatment

FACTS & FIGURES

226 companies active in Life Sciences (including Sanofi and Merck), with over 1,650 employees.

The regional export of pharmaceuticals and chemicals in 2017 amounted to over 1.6 billion Euros.

Main business sector specializations:
- Advanced Pharmaceuticals
- Biomedical Devices
- Advanced Diagnostics
- ICT (Bioinformatics - Telemedicine - eHealth)
- Cosmetics
- Surgical and Medical Supplies

Contact info

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Business opportunity

Apulia is an authentic and modern region which offers many advantages to potential investors and represents the ideal location for companies looking to invest in Europe, at the heart of the Mediterranean.

The region is building a strong reputation as a hub for innovation thanks to the work of its more than 415 private and public entities, including universities, business and technology clusters and laboratory networks start-ups, all of which are active in research and development.

The Apulia regional government stands out for its commitment to investment in research and innovation, and is focused mainly on smart technologies and providing a significant boost to hi-tech sectors.

Through Puglia Sviluppo, the regional development agency, potential investors in Apulia can access a raft of incentives, as well as assistance throughout the initial setting-up phase in identifying business locations, local business and research partners and so on.

Overall, Apulia is an increasingly attractive business location thanks to its strategic geographic location, the availability of a young, skilled and efficient workforce, government aid and assistance making for competitive operational costs, a well developed and highly integrated ecosystem for scientific and technological R&D.

Incentives and funding

Regional Contract Programmes: regional grants scheme supporting business innovation and investment projects for existing companies or for new companies to be located in the region, with investment budgets falling within the range between 5 million and 100 million Euros;

Integrated Incentives Packages (PIA): regional grants scheme supporting business innovation and investment projects for existing SMEs or new ones to be set-up in the region, with investment budgets falling within the range between 1 million and 40 million Euros;

Tecnonidi: regional grants initiative which supports investments projects for innovative start-ups and SMEs, with a high-technology content aimed at introducing new products, services and/or business solutions, with investment budgets falling within the range between 25,000 and 350,000 Euros.

Sites and buildings

2 Business Incubators located in Puglia Sviluppo’s premises in Modugno (BA), suitable for service industry and digital start-ups and Casarano (LE), suitable for research and manufacturing activities, offering competitive costs and 100Mbps ultrafast broadband.

H BIO - Apulian Biotech Cluster based in the University of Bari.

Success story

- In 2018, Gelesis, a biotechnology company based in Apulia and co-founded by PureTech Health (an advanced, clinical-stage biopharmaceutical company from Boston - USA), developing first-in-class mechanotherapeutics to treat chronic diseases related to the gastrointestinal (GI) pathway, closed an international financing round, raising $ 30 million of funding. The proceeds from the financing will be used to support commercial-stage manufacturing, product launch preparations, company operations, and clinical advancement of the Company’s pipeline of additional product candidates for gastrointestinal disorders, including Type 2 diabetes and non-alcoholic steatohepatits/non-alcoholic fatty liver disease (NASH/NAFLD). On April 14th Gelesis announced that the United States Food and Drug Administration (FDA) has cleared the Company’s lead product candidate, PLENITY™ (Gelesis100), as an aid in weight management in adults with a Body Mass Index (BMI) of 25–40 kg/m2, when used in conjunction with diet and exercise.

- In 2017 the French multinational Sanofi, active in pharmaceutical sector decided to invest 6 million euros in the Brindisi plant, for the development of an industrial biotechnology project that aims to develop innovative technologies for the genetic improvement of the microorganisms and of the processes of fermentation extraction and purification of active ingredients.
Emilia Romagna

Infrastructures and connections

- 3 international airports: Bologna (the main regional hub) Parma and Rimini
- 7 main freight villages/intermodal terminals:
  - main freight villages are in Bologna and Parma (CEPIM).
  - Important hubs are located in Piacenza, Villa Selva (Forlì)
  - Ravenna, Bologna S.Donato.
- 1 commercial port (Ravenna And a regional system of fluvial ports and regional connection to all the main ports along the Adriatic and
- Tyrrenian coasts.

FACTS & FIGURES

- The health care industry in EmiliaRomagna boasts excellences and strong potentials, with mature biomedical district and prostheses centres, pharmaceutical industry with high growth trends, a renowned healthcare system, the Wellness Valley.
- EMPLOYEES: 137,816
- LOCAL UNITS: 43,783 (2015, Istat-Asia)
- EXPORT: 3.06 billion Euro
  - 7.5% of the national cluster
  - 4.8% of the total regional export
  - regional exports of the cluster are ... the imports (2018, Istat – Coeweb)
- TURNOVER 10.7 billion euro (Aida – 2017)
- S3 –SMART SPECIALIZATION STRATEGY
  HEALTH AND WELLBEING
  - 300 projects financed by regional policies from 2014 to 2018, providing 84 million euro of incentives (on 158 million of total investments), hiring 272 new researchers

R&D network

Emilia-Romagna is one of the Italian regions with the highest proportion of R&D personnels per 1,000 inhabitants (7.2% in 2015 while Italian average is 4.3%). There are 31,919 employees in R&D sectors, 96 research facilities in the High Technology Regional Network (HTN), while total investment in R&D amounted to 2,682 million Euro in 2015.

The Emilia-Romagna regional authority considers the Health and Wellness sector to be one of the key sectors for the development of adequate innovation policies to maintain the highest standards and bring together important social and economic repercussions for the territory regional.

The Clust-ER Health and Wellbeing is an association recognized by the Region, consisting of large companies, SMEs, laboratories of the HTN, research centers, health facilities and training institutions that share skills, ideas and resources to support the regional competitiveness of the Health and Wellness Industries. The Region has identified Clust-ER as a key player in the innovation ecosystem capable of multiplying the opportunities for territorial development through the collaborative and participatory approach of its members.

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Paola Maccani

R&D network

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Industrial base
Emilia-Romagna is the first region in Italy for the efficiency of its health system and has always been on the top of the list for quality of universities, number of researchers and quality of the training system.

Alongside these public excellences, there is a strong and mature industrial system, which boasts the most important biomedical district in Europe, large companies in the pharmaceutical sector and emerging technological niches, such as those of regenerative medicine, which push the region to the top of the world industry innovation. The Life Sciences cluster is widespread in the region with top companies and highly specialized SMEs leaders in their respective niches. The main specializations and outstanding niches of the Life Sciences cluster are:
- the Mirandola Biomedical District (Modena) with companies as Livanova, Gambro Baxter, Fresenius Hemocare, etc. The district is leader in the manufacture of dialysis, heart surgery, transfusion equipment, along with other top technology content products, as well of disposable plastic products for medical use;
- a specialization in the production of medicines and pharmaceutical preparations in the province of Parma and in Bologna (e.g. Chiesi, Acme, Alfasigma, GSK);
- the Regenerative Medicine Hub with its important research centres, companies and startups (Holostem, Finceramica, Greenbone) along with several advanced biomaterial centres (ISTEC, CNR...);
- leading centres for the production of prostheses and rehabilitation in Budrio (Bologna), e.g. Inail centre;
- the Wellness Valley in the Romagna area, with excellences as Technogym and a widespread presence of spas and wellbeing centres;
- packaging machinery/solutions for pharmaceuticals and biomedical products (e.g. IMA, Marchesini, Marposs);
- machinery, equipment and gears for electromedical as well as measuring, checking and surveying instruments (e.g. Cefla, GVS, Bellco)
- regional district of health-related information technology and digital health, with one of the most important industrial poles for health and electronic welfare in Italy and one of the most significant ones in e-health and ICT.

The regional companies are particularly receptive to the innovations of the Industry 4.0.

Incentives and funding
There are many great opportunities to get financial incentives in Emilia-Romagna, especially to set up a research lab (infrastructure) and/or to realize R&D projects, and also through a combination of regional and national instruments.

The Regional Law for the Promotion of Investments (n.14/2014) provides incentives and facilitation for businesses investing in EmiliaRomagna. The “Agreement for the Settlement and Development of the Enterprises” is the main tool provided by the law to develop programmes aimed to foster new employment and innovation. It has to be signed by the Regional Government, the investor, local bodies and other stakeholders involved, and binds these parties. The Regional government periodically publishes Calls for companies that can receive also financial support for the following types of action: R&D Research & Development, Research Facilities, Environmental Protection, Training Projects, etc. The key sectors identified by the regional S3 Strategy – including Health and Wellbeing - are a priority for the selection of the investment. Life sciences companies already financed include B. Braun and IRCCS IRST.

European Regional Development Fund provides 481 million euro in the period 2014-20. Among main areas where funds and incentives will be allocated we find: R&I; Industry 4.0; ICT development.

Sites and buildings
The region offers a wide range of business parks (most of which are located less than 10 kilometres from major motorway and rail junctions) with different features and characteristics for production plants, offices and innovative start-ups. Costs vary according to several factors and development agencies and other operators offer support to identify the right solution. The presence of territorial areas with a high level of specialization gives the chance to integrate the companies with a wide system of suppliers and customers. A selection of strategic business parks has been identified by joint efforts involving the Regional Government, Provinces and Municipalities (e.g.: Ecologically Equipped Business Parks) but the regional offer is much wider. Public properties of different types (e.g.: industrial/logistic, office, commercial) with high potential in terms of access to the regional natural and cultural heritage are available in the DB “Invest in Italy Real Estate”. A network of incubators and coworking spaces is available for innovative start-ups. Technopoles are a network of infrastructures hosting and organizing activities and services for industrial research, experimental development and technology transfer.
Success story

- In October 2018 the research-based pharmaceutical company GlaxoSmithKline, headquartered in Uk, expanded its presence in San Polo di Torrile (Parma) with a 1,500 sq. m plant devoted to production and packaging of a medicine for HIV-treatment, investing 30 million euro. The Plant Director Maria Chiara Amadei stated: “Parma has given an important contribute (...) in the deep technological and innovative transformation that is revolutionizing the health sector at global level”. B. Braun Avitum deals with therapeutic systems for hemodialysis, dialysis for acute and apheresis patients. In the Mirandola district it employs more than 250 people and exports made in Italy medical excellence. In 2017 the company started a new R&D investment employing 50 additional workers (of which 20 graduated) supported by the Regional Law for the Promotion of Investments, providing 1.5 million euro of financial incentives.

Business opportunity

**BUSINESS OPPORTUNITY 1 – THE “BIG DATA TECHNOPOLE - BOLOGNA HUB”**

The Technopoles are a network of 10 infrastructures located in 20 locations throughout the Emilia-Romagna region (www.retealtatecnologia.it/en/technopoles), hosting and organizing activities and services for industrial research, experimental development and technology transfer. The “Big Data Technopole - Bologna Hub” is a new space for Digital Economy with an area of about 40,000 sq.m available for new investments in an outstanding business environment. The main objective is to make the Big Data Technopole a global benchmark for computing capacity and data management for the industrial ecosystem. By 2019, the Hub will host the ECMWF data centre, and by 2020 will host CINECA with one of the top 20 world most powerful HPC computers, the Competence Center Industry 4.0 BI-REX, INFN complex (National Institute of Nuclear Physics), the bio-banks of the Rizzoli Institute of Bologna, Arpae Emilia-Romagna, ENEA, and other small and large companies and organizations also related to health industries. Emilia-Romagna region is strongly investing on the development of an innovative ecosystem based on Big Data management/exploitation: The Bologna Technopole for Big Data and artificial intelligence calls for an investment of over €350 million. The investment plan includes taking part in a European tender to host a world class pre-exascale HPC supercomputer acquired by the Joint Undertaking EuroHPC at the Bologna Technopole, at a cost of €120 million that the Region intends to fund in close collaboration with the national government. Incentives and funding. There are many great opportunities to get financial incentives in Emilia-Romagna, especially to set up a research lab (infrastructure) and/or to realize R&D projects, and also through a combination of regional and national instruments.

The Regional Law for the Promotion of Investments (n.14/2014) provides incentives and facilitation for businesses investing in EmiliaRomagna. The “Agreement for the Settlement and Development of the Enterprises” is the main tool provided by the law to develop programmes aimed to foster new employment and innovation. It has to be signed by the Regional Government, the investor, local bodies and other stakeholders involved, and binds these parties. The Regional government periodically publishes Calls for companies that can receive also financial support for the following types of action: R&D Research & Development, Research Facilities, Environmental Protection, Training Projects, etc. The key sectors identified by the regional S3 Strategy – including Health and Wellbeing - are a priority for the selection of the investment. Life sciences companies already funded include B. Braun and IRCCS IRST. European Regional Development Fund provides 481 million euro in the period 2014-20. Among main areas where funds and incentives will be allocated we find: R&I; Industry 4.0; ICT development.

**BUSINESS OPPORTUNITY 2 – REGENERATIVE MEDICINE INNOVATION HUB**

The Regenerative Medicine Innovation Hub of the Emilia Romagna Region is a combination of research centers with deep experience in development and industrialization of GMP compliant ATMPs, companies, facilities and innovative projects focused on regenerative and restorative medicine. It can count on several strategical assets, such as:

- Centre for Regenerative Medicine “Stefano Ferrari”
- Multiparametric platform for patient and cells profiling
- High Performance Computing Infrastructure for Big Data Analytics in the life sciences, advanced materials, and innovative production systems
- Epidermolysis Bullosa Hub
- BioBank Network
- Startups.

The Hub is ready to establish Industrial and technological partnership with:

- Pharma companies interested in investigating the potential of regenerative medicine
- Research centers interested in activating joint labs
- Investors interested in startups
Friuli Venezia Giulia

Infrastructures and connections

- Airports: Venice Marco Polo Airport, Treviso A. Canova Airport and Trieste Airport Friuli Venezia Giulia are 30/60 minutes driving from regional main towns.
- Railway: Connections from Udine and Trieste railway stations to Milan, Rome, Turin and Venice.
- Maritime connections: Trieste, Monfalcone and Porto Nogaro commercial ports.
- Interports: Cervignano, Pordenone and Trieste.

- Broadband: ERMES, with its 2,600 km of cables 260,000 km of optical fiber, 1,679 km of backbone infrastructure and 720 km of cable infrastructure in the 86 industrial areas, is the wider broadband geographic area in Italy.

Industrial base

Bio-high-tech in Friuli Venezia Giulia consists of about 150 companies working in Smart Health within three closely related Bio fields: Bio-Med (including Living Environment Technologies), Bio-Tech and Bio-ICT. Among the large companies, we can mention Lima Corporate spa (one of the world leading companies in prosthetics), and Biofarma spa (working in nutraceutical).

Medium-sized enterprises include ALIFAX srl (R&D and producer of clinical diagnostic instrumentation), Eurospital spa (R&D and producer of pharmaceutical products, medical and surgical devices, in vitro diagnostic devices), and Diaco Biofarmaceutici srl (expert in the manufacturing of quality sterile liquid products), while small and micro enterprises represent 90% of the whole field.

Incentives and funding

Friuli Venezia Giulia has several types of incentives and funding: companies meeting specific criteria can benefit from regional taxes reduction; public grants can be awarded to support the creation of new enterprises and implement RDI projects.

Other types of incentives to support competitiveness of SMEs and measures to finance innovation technology investments are provided. Different kinds of regional subsidised financing can be granted to support investments and business development.

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FACTS & FIGURES

SMART HEALTH CLUSTER
Export: 300-315 mln €
Turnover: 900 mln €
Enterprises: 150
Employees: 5,000
Foreign companies: 4

BIOHIGHTECH INDUSTRY FOCUS
- Biomedical
- In vivo and in vitro diagnostics
- Medical informatics and Bioinformatics
- Innovative Therapy
- Ambient Assisted Living
R&D network

Key players in research and innovation: 150 companies (MedTech and in-vivo diagnostics 30%, in vitro diagnostics 18%, Medical informatics 20%, Innovative therapies 17%, Ambient assisted living 15%); three Universities (Trieste, Udine, Sissa); two CNR (National Research Council of Italy) sites; five international research institutes (ICGEB-International Centre for Genetic Engineering and Biotechnology, Elettra Sincrotrone, LNCIB-Biotechnologies University Consortium National Laboratory; Italian Liver Foundation; Callerio Foundation for oncologic diseases); two IRCCS-Sanitary Research and Care Institutes (Burlo Garofolo in Trieste and CPO in Aviano, Pordenone); two academic medical center hospitals (Trieste and Udine, both certified by the Joint Commission International); four technology and science hubs, including AREA Science Park. The Burlo Garofolo Pediatric Institute is a children’s hospital recognised as the best one in Italy for its research activity and 28th all over the world.

Know-how and specialisation in the following fields: in vivo diagnostics, prosthetics, regenerative medicine, biosensors and advanced microscopy, in vitro diagnostics and biospharmaceutics (bio-similar) with particular specialisation in cardiology, neurology, oncology, pediatrics, gynecology, genomics (Next Generation Sequency), nutraceutics, informatics, including all the IoT (Internet of Things) technologies (telecommunications, big data, informatics safety, cloud infrastructures for health, mobile technologies), all the HPC (High Performance Computing) technologies, hospital and welfare information technology, bio-images and bio-signals IT, telemedicine, remote assistance, smart home automation systems, wearable technologies, decision support systems.

CBM represents the Smart Health Cluster of Friuli Venezia Giulia with a leading role in building relationships between all the actors in this field - entrepreneurs, researchers, clinicians, policy makers and people involved in finance and education. CBM is focused on internationalisation activity in order to increase its network with European countries (i.e. Bavaria, Austria, Poland, Balkan regions) and U.S., Cuba, Thailand, Australia and others.

Sites and buildings

Area Science Park – Science and Technology hub
Polo Tecnologico di Pordenone - Science and Technology hub
Consorzio Innova FVG - Science and Technology hub
Friuli Innovazione - Research and Technology Transfer hub
BIC FVG S.r.l. – Enterprises incubator
Port of Trieste Industrial area – This is the leading Italian port for total tonnage movement and railroad traffic, with almost 10,000 trains/years reaching the main European industrial destinations.

Fully operative Free zones in Trieste (unique in the EU context) offering warehousing, storing, examining, sorting, packing and repacking, manufacturing and industrial processing at convenient economic condition also for industrial processing of non-EU goods destined for EU and non-EU markets.
Success story

VivaBioCell was founded in 2007 as a spin-off of University of Udine, Italy. The company develops, manufactures and commercializes automated bioreactors to support advanced therapy medicinal products manufacturing for innovative and regenerative medicine therapies like autologous stem cell transplantation. Medical Devices are coherent to the “Good Manufacturing Practice - GMP in a box” concept. These are “Closed Systems” that do not necessarily require to be located in a high sterility clean room environment. The mission is to make new medical treatments become affordable. Current applications include developing stem cell for the treatment of osteoarthritis and advanced cell and gene therapies, as the automated “GMP-in-a-Box” system will be used to develop next generation immune cells production in the treatment of cancer trough natural killer cells. In 2015 VivaBioCell has been fully acquired by NantCell Inc, a subsidiary of NantWorks LLC group, based in Los Angeles (CA), USA.

Business opportunity

Proposer: Biovalley Investments spa
Investment type: Funding
Description: streaMED.ai is a SaaS platform designed to support effective patient flow management in surgery units of public and private healthcare providers. Key advantages:
• The project aims at solving a problem experienced by surgery units for years, producing relevant cost savings with AI technology developed in collaboration with a specialized center of the University of Trieste.
• As of today, there are no comparable solutions available in terms of integration of technologies and clinical data management.
• The consortium of partners gathers skills, expertise, and technology acquired during 20 years of direct professional experience in developing middleware, connectivity and integration of clinical, laboratory and medical image data for hospital organization.
- In order to produce a deliverable prototype, an estimated investment of € 900,000 is required to cover the development costs for the first three years. Based on current negotiations with two research hospitals, the team expects to receive from these institutions € 300,000 in the 3 years; a portion of this funding will be received upfront to develop the prototype.
- The team looks for pure investors and/or commercial partners.
**Infrastructures and connections**

- 2 International Airports (Fiumicino Leonardo Da Vinci, Ciampino)
- 3 commercial ports (Civitavecchia, Gaeta, Fiumicino)

**Industrial base**

Lazio is Italy’s 2nd most important and one of Europe’s most important pharmaceutical industry hubs.

- Home of international players and highly innovative local SMEs operating in synergy with the important public research network.
- Main areas of specialisation and high added value production are: pharmaceutical innovative drugs, e-Health and medical devices production.

**R&D network**

Presence of important industrial and multinational groups with their own R&D centers

Some of the main national and international players: BSP Pharmaceutical, Sanofi Aventis, DPhar, SPL, Menarini and Alpha - Sigma.

Areas of specialisation:

- Pharmaceutical: pre-clinical development of inhibitors for the treatment of solid cancers
- Medical devices: development of new optical systems for subcellular resolution retina analysis
- E-Health: development of systems for integrated tele-rehabilitation remote

**FACTS & FIGURES**

- 22,000 employees
- 8 billion euro exports (40% of regional exports)
- 45 Biotech companies (about 10% of the total in Italy)
- 25,96% contribution to biotech turnover
- 26 specialized research centres
- 10,000 researchers
- 7,468 graduates in life sciences per year
- High presence of public and private research infrastructures
- Innovation agreements: 200 M € for projects concerning R&D

**Incentives and funding**

LAZIO INNOVA, as an agency owned by the Lazio Region, operates to the advantage of businesses and local public administration in the provision of:

- incentives from regional, national and/or European resources;
- in credit support and the issuance of guarantees;
- in interventions in risk capital;
- in services for the internationalization, promotion of business networks and regional excellence;
- in services for the creation and development of business;
- in measures for social inclusion.

**Sites and buildings**

Lazio Innova has areas dedicated to the incubation of start-ups and is connected with the main scientific parks of Lazio. Some of these Science Parks have equipped sites available to companies.
BUSINESS PROPOSAL
EVVIVAX plans to launch the first immunotherapy product (Tel-eVax) for canine lymphoma on the basis of a strategic plan. At the moment, the most important market barriers to be overcome to realize commercialization of Tel-eVax is the lack of investors and a commercial partner in USA. EVVIVAX is seeking one or more partners willing to invest or co-develop the product. The time to first sales is predicted to be 2 and 4 years after financing in USA and EU, respectively. The financing needs in the next three years are about 3 million$.

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MODIAG - MODELING FOR DIAGNOSTIC
REGION: Italy
PROPOSER: ACT Operations Research, European Brain Research Institute (EBRI) and the Italian National Research Council (CNR).
AREAS OF ACTIVITY: Bioinformatics, Big data analytics; Genetics & Genomics; Medical research; Life sciences related activities
INVESTMENT TYPE:
- R&D
- Industrial/technological partnership
- Funding
BUSINESS PROPOSAL:
Alzheimer’s facts and figures
47 Million of people affected worldwide
11 Million in Europe
Dementia is WW second cause of disability
$ 800B WW cost; $ 280B in Europe
10,000 WW new cases per year
Predictions:
75 Million of people affected in 2030 of which 14 Million in Europe;
130 Million in 2050 worldwide.
Delay of the onset of the illness of 5 years leads to 40% reduction of patients in 25 years. The economic advantage for an early and accurate diagnosis would lead to a substantial cost saving, particularly for home caregivers and hospitalisation. Concerning misdiagnosis, a US study estimates that the excess medical cost for Parkinson’s Disease misdiagnosis, often with symptoms overlapping other forms of dementia, may exceed 10000 Euro/year of incorrect diagnosis. Our Healthcare Operations Planning aims to develop, considering the ROI such solution, an application to predict, simulate and plan resources for early and most accurate diagnosis with a cost from 5K€ to 80K€/ year. Set-up services to be added for about 20-80 K€ per application. A solution for the optimization of the drugs inventory can cost from 2 to 20 K€ per year per warehouse and a set-up fee around 10-80 K€.
Diagnostics Intelligence: 30-80 €/patience per year per type of disease

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Lombardy

Infrasctructures and connections

- 4 International airports (Linate, Malpensa, Orio al Serio, Montichiari)
- 3 commercial fluvial/lake ports (Porto Bertelli- Lake Iseo, Cremona, Mantova Valdaro, Sistema portuale mantovano)
- Main Highways: A1 Naples-Rome-Milan/
- A4 Torino-Trieste / A7 Milano-Genova/ A8 Milano- Varese / A9 Milano-Como

Industrial base

The Health industry is strongly oriented to the future needs of society, becoming an important driver to create or recognize new emerging markets. Lombardy leads the way in innovation and development: 6 Sciences and Technology Parks, 182 innovative business, 11 National Research Councils and 267 in-house research Institutes. In Lombardy the Health Industry contains a very rich and diversified system of competences, which includes the following themes: Biotechnologies, Pharmaceuticals, Medical devices, Food, Creative industries. More than a third of the Italian patents recognized by the EU are registered in Lombardy. Lombardy boasts the record in Italy in the clinical trial sector, with more than 50% of the trials activated every year in the pharmaceutical field.

R&D network

The most significant quantitative contribution to research comes from drug companies that in Italy have invested 1.5 billion in R&D in 2017-18 (7% of the total national research, up + 20% in the last three years only), employing 6,400 people in this business. The Lombardy pharmaceutical companies have contributed about 1/3 of the investment in national R&D. Lombardy is the house of MIND – Milan Innovation District (located at the former Expo Milano 2015 site), which will host a vibrant ecosystem of highly connected businesses, service providers and research institutions including the Human Technopole, research hospital Galeazzi and the scientific faculties of the University of Milano Statale, boasting state of the art research infrastructure and world-class researchers in precision medicine and food, advanced manufacturing, genomics, medtech & services, computational biology, nanobiotechnology. Lombardy is also very active in scientific publications: almost 1 out of 3 high-impact scientific publications produced in Italy come from the region.

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FACTS & FIGURES

- Lombardy is the most developed Italian region in the life sciences sector: with a production value of 63.4 billion and over 23.5 billion of added value, the regional supply chain affects the national total with shares of 31% and 25% respectively
- The incidence of GDP is 12.4% of the regional total, with a value of over € 45.8 billion (2.7% of national GDP)
- 347 thousand employees, equal to 20% of the national value
- Lombardy has 14 universities, 7 medical faculties with 260,000 students, 32 research centers and 19 scientific institutes and 6,000 researchers active in the sector.
- The two most relevant segments of the supply chain are health services (14 billion of added value, the 59.6% of the total value of the supply chain) and the pharmaceutical industry (4.3 billion, 18.5%)
- 1st region in Italy for European funds obtained in the health sector (4th among European regions)
- With 28% of businesses and local units based in Lombardy (162 units), 23% of investments and 32% of the turnover, Lombardy is confirmed the first region of Italy for presence, commitment and results in Biotech
- 816 biomedical enterprises (307 with more than 20 employees) that employ 40% of the Italian workforce of this sector
Incentives and funding

Regione Lombardia supplies incentives for corporate investments and Start-ups. For example: Thanks also to the ERDF – European Regional Development Fund, Regione Lombardia allocated in the 2014 – 2020 program period 36% of the fund (£349.2 M) to strengthen the research sector, foster technological development and innovation. In the same way, 30% of the fund (£294.6 M) is allocated to promote the competitiveness of SMEs and improve access to loans.

Main incentives:

«AL VIA» Corporate Investments: The incentive consists of 5% to 15% non-repayable grant for capital expenditures in productive assets, with Long-term financing from £50,000 to £2.85m at favorable rates. Dedicated to companies with an operating office in Lombardy active for at least 24 months.

«INTRAPRENDO» Incentives for Startups: The incentive consists of a zero-interest-rate loan and a non-repayable grant (min £25,000 to max £65,000), covering from 60% to 65% of the total eligible costs of the project. Dedicated to individual entrepreneurs that have started their own entrepreneurial activity for no longer than 24 months.

«INNOVALOMBARDIA» Financing for Innovation: Financial support for companies that invest in innovation of their products or processes. Dedicated to SMEs and Mid Cap (less than 3000 employees). The intervention consists in a subsidized financing that can cover up to 100% of the eligible expenses, ranging from € 300.000 to €7 mln. Interest rate subsidies up to 2.5%, and in any case lower than the due interest rate.

Sites and buildings

• AttrACT-www.attractlombardia.it, promoted by Regione Lombardia together with Unione Camere Lombardia, gives access to more than 100 investment opportunities (greenfield and brownfield opportunities), located in 55 Municipalities across the region

• MIND Milano Innovation District - http://www.mindmilano.it/en/, a public private partnership between the State-controlled company Arexpo and its private partner Lendlease. The mission is to transform the 1 million square meters Expo 2015 area into an innovation hub for Milan, Italy and Europe.

• Within the Lombardy Life Science Cluster: PARCO TECNOLOGICO PADANO (Lodi, http://www.ptp.it/)


Success story

❖ SANOFI is a French global healthcare leader in the world. With more than 100,000 employees present in 100 countries, the company has 79 manufacturing sites in 36 different countries. In 2017, the sales reached € 35bn. SANOFI is one of the leading pharmaceutical company in Italy, where it has a strong industrial presence. The Italian subsidiary manufactures and markets drugs in all the group’s business areas. SANOFI Italia has its headquarters in Milan and another branch in Modena. In Italy, there are 4 industrial plants of SANOFI. A unit of clinical research (CSU- Clinical Study Unit) with 39 collaborators, dedicated to conduct clinical studies operates at SANOFI site in Milan. The Lombardy site is an example of positive growth which has been going on for some time, thanks to an investment plan of € 19 M over the last three years enabling to expand the production capacity.

❖ NOVARTIS is a global healthcare company based in Switzerland working in the pharmaceutical sector. Second pharmaceutical multinational in the world by turnover Novartis is present in Lombardy with Alcon Italia SpA in Milan and Novartis Farma SpA or Sandoz SpA in the province of Varese. Novartis is planning to increase its investments in Italy. The group’s investments will be mainly allocated to R&D, collaborating with research centers and hospitals to carry out clinical trials, investing in data collection, training doctors and supply advanced drugs. In 2017 Novartis already invested € 61 M in Italy to do 224 studies involving 10,000 patients. In Italy the group planned to launch an investment of € 200 M in R&D in three years.

Business opportunity

MIND - MILANO INNOVATION DISTRICT

An international RDI Hub building on regional strengths and Italian creativity. The former Expo 2015 site will be transformed into an Innovation District, i.e a physically compact, transit-accessible, technically-wired urban area offering mixed-use housing, office, and retail space where leading-edge anchor institutions and companies cluster and connect with start-ups, business incubators and accelerators (Katz&Wagner, 2014). MIND will develop around the complementary RDI strengths of its 3 Anchor Institutions, boasting world-class researchers and state of the art laboratories and facilities in the personalized medicine and nutrition domain, including Human Technopole’s Central Genomics Facility, Imaging Facility and High-Performance Computing Facility and Storage; Università Statale’s Unitech OMICs Facility, Electron accelerator based X-ray source, Single-cell RNA-sequencing and imaging, 3D printing and microfluidics technologies, and Galeazzi’s advanced therapy and molecular diagnostics labs.

This research-dense ecosystem will be magnified by fostering highly intentional collaboration with large and small companies and research institutions, building on the strengths of the region to attract national and international investment and human capital. Support services will facilitate technology transfer, open innovation, incubation and acceleration of start-ups and scale-ups, advanced manufacturing and relocation processes both at the organizational and individual levels.

The 1 million sqm development, with over 4 billion of public and private investment already allocated, will host around 60,000 people daily, including 18,000 students, over 5,000 researchers and 5,000 visitors: outstanding architectural features and green and public spaces are conceived to enhance collisions and collaboration, with a living lab approach touching all aspects of a city of the future: from smart mobility to proptech, smart grids, 5G connection, without forgetting art, creativity and sports.
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FACTS & FIGURES
- More than 400 companies operating in the life sciences field
  Over 250 companies specifically in the healthcare and medtech supply chain.
- 347 thousand employees, equal to 20% of the national value
- Almost 10k employees in 21 multinationals
- 4th Italian region with 52 companies in the biotechnology field
- 820 research groups of which 60% in healthcare and medtech fields scientific production
- 3 Public Universities
- 3 Incubators: 2I3T, I3P, ENNE3
- 1 Science & Technology Park dedicated to biotechnology: Bioindustry Park Silvano Fumero
- 1 Innovation Cluster for biotechnology: BioPmed Among Piemonte’s leading key players:
  Advanced Accelerator Applications Srl (AAA) A Novartis company, Ephoran, Huvepharma, Ab Sciex, Agilent Technologies, Bracco Imaging, Merck,Sicor (Teva), Diasorin, Delpharm, Livanova, Olon,L’Oreal, ELitechGroup, CID – Carbonstent & Implantable Devices, Sienna Biopharmaceuticals, Uncyte Fresenius, TrovaGene, im3d, Consort Medical, Horizon Discovery
- Regional Technological Platforms and Innovation Hubs
- 2 world class hospitals in Torino and Novara (to be built)
- Top public healthcare system: leader in Europe in Organic Transplantology, excellence in the Oncology and Cardiology

Industrial base
Life sciences - specifically biotechnology, pharmaceuticals and medical devices - represent one of the most promising hi-tech industrial sectors in Piemonte.
More than 400 local companies+ 21 multinationals.
Sectors: Biotech, Pharmaceuticals, Food Supplements, Cosmetics, Disposable, Services & Techno Care, Digital Health, Hospitals, LABS, SPA & Fitness.

R&D network
A network of research centres, multinational companies and SMEs, makes of Piemonte a cluster of innovation, education and technology transfer and the core of a robust, interlinked system active in pharmaceuticals, biotechnology, wellness and health massively supported by converging technologies.

Piemonte ranks high in Europe as a strategic partner for cooperation, R&D and investments in the life sciences and converging technologies sector, making the region a powerful location for scientific and industrial partners and for new businesses to set up operations.
The Regional Technological and Innovation Hubs are drivers of innovation and research programs involving the public system, big players and companies: successful results in terms of medical applications, diagnostics, medical sensor technology and automation.

Infrastructures and connections
- 1 International airport (Torino International Airport)
- 1:00h from Milano Malpensa Airport
- Crossed through the Mediterranean and Genova-Rotterdam EU railway
- Vicinity to the upper Tyrrenian ports (Genova and Savona)
- 3 interconnected logistics hubs.

Piedmont
Success story

- Regione Piemonte (Regional Government) has recently contributed to the successful installation of 3 companies in its territory. All these companies have benefited from the financial support of the ROP ERDF 2014/2020 Axis I Action I.1b.1 - IR2 - Industrialization of Research Results
- Huvepharma Italia Srl will start a new strategic project for a total of eligible expenses equal to € 10,896,740.00. In collaboration with the Department of Chemistry and Drug Science and Technology of the University of Turin, Huvepharma Italia Srl aims at identifying new alternative solvents characterized by greater sustainability. In the context of circular economy, the company will also implement a sludge and waste treatment for their re-use as fuel therefore minimizing its disposal. The project is expected to increase the company's competitiveness and consolidation in the API market as well as to offer employment opportunities for the local market.
- CID S.p.A, company of the Alvimedica group, will start a new strategic project for a total of € 6,000,000.00 in eligible expenses. The company aims at developing innovative stents that besides fulfilling the mechanical function can also slowly release a drug capable of preventing tissue proliferation, which tends to occlude the lumen of the blood vessel. The most important feature of this highly innovative stent is the possibility to use it in diabetic patients.
- Bracco Imaging S.p.A. will start a new strategic project for a total of € 10,000,000.00 in eligible expenses. The company aims at developing innovative stents that besides fulfilling the mechanical function can also slowly release a drug capable of preventing tissue proliferation, which tends to occlude the lumen of the blood vessel. The most important feature of this highly innovative stent is the possibility to use it in diabetic patients.

Business opportunity

Piemonte is implementing the future of medicine-related sciences. The cities of Torino and Novara will be the center of this innovative renovation thanks to their New Teaching and Research Hospitals that will position Piemonte's regional healthcare system, the medical-scientific research and life sciences and human health related sectors, among the international leaders. The New hospitals will be at the forefront of innovations in terms of design and interaction between the patient care, R&D and teaching. The two hospital will also house the teaching and research activities of the respective University Faculty of Medicine. The hospitals will therefore be the opportunity to strengthen the cooperation with new and existing businesses, research and training centers aiming at creating value and distributing services. In a few words to foster the cooperation between the public and the private sector. With this objective, Piemonte Region is preparing a new measure aiming at supporting new research labs set up and R&D activities in the smart health field (about 60 mil € ).

Incentives and funding

- ROP ERDF 2014/2020: Action I.1B.2.2 - Objectives: to foster research and development projects Fields of application - smart factory, bioeconomy, life sciences, space economy
- Regional Investment contract for big companies with a foreign shareholder or a controlling one
- ROP ERDF2014/2020 Action III.3c.1.2 - Investment attraction through Financial Support. Ensuring Positive Effects on local SMEs for SMEs not active in Piemonte yet; local SMEs that have delocalized production, SMEs already operating in Piemonte that want to develop a functionally different type of investment
- Human Resources – High Level training and Research apprenticeship (ESF 2014-2020) for people aged from 18 to 29 including PhD and Academic Diploma of Research Training, research activities
- ROP ERDF 14/20 Axis I Action 1.1.b.41 - support to Start-ups development programs
- L.R. 34/04 - Objectives: to foster start-up, expansion and diversification of a productive local unit and process/product innovation.

Moreover, Piemonte Region in order to promote the public and private partnership in the framework of the New Teaching and Research Hospitals is preparing a new measure aiming to support new research labs set up and R&D activities in the smart health field (about 60 mil € ).

Sites and buildings

The Bioindustry Park offers business location services, both centralized and on-demand, to laboratory, research center, pilot plant, companies-including SMEs with a complete organizational structure, research centers, or institutes meeting certain criteria: e.g. Investigate intensive or high technology areas related to the Life Sciences and Human Health (or in synergic areas such as ICT, new materials, nanotechnology etc.).

Rejione Piemonte and Torino City offer industrial areas and location solutions for high tech service companies willing to invest in Piemonte.
Tuscany

Infrastructures and connections

- 2 integrated international airports (Florence and Pisa), serving over 50 international destinations
- 1:30h from Florence to Rome by high-speed train, 1:40h from Florence to Milan by high-speed train
- Tuscany is crossed by: the major Italian highway (A1) connecting Milan with Rome and Naples, the EU “Scandinavian-Mediterranean Core Network Corridor” linking the Baltic Sea with Southern Italy and Malta
- 1 main commercial port (Livorno) with direct links to the 10 major Mediterranean ports
- 3 main logistic parks (Livorno, Prato and Arezzo).

Industrial base

Leading region in R&D: Tuscany is one of the world leading regions in terms of research in vaccines, oncology, cardiovascular, neurology, biorobotics & biomaterials (one of the most recent vaccines, anti-meningococcus B has been developed in Tuscany – Novartis – GSK). First class public health system with high expertise in all the fields of medicine, operating with cutting edge procedures for clinical trials
Synergy between public and private research thanks to a well developed technology transfer model all around Tuscany:
- 4 business incubators for life sciences based companies
- Tuscany Life Sciences Cluster (that counts more than 300 affiliated companies, 19,000 employees, 823 patents)

Many international companies have set up their headquarters for Italy and Southern Europe in Tuscany (Eli Lilly, Kedrion... ) and many international companies have set up in Tuscany local units for manufacturing products, organizing clinical studies with domestic partner (Biomérieux, Novartis – GSK)

R&D network

3 major Universities (Florence, Siena and Pisa)
2 Superior Graduate School (SSSA - Scuola Superiore Sant’Anna, SSNP - Scuola Normale di Pisa)
Advanced Institutes (IMT - Institute for Advanced Studies of Lucca, SUM - Italian Institute of Human Sciences, in Florence)
3 National Research Centres
- National Institute for Nuclear Physics (INFN)
- National Institute for Astrophysics (INAF)
- National Research Center (CNR), present in Tuscany with 19 Institutes of Research

FACTS & FIGURES

- 370 firms in life sciences (42 pharma, 80 biotech, 120 medical devices and 128 software & services)ices and 128 software & services)
- Turnover: EUR 8 billion
- 7.5% Regional GDP
- 19,000 employees (= 1.2% of total Tuscany’s employees)
- 2,000 employees in R&D activities
- 1.45 bln € export (=18% of LS Turnover)
- 3 Universities involved in LS R&D, with a total of 19,000 students in scientific fields
- Main Research areas in LifeScience in Tuscany

- 2. Software (Bioinformatics - Communication systems - eHealth - Telemedicine - Telematics - Telemetry - Image Analysis - IT infrastructures - Mobile App)
- 3. Biotechnology (Genomic search for new diagnostics - Protein atom depth analysis)

Incentives and funding

For detailed information please visit www.investintuscany.com/incentives

Sites and buildings

- 4 business incubators for life sciences based companies
- Tuscany Life Sciences Cluster (that counts more than 300 affiliated companies, 19,000 employees, 823 patents)
Success story

- 1. In 2018 Yf Capital, a Chinese private equity fund co-founded by Jack Ma, acquired 100% of the ESAOTE group, a leader in the biomedical sector present in Florence with a plant that employs 220 workers.
- 2. In 2018 the Swiss multinational Lonza, active in the biopharmaceutical sector, has decided to invest in the Sienese startup Exosomics, which develops non-invasive liquid tests for the screening and diagnosis of cancers in the initial phase.
- 3. In 2017 The Swiss pharmaceutical group Skan has invested 6 million euros in the Sienese startup Pharma Integration, which specializes in the development of fully robotic systems and production lines for filling syringes and bottles for vaccines and oncological products.

Business opportunity

PHARMA AND MED TECH LOGISTIC AND DIGITAL HUB
Greenfield Project
Investors: Financial or Industrial operating in pharma sector
Proposing Companies: 4 Pharma companies already operating in Tuscany
Description: the possibility of investing in a digital logistical platform to support the industries operating in the life sciences sector, which will make it possible to optimise the distribution chain of medicines produced in Tuscany, and more generally in central Italy. The investment is aimed at equipping an area of 125,000 square meters, half of which will be built, to build 21,000 square meters of warehouses, with temperature-controlled environments, suitable for the storage of pharmaceutical products, with 8 loading areas and as many intended for the shipment of goods, as well as about 6,000 square meters of offices.
It is a platform designed to have high expansion capacity, to serve any other interested companies in the many areas of life sciences, as new warehouses can be built for an additional 20,000 square meters of floor space.
The storage capacity, from a pre-feasibility analysis, is estimated at 38,000 initial pallet places, three quarters of which can hold temperatures between 15° and 25° and one quarter between 2° and 8°.
70% of stocks will be for raw materials and packaging, 30% for finished products, which will be handled at a rate of 52,000 pallets per year. 80% are destined for export and 20% for the domestic market.
M&A IN COMPANY OPERATING IN MEDICAL IMAGING AND ULTRASOUND TECHNOLOGIES
Brownfield Project
Investors: Financial or Industrial operating in pharma/medicale device sector
Value of total Investment: to be defined
Proposing Companies: Local firm searching for strategic partnership
Core business: the company, born as a Spin-Off company of the Italian National Research Council and University of Pisa, is specialized in Medical Imaging and Innovative Ultrasound Technologies. The company produces its Cardiovascular Suite, a CE marked medical device software for assessing early markers of cardiovascular risk. The company aims to design a next generation of biomedical ultrasound systems.
Assets:
Commercial distribution on the global market based on 14 distributors and 8 agents monitoring the system and focused on medical devices sales.
Synergies and collaborations with the Italian National Research Council CNR, the University of Pisa and several research institutes at global level.
Strong scientific references on the products usage validating the system. The Cardiovascular Suite is CE marked and the company got the ISO 9001:2008 certification.
High market’s recognition and high investments budget ratio.
**FACTS & FIGURES**

- **Healthcare & Life Sciences CLUSTER**
- Export: 106 million euros
- 40 companies
- 5th Region for turnover generated
- 20 million € invested for R&D by the Public Sector
- 11 million € for R&D on biology and biotechnology
- 1.5 million € for R&D on digital Healthcare
- 400 researchers, 200 employees
- Foreign companies: Novartis-Sandoz, OPT SurgiSystems
- Specialization areas:
  - Biology and Biotechnology
  - Medical devices
  - Rehabilitation
  - eHealth

**Industrial base**

- Industrial Know-how:
  - Medical devices, pharmaceutical and food supplements, diagnostic applications, biomedical engineering, biomolecular and microbiological investigation.
- Main companies:

**R&D network**

- Research Centers: CIBIO, University of Trento (Department of Integrative Biology), Bruno Kessler Foundation (ICT, microsystems, smart materials), Edmund Mach Foundation (agrifood, genomics, environment).
- Trentino Salute 4.0 is the first Competence Center in Italy focused on digital healthcare between the Healthcare Institution, FBK and the Autonomous Province of Trento.
- Labs: LaBSSAH – Laboratory of Biomolecular Sequence and Structure Analysis for Health, CIBIO – Centre for Integrative Biology, Neuroinformatics Lab, Ausilia – Assisted Unit for Simulating Independent Living Activities, CimeC – Center for Computational and System Biology, Proton Therapy Center.

**Incentives and funding**

- Up to 80% local grant on R&D project
- Up to 70% local grant on internationalization
- Up to 60% local grant for researchers hiring
- Up to 50% local grant on innovation
- Private – Public equity financing up to 1.5 million €.
Success story

- The Department CIBIO – at the University of Trento, created in 2009, with more than 300 researchers is an excellence that will pursue the task of creating a suitable environment for merging classical cellular and molecular biology approaches with the new powerful tools of systems and synthetic biology, and with the contribution of chemistry, physics, informatics, mathematics, and engineering in an integrative view of basic biological processes and of their derangement in disease.
- The last ten years have witnessed an unprecedented revolution in biology. The availability of complete and annotated genome sequences for many species and the increasing affordability of high-throughput approaches for the global monitoring of macromolecules in cells are providing the basis for the mechanistic understanding of living tissues, both in their physiology and in the determinants of their diseased state.
- In January 2018, Nature Biotechnology published an invention made in CIBIO “A highly specific SpCas9 variant is identified by in vivo screening in yeast”. A variant y of CRISPR-Cas9 nucleases for genome editing that will allow scientists in performing different applications for therapeutic purposes.
- In 2019, the University of Trento license the use of the invention to a spin off company, Alia Therapeutics that is the first Italian company dedicated to the application of this disrupting technology.

Business opportunity

- Trentino Sviluppo, in-house company of the local Government, has 2 science park, 6 BIC (Business Innovation Centre)
- We provide: fully equipped spaces and infrastructures, support on technology transfer, technology partnership, supply chain development, HR selection, incentive selection
- INVEST IN TRENTINO: significant local incentives, efficient and reliable autonomous government, #1 quality of life in Italy, supportive R&D environment, 0 local tax (for 5 years), a workforce you can count on
- Provide Equity trough Trentino Invest.
- Provide support to innovation and technology transfer trough HIT-Hub Innovazione Trentino.
**Valle D’Aosta**

**Infrastructures and connections**
- 1 regional airport Corrado Gex (allows the operation to aircraft up to a maximum of 70/80 places).
- Highway: AS linking Aosta with Turin and Milan
- Tunnel Mont Blanc: linking Aosta with France
- Tunnel Gran San Bernardo: linking Aosta with Switzerland
- 1:00 h from Aosta to Turin; 2:00 h from Aosta to Milan; 7:00 h from Aosta to Rome; 2:00 h from Aosta to Paris; 2:00 h from Aosta to Geneva.

**Industrial base**
In Aosta Valley operate numerous companies that provide possibilities of business operates:
- Engineering S.p.A. (data center), STMicroelectronics LTD (semiconductors),
- Thermoplay S.p.A. (hot runner systems for injection molding of plastics),
- Eltek S.p.A. (electromechanical components),
- Brabant Alucast LTDt (magnesium and aluminum components),
- Podium advanced technologies LTD (electric drive systems),
- Mavel LTD. (electric engine for high speed),
- Honestamp LTD (molds for thermoplastic),
- MDM LTD (bolts and screws),

Aosta Valley is autonomous in water. C.V.A S.p.A. produces and distributes hydroelectric power from a huge catchment area consisting of weirs and dams of significant magnitude.

**Sites and buildings**
The Region, can make available to companies many industrial sites:
- technology park Espace Aosta, with lots and buildings of different sizes;
- technology park Ilssa Viola in Pont-Saint-Martin, with lots and buildings of different sizes;
- industrial area in Châtillon of 16,660 sqm;
- industrial area in Verrès of 16,042 sqm.

**FACTS & FIGURES**
- 1 large company: Eltek S.p.A.
- 2 SME’S:
- Engineering S.p.A. - CCS srl
- Genetics & Genomics - Bioinformatics, Big data analytics - Biotechnologies (Pharma&MedicalDevices)

**R&D network**
The Smart Specialization Strategy (RIS3) of the Aosta Valley identify 3 areas target for R&D, Mountain of Excellence, Intelligent Mountain and Sustainable Mountains, subject to reciprocal cross-fertilization actions, mainly through the use of KETs (ICTs, Nano-microelectronics and biotechnologies).

In the Region there is the headquarters of the University of Valle d’Aosta and a seat of the Polytechnic of Turin, as well as research centers, such as the Astronomical Observatory, the Safe Mountain Foundation, the Institute for agriculture.

Research is particularly active in biotechnology, information technology, electric mobility, land monitoring and the enhancement of cultural heritage.
Success story

Podium advanced technologies LTD.
In 2011 a small group of graduates and PhDs from Politecnico di Torino joined forces to create an innovative engineering firm, building upon their interests and passion for motorsport, cars and applied research on hybrid and electric mobility.

Podium Advanced Technologies offer a comprehensive set of services in automotive high performance development, covering conventional, hybrid and full electric powertrains, supported by a unique hands-on experience in all facets of international motorsports.

In 2019, the company has 30 employees and covers an area of 6,000 sqm. For the second year in a row, Financial Times recognizes Podium Advanced Technologies among Europe’s fastest growing companies.

Business opportunity

The Aosta Valley region is creating a research center supporting personalized, preventive and predictive medicine, on a scale appropriate to the size of Valle d’Aosta, to boost the region’s research and health sector in an innovative way, implementing the specialization zones and technology transfer model set out in the Valle d’Aosta regional Research and innovation strategy for smart specialization for the period 2014/2020.

The main objective is to improve health, with particular reference to various neurodegenerative and oncological diseases. The research will also focus on building the genome profiles of samples of the population in order to establish a regional bioinformatics database.

The research activities are carried out by a partnership composed of research body and enterprises.

The project has available a total funding amount of 15,000,000 Euros for 5 years.

The proposals presented in response to the call are being evaluated. The activities are expected to begin on 1 July 2019 and the center will be fully operational on 1 January 2020.

The operation aims to establish technology transfer and create start-up and spin-off businesses. For example, it could be possible to support the creation of businesses which would focus their activity on identification of the diagnostic bio-markers which are needed for the development of new diagnostic kits which could be used by medical analysis laboratories, hospitals, clinics and care home.

We are looking for companies, start-ups or consolidated companies, which intend to establish in the Aosta Valley region to benefit from the transfer of technology from the research center, to be supported with regional incentives for research and development, which provides grants to companies.

We are looking for researchers in biotechnologies or information technologies who want to come to work in a cutting-edge scientific context and in an environmental and natural context of excellence.