meet in italy
FOR LIFE SCIENCES
STARTUP BREEDING 2023

MEET IN ITALY FOR LIFE SCIENCES 2023

Startup Breeding 2023 - Final Pitching Event

31st October 2023
Palazzo Mezzanotte - Milan

Discover the selected startups for Startup Breeding 2023
and their innovative proposals

ALISEI
Advanced Life Sciences in Italy

meet in italy
FOR LIFE SCIENCES 2023

ALISEI
Advanced Life Sciences in Italy

Meet in Italy for Life Sciences - MIT4LS - the leading international partnering event in the Life Sciences sector in Italy – shows a special attention for startups, with over 660 startups participating in the networking sessions along seven editions.

MIT4LS is powered by the **National Technological Cluster for Life Sciences - ALISEI**, which associates all the main organizations working for the promotion and growth of the Life Sciences sector in Italy, from reaserch to industry. At international level, it is supported by **Enterprise Europe Network - EEN**, that promotes the internationalization of European SMEs and supports the event since its first edition, with several of its 600 members.

MIT4LS Startup Breeding is the initiative dedicated to startups and business proposals. The goal is to provide them with the expertise, tools and connections to boost and fully exploit their business potential, thanks to the support of a wide network of startup mentors, coaches, experts and several investors.
At the end of the training, the selected finalists will pitch their proposals in occasion of **Meet in Italy for Life Sciences 2023 - Final Event, in Milan, on the 31st October 2023.**

meet in italy
FOR LIFE SCIENCES
STARTUP BREEDING 2023

FINAL PITCHING EVENT
31st October 2023, Palazzo Mezzanotte - Milan, Italy

Discover the entire MIT4LS - Final Event programme **here**.

WHEN?
31ST OCTOBER 2023

WHERE?
MILAN, PALAZZO MEZZANOTTE

Will partecipate:
- RESEARCH AND ACADEMIA
- STARTUPS
- ENTERPRISES
- FINANCE

REGISTER HERE

Durig MIT4LS Final Event, a jury of experts will assign the title of **MIT4LS 2023 most innovative proposal award** and other special awards, offered by the network of partners of Startup Breeding 2023.

Investors and corporates are invited to participate on the 31st October and explore the Life Sciences innovation showcase and the unique opportunities of investments, joining the several investment funds and organizations already supporting Startup Breeding 2023.

For information, please contact: **mit4ls@meetinitalylifesciences.eu**

ALISEI
Advanced Life Sciences in Italy

Startup Breeding 2023
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Startup Breeding 2023
FINALIST STARTUPS
OVERVIEW

CHRONOLIFE

Real Time Intelligence for Healthcare

Chronolife is developing a remote patient monitoring service, Keesense, based on a connected medical T-shirt and its smartphone application. Keesense has been designed to be as comfortable and easy to use as possible. The solution interfaces with several remote monitoring platforms, enabling our customers (hospitals, healthcare professionals) to choose the most suitable

CLEPIO Biotech

3D histology, made easy

The company offers an innovative technology for 3D quantification of histological biomarkers. Their goal is to create a new standard for the analysis of cancer tissue biopsies, where the full 3D volume of the sample is considered instead of the current standard where one or few 2D slices are used, losing more than 99% of the available information.

GENESYS

Medical Devices, pathogens' genetic signature detection system

GeneSys emerged from the urgent need for a groundbreaking PCR-based solution, enabling rapid pathogen monitoring in under 1 hour, anytime, anywhere. Its initial focus is on swiftly detecting urinary tract infections, prevalent among elderly and hospitalized individuals.

MEEVA

Innovating therapies for autistic youth

Nowadays, MEEVA is on a mission to provide universal access to therapies for all autistic teens. We have developed a digital solution leveraging Virtual Reality and ML-based data analytics fostering social skills through a multi-player serious game.

NANORADOX

Medical Device for oncological disease

Vision S.p.a. ("Vision") develops a medical device for the treatment of Head and Neck Cancers(HNC) through localized hyperthermia. They have identified an unmet medical need in the treatment of HNCand worked on a non-invasive solution that would allow patients a longerand good quality life,"Nanoradox®".

Paperbox Health

PAPERBOX HEALTH

Intervention in neurodevelopmental disorders

Paperbox Health aims to empower every child, ensuring their potential isn't limited by learning challenges. Through their solution, DINO, a game-based approach, they're breaking down accessibility barriers, enabling early identification and effective intervention on neurodevelopmental disorders.

Previeni

PREVIENI

Medical Imaging of soft and hard tissues

Previeni aims at bridging the diagnostic gap left unserved by the current state of the art in medical imaging by offering doctors the possibility to see inside their patients right on the field, at their home, or their room bed, without requiring a critical patient to move, and without harming the patient with the usage of harmful ionizing radiation as found in portable x-ray machines.

Resalis THERAPEUTICS

RESALIS

Tackling metabolic disorders with non-coding RNAs

Resalis is developing a first-in-class antimiR-22 therapeutic (RES-010) to address highly unmet medical needs in metabolic liver diseases. RES-010 is an antisense oligonucleotide that targets miR-22 and is designed to become a safe and convenient treatment option with durable disease-modifying therapeutic impact.

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soundsafe Care

SOUNDSAFE Care

For a safe and sound surgical care

Nowadays, chemotherapy and radiotherapy are well-established approaches to treat cancer but they are not free from invasiveness. Soundsafe Care can improve the lives of millions of patients by introducing a novelintegrated robotic devicefor performing focused ultrasound surgery on oncological organs in a totally non-invasive manner using focused ultrasound (FUS).

TTOP
TRUE TISSUE-ON-PLATFORM

TTOP

True Tissue On Platform

TTTOP is a modular, versatile MicroPhysiolgical platform that aims at improving the effectiveness of preclinical prediction guaranteeing more predictive results than conventional technologies, replicating complex human pathophysiological conditions and minimizing the controversial animal use in research.

VRG THERAPEUTICS

VRG Therapeutics

Generation of miniproteins for therapeutic use

VRG Therapeutics (VRG Tx) is an innovative biopharmaceutical R&D company head quartered in Budapest, Hungary. VRG Tx is committed to leveraging its proprietary miniprotein ISEP technology to tackle diseases through mechanisms that conventional biopharmaceutical approaches cannot achieve.

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STARTUP BREEDING 2023

Startup Breeding 2023
FINALIST STARTUPS

INSIGHT

ALISEI
Advanced Life Sciences in Italy

CHRONOLIFE

Real time intelligence for Healthcare

BASED IN: Paris, France
INCORPORATION YEAR: 2015
STAGE OF DEVELOPMENT: TRL 9
IP: 3 patents
FUNDING NEED: around 5 M

Chronolife is a service operator offering preventive health solutions through remote monitoring services. Based on its own wearables in the form of t-shirt as well as 3rd-party devices, Chronolife covers a variety of use cases from remote patient monitoring to risk prevention and research. The company also offers the possibility to develop custom wearables for specific needs and use cases.

Context

As the population ages, the number of people suffering from chronic pathologies continues to rise. At the same time, healthcare budgets are being cut, hospital beds are being reduced, and the population is growing steadily. Finding solutions to these challenges is therefore a priority, and remote patient monitoring is one way of meeting these challenges. Indeed, more and more patients are being monitored remotely, but the programs often only integrate a connected scale, which apart from the patient's weight, does not allow the measurement of physiological parameters for monitoring the evolution of health status. There is a need for end-to-end remote monitoring solutions, that could help healthcare professionals monitor and diagnose their patients and allows patients to feel secure at home, without interfering in their daily live.

Value Proposition

The remote patient monitoring service, Keesense, is based on a connected medical t-shirt, and its smartphone application. The connected t-shirt automatically and continuously collects 6 physiological parameters, generating over 20 health indicators. Keesense enables patient monitoring in real-life situations: the wearable has been designed to be as comfortable and easy to use as possible. The t-shirt can be machine-washed like any other everyday garment. The solution thus facilitates patient compliance. The Keesense solution is interoperable and interfaces with several remote monitoring platforms, enabling customers (hospitals, healthcare professionals) to choose the most suitable, or even their own. The solution responds to the need to monitor patients outside hospital walls, in order to detect deterioration in their state of health as early as possible, and thus take appropriate therapeutic action, which is more effective because it is implemented at an earlier stage.

Market Overview

The evolving landscape of national legislation around reimbursement policies regarding RPM attests to a growing willingness to pay. Most of the countries now have reimbursement codes for RPM and more and more public funds are used to support RPM. Keesense is CE Class II marked (under the MDD) and is being certified under the MDR. Our target clients are hospitals, clinics, healthcare professionals, pharmaceutical companies, telemonitoring platforms but also insurances, defense and security sectors. Chronolife already work with manufacturers for the wearable, and already have a partnership with a logistician.

The Team

Wearable

Remote health monitoring

Medical Device

https://www.chronolife.net

CLEPIO Biotech

3D histology, made easy

Clepio Biotech opens a new dimension for cancer understanding and diagnosis. The company offers an innovative technology for 3D quantification of histological biomarkers, leading to a more comprehensive view of the tumor microenvironment and a better selection of patients for immunotherapy. Their goal is to create a new standard for the analysis of cancer tissue biopsies, where the full 3D volume of the sample is considered instead of the current standard where one or few 2D slices are used, losing more than 99% of the available information.

BASED IN: Sesto Fiorentino (FI), Italy
INCORPORATION YEAR: 2023
STAGE OF DEVELOPMENT: TRL 4/5
IP: 3 patents by CNR and LENIS
FUNDING NEED: about 4 M

Context

Immunotherapy has been a game changer for the treatment of many solid tumors. As only a fraction of cases responds to this treatment, selection of patients is crucial. To this aim, several biomarkers have been proposed, like the quantification of cells expressing PD-1 or PD-L1 on histological slides extracted from patients' biopsies. However, the accuracy of such biomarkers in predicting immunotherapy outcome remains modest. One of the main limitations concerning histological biomarkers is selection bias due to the observation of a small portion of tissue (a slice of few µm from a mm-sized or cm-sized sample). Indeed, previous studies have shown that PD-L1 density is highly variable across different planes in the sample, questioning the overall reliability of the method. 3D analysis is seen as a potentially game changer for a better sample classification, both in research and clinical settings, based on a comprehensive analysis of the cellular composition of cancer and of its microenvironment. 3D sample analysis is feasible in principle, but in practice, it is very difficult to achieve for those who are not experts in the field of microscopy and image analysis.

Value Proposition

Clepio Biotech offers a scalable and accurate technology for 3D quantification of histological biomarkers. Differently from the classical paradigm, where the microscope producer only sells an optical instrument, they aim at providing a complete pipeline, encompassing sample clearing/labeling, 3D imaging with a patented light-sheet microscopy implementation, and data analysis. The paradigm shift proposed by Clepio Biotech will enable users without specific skills in optics or computer science to perform routine 3D analysis of tissue samples. Our technological advantage gives us the possibility to scale up 3D tissue analysis to an unprecedented level compared to present solutions.

Market Overview

The Clepio Biotech goal is to develop the company following a user-centered approach. They are in contact with several early adopters in the research and clinical segment, and are actively working to expand this network by contacting potential users via email, LinkedIn, or phone. The aim is reaching over 1 M€ of market in the research field within 3 years, thanks to the uniqueness of methodology, the vast number of applications where it can provide significant improvement, and the lack of effective solutions. In the mid-term (4-6 years), they want to become a companion/complementary diagnostic tool for immunotherapy prescription, moving from the research segment into the much wider (10X) clinical market. Starting from the beginning, Clepio Biotech will store all data in a dedicated database, that will be represent in the future a invaluable source of curated data for the development of new biomarkers, diagnostic support strategies and machine learning tools.

The Team

TRL 4/5 | Digital health | 3D Analysis | Cancer Diagnosis

https://www.clepiobiotech.com/

GENESYS BIO

BASED IN: Montefiascone (VT), Italy
INCORPORATION YEAR: 2023
STAGE OF DEVELOPMENT: TRL 3
IP: 2 patents pending
FUNDING NEED: USD 5.1 M in total in 2 rounds; first round USD 700K

GENESYS Bio

Medical Devices, pathogens' genetic signature detection system

GeneSys emerged from the urgent need for a groundbreaking PCR-based solution, enabling rapid pathogen monitoring in under 1 hour, anytime, anywhere. Its initial focus is on swiftly detecting urinary tract infections, prevalent among elderly and hospitalized individuals. GeneSys taps into a lucrative USD 5B B2B market encompassing clinics, hospitals, and corporations, with ongoing collaborations including partners in Italy and Siemens. Backed by Key Opinion Leaders and a seasoned team, GeneSys seeks investment to seize this market opportunity. Join us in revolutionizing healthcare.

Context

The detection for the presence of pathogens is crucial. It must be rapid, sensitive, specific, and accessible to prevent terrible consequences. Among various infectious diseases the Urinary Tract Infections are responsible for over 40% of the infection-related hospitalization, more than USD 7B in direct costs for the healthcare system and over 240.000 deceases per year. Those is mainly due to the lack of rapid, sensitive, and accessible screening system

Value Proposition

GeneSys is a pathogens' genetic signature detection system that allows daily monitoring of clinically relevant urinary tract infections (UTIs), in less than 1 hour and wherever it is needed. Clinicians need only to collect a few drops of urine, add into the prefilled vials (that contain all the reagents needed for the test), load the vial onto the device and press start. Within 1 hour, the device processes samples and sends results to a dedicated app and by a green or red light on the device 'chassis. The device is fully portable and does not require any technical skill to be used. Current competition ranges between rapid but low-sensitive and low-specific indirect tests and time consuming-high-cost laboratory tests. GeneSys merges the rapidity of a rapid tests with lab-grade sensitivity and specificity. GeneSys device is considered at TRL3. Both the device and the kit have been validated with bioinformatic tools and the final prototype is under production with the expected deadline within the end of Nov. 2023

Market Overview

GeneSys adopts a B2B market strategy by generating revenues from the consumables (kits), and monthly fees generated by the app and the dashboard. The Device can be another source of revenues. Being a medical device company, it makes reasonable to promote GeneSys through medical KOL articles, case4studies, scientific papers and congresses. Main customers will be a mix of direct customers distributors and corporates. The main critical point is that the technology is in a very early stage and cash injection in needed to maintain the competitive advantage and pushing products on the market. The UTI pathogens detection market worth USD5B globally.

The Team

Medical Devices | Urinary Tract Infections | Digital Health | B2B market

https://www.genesysbio.com

MEEVA Srl Società Benefit

Innovating therapies for autistic youth

BASED IN: Trento, Italy
INCORPORATION YEAR: 2022
STAGE OF DEVELOPMENT: TRL 5
IP: 1 patent preparation in progress
FUNDING NEED: 250K M

MEEVA is on a mission to provide universal access to therapies for all autistic teens. We have developed a digital solution leveraging Virtual Reality and ML-based data analytics fostering social skills through a multi-player serious game. Preliminary studies in international experimental pilots shown high acceptance, strong engagement & increased social interaction.

Context

Autistic Individuals typically present some deficits in social communication and are often characterized by the presence of restricted interests and repetitive behaviors. Despite the fragmentation of the studies performed in Europe concerning early detection, diagnosis and intervention services for autistic individuals, there is clear evidence about the unfair access to therapeutic services due to a number of factors including diagnosis delays, limited number of trained personnel and closeness to rehabilitation centers. As a consequence, Rehabilitation Centers are struggling to face the rising demand with tight resources since the current approach to rehabilitation services is strictly dependent to available therapists and physical space to host sessions. For autistic teens, lack of therapies leads to higher rates of socially isolated individuals in their adulthood, which may lead them to difficulties in finding a job and gaining personal autonomy.

Value Proposition

MEEVA proposes a digital platform based on Virtual Reality (VR) that assists therapists in delivering group therapy sessions to improve social skills of autistic adolescents from remote or in-presence. The solution is composed by a VR application running on headsets that engages a group of teens in immersive serious games by exposing them to collaborative missions that strengthen their cooperative & emotional skills; an ML-based biometric data analytics software capable to warn therapists about potential stressful conditions of players; a dashboard facilitating the identification of the more appropriate therapeutic journey per each teen. We create value to autistic teens and their caregivers through an effective therapeutic activity, while cutting time and transportation costs. We deliver value to Rehabilitation Centers by providing a tool that let them scale better geographically and reduce their OPEX.

Market Overview

Our reference market is the one of autism and neurodevelopmental disorder treatments, estimated to grow up to 43.2B$ worldwide by 2031 with +4.6% CAGR, whose 55% is devoted to behavioral approaches. These numbers should be interpreted together with the ones coming from the VR healthcare market projected to grow up to 6.20B$ by 2029 (+38.7% CAGR), in vast majority devoted toward the use of VR to diagnose, treat and support mental health issues through a cognitive-behavioral approach. There are no precise numbers related to the amount of autistic individuals in Italy or Europe, however considering an average rate of 1 in 100 EU children diagnosed, we estimate 45.000 teens in Italy and 469.000 in EU. In terms of Centres, there are 1.200 at national level (Osservatorio Nazionale per l'Autismo), a market which is 10x bigger in Europe (Autism Europe). MEEVA B2B pricing strategy leverages on a subscription model where each Center pays per user connected. The pre-money evaluation of the company is set to 1.250.000 Eur

The Team

TRL 5

Digital platform

Virtual Reality

https://www.meeva.eu/it/

NANORADOX - a Vision SpA project

Medical Device for oncological disease

BASED IN: Milan, Italy
INCORPORATION YEAR: 2022
STAGE OF DEVELOPMENT: TRL 4
IP: 1 patent pending
FUNDING NEED: 5 M

Vision S.p.A. ("Vision") develops a medical device for the treatment of Head and Neck Cancers (HNCs) through localized hyperthermia. They have identified an unmet medical need in the treatment of HNCs and worked on a non-invasive solution that would allow patients a longerand good quality life,"Nanoradox®".

Context

HNCs are the7th most common cancer globally, the 8th in Europe. HNCs are frequently a lethal cancer and most HNCs are squamous cell carcinomas (HNSCCs) traditionally considered tobacco and alcohol exposure related. Globally, five-year survival for HNC averages at 50% of cases, with hypopharynx experiencing the worst outcomes. The low 5-year survival would be sufficient to identify an unmet medical need, but further analysis highlights the strong limitations of surgery, the serious risks associated with radiotherapy and the lack of options for patients suffering from relapses.

Value Proposition

Nanoradox® is a nearly non-invasive treatment, it can be repeated in day hospital over time and can be the solution for many patients for whom only palliative care is available today. Nanoradox is a Class III Medical Device and consists of a solution of iron oxide nanoparticles, which is injected into the tumor mass, that is then irradiated by an electromagnetic field. Irradiation Induces heating of the nanoparticles, which causes apoptosis of tumor cells. It is an economic treatment, which is carried out in day hospitals, that does not require expensive equipment or particular medical skills. Nanoradox® can be used in combination with immunotherapies or drug therapies to enhance their effect. To date there are no similar treatments on the market. Thanks to the patent application and to the treatment with specific equipment, up to date the treatment can't be easily duplicated by competitors, but can be easily scaled - up by the company.

Market Overview

Nanoradox® is considered in Europe a class III Medical Device. Vision aims to obtain the market authorization of Nanoradox® in Europe by mid 2026and to negotiate a licensing agreement. The injectable solution can be produced and packaged in Italy with a favorable quality/price ratio while the radiation equipment can be produced by numerous operators in Europe. The Vision plans to spend the next three years developing the product up to market authorization and negotiating the license agreement. The development will require 5 million euros spread between the completion of the IND package and the clinical testing/market authorization.

The Team

TRL 4

Medical Device

HNC tumor

Paperbox Health

BASED IN: Torino, Iltaly
INCORPORATION YEAR: 2022
STAGE OF DEVELOPMENT: TRL 4/5
IP: Open innovation + patentability
FUNDING NEED: Around 550 K

PAPERBOX Health

Intervention in neurodevelopmental disorders

Paperbox Health aims to empower every child, ensuring their potential isn't limited by learning challenges. Through their solution, DINO, a game-based approach, they're breaking down accessibility barriers, enabling early identification and effective intervention on neurodevelopmental disorders. With the expertise of specialists and the involvement of educators, they build a customized intervention path, optimizing effectiveness, increasing accessibility, and engaging the child.

Context

According to EMA an Unmet Medical Need arises when all actors in the public and private sectors actively suffer damage from the combined effect that a late diagnosis entails for society, the social and health system. This could lead to developing depressive disorders and anxiety disorders (2-3 times higher in people with dyslexia). People affected by learning disorders are less likely to complete high school (up to 3 times compared to average), and they have a higher risk of entering the juvenile justice system. Current solutions, which are mainly paper-based tests, do not allow the spread of identification and intervention due to their “not-accessible” nature.

Value Proposition

DINO is a video game for the early identification and treatment of learning disorders. It can generate a cognitive report starting from the age of 5 (current diagnostic methods can be applied from 7 years of age). The average duration is 15 minutes, there are no waiting times, and it is designed for different caregivers to guarantee full accessibility for families. DINO can be played by any device (min 9,5’) and it is also language-free. DINO is totally accessible, can be run autonomously, and does not put children in a stressful scenario during usage. Combining the usage of DINO with the support of specialists it is possible to build a strong customized path for the child and an accessible experience for the family within one platform.

Market Overview

They have a 3-step commercialization model. Step 1, DINO requires calibration and it’s not certified as a medical device: focus on schools and educators, proposing DINO as an “interactive educational lab” in order to improve our data collection and calibration capability. Step2, DINO is certified as a class I medical device and can provide risk indicators but not specific evaluations: in this stage, provide DINO to speech therapists and psychologists as a SAAS to allow early identification and mass screenings. Step 3, DINO is certified as a class II medical device and can provide specific evaluations and follow-up suggestion over neuro development disorders.

The Team

Video Game

Learning disorders

TRL 4/5

https://www.paperbox.health/

PREVIENI

Medical imaging of soft and hard tissues

By developing a novel technique and device for emergency sceario and field medical imaging, Previeni aims at bridging the diagnostic gap left unserved by the current state of the art in medical imaging by offering doctors the possibility to see inside their patients right on the field, at their home, or their room bed, without requiring a critical patient to move, and without harming the patient with the usage of harmful ionizing radiation as found in portable x-ray machines.

BASED IN: Segrate (MI), Italy
INCORPORATION YEAR: 2023
STAGE OF DEVELOPMENT: TRL 3.5
IP: 1 patent granted, 4 pending
FUNDING NEED: Around 330K

Context

Patient Mortality and Lenght Of Stay in Urgency Departments double due to the absence of easy to use monitoring devices and trained people to perform joint Echography and X-Rays in order to accurately evaluate the health state of a patient, and set the right treatment in a speedy manner. ICUs in field hospitals are one of the main context with a fundamental lack of lung water monitoring techniques or non invasive ICU devices. The gold standard for this analysis are CT scans, which are not portable, x-rays, which do not show soft tissues in a usable manner and pose a health risk, and ultrasounds, which are operator dependent and cannot produce tomographic images.

Value Proposition

A point-of-care, diagnostic device that can analyse and monitor patients without prior training to use it by performing automatic measurement, without requiring patient contact nor patient stillness. By being portable and easy to use, Previeni addresses the lack of devices and trained people, while providing diagnostic imaging without posing health risks to the patient nor the medical operator. Previeni's imaging device is based on Electromagnetic Radar Spectroscopy Imaging (ERSI) technology, a non-ionizing, safe to use technique developed at CERN and INFN. ERSI is therefore not only capable of resolving grey-scale images, but to give colors to the images by identifying the nature of the target, therefore highlighting where in a human body there's a higher or lower concentration of blood, water, CSF, fat or foreign objects.

Market Overview

Urgency and ICU departments of field hospitals are the beachhead market, where higher urgency, and harder access to resources, both technical and human, increase the need for Previeni's solution. High Patient Mortality and excessive Lenght Of Stay in Urgency or any other Hospital Department are just two of the problems that may be solved by the capabilities of Previeni's novel approach and potential. A point-of-care, diagnostic device that can analyze and monitor patients without prior training to use it, and with Previeni's capabilities, has a wide set of applications. Previeni is fundraising for a POC round, asking 330.000 euros for 18mo of a runway to be devided in Device R&D, Intellectual Property protection, Business Development by demonstrating the TRL 5 POC in 2 hospitals, and administrative and general costs.

The Team

TRL 3.5

Medical Device

Emergency

https://www.previeni.org/

RESALIS Therapeutics

Tackling metabolic disorders with non-coding RNAs

Resalis Therapeutics' transformative metabolic disease approach targets a master regulator of multiple pathways underlying obesity and fatty liver disease. The company is applying its profound understanding of the non-coding RNA drug modality and lipid metabolism to develop its lead program, RES-010, into a safe and convenient treatment providing disease-modifying therapeutic impact including durable weight loss and reduction of hepatic steatosis. Building on robust preclinical evidence, Resalis will rapidly bring RES-010 into clinical trials for a range of metabolic disorders.

BASED IN: Torino, Italy
INCORPORATION YEAR: 2021
STAGE OF DEVELOPMENT: TRL 5
IP: 6 patents granted, others in progress
FUNDING NEED: 10 M eround A; 35 M phase 2

Context

Obesity is a chronic disease due to both lifestyle and epigenetic factors. This in turn causes hypertension, diabetes, heart failure, dyslipidemia and liver diseases such as non-alcoholic fatty liver disease (NAFLD) and 2non-alcoholic steato-hepatitis (NASH). There are no drugs having a disease modifying approach to fat accumulation and related diseases, but all address calories intake by reducing appetite or reducing the triglyceride absorption. However, we believe that these diseases are multifactorial and intrinsically complex, making it hard to resolve addressing a single metabolic pathway.

Value Proposition

Resalis is developing a first-in-class antimiR-22 therapeutic (RES-010) to address highly unmet medical needs in metabolic liver diseases. Resalis has elucidated the central role of non-coding RNA (ncRNA) miRNA-22 (miR-22) at the intersection of a range of molecular pathways underlining metabolic disorders. By applying a deep understanding of the ncRNA modality together with these insights, the company has developed its lead candidate, RES-010. RES-010 is an antisense oligonucleotide that targets miR-22 and is designed to become a safe and convenient treatment option with durable disease-modifying therapeutic impact. In animal models (mice and monkeys) and in human liver organoids, RES-010 has demonstrated a reduction of body weight, liver fat and inflammation, a reduction of total cholesterol and triglycerides and in the deposition of collagen that causes fibrosis.

Market Overview

The strategy pursued by Resalis is not to directly compete with to replace GLP-1s or other MoAs, but to be mainly used as an add on to improve the results in this high medical need therapeutic areas. If approved in Obesity and NASH in USA, EU, China and Japan, RES-010 would be probably developed as separate brands for the two indications to remain flexible with the pricing strategy. In the years 2034-2036 RES-010 would generate yearly revenues around 11B$ worldwide. In the Obesity market, conservatively considered not reimbursed, RES-010 projects for a peak sales of 3B$ in 2034. Overall, conducting the phase 1 study (2024-2025) will cost around 5M€; for the phase 2 (2025-2026), including all preliminary activities, around 35M€.

The Team

TRL 5 | Metabolic Disorders | RES-010 | antimiR-22

https://www.resalistherapeutics.com

SOUNDSAFE Care S.r.l.

For a safe and sound surgical care

BASED IN: Milan (operative: Pisa), Italy
INCORPORATION YEAR: 2023
STAGE OF DEVELOPMENT: TRL 5
IP: Omnibus patent (pending)
FUNDING NEED: 5 M euro up to market

Soundsafe Care is a MedTech startup that is disrupting the conventional ways to perform surgery by combining robotics and ultrasound technologies. The company proposes a novel medical device to perform oncological surgical treatments with precision and non-invasiveness. Soundsafe plans to first enter the veterinary market within 2025 and then reach the human clinical market in the long way. The vet market could represent a steppingstone, thus guaranteeing short-term revenues to financially support the goal of selling a medical device within 2028.

Context

Cancer is the second-leading cause of death in the world. Nevertheless, survival rates are improving for many types of cancer thanks to advances in cancer prevention, screening, and treatment. Nowadays, open surgery, laparoscopic surgery, chemotherapy, and radiotherapy are well-established approaches to treat cancer. However, they are not free from invasiveness and toxicity issues. Soundsafe Care can eliminate these issues by introducing a novel integrated robotic device for performing focused ultrasound surgery (FUS) on oncological organs in a totally non-invasive manner. The device is composed of 3 main modules: i) positioning: a robotic collaborative arm, that matches the requirements for interaction with patients and physicians; ii) therapeutic: a dedicated FUS transducer to perform the treatment; iii) monitoring: an echographic probe to visualize where to perform the treatment. Soundsafe primary goal is the non-invasive surgical treatment of oncological diseases. Due to its flexibility, Soundsafe can address multiple anatomical sites, like liver, pancreas, kidney, uterus, prostate, breast, thyroid.

Value Proposition

Soundsafe aims to sell a medical device for surgical treatments and chose the veterinary domain as its market entry point. Cancer is the most common cause of death in dogs. While dogs and humans have a similar lifetime risk of cancer, dogs have an annual incidence of cancer up to 10-fold higher than humans. To date, no FUS vet market is established, thus Soundsafe could represent both a pioneering solution for pet cancer treatment and a breakthrough technology for starting an innovative market niche.
Instead, FUS devices exist on the human clinical market. However, these devices shared some limits already known to the stake holders. The competitive positioning of Soundsafe is given by solving some major needs of both patients and physicians, as the lack of flexibility in therapy delivery. Indeed, the robotic arm guarantees high flexibility in reaching different positions extending the applicability of the device to various procedures. Soundsafe can address multiple anatomical sites, and both static and moving targets, safely and non-invasively. The treatment happens in daily-surgery, reducing hospitalization time and costs.

Market Overview

Soundsafe plans to target the vet market first (2025), and successively the clinical market (2028). Soundsafe has started a beta program to guide the vet market entry. The pre-commercial use of the device will be regulated by a free loan + pay per use model. Soundsafe plans to commercialize its product to 5 veterinary centers within 2 years from now. To sustain this plan, Soundsafe raised 1.75M€ in June 2023, with a company pre-money evaluation of 4M€.The revenues from the vet market are estimated to be approx. 2.5M€/year. These first revenues, together with a series A round of approx. 5M€ will financially sustain the clinical market entry in 5 years from now.

The Team

Non-invasive therapy

Medical Device

Surgical robotics

https://www.soundsafecare.com

TTOP
TRUE TISSUE-ON-PLATFORM

BASED IN: Milan, Italy
INCORPORATION YEAR: 2022
STAGE OF DEVELOPMENT: TRL 4/5
IP: 1 patent granted
FUNDING NEED: 1-2 M euro round 1; 3-6 M phase 2

TTOP
True Tissue On Platform

TTOP's mission is to boost drug development process by enabling safer and faster preclinical evaluations. The main challenge is the lack of reliable and efficient preclinical models able to effectively predict drugs toxicity and kinetics. TTOP has developed a proprietary platform mimicking the complex dynamic human microenvironment, to improve drug candidates selection for the clinical phase, reducing R&D costs/drug and minimizing the controversial use of animal models.

Context

Drug discovery and development is a long, costly, and high-risk process that takes 10–12 years of R&D for each new drug to be approved for clinical use. A key unmet need is the lack of reliable preclinical models able to recapitulate the complexity of human physiology. Currently, preclinical drug safety and efficacy are evaluated using animal models. However, the differences in the processing of drugs between animals and humans limits their reliability as predictors of drug toxicity/efficacy in humans. This biological discrepancy between available preclinical models and humans creates the "valley of death" between drugs that work in preclinical models and drugs that actually work in the human body.

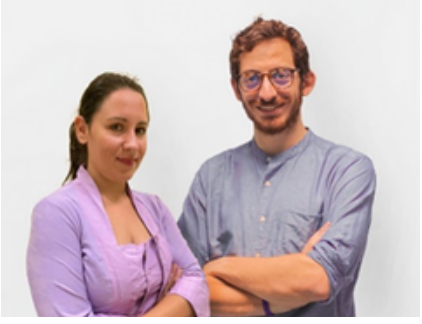
Value Proposition

They have developed True Tissue on a Platform (TTOP): a versatile platform that replicates the complex human pathophysiological microenvironment in vitro. Human tissues cultured with TTOP will simulate at the preclinical stage what will be the future tissue/organ response to the drug in the human body. Implementation of TTOP in preclinical testing has the potential to minimizing the controversial use of animal models. It works with existing lab equipment and provides direct access to the biological sample. Cartridge versatility and modularity are the key innovations that will enable researchers and biologists worldwide to obtain reliable results in preclinical toxicity/efficacy studies.

Market Overview

The next step will be focused on the scale up of the technology, in order to enter in the industrialization phase in 2024 and to reach the market in 2026. They foresee to address two main customers: pharmaceutical companies and CRO.
The customer acquisition will be firstly fostered by scientific publications of our gut and vascular system on peer reviewed journals. TTOP devices and electronics will be distributed in R&D laboratories and a lock-in strategy will be actuated.
The growth strategy will be based on continuous R&D to develop new modules and in vitro models and to expand our market, starting from the already developed single-organ in vitro models, towards an integrated multi-organ configuration. They are looking for a €1M to sustain the shift from TRL 4/5 to TRL 6 for 18% of equity and then €2M to shift from TRL 6 to TRL 8 in exchange for another 12% of the shares, accordingly to the new firm evaluation. Total equity = 30% for €3M.

The Team



Medical Device

Drug Development

https://www.ttoptechnologies.com/

VRG Therapeutics Ltd

Generation of miniproteins for therapeutic use

BASED IN: Budapest, Hungary
INCORPORATION YEAR: 2023
STAGE OF DEVELOPMENT: TRL 3
IP: fully owned patent to be submitted in 2023 Q4
FUNDING NEED: 4 M euro

VRG Therapeutics (VRG Tx) is an innovative biopharmaceutical R&D company headquartered in Budapest, Hungary. VRG Tx is committed to leveraging its proprietary miniprotein ISEP technology to tackle diseases through mechanisms that conventional biopharmaceutical approaches cannot achieve.

Context

Current treatments of autoimmune diseases (ADs) and chronic inflammatory conditions are based on non-specific immunosuppression, which can lead to serious side effects. There is a high unmet need for more precise solutions providing effective and safe treatment, hence pharmaceutical and biotech companies allocate high efforts to the development of selective immunomodulators. These projects aim to modulate immune responses by targeting specific pathways involved in autoimmune processes. The primary beneficiary of the proposed solution are the hundreds of millions of patients with autoimmune diseases and chronic inflammation conditions. Secondary beneficiaries are healthcare systems and society as a whole.

Value Proposition

Selective pharmacological inhibition of Kv1.3 has been shown to be suitable for the treatment of various ADs and chronic inflammatory conditions. This mechanism of action has been validated to be effective in animal models and in clinical setting without compromising the protective immune response. Potassium channels are important for T cells due to their role in regulating their activation, proliferation, and function. By specifically targeting Kv1.3 ion channels, the solution aims to modulate only the activity of autoreactive T cells without disrupting the protective functions of naïve and central memory T cells. VRG-K1, VRG Tx's lead compound, has subnanomolar affinity on Kv1,3 channels, over 12,000-fold selectivity over other, closely related ion channels and extremely long (>>24h) serum half-life. VRG-K1's efficacy has been proven in both in vitro and in vivo,

Market Overview

The primary strategy is to reach IND submission and enter clinical development with a partner. They are regularly attending business meetings and building a network with various biotechnology and pharma companies. The company will complete preclinical research using venture capital funding, sources needed to reach preclinical development are covered. Costs of preclinical development and CMC of clinical batches, taking approximately 18 months, are estimated to be 4M EUR. Clinical development will start in 2026 and therapy will reach the market in 2031. They're seeking investors to speed up our R&D activities and complete preclinical development until IND enabling status so they can go into a licensing or codevelopment agreement with a pharma partner.

The Team

TRL 3

Autoimmune Diseases

Miniproteins

https://vrgtherapeutics.com/

meet in italy
FOR LIFE SCIENCES
STARTUP BREEDING 2023

https://meetinitalylifesciences.eu/
https://www.clusteralisei.it/

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