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BIO International Convention 2024

June 3-6, 2024 · San Diego Convention Center – San Diego, CA

Open Innovation in Friuli Venezia Giulia

CLUSTER SCIENZE DELLA VITA
FRIULI VENEZIA GIULIA
Polo Tecnologico Alto Adriatico "Andrea Galvani"

POLO TECNOLOGICO ALTO ADRIATICO Andrea Galvani

Open Innovation in Friuli Venezia Giulia - Italy

DESCRIPTION

The Life Science Cluster of Friuli Venezia Giulia is an organization established by regional law and managed by the Upper Adriatic Technologic Park aimed at fostering the development of a dynamic and competitive life science ecosystem in the Italian region of Friuli Venezia Giulia. The Life Science Cluster plays a leading role acting as a bridge between the regional industrial and research sectors by promoting innovation, entrepreneurship, business opportunities and building relationships between all the actors involved in the regional life science field.

Field of activity and technology

Life Science, innovation

Proposer	Life Science Cluster of Friuli Venezia Giulia – Upper Adriatic Technology Park Andrea Galvani
Area of activity	Life Science, MedTech, Innovative therapies, Biotechnology

Open Innovation in Friuli Venezia Giulia - Italy

BUSINESS PROPOSAL

The Life Science Cluster of Friuli Venezia Giulia plays a leading role in building business opportunities between local industries and research sectors, promoting innovation and entrepreneurship among over 170 companies, 3 universities, and 5 national/international research centers in the life sciences sector. The Cluster supports the regional administration therefore promoting a series of financing tools aimed to enhance research collaboration and open innovation between local and international partners. Following an analysis of the regional life science innovation needs, the Cluster offers co-innovation and collaborative partnerships to highly innovative foreign companies for R&D projects with local entities.
The Cluster will support selected companies in establishing projects with the most suitable local partner and provide a full package of services and resources including business development and access to public funding.

Requested investment To be defined case by case

Target investor Innovative companies interested in developing R&D projects and new technologies in collaboration with local life science entities

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Nano-Amp: toward protein biomarkers PCR-based amplification

ULISSE BioMed

Nano-Amp: toward protein biomarkers PCR-based amplification

DESCRIPTION: the aim of the project is to create a cutting-edge diagnostic platform capable to quickly detect, in one simple reaction step with unmet sensitivity, protein biomarkers using a PCR machine, an instrument present in any laboratory.

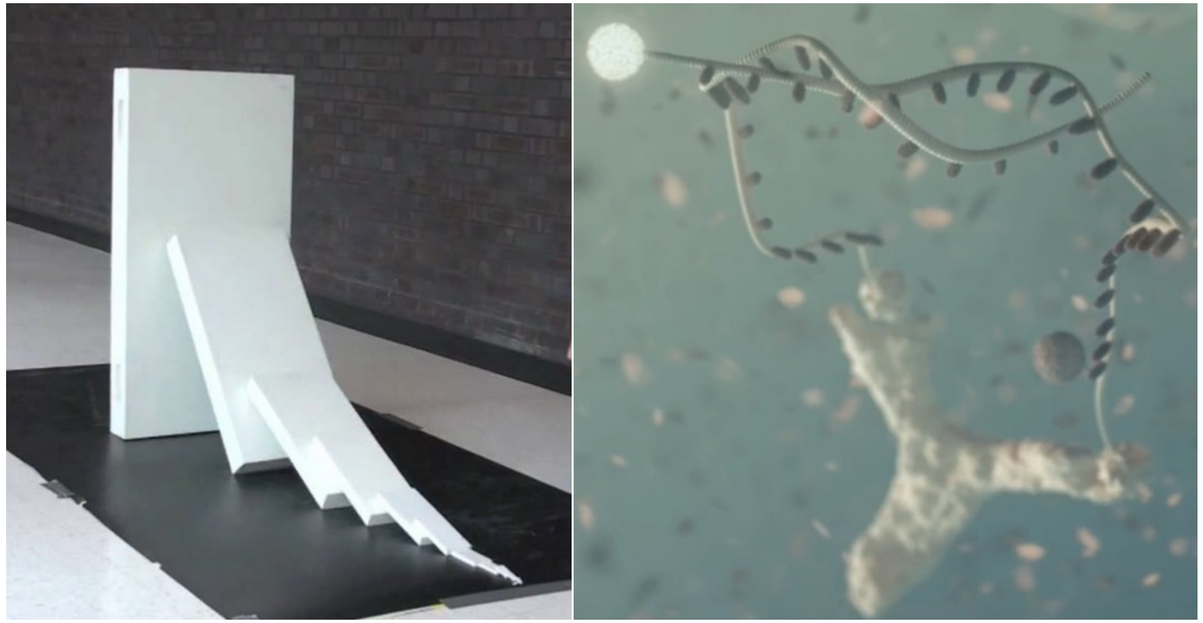
Field of activity and technology: Nano-Amp is a nanotechnology-based platform for protein biomarkers detection which exploits proximity assay and polymerase chain reaction principles. This technology aims to substitute ELISA and CLIA techniques. Nano-Amp, compared to ELISA and CLIA, is faster, easier, no washing and time consuming steps, it is extremely sensitive, affordable and suitable for point of care applications. Moreover, due to the extreme sensitivity of nanoamp it will be possible to open new and unprecedented scenarios in the early diagnosis field.

Development stage

Nano-Amp is currently at TRL4 stage, since Ulisse BioMed reached the proof of principle that a protein biomarker can be detected using PCR machine even in rough biological matrices.

Capital raised

500.000 $



Proposer	*Ulisse Biomed SpA – Listed company*
Area of activity	*Immunoassay - PCR*

Project title/investment proposal

BUSINESS PROPOSAL

Ulisse BioMed want to create a new paradigm in the immunoassay world proposing NanoAmp as a new golden standard for protein, antigen and antibody detection, capable to substitute ELISA and CLIA immunoassay formats for antibody and antigen detection, especially for point of care applications. The global immunoassay market size was evaluated at USD 32.46 billion in 2022 and is expected to hit around USD 51.33 billion by 2032 with a noteworthy CAGR of 4.68% from 2023 to 2032. Ulisse BioMed aims to develop a panel of Nano-.Amp-based assays targeting the top 10 most diffused protein cancer-related biomarkers.

Requested investment *€ 3M*

Target investor *Industrial partner operating in the immunoassay sector with access to the distribution market*

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SYNDIAG SRL
AI for Early Diagnosis of Cancer with Sonography

SynDiag

SYNDIAG SRL – AI for Early Diagnosis of Cancer with Sonography

DESCRIPTION

SynDiag is an innovative startup and spin-off of the Polytechnic University of Turin - Italy, working in the field of **Med Tech** and **Digital Medicine**. In collaboration with hospitals in Italy and Israel, SynDiag developed OvAi, a medical device for **Early diagnosis of Cancer with sonography**, based on **Artificial Intelligence and Telemedicine**, with CE Mark according to EU Directive 93/42/EEC. SynDiag is present on the market in Italy and aims to enter the EU market in 2023. SynDiag raised up to date more than 2000.000€ from private investors, public grants and bank loans.

Field of activity and technology

Med Tech, Fem Tech, Digital Medicine

Development stage

Commercially Ready

Capital raised

2.000.000€

Daniele Conti, CEO; Rosilari Bellacosa Marotti, R&D Director; Federica Gerace, AI Director

Proposer	SYNDIAG SRL, Innovative startup and spin off of Polytechnic University of Turin (Italy), with Head Office in Turin-Italy and Operative site in Pordenone-Italy.
Area of activity	Artificial Intelligence and Telemedicine, Early Diagnosis of Cancer in Gyneacology and Urology, Medical Ultrasound

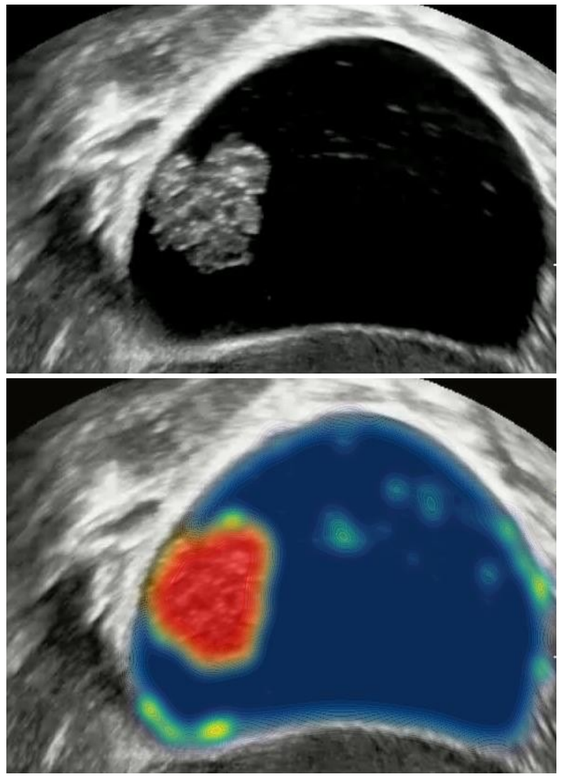
SYNDIAG SRL – AI for Early Diagnosis of Cancer with Sonography

BUSINESS PROPOSAL

SynDiag is an **innovative company** born to guide **Digital Transformation in Diagnostic Sonography.** It is currently active in **Italy and Israel**. **Sonography** is the most widespread medical imaging examination in the world, as it is cost- effective and not dangerous for patients. However, it shows the highest operator-dependence and leads to relevant late diagnosis. Ovarian cancers, the first business segment addressed by **SynDiag**, has 75% late diagnosis and lower than 30% 5's year survival rate. Next application will be in Urology.

SynDiag develops **OvAi Platform**, a solution ecosystem for **Digital Sonography**, with initial focus on **Ovarian Cancer**, based on **Explainable Artificial Intelligence**. **OvAi is a CE marked medical device** (Class I According to European Directive 93/42/EEC), **commercialised in Italy with SaaS business model**, for **hospitals**, **medical centers** and **operators at the Point of Care**, aiming to enter the EU market in 2023 and USA market in 2024.

OvAi's IP is covered by **4 international patents protecting Europe, USA, Japan, China, India**. SynDiag is working to **upgrade OvAi's Functionalities with differential diagnosis and virtual biopsy and CE-mark them, within 2023, according to new European Regulation 2017:745** (substituting the Directive) **and submit it for FDA approval**. SynDiag with OvAi brings to physicians the most relevant solutions for Gynecological early diagnosis, with Explainable Artificial Intelligence and Telemedicine.



Pictures of AI based elaboration of Ovarian Cancer sonography examination

Requested investment 5M€ for conclusion of UE and US regulatory process (CE mark according to new MDR Regulation and FDA submission), International commercialization, opening of Urology market segment

Target investor Med Tech and Digital Venture Capital Fund

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Anti-Fungal Drug Resistance Diagnostics

Anti-Fungal Drug Resistance Diagnostics

DESCRIPTION – Rapid Diagnosis of Anti-Fungal Drug Resistance in Candida

Field of activity and technology – Real time PCR and NGS

Development stage – Early Stage of Development

Capital raised – None applied for

Proposer	**LionDx** Company operating in the molecular diagnostics sector and was founded in 2019 by Mikkel Johansen and Diatech Pharmacogenetics.
Area of activity	Microbiology, Neonatology, Oncology

Anti-Fungal Drug Resistance Diagnostics

BUSINESS PROPOSAL The incidence of invasive fungal infections (IFIs), particularly candidiasis, is steadily increasing in patients admitted to the intensive care unit. Prompt, accurate diagnosis and timely treatment of invasive candidiasis are crucial as they affect the prognosis by significantly reducing mortality. Several recent publications have highlighted that the main mechanism of azole resistance in Candida is based on point mutations in the ERG11 gene.
LionDx intends to develop real-time PCR kits, in collaboration with hospital centers of excellence, to investigate the presence of mutations associated with drug resistance mechanisms. The analytical systems in question, based on the use of Real-Time PCR technology with hydrolysis probes, should allow the identification of the main Candida species and, at the same time, search for the presence of point mutations associated with drug resistance, starting from a serum or plasma sample taken from patients with suspected sepsis. Another goal is to develop NGS kits for fungi. Currently, in fact, there are no diagnostic solutions for fungal diagnostics available on the market, complete with CE IVD-labeled interpretation software using the Next Generation Sequencing technology.

Requested investment	1.000.000 €
Target investor	Private investors

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EPIGENETICALLY-BASED CELLULAR VACCINE FOR CANCER TREATMENT

Epigen Therapeutics™

Innovative Medicines in Immuno Oncology

EPIGENETICALLY-BASED CELLULAR VACCINE FOR CANCER TREATMENT

DESCRIPTION

Field of activity and technology

Epigen Therapeutics™ is an innovative biopharmaceutical company, focused on Immuno-Oncology, active in the development and in the transfer to the clinic of a proprietary innovative platform of live multivalent Cancer Testis Antigens (CTA)-based autologous cellular vaccines (DeMethAVax™, patent PCT/IT2002/000488), for cancer treatment.

Development stage of DeMethAVax™:

-In vitro characterization (molecular and phenotypic immune profiling, microarray transcriptome profiling, clonogenicity, cytokine release, functional immunological assays, potency maintenance, cryopreservation and freeze-thaw stability, technology transfer): completed.

-In vivo Safety, Tumorigenicity, Immunogenicity, Biodistribution: completed

GMP validation and NGS characterization: ongoing.

-First in Human/Phase I dose-ranging tolerability immunogenicity and combination therapy study: in planning.

Capital raised 1.6 million raised so far.

Proposer	Roberto Camerini, MD_ Chief Medical Office
Area of activity	Cancer immunotherapy

EPIGENETICALLY-BASED CELLULAR VACCINE FOR CANCER TREATMENT

BUSINESS PROPOSAL: find a partner to finance the translation of DeMethAVax in the clinic (Immuno-Oncology setting) for the treatment of cancer patients within a First-in-Human/Phase I clinical study.

Strengths of DeMethAVax: Infinite vaccine source, no autologous tumor requirement, Produced in 1 week; multivalent CTA (multi-epitope targeting to limit tumor immune escape); expandable to different tumors regardless of their specific histotype; all cancer patients are targetable.

Epigen Therapeutics is acquiring (binding agreement):

•A licence submission patent (US11083743) that covers the rights to use therapeutic combinations DNA hypomethylating agent + immune checkpoint blocking Ab +/- targeted therapy.
•A division (n.17/373129) of the application that covers the rights to use therapeutic combinations of DeMethAVax™ + DNA hypomethylating agent + immune checkpoint blocking Ab.
•A licence submission patent (EP14706539.5), that covers the rights to use the combinations of DNA hypomethylating agent + anti-CTLA-4 +/- targeted therapy.

Requested investment **€ 5.1 million (36 months)**

Target investor **Big Pharma players, venture capitals, private investor**

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Bio IMeD - DomotIA

bio IMeD
Intelligent Medical Devices

DomotIA

DESCRIPTION

Remote home automation system for patient monitoring based on ML and IoT-centric solutions for healthcare professionals, patients and caregiver.

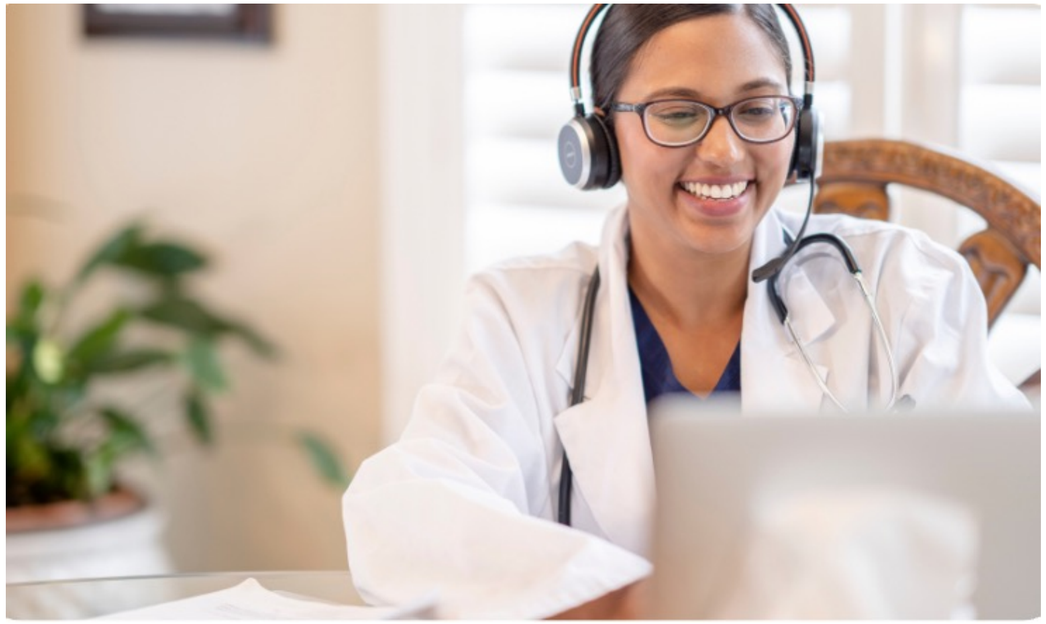
Field of activity and technology

Telemedicine, IoT

Development stage

TRL 9

Capital raised
56.000,00€



Proposer	Bio IMeD
Area of activity	Telemedicine, IoT

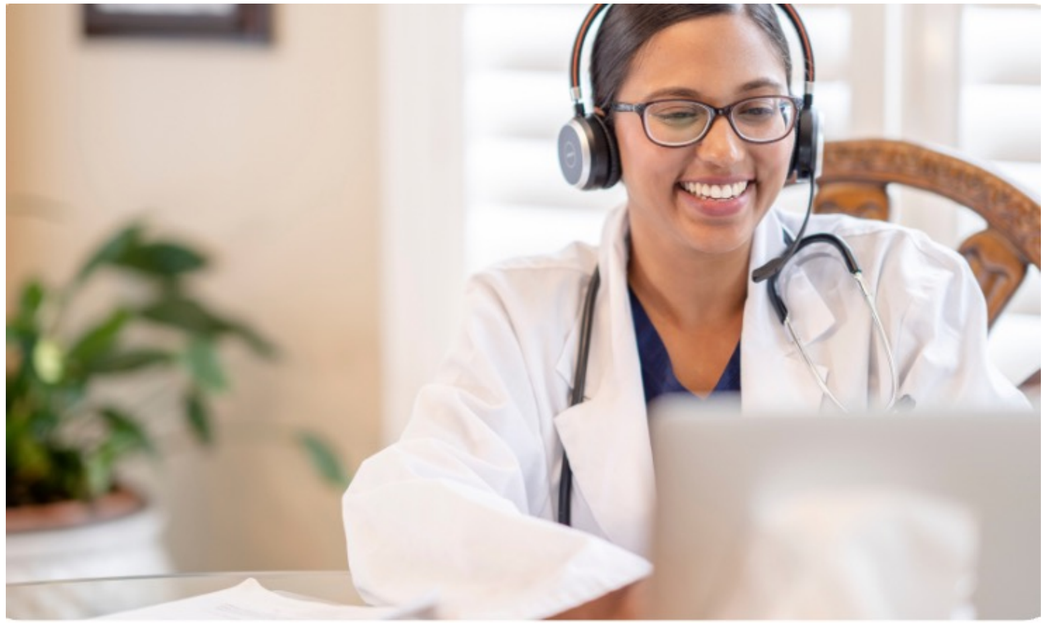
DomotIA

BUSINESS PROPOSAL

We have created an integrated organizational model for remote home monitoring of frail subjects with heart failure (and not) in order to monitor the deviation of the subject's home behavior from the usual one by improving the monitoring of clinical parameters (in collaboration with the ASL) and the welfare, organizational and economic aspects with respect to the current situation.The platform can be used through web-based solutions and compliant with stability and security requirements.

It is made up of:

- by hardware and sensor devices to acquire and process information relating to the subject which will be conveyed to a gateway,
- by the Web server for receiving and processing the data received from the gateway based on ML algorithms that will make it possible to identify clinically "anomalous" behavior and to generate alerts on predefined parameters,
- from the Web/mobile app for viewing information by the caregiver/medical-health personnel in order to make the acquired data available online to all authorized users, through dashboards that give immediate evidence of any anomalies found.



Requested investment Partnership

Target investor Commercial companies in the Healthcare sector, hospital companies

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QUALITY FIRST S.R.L.

QUALITY FIRST S.R.L.

DESCRIPTION

Field of activity and technology

In vitro diagnostic medical devices

Development stage

Early stage

Capital raised /

Proposer	Quality First s.r.l.
Area of activity	In Vitro Diagnostic Medical Devices

QUALITY FIRST S.R.L.

BUSINESS PROPOSAL

Quality First is an innovative start-up establishing in Friuli Venezia Giulia - Italy. Its short-term ability to acquire the status of Notified Body pursuant to the IVDR Regulation will make Quality First the first Italian and one of the few European companies offering certification, validation, and evaluation services as a certification body (notified body) according to the new EU regulation IVDR. Currently, the 88% of IVDs distributed on the Italian and European markets do not have a certificate suitable for the new legislation and over 50% of producers or distributors struggle to find a competent body capable of starting and completing the necessary procedures. The entry into force of the IVDR is believed to put about 22% of diagnostic tests off the market, with serious economic consequences for companies and serious repercussions for healthcare professionals, medical personnel, and patients. Quality First will contribute to completing the regulatory framework for the implementation of the EU regulation on in-vitro diagnostic medical devices according to the priorities of the Italian Ministry of Health's strategic action.

Requested investment 300.000 EUR

Target investor Business angels, other private investors