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CLUST-ER HEALTH SALUTE E BENESSERE

INVEST IN LIFE SCIENCES IN EMILIA-ROMAGNA

Pharma, biotech, medical devices, digital health & wellness

Investment opportunities promoted by Clust-ER Health

EMILIA-ROMAGNA REGION

LEADING THE INNOVATION OF THE HEALTH & WELLNESS INDUSTRIES IN ITALY

1ST REGION FOR...

INNOVATION

(European Innovation Scoreboard 2021 and Transatlantic Subnational Innovation Competitiveness Index 2022)

EFFICIENCY OF THE HEALTHCARE SYSTEM

(Demoskopika, 2022)

Innovation projects by companies & universities looking for investments...

Tech Transfer

Round A (1M€ to 10M€)

Round B (10M€ to 50M€)

TECH TRANSFER / LICENSING

Tech-OECT by Unibo

ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

CLUST-ER HEALTH
SALUTE E BENESSERE

University of Bologna developed an electronic, smart multiwell that can perform a fast, real-time, and automatized evaluations of cell health status during in-vitro assays, returning quantitative and reliable data.

Field of activity and technology

The TECH-OECT boosts in-vitro assays, returning quantitative and real-time information electrically read by the sensing platform, reducing the operator exposure to potentially dangerous substances and complementing their end-point assays. Its use spans from serum-neutralization and vaccine efficacy/lifetime, to anti-viral and anti-bacterical testing, up to toxicological analysis of substances/molecules.
Boosting, wide-spreading and automatizing in-vitro assays would strenghten sanitary industry in vaccine and therapy development, pandemic and infection tracking, and animal reservoir identification reducing personnel cost and exposure, together with in-vivo studies.

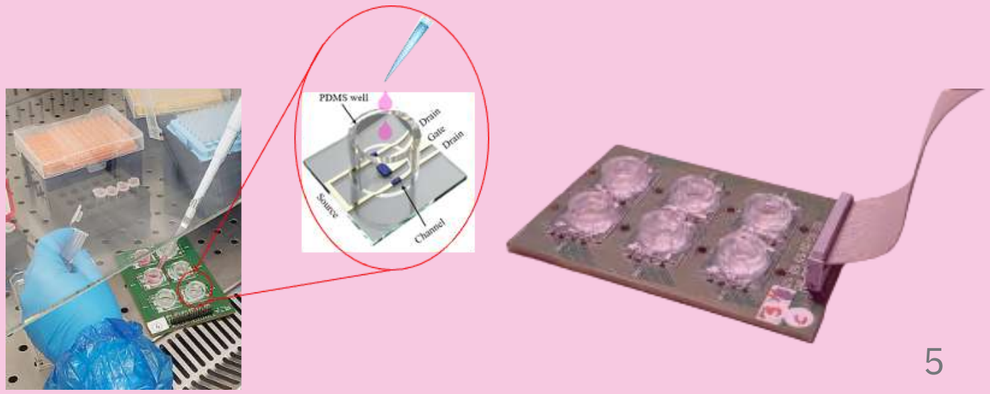
Development stage

TRL 6: prototype is currently monitoring up to sixdifferent cell cultures and could be interfaced with an electronic data acquisition setup.

Requested	1 Mln USD
Investment target	Prototype scale-up and in-field validation

WHY INVEST

Current in-vitro assays rely on technologies which (i) need the constant presence of a specialized operator, subjected to human error and interpretation, (ii) only provide quantitative analysis with slow data extraction and end-point test, (iii) lack versatility towards all cell lines and viruses/bacteria/cytophatic effects, and (iv) are cumbersome, expensive, and not portable.
The TECH-OECT overcomes slow data extractions and subjective reading limitations that still affect assay evaluations, while mimicking the standard multiwell template and allowing for the parallel implementation of the gold-standard protocols.
The electronic platform would be given on loan for use while the sensing units (re-usable up to three times) would be sold as consumables, building user loyalty.



Implantable device for local release of drugs for spinal cord injury by Unibo

ALMA MATER STUDIORUM
UNIVERSITÀ DI BOLOGNA

CLUST-ER HEALTH
SALUTE E BENESSERE

University of Bologna developed an implantable medicine based on PLLA electrospun scaffold for the local, spinal delivery of a drug combination intended to stop secondary degeneration (Ibuprofen® + T3®). It's exploitable to traumatic brain injury and stroke

Field of activity and technology

The proposed device will target neuroinflammation and related molecular events leading to neurodegeneration using combinations of two drugs loaded in tailored biomaterials. By targeting different events of the cascade at the right time frame, we are able to suppress neuroinflammation and prevent secondary neurodegeneration more efficiently.

Development stage

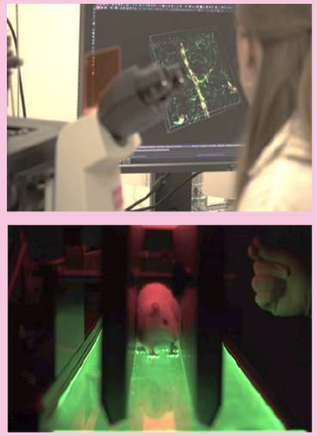
- *Fully characterized biomaterial and in vitro drug release (Pharmaceutics, 2021, 13:848-867);*
- *PoC study in rat SCI contusion model (J. Neurotrauma, 2020, 37:1708);*
- *Two GLP in vitro studies for safety.*
- *PCT/IT2018/000084*

Requested	1.4 Mln USD
Investment target	Healthcare investors, pharma and medical device companies active in the field of regenerative medicine

WHY INVEST

Traumatic spinal cord injury is a catastrophic event that is sudden and unexpected and can be devastating and costly in human and social terms. No therapies are available to interfere with the secondary degeneration, even as "disease-modifying", or to improve the clinical outcome.

What are its unique benefits? Local release of the appropriate concentration of the drug combination, over the appropriate time-window (14 days), avoiding systemic side effects. It Is proposed as "disease-modifying" for an EMA and FDA orphan condition (ORPHA:90058)



Vertebral prosthetis by University of Modena

University of Modena and Reggio Emilia patented a 3D-printed biomimetic vertebral implant with an auxetic characteristic, which can be adopted as a vertebral cage for the reconstruction of the resected portion of the spine, following a total VBR surgery.

Field of activity and technology

The present invention concerns an innovative biomimetic, 3D printed, titanium vertebral prosthetis designed using auxetic meta-biomaterials, suitable as a bone replacement implant in the oncology and degenerative field, following a total VBR surgery.
The bio-inspired geometry and the auxetic behavior provides the structure mechanobiological properties similar to those of human vertebral bones, thus avoiding stress-shielding and subsidence phenomena.

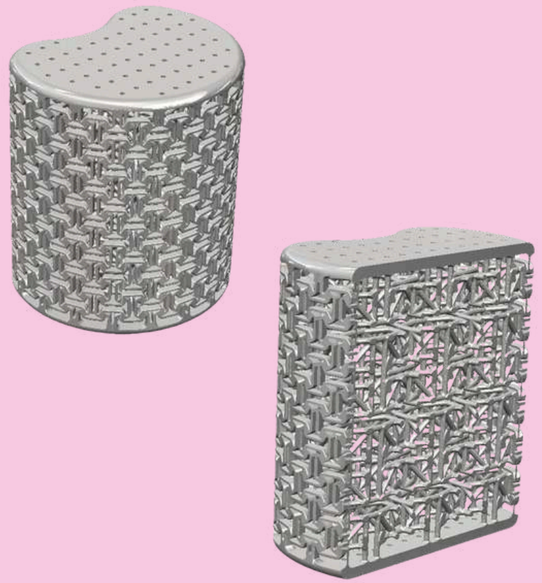
Development stage

- *Titanium 3D prototyping of the prosthesis*
- *Static and fatigue experimental characterization of the implant*
- *Refinement of the prosthesis design.*

Requested	1 Mln USD
Investment target	Orthopedic institutes, medical device companies, companies specialized in 3D printing.

WHY INVEST

Vertebral fractures, spinal tumors and post-traumatic deformities very often require the removal of the injured vertebral body, a surgical procedure known as Total Vertebral Body Replacement (VBR).



What are the unique benefits of the proposed solution?
The peculiar micro-architecture of this implant allow to achieve specific mechanical properties (stiffness and elastic capabilities) that optimize the structural response of the prosthesis for each patient, minimizing the phenomena of bone underloading (stress-shielding) while promoting bone ingrowth.

ROUND A

HyperTorque by Xenturion

Xenturion Diagnostics srl is a SME dedicated to develop molecular Point Of Care Testing (POCT) diagnostic systems for the detection of pathogens and Anti Microbial Resistance with a One-Health Perspective

Field of activity and technology

Xenturion diagnostic POCTs are based on a:

- isothermal proprietary technology Hyperfluux® for the simoultaneosly detection of multiple targets (i.e. pathogen + Internal Control in the same reaction) combined with
- easy & quick solution for biological sample preparation Xample-Prep

HyperTorque is designed to significantly reduce the economic impact due to miniaturization and for the fact to be “all in one”; thanks to GPS integration remote monitoring and assistance are possible as well as a prompt communications of positive results to public authorithy.

Development stage

Hyperfluux technology and Xample prep are currently in use in CE-IVD diagnostics kits thus already on the market (TRL9).
Miniaturized device with special and innovative biosensor is a TRL 4/5
Capital raised: 200.000 €

Requested	1 MIn USD
Investment target	Healthcare VC, Growth/Strategic Corporate Investor, In Vitro Diagnostic Corporation

WHY INVEST

Point of care Testings (POCT) is a part of the «Decentralized Diagnostics» that can be performed bedside to the patient thus directly «on field» permitting prompt diagnosis and consequent timely treatments.
HyperTorque is a project to miniaturize and compact all the instrumentations and equipments needed to perform Xenturion POCT in a single portable device.
The main feature is an Innovative Biosensor affordable in terms of costs effort and with a high sensitivity.

Functional foods by Cor.Con.

Cor.Con. International

Cor.Con. International is a private Italian company that daily researches and develops innovative solutions to wellness problems. We develop natural food supplements, cosmeceutics and functional foods from rationale to market through clinical studies, scientific publications, patenting and production.

Field of activity and technology

Our research starts from studying wellness problems and rationally designing innovative formulations capable of addressing them. We clinically test them in vivo to validate their efficacy and safety and to collect data to protect the products through patents and to promote them through scientific international publications. We apply a production process able to deliver the full quality the products deserve. And, finally, we look for pharmaceutical companies or distributors to bring the products into the market.

Development stage

TRL 7

Requested	1.1 Mln
Investment target	Pharma/Food Company, Distributors

WHY INVEST

We developed and patented functional foods for metabolic syndrome management, by reducing body weight and cholesterol levels. The project focuses on pasta and bred with a strong outlook to the fast-food sector. In 2022 2.5 billion adults (> 18 y) and over 390 million children and adolescents (5-17 y) were overweight and estimates for the future are not encouraging. We already performed clinical studies on the efficacy and safety of our functional foods. The products already boast a European claim for LDL-cholesterol reduction, and we want to extend the health claims to weight reduction as well. Finally, an industrial-scale product acceptance test has been already conducted in Italy.

ALS monitoring by eSteps

eSteps is specialized in remote monitoring of multiple sclerosis and other neurodegenerative diseases to improve patient management. The company has developed a high-tech shoe insole connected via Bluetooth to an app that allows patients and their physicians to constantly monitor stability, gait and disease progression, enabling rapid treatment adjustments when indicated.

Field of activity and technology

Remote monitoring, health technology

Development stage

The company, with its headquarters in the United States, is finishing clinical validations to proceed to FDA clearance thereafter.

Capital raised

Is actively fundraising and has already joined two institutional VCs with $350.000

Requested	1.5 Mln USD
Investment target	Pharma Company, Healthcare VC

WHY INVEST

eSteps is a fast-growing company that collaborates with major advisors who support the work in the field of multiple sclerosis and neurodegenerative diseases.
The company is seeking $1.5 million to clinically validate the service in movement disorder-related diseases and enter the market by the end of 2023.

Uell by Lingatech

UELL is a psycho-physical assessment digital platform.
It integrates 4 areas of science:
Genetics, Sports Sciences, Nutrition and Psychology.
The goal of UELL is to create the scientific basis for organizing training programs aimed at maintaining good health and wellbeing.

Field of activity and technology

From Fitness's customers to everyone

Development stage

Early adopters

Capital raised
150.000 €

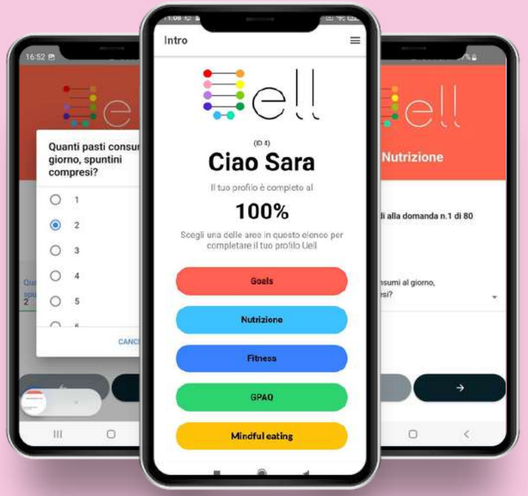
Requested	1.5 Mln USD
Investment target	Not specified

WHY INVEST

1) Product's research and development
(Uell check, feedback loop, English language)
2) Uell analytics (Full Time Data Scientist)
3) Implementation of the B2C phase
4) Uell School (E-learning portal)
5) Improvement of new scientific tests

Why?

- Ethical and social motivations
- The Business Model is highly scalable and disruptive
- The target market is very large
- Huge future applications



Celector by Stem Sel

Stem Sel® is a spin-off company of the University of Bologna active in the development, production and sale of Celector® - the cell chromatograph.

Field of activity and technology

With Celector®, the cell suspension is separated and collected based exclusively on cellular physical parameters such as size, morphology, density and membrane rigidity. Cells that are not identified by a single marker, or are derived from complex biological samples, can be identified and sorted.
As an example, mesenchymal stem cells can be isolated from fresh bone marrow and immediately used for further purposes without additional manipulation or the senescent cells are depleted from the expanded cell culture of adipose stem cells to obtain the most vital and proliferative cells.

Development stage

MKT growth and GMP compliance.

Requested	2Mln USD
Investment target	Growth/Strategic Corporate Investor

WHY INVEST

Celector® is the only instrument in the world that tag-less analyses and separates living cells exploiting solely their physical characteristics - highlighting even minimal differences: no antibody labeling, as it is necessary with current reference techniques.
Dual features: label-free cell sorting technology and quality control in ATMP production.
Technology and device worldwide are patented. Cells are not manipulated, sterility is kept, and cells can be amplified in a bioreactor for cell production after collection. Celector plays also as a QC system to check the purity and homogeneity of cell products.

Lazarus by Omnidermal

Lazarus is the first telerehabilitation solution integrating remote monitoring with a connected stimulation system in one miniaturized device. It's composed by a wearable device enabling remote rehabilitation therapy for patients, through continuous monitoring of muscle response and modulated stimulation of patients' muscles.

Field of activity and technology

Lazarus is an innovative medical device for telerehabilitation, and a potential tool for practitioners working in healthcare. It enables the movement of the healthy subject (e.g., a therapist) to be analyzed by an AI algorithm and then replicated on the patient through FES stimulation, making remote therapy implementation more accurate and effective, thus improving life-quality of patients while lowering costs.

Development stage

Omnidermal developed a first prototype and successfully tested it on a group of patients. Next steps: Multicentric clinical trial and MDR certification.
Capital raised: 200.000€

Requested	2.35 Mln USD
Investment target	Healthcare investors, companies active in the field of medical devices for rehabilitation

WHY INVEST

Lazarus can perform real remote rehabilitation without the need for direct contact between therapist and patient. It is also possible to use pre-recorded stimulation patterns previously collected by the therapist. This innovative system will be an important tool for healthcare professionals that will also guarantee continuity of care for all patients. In addition, Lazarus will make rehabilitation therapy more accessible and will allow for a better and faster patient recovery in hospitals, clinics, and nursing homes.

Neutronbrush® x nIORT® by TheranostiCentre

Neutronbrush® x nIORT® is a Compact Neutron Generator (CNG) for the treatment of advanced solid tumors developed by TheranostiCentre Srl.

Field of activity and technology

The CNG is a mobile, light, self-shielded, cylindrical-shaped device (about 35cm long x 18 in diameter and with a weight of around 120kg).
Neutronbrush® can generates a flux of high energy neutrons which can penetrate around 2cm of tumor tissue after surgical resection
Invention patented by TC Srl which generates a mix of radiation ionizer formed from neutrons “slow down” (le golden bullets silenced) and from gamma radiation (the transversal wave to the bundle of bullets).

Development stage

First laboratory prototype ready and installed at the ENEA Research Centre at Brasimone (BO), Italy. Second prototype in construction for in-vitro and in-vivo tests.

Capital raised
500.000 €

Requested	2.5 Mln USD
Investment target	Companies investing in research projects and with connections in medical fields

WHY INVEST

Radiobiological efficiency of Neutronbrush® is 16 times higher than the IORT devices currently in use.

By breaking the DNA of cancer cells into several parts, it makes it difficult to repair them and therefore reduces the risk of tumor recurrence.
The irradiation of CNG acts like a "foam" in the surgical cavity and because it has a uniform distribution inside it, it has no pointing problems, thus allowing to sterilize the walls and margins from the tumor micro-cells present - an action that traditional IORT devices do not allow.

The IORT treatment times with the current systems are approximately 30 minutes, while the nIORT® reduces the treatment time by a quarter. The production costs of CNG are contained. The cost of the final device will depend considerably on the cost of the robotic arm and the software used, but it will certainly not exceed €1 million. For the electron-based IORT (IOERT), the medical device costs approximately €1.5 million.

ROUND B

IppocraTech

IppocraTech has developed a technology that can simultaneously calculate the 5 vitals identified by the WHO to assess a person's health status. By simply touching the device, it will collect all the signals needed by IppocraTech's algorithms in the cloud to monitor heart rate and respiration, body temperature, blood saturation, one-lead ECG and blood pressure.

Field of activity and technology

Remote Patient Monitoring. This technology has been patented and received CE Class IIa certification. The technology has been approved through clinical studies in some important Italian hospitals and publications in international medical journals.

Development stage

Early Stage

Capital raised
5 Mln €

Requested	10 Mln USD
Investment target	Venture Capital Fund

WHY INVEST

IppocraTech aims to enter the US market by 2025, once FDA certification is obtained.
The goal is to raise $10 million by 31 December 2024 in order to enter the US market. IppocraTech currently has a unique technology in the world.
With this budget, all 5 vitals identified by WHO as the main indicators of an individual's state of health will be measured in a non-obtrusive way. In addition, the technology allowing lactate measurement non-invasively and in a non-obtrusive way will be developed.

Inhalable Teicoplanin by Neupharma

Neupharma is a young and modern company focused on innovation in the field of rare diseases, particularly cystic fibrosis, a genetic disease that affects about 30,000 people in Europe.

Field of activity and technology

Cystic fibrosis is a rare disease, and MRSA lung infection affects approximaely 25% of CF patients.
The repositioning by nebulization of an established glycopeptide antibiotic (teicoplanin, very effective against MRSA) could solve the problem of the chronic infection. This approach may become the standard therapy for the treatment of lung infection in CF patients, avoiding the risks connected to systemic administration and reducing the risk of resistance development.

Development stage

Phase 1 successfully completed

Requested	15 Mln USD
Investment target	Pharma companies interested in rare diseases. Venture Capitalists

WHY INVEST

Methicillin-resistant Staphylococcus aureus (MRSA) has emerged as a particular challenge in cystic fibrosis (CF). The prevalence of MRSA in individuals with CF has increased dramatically over the last 15–20 years. Individuals with persistent MRSA infection have decreased life expectancy compared to those who remain MRSA negative.
MRSA lung infection affects approximaely 25% of Cystic fibrosis patients.
The formulation of inhalable teicoplanin, with its customized nebulizer, has been granted an Orphan Drug Designation by both EMA and FDA and an Orphan Pediatric Designation by FDA.

Angiopulse by Angiodroid

Angiodroid proposes to develop and commercialize an innovative console to help patients with heart failure and cardiovascular pathologies. In contrast to other intra-aortic balloon pump (IABP) consoles, it is based on passive counterpulsation, attending the patients both in the IABP therapy and the weaning from it.

Field of activity and technology

The console will be used in ICU wards for the resuscitation of patients with cardiac failures and for a gradual assistance towards autonomous cardiac function.

Development stage

TRL 7: a first device was handcrafted for functional verification and bench tests. Once all tests were completed, a first prototype was developed for clinical tests in relevant environment on 10 patients in Sant'Orsola University Hospital. Angiopulse needs a clinical validation according to the newest European standards for medical devices in order to reach TRL9.

Capital raised: *2 Mln €*

Requested	15 Mln USD
Investment target	R& D Funds, Private Stakeholders in the Healthcare field

WHY INVEST

The Angiopulse project proposes to expand the tractable user base compared to those for whom the typical therapy presents some limitations, such as ventricular arrhythmia problems and patients who need a gradual assistance towards cardiac autonomy, without burdening the heart further.
Thanks to its compatibility with any other IABP consoles,
Angiopulse's technology allows principal end-users (medical staff) to promptly switch from active (typical) to passive (innovative) counterpulsation, without risking the patients' health. Considering the environment where an IABP console must be used (Intensive Care Unit, Heart-Surgery), an aspect not to be overlooked when talking about Angiopulse is that it is silent, free of noises that can alert patients that are already shaken.

MyDial by IBD

IBD is an innovative SME, a manufacturer of biomedical devices that has developed MyDial, a new portable device for hemodialysis suitable for home treatment of end stage renal disease patients.

Field of activity and technology

MyDial is a portable device designed for home hemodialysis that replicates the hospital therapy.
MyDial technology is based on: 1) an original hydraulic circuit (patented) that integrates innovative sensors and actuators; 2) a safety sensor for the venous needle dislodgement monitoring; 3) a telemedicine system for remote monitoring of the patient; 4) a simple and low-cost disposable.

Development stage

TRL 6. Next steps: Product finalization, clinical validation, CE certification according to MDR, industrialization and production.

Capital raised
2.5 Mln € (partners, public funds and VCs)

Requested	15Mln USD
Investment target	Growth/Strategic Corporate Investor

WHY INVEST

Hemodialysis is the most widely used treatment for End Stage Kidney Failure, a deadly condition if left untreated. In-center dialysis is very expensive: in Europe, the annual cost of in-centre hemodialysis treatment is €21 billion, about €60,000/year per patient, which is equivalent to 2% of the healthcare budget, while in the US its annual cost is $42 billion, about $89,000/year per patient.

MyDial works with an innovative hydraulic circuit and a customized and low-cost disposable, designed to significantly reduce the economic impact of chronic dialysis treatment (up to 70% cheaper than competitors) and make de-hospitalization possible. Thanks to the telemedicine system and the venous needle dislodgement sensor, MyDial allows treatments to be carried out in maximum safety in a domestic environment.

b.Bone® by Greenbone Ortho

Inspired and derived from nature, b.Bone® by Greenbone Ortho is the only biomimetic technology available in the orthopaedic industry of synthetic bone substitute.

Field of activity and technology

Because of its unique combination of chemical composition, porosity and nano-crystalline structure, b.Bone® is BIOACTIVE showing osteoconductive, osteoinductive and anti-bacterial properties with prevention of biofilm formation. b.Bone® is the only synthetic bone graft that has the promise to replace current Gold Standards in the market (Autologous Bone Graft and Allograft). b.Bone® technology is covered by International IP as well as its manufacturing process.

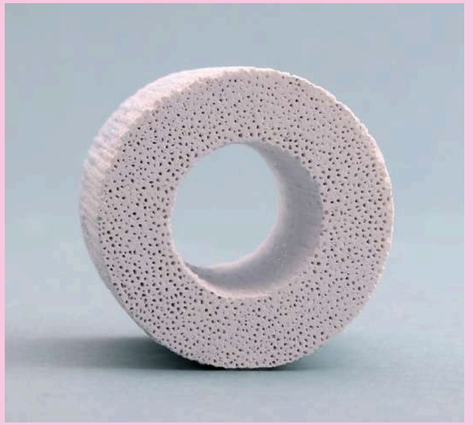
Development stage

Already in European market with a focus on UK, Italy and Germany. MDR Certified since February 2024. 2 Pre-Market clinical studies completed. Ongoing post-market clinical study. Completed Pre-submission to FDA with confirmation of 510k regulatory path. Clearance expected in Q4-2025. Spinal version to be cleared by FDA and MDR. Completed 6 month follow-up of the b.Spine pre-market clinical study.

Requested	15 mln USD
Investment target	Growth/Strategic Corporate Investor

WHY INVEST

The bone graft substitute market is a very large and growing market valued at over 4 billion USD. It is currently dominated by autograft & allograft procedures (70% of total market) which are considered the gold standard today. However, these procedures have significant co-morbidities: significant chronic pain, infection, nerve damage and fractures at the donor site; infection and immune response / inflammation at the recipient site. These issues increase length of stay, recovery time, and total cost of the procedure. Greenbone is the only technology today which heals bone at an equivalent or faster rate as autologous and allografts without any of the associated co-morbidities. As a result, it is the only synthetic solution which will be able to access the largest segment of this market.



HOLOCLAR® tissue engineering by HOLOSTEM

Holostem is a commercial stage biotech company entirely devoted to development, manufacturing, registration and distribution of Advanced Therapies Medicinal Products (ATMPs) with a focus on cultures of epithelial stem cells both for cell and gene therapy.

Field of activity and technology

Holoclar is indicated for the reconstruction of the corneal surface in patients with moderate to severe limbal stem cell deficiency unilateral or bilateral due to ocular burns with a min of 1-2 mm2 of undamaged limbus Holoclar is the only service platform that offers a comprehensive strategy to manage patients with LSCD, from surgery, to training to post-op advice and following

Development stage

Conditional EU market approval in 2015 as the first stem-cell based therapy approved; US Orphan Drug Designation from the FDA in 2018. Phase 3 successfully completed

Requested	50 Mln USD
Investment target	Pharmaceutical companies interested in rare diseases. Venture Capital

WHY INVEST

Due to the very high medical need and the rarity of the condition, a simplified development path can be agreed with FDA: there is the possibility to complete the clinical development plan in USA, similarly to EU, involving a limited additional number of patients in the trials.
Based on these assumptions, considering that the development was completed in EU and Conditional Marketing Authorization was obtained, time and costs can be significantly reduced compared to a usual development path. Moreover, the formulation of HOLOCLAR® Advanced Therapy Medicinal Product of Tissue Engineering, with its personalized medicine approach, has been granted an Orphan Drug Designation by both EMA and FDA

CLUST-ER HEALTH
SALUTE E BENESSERE

Clust-ER Health is an association made of large companies, SMEs, laboratories of the High Technology Network, research centers, health facilities and training institutions that share skills, ideas and resources to support the competitiveness of the Health Industries and Wellness of Emilia-Romagna.

EMILIA ROMAGNA GO HEALTHY

RegioneEmilia-Romagna

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To get in touch with representatives of the companies, contact us via:

info@health.clust-er.it

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