

LIGHT TEASERS OF RED BIOTECH / MED DEV STARTUPS

Headline	Intelligent robotic system for autonomous execution of nasopharyngeal swabs
Cluster	Red Biotech and Medical Devices
Business Model	B2B
Development Stage	Idea
Description	We are currently experiencing a global health emergency, namely the COVID-19 pandemic. The verification of the contagion with the execution of a nasopharyngeal swab on the patient is currently entrusted to health professionals. Our idea focuses on a product that can replace humans in carrying out this operation, that is an intelligent robotic system appropriately sensorized, capable of carrying out the procedure for collecting the saliva or mucus sample in a completely autonomous way. System is designed to be used in hospitals, airports, stations and all those places considered critical points for the transmission of the virus. The advantages of using an autonomous robotic system for the acquisition of nasopharyngeal swabs would be many, such as the distance between patients and healthcare professionals and a greater number of tests carried out in less time through the use of more units in parallel.
IP	No
Investment Needs	€70K to reach TRL7

Headline	Mechanical engineering, biomedical, patenting and prototyping of Made in Italy products.
Cluster	Red Biotech and Medical Devices
Business Model	B2B / B2C
Development	On Market
Stage	
Description	The company was born from the union of an engineering company and the most important European incubator for new businesses. It is an innovative startup, specializing in mechanical engineering, biomedical, patenting and prototyping of Made in Italy products. They aim primarily to highly innovative products as well as to the special comfort and attentive to the refined aesthetic taste, which is recognized to the Italians. This is thanks to the team work that inspires it, made up of young professionals, each contributing according to their aptitudes and skills. The core activity of the company is represented by manufacturing of exclusive mobility aids for persons with disabilities. The Mission is to mitigate the effects of the disability, by providing persons with physical disabilities with tools that support the mobility: from this idea born our wheelchairs and all our products, in their multiple models.
IP	Yes
Investment Needs	Not specified

Headline	A candidate to become the first portable device for the pre-hospital screening of brain injuries.
Cluster	Red Biotech and Medical Devices
Business Model	B2B
Development	Prototype
Stage	
Description	An innovative diagnostic device for the diagnosis of stroke pathologies in the pre-hospital phase. The instrument has the interesting characteristics of being transportable, low cost and low risk for the patient. Stroke is one of the leading causes of disability worldwide; rapid diagnosis and adequate treatment are crucial operations to limit brain damage and the consequent costs for the health system. Diagnosis is currently based on neuro-imaging tests performed with Computed Tomography (CT) techniques, which can therefore only be performed in hospitals. A pre-hospital diagnosis would allow doctors to better manage the patient upon arrival at the hospital and reduce treatment delays. In this scenario, the low-cost, transportable Device is set to become the first device for the pre-hospital diagnosis of brain injury.
IP	No
Investment Needs	Initial investment of €500K with ROI of 14% by 2024 and 32% by 2025

Headline	Medical Devices and Equipment (Medical Lab Instruments) – Liquid Biopsy, single cell live & untouched Circulating Tumor Cells selection.
Cluster	Red Biotech and Medical Devices
Business Model	B2B
Development	Prototype ready
Stage	
Description	Understanding cancer paves the way to its cure. The company can give easy access to single, intact Circulating Tumor Cells, enabling research to uncover cancer mechanisms. The company's liquid biopsy promises that earlier diagnosis and treatment guidance will impact patient care in just a few years.
IP	Filled several patents.
Investment Needs	1MI€

Headline	Gene therapy company fostering 2 major projects: Autoimmune diseases and Myeloid disorders
Cluster	Red Biotech and Medical Devices
Business Model	B2B
Development	Idea
Stage	
Description	Founded on Dec-2017; an innovative start-up in gene therapy developing two main projects, presently in preclinical phase: 1) an innovative strategy for the treatment of T1D and MS based on PD-L1/PD-1 modulation by LV-transduced HSC to express PD-L1, and 2) an approach of immunotherapy based on CAR-T technology for the treatment of myeloid disorders (AML as 1st indication) thank to the identification of specific tumor antigens expressed on tumour stem cells only. The startup has developed a solid relationship with 2 Universities in Italy, activating several sponsored research agreements to develop its projects. Yet, it is spin-off of an Italian University.
IP	Five patent families; 2 already issued in the US. At pre-clinical stage, the company is promoting studies to ensure safety and Proof-of-Concept efficacy (IND-enabling) to obtain regulatory authorization for clinical testing over the next 2-3 years
Investment Needs	In 2018, Round A raised \$17mln from seasoned biotech private investors; 78% R&D, 15% Personnel, 8% IP/legal, 2% others.

Headline	LINC01087 for the diagnosis of breast cancer subtypes
Cluster	Red Biotech and Medical Devices
Business Model	B2B / B2C
Development	Idea
Stage	
Description	Considering the negative impact that the heterogeneity of breast cancer exerts on the clinical decision-making, there is an urgent need for identifying specific biomarkers allowing to easily and precisely, as well as less invasively distinguish between the different BC subtypes. Liquid biopsy is a less invasive method that limits the need for tissue. Using a simple biofluid sample (i.e., blood, serum), it's possible to detect and monitor biomarkers of disease more frequently and efficiently. Our team has the aim to create and commercialize a rapid diagnostic kit (from sample processing to data interpretation) able to discriminate with high specificity and sensibility between the molecular subtypes of BC accordingly to the expression levels of LINC01087 in exosomes extracted from serum specimens of affected individuals.
IP	No
Investment Needs	For a validation cohort of 500 patients: 80,000€. Costs for launching/commercializing the kit: 50,000€ (at least). Use of funds: Multi-institutions study in collaboration with industrial partners to validate the clinical utility of the diagnostic kit for LINC01087 / Production and commercialization of a specific, time/cost-saving diagnostic kit for all women affected by Breast Cancer

Headline	Biotech company dedicated to personalized cancer therapy.
Cluster	Red Biotech and Medical Devices
Business Model	B2B / B2C
Development	Prototype
Stage	
Description	Founded in 2020 in Rome as a spin of a big Biotech company. Strong expertise in Oncology and Infections Diseases R, Gene Therapy, Development of innovation vaccines, Identification of Novel Targets and Biomarkers, Immunotherapy for rare cancer. Proprietary vaccine technology based on DNA electroporation to induce potent immune responses against neoantigens. Needle-to-needle in 9 weeks! POC of the technology successfully achieved in preclinical animal models
IP	No
Investment Needs	Seed round closed for €0.5mln + €0.7mln non-dilutive award
	Accelerator grant for €4mln

Headline	Italian biotech innovative SME focused on Plant Molecular Farming: using plants as bioreactors to produce sustainable biopharmaceuticals.
Cluster	Red Biotech and Medical Devices
Business Model	B2B
Development	On Market
Stage	
Description	An innovative SME that develops green solutions to produce sustainable biopharmaceuticals, focusing on orphan therapeutics for rare diseases and niche applications. Their focus is on rare skin disorders which dramatically lower the quality of life of patients, especially when involving mucocutaneous ulcerations. The solution is a new, smart topical treatment for rare skin disorders. It is based on a biologic anti-inflammatory drug which we produce in an innovative green platform.
IP	Achieved IP protection for our production method and are about to enter the preclinical phase for our candidate.
Investment Needs	Raising a Seed funding round of €2M for going through the preclinical phase whilst completing the scaling-up of the production. Looking for a lead investor with experience in working with realities in the biotech sector.

Headline	A diagnostic system that allows to accurately diagnose the inflammatory bowel diseases (IBD), distinguish their two main subtypes, ulcerative colitis (UC) & Crohn's disease (CD).
Cluster	Red Biotech and Medical Devices
Business Model	B2B
Development	Idea
Stage	
Description	A spin-off of one of the major Italian Universities. A diagnostic system that allows fast and accurate diagnosis of inflammatory bowel diseases (IBD) by MALDI-TOF/MS analysis of stool. The start-up initiative is intended to develop a completely automated laboratory system able to process the stool sample, to prepare the MALDI plate, to analyse the peptidomic profile (1000-4000 m/z) and, by the integrated patented algorithm, to provide patient's classification with diagnosis of IBD. The diagnostic system is characterized by a high negative predictive value, allowing to rule-out IBD in the 30% population with abdominal discomfort due to functional gastro-intestinal disorders.
IP	Patent for the system was approved in June-2020
Investment Needs	Not yet defined

Headline	Expansion of dental implantology solutions to all patients who suffer from bone loss and currently do not have definite and lasting solutions.
Cluster	Red Biotech and Medical Devices
Business Model	B2B
Development	Prototype
Stage	
Description	A medical startup operating in the dental sector. Studies by Helmi et al. (2019), suggest that 23.5% of patients suffer from medium or severe bone loss (more than 3 mm). This causes the impossibility of implantology techniques if not preceded by expensive regenerative therapy. The technologies developed and patented the company have led to the development of a dental implant capable of leading to the formation of new autologous bone in the patient without the need for regenerative techniques. In fact, this device performs the dual function of implant and osteogenic distractor, solving the problems of medium to severe bone deficiency, reducing recovery time from 18 to 3 months, the associated costs and the number of surgeries required. The company complements this device with cloud-based guided surgery software, which is free of charge and can customize the device for the specific patient. The aim is to increase the number of patients who can be treated, while reducing costs exponentially.
IP	Implant-distractor patent application filed.
Investment Needs	€200K (at least): 71% R&D, 27% Preclinical studies and 2% hardware.

Headline	The solution for human ulcers; a completely automated system including a machine and a disposable kit to create a patch derived by patient's own blood combined with a biopolymeric mix for the treatment of difficult to heal wounds.
Cluster	Red Biotech and Medical Devices
Business Model	B2B
Development Stage	On the Veterinary market – Prototype phase for humans.
Description	Develops medical devices for regenerative medicine and, in particular, in the wound care field. The first product: a personalized and bioabsorbable patch for wound care, combining patient's blood with biomaterials. The patch acts like a second skin, reducing healing times by 50%, without scars. The patch is obtained by the clinician through our automated machine, that extracts the active molecules from the blood of the patients, combining them with biomaterials supplied in a disposable kit. It is already on the Veterinary market since Feb-2020, demonstrating already its efficacy and safety on several animal cases. The goal is to certify the patch for human use in the treatment of difficult to heal wounds, such as bedsores, diabetic ulcers. In this big market (€20BIn), the field of innovative therapies is growing very fast (25% CAGR), demonstrating that patients and hospitals yearn to find a product like The Patch, that represents the future of personalized regenerative medicine.

IP	3 patents have been already filed; 1) covering the formulation of the patch; 2) covering the device and its process; 3) covering the kit.
Investment Needs	Phase 1 for 2 years budget of €1.9mln; Industrialization, Preclinical Testing,
	ISO & Machine CE certification.
	Phase 2 for 1.5 years budget of €3mln; Clinical Trails for CE class III, Go-To-
	Market Implementation.