STARTUP BREEZE

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STARTUP BREEZE 2024

Startup Breeze

StartUp Breeze is a refreshing journey supporting pharma, medical devices and digital health business ideas and startups in focusing and improving their value proposition.

Thanks to an extensive network of life science partners (investment funds, innovation centers, incubators, accelerators and other industry players) Startup Breeze provides expertise, tools and networking to the companies selected by the evaluation committee of expert and specialized investors, in order to refine and fully exploit their business potential.

The selected finalists benefit from a tailor-made entrepreneurial journey, with thematic seminars and in-depth sessions with coach expert in the field.
The journey ends with the presentation of the proposals to investors and potential business partners at the final event, the Pinwheel Pitching Stage, where an expert jury assigns the title for the most innovative proposal and the Special Awards offered by initiative partners are also appointed.

Startup Breeze was born from the more than a decade experience of its organizers in supporting creation and development of startup and it is realised thanks to the fundamental free contribution of its network of partners.

For the 2024 edition, the final Pinwheel Pitching Stage event will be held on the 9th of October 2024 in Florence, hosted by EventX Life Sciences, the life sciences event representing the crossroad between research, clinics, market, innovation, healthcare.

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DIGITAL HEALTH BLOGS

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C. Maiorino – EIT Health

F. Mazzini – Fondazione Toscana Life Sciences

R. Gilardi – G-Gravity

M. Gullà & M. Gaiotto – Health Technologies Holding

D. Pierobon – I3P

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E. P. Lanati – Indicon, IAB

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A. Alessandrino – Medtech mentor

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Startup Breeze 2024 Coaches

E. Negroni – AurorA Science, Inorgen

S. Falvo – Bioindustry Park Silvano Fumero

F. Menegoni – Biovalley Investments

C. Ceruti - Bugnion

F. Conicella – Chiesi

A. Floris – Club degli Investitori

R. Del Grosso – Cube-Labs

C. Maiorino – EIT Health

F. Mazzini – Fondazione Toscana Life Sciences

R. Gilardi – G-Gravity

D. Pierobon – I3P

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A. Alessandrino – Medtech mentor

A. Ballerini & B. Castellano – Panakes Partners

V. Franchini & M. Elli – Pariter Partners

M. Gardino & S. Chiarva – RP Legalitax

C. Somma – Seroba

G. Arturo – Startlab Service

BREEZE STARTUP Final Event

Pinwheel Pitching Stage 2024

9th October Florence Stazione Leopolda

BREEZE STARTUP

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Pinwheel Pitching Stage

9th October 2024
Hosted by EventX Life Sciences
@ Stazione Leopolda, Florence & streaming

09:30	Welcome address & intro F. Landi, F. Mazzini, Fondazione Toscana Life Sciences
09:45	Finalists pitch presentations – first session
11:00	Break
11:15	Finalists pitch presentations – second session
12:30	Life science startup and investments landscape F. Cerruti, Italian Tech Alliance
13:00	Awards Ceremony

Register through EventX LS platform or here for in presence or remote participation

BREEZE STARTUP

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Startup Breeze 2024 - The jury

tbc

Francesca Mongardi
Project Manager
LIFTT

Simona Varani
Associate
XGEN Ventures

Carlo Antonio Sanfilippo
Senior Investment Manager
Indaco Venture Partners

Francesco Senatore
Business Development Manager
Bio4Dreams

The Finalists

A.D.A.
Advanced Drug Administration

A.D.A.

Nanomedicine for advanced inhalation therapies

A.D.A. aims to improve the health of patients affected by chronic lung diseases by developing the next generation inhalation therapies by combining the advantages of the local therapy with those of the nanotechnology. The current pipeline includes the development of the treatments for two rare diseases: systemic sclerosis associated with interstitial lung disease (SSc-ILD) and idiophatic pulmonary fibrosis (IPF). SSc-ILD project is at most advanced stage (TRL 4) with a patent application for a new nanoformulation of immunosuppressant prodrug showing very promising results in the in-vivo efficacy tests. Regarding the IPF project, the Italian patent application was recently filed.

- *Incorporated*: 2021
- *Stage*: preclinical in vivo efficacy tests (SSc-ILD and IPF)
- *IP*: 2 patent pending
- *Funding need*: ~2.5 M to complete pre-clinical certified phases

Context

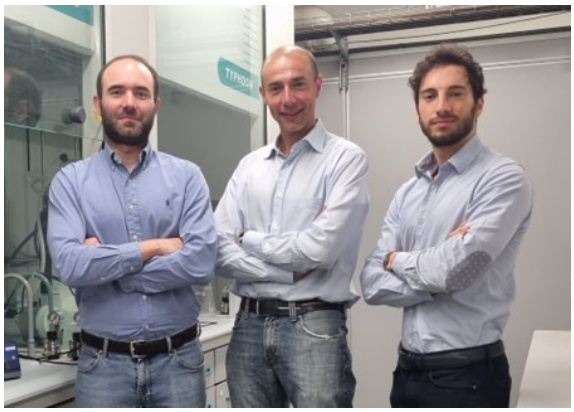
Respiratory diseases are among the leading causes of death and disability worldwide. The number of deaths due to chronic lung diseases increased significantly in the last decades (+28.5% in the last 30 years). Currently, SSc-ILD and IPF treatments are based on oral administration of drugs, but this route of administration shows limited efficacy and side effects. While inhaled drug delivery therapies have a number of advantages over oral and intravenous routes, their use has been limited by multiple physiological barriers. Nanotechnology approach is emerging as the one being able to overcome those issues, allowing optimized nanocarriers and much more effective inhaled therapies against lung diseases.

Value proposition

A.D.A is a preclinical company developing nanomedicine-based inhaled therapies for the treatments of chronic respiratory diseases, enhancing drug delivery directly to the lungs, through the reformulation of drugs currently administered orally. A.D.A. works on the new concept of “Drug AND Delivery” by designing nanoparticles with both carrier and therapeutic functions; this allows the development of combination therapy, thanks to the ability of this therapeutic nanoparticles to encapsulate other drugs, able to acts on different pathological pathways at the same time. Furthermore, A.D.A. develops powders for inhalation based on "nano in micro" technology that ensures higher lung deposition and optimal therapeutic outcomes, reducing side effects compared to traditional oral medications and the possibility to overcome physiological barriers such as the mucus. The reformulation of existing drugs accelerates the development process and lowers costs, enabling the company to secure new patent protections and expedite market readiness. In particular, target diseases are idiophatic pulmonary fibrosis (IPF) and systemic sclerosis associated with interstitial lung disease (SSc-ILD), the latter being in the most advanced phase of development (TRL 4). In that regard, a patented new nanoparticulate form of immunosuppressant prodrug was developed and tested in vivo with very promising results.

Market overview

The overall market for IPF and SSc-ILD reached annual revenues of around $4,6 B in 2023. The CAGR is expected to increase, reaching an average value of 7,5% over the next ten years. IPF and SSc-ILD are rare diseases, with very limited therapeutic options, all administered orally.



Pharma

Drug delivery

Rare respiratory diseases

Nanomedicine

https://www.ada.srl/

Clepio Biotech

3D histology made easy

- *Incorporated*: 2024
- *Stage*: 3D vs 2D biomarker quantification
- *IP*: 1 patent granted, 2 pending
- *Funding need*: 1.5 M for research only launch, 3 M for CE-IVD

Clepio Biotech opens a new dimension for cancer understanding and diagnosis, offering an innovative and automated service for 3D reconstruction and analysis of tissue biopsies, overcoming the possible risk of misdiagnosis of 2D histological analysis. Born from the strong experience in light-sheet microscopy, tissue clearing and image analysis, the system is compliant with the quality and process standards required for clinical use, achieving more reliable quantification of histological biomarkers through quantitative and scalable volumetric analysis of biological tissues.

Context

Histopathology is the baseline of modern diagnosis currently carried out through 2D analysis, but traditional 2D biopsy analyses risks to miss vital information, such as the spatial arrangement of biomarkers and the size of metastases, leading to potential ambiguities in diagnosis and treatment planning. In that regard, 3D analysis can provide huge benefits for a more accurate assessment, but its practical implementation remains challenging due to low throughput, need of skilled operators (imaging parameters need to be manually adjusted), cumbersome data management, protocols lacking scalability and reliability required by clinical procedures.

Value proposition

Clepio Biotech offers the first pipeline for 3D quantitative imaging of biological tissue at cellular resolution, with molecular specificity and large scalability, through light-sheet microscopy. The patented solution allows a comprehensive service that includes sample preparation, high-resolution imaging with light-sheet microscopy, and detailed data analysis. This service allows users to transition from cumbersome in-house microscopy to an efficient and fully automated 3D analysis process, addressing the need for accurate, scalable tissue examination. By delivering detailed, quantifiable insights across entire specimens, Clepio Biotech aims to establish a new standard in cancer tissue analysis, improving biomarker quantification and overall diagnostic precision.
The technology has already been successfully tested on multiple sample types, and a PoC retro-prospective study is on the way to validate the higher diagnostic accuracy enabled by 3D vs 2D biomarker quantification.

Market overview

The spatial biology market is growing at an exceptionally fast pace (CAGR 30%) and is expected to reach $ 1.2 Bn in 2027. More specifically, the light-sheet microscopy market was valued at $ 105 M in 2022 and it is expected to grow to $ 260 M by 2027 (CAGR 16.3%). Cancer tissue diagnostics market is expanding at a 6.6% CAGR, projected to grow from $ 5.3 Bn in 2022 to $ 10.7 Bn by 2033.






Diagnostics

Digital Pathology

3D Histology

Biomarker quantification

https://www.clepiobiotech.com/

EsoSoft
LET ME GROW, MY FUTURE WILL BE BRIGHTER

Esosoft

Soft treatment for congenital esophageal atresia

- *Incorporated*: beginnning 2025
- *Stage*: proof-of-concept completed
- *IP*: 1 patent pending
- *Funding need*: 500 k for device optimization and preclinical trial study

EsoSoft is developing a minimally invasive soft robotic device for the timely treatment of the esophageal atresia (EA), a congenital abnormality affecting 1 in 2500 newborns, in which the esophagus is disconnected from the stomach at birth, preventing baby feeding from the mouth. EsoSoft aims to enable the natural growth of the esophagus through soft mechanotherapy, improving long-term outcomes and reducing treatment costs of the currently used complex surgery procedures, that require extended ICU hospitalization under sedation.

Context

Neonatal Esophageal Atresia (EA) is a serious congenital defect in which the esophagus ends in a blind pouch instead of connecting to the stomach, splitted into two disconnected segments between mouth and stomach, preventing swallowing and feeding in the affected newborns. Complex surgery approaches are then required, accompanied by long-term complications, the current gold standard being the Foker technique. This technique involves a high-risk, invasive surgical procedure in which traction forces are applied to elongate the esophagus via manually pulled sutures by an experienced neonatologist, with high risks of sutures tearing and tissues damage. This process, which spans at least 14 days and requires total sedation in a critical care unit, prepares the esophagus for a subsequent anastomosis surgery to reconnect the segments.

Value proposition

EsoSoft represents a groundbreaking solution for the treatment of EA, designed under the guidance of expert pediatric surgeons from Ospedale Pediatrico Bambin Gesù. It is a minimally invasive soft, flexible robotic device designed to apply traction forces to the proximal segment of the esophagus, inducing its growth. Its key advantage lies in its simplicity of insertion into the oral cavity, rendering surgical procedures unnecessary and minimizing sedation time, which is an important factor for the psychological development of the newborn, as it can be applied for the needed time and then removed, allowing discontinuous treatment sessions. Beyond its minimally invasive nature, EsoSoft boasts inherent safety features and excellent acceptability due to the flexibility and softness of its materials and structures, ensuring gentle yet effective treatment for the most fragile patients. Esosoft treatment can start in the very first days after birth, and it is expected to provide the same results of the Focker procedure in five to seven days (half of the time needed in the current clinical practice), with minimized sedation time, thus reducing hospitalization and treatment time, potential long-term complications and costs for the healthcare system.

Market overview

Esophageal atresia is a condition affecting 1 in 2500 newborns. Currently there is no device on the market for its treatment. US yearly market has been estimated at $ 144 M. Hospitalization and associated processes costs have been estimetd at $ 580 k on average per baby.

Medical device

Esophageal atresia

Soft robotics

Minimally invasive

INTA
DIAGNOSTICS FOR EVERYONE, EVERYWHERE.

INTA

Ultrasensitive, portable, rapid lab-on-a-chip

INTA develops and commercialize rapid, accurate and portable diagnostic biosensing devices. Its flagship product is the NanoAnalyzer, a portable, ultrasensitive lab-on-a-chip design, AI-powered multiplexed biosensing system for the diagnosis of mild traumatic brain injuries (TBI). Every year, ~1.5 M people with TBI are hospitalized in EU, and a ~1% incidence has been estimated for not treated at hospital TBI. NanoAnalyzer provides cost-effective and very rapid blood analysis in respect to expensive and time-consuming CT scans, allowing timely and accurate assessment to manage and mitigate the impact of TBI, especially in emergency settings.

- *Incorporated*: 2020
- *Stage*: prototype validation completed
- *IP*: 2 patents families
- *Funding need*: 4 M round A for first in-human validation, ISO 13485 certification and CE-IVD pre-compliance

Context

Traumatic brain injury (TBI) is a global public health problem and a leading cause of mortality, morbidity, and disability. Each year, ~1,5 M people with traumatic brain injury (TBI) are hospitalized in the European Union, and ~57 k die as a result of a TBI. The incidence including injuries not treated at hospitals has been estimated 800 per 100,000 inhabitants, and is expected to grow in the future. TBI current diagnostic practices heavily rely on expensive and time-consuming CT scans, particularly critical in emergency settings. CT scans incredibly turn out negative in 90% of cases. There is a growing need of tailored and cost-effective TBI diagnosis to manage the right treatment. In that regard, TBI blood biomarkers have demonstrated their potential in refining diagnosi, triage, injury characterizations, in particular in mild TBI patients, thereby preventing unnecessary imaging.

Value proposition

INTA's NanoAnalyzer is a patented portable, multiplexed biosensing system designed to provide diagnosis of mild traumatic brain injuries (TBI) through rapid blood analysis. The NanoAnalyzer addresses the critical medical need for a swift, accurate, and cost-effective diagnostic tool that can be used in emergency settings, thereby reducing reliance on expensive, time-consuming, and often unnecessary CT scans. The NanoAnalyzer employs state-of-the-art nanoelectronics and biotechnology, leveraging a lab-on-a-chip design. This technology enables the detection of multiple biomarkers simultaneously, supported by advanced data science algorithms, including machine learning and AI, which enhance the accuracy and speed of diagnostics. The device uses a small, disposable cartridge containing INTA's patented BRAIKER chip. When a blood sample is introduced, the chip detects specific biomarkers indicating TBI. Competitive advantages include AI-powered high performance, ease of use, portability, multiplexing capability, rapid response, and cost-effectiveness.

Market overview

TBI market was valued $ 2.7 Bn in 2024, expected to grow to $ 3.8 Bn in 2028 with a 8.7% CAGR. Immunosensing and portable applications market in the medical, industrial and environmental fields was estimated to reach $ 62 Bn at 5% CAGR by 2032.

IVD Diagnostics

Traumatic brain injury

Lab-on-chip

AI-powered multiplex

https://intasystems.net/en

Medical FLOWeR
For Life Organs We Research

Medical FLOWeR

Customizable hypo/normothermic organs perfusion

- *Incorporated*: expected January 2025
- *Stage*: prototype validation in progress
- *IP*: 1 patent pending, 2° on the way
- *Funding need*: 1.5 M for device optimization and preclinical trial study

Medical FLOWeR is developing an innovative patented medical device for extracorporeal organ preservation, offering advanced and customizable features compared to traditional methods, such as both normothermic and hypothermic perfusion performing a continuous temperature adaptation to the physiological needs in extended range of temperature (2°-40°) a wide set of integrated biosensors, AI control system for perfusion parameters optimization, ensuring a comprehensive control of the preservation process, and thus allowing the increase of transplant success rates.

Context

In the context of organ transplantation, the critical issue to address revolves around the quality and availability of organs for transplant. Currently, there is a severe shortage of donated organs compared to demand (about 10% of demand is met) leading to long waiting times, uncertainty about survival perspectives, and resulting in death of waiting patients in same cases. Moreover, transplant efficacy is compromised by issues such as organ deterioration during preservation and the risk of post-transplant rejection. The ongoing discrepancy between organ demand and supply has been pushing the implementation of rescue strategies for organs considered marginal or unsuitable for transplantation, or even extending the donor pool to deceased donors. In that regard, in the last decade perfusion machines evolution have been emerging as the main tool to support extension of the candidate organs for transplants, preventing their decline after explant through innovative perfusion techniques.

Value proposition

Medical FLOWeR, which has its R&D heart at University of Florence, is developing an innovative patented medical device designed for extracorporeal organ preservation, offering advanced features compared to traditional methods. Its key features include multi-configuration perfusion system, biosensors for comprehensive monitoring and control of organ preservation process, flexibility, functional suitability assessment. performing a continuous temperature adaptation to the physiological needs in extended range of temperature (2° - 40°) than competitors. Additionally, Medical FLOWeR utilizes an advanced AI control system, which optimizes perfusion parameters in real-time based on continuous data from the integrated biosensors, allowing for dynamic adjustments to the preservation conditions, further improving the viability of organs and increasing the likelihood of successful transplants. The system can be used also as a research, training or simulation platform. The perfusion device is reaching TRL 5.

Market overview

The global market for organ perfusion devices is rapidly growing and presents enormous potential. Market size was estimated to be $ 1.5 Bn in 2024, and it is expected to grow at a 6% CAGR to $ 2.2 Bn by 2023, the expansion being driven by the increase in chronic diseases, aging population, and technological advancements improving success rates of organ transplants

Medical device

Organ perfusion

Transplant

Normo and hypothermic perfusion

meditype
FAMA LABS

Meditype by Fama Labs

Configurable AI companion for therapy journeys

- *Incorporated*: 2022
- *Stage*: pilot project completed
- *IP*: evaluating algorithm protection
- *Funding need*: 700 k for 2nd pilot project, ISO 27001 certification, market launch preparation

Fama Labs is a digital health company dedicated to enhancing therapeutic adherence through innovative technology, with over 5 years of collaboration with scientific societies and research institutions. Its flagship product, Meditype, is a configurable, voice-enabled AI companion designed to support patients in their journeys, including therapeutic program, symptoms collection, vital signals monitoring and educational contents. The virtual companion interacts with patients maximizing engagement and adherence, reducing healthcare costs and providing valuable data insights.

Context

The healthcare sector faces a critical issue with only 50% of patients adhering to prescribed treatments, leading to poor health outcomes and increased costs for healthcare professionals and providers. Clinical trials are similarly impacted, with a 30% patient dropout rate causing delays and additional costs, leading to delays (or closure) in clinical studies in 85% of cases on average. Despite the current use of manual follow-ups and basic digital tools, these methods are still insufficient. There remains a significant need for effective tools to improve patient adherence and engagement in treatment and trials.

Value proposition

Fama Labs offers Meditype, a configurable, voice-enabled AI companion designed to enhance patient engagement and adherence throughout therapeutic journeys. The assistant utilizes generative AI and ML to personalize therapy of patients participating in the journey, which can be configured by associated phMeditypecians or specialists, offered by the platform or created by pharmaceutical companies for specific patient support programs or clinical trials. A configurable journey can include therapeutic programs, symptoms and vital parameters collection and monitoring, educational content for self-learning. The platform automates monitoring, educates patients, and fosters engagement with an empathetic companion. In addition, the product is built on a decentralized cloud platform, catering to various use cases. By addressing the critical issues of low patient adherence and high dropout rates in clinical trials, Meditype helps reduce healthcare costs and improve data accuracy. Fama Labs brings a proven track record in clinical research and strong collaborations with leading scientific institutions, making Meditype a standout solution in the digital health market for its comprehensive approach and advanced technology.

Market overview

The patient engagement solutions market size was globally valued at $ 16 Bn in 2023 and expected to grow from $ 17.9 Bn in 2024 to $ 48.7 Bn by 2032 at a CAGR of 13%.

Digital health

Patient adherence

Patient engagement

Voice-enabled AI companion

https://www.famalabs.com/

- *Incorporated*: January 2025
- *Stage*: phase 1 clinical trial close to start
- *IP*: 2 patents pending
- *Funding need*: 10 M for phase 1 clinical trial

Microvaxxine

Turning microbes into allies for cancer vaccines

Microvaxxine is developing innovative antitumor vaccines based on antigens derived from viruses and bacteria (MoAs) with high homology to multiple tumor antigens (TAAs). Such mimicking non-self microbial-derived antigens are highly immunogenic and induce a cellular response capable of cross-reacting against tumors. First focus is the hepatocellular carcinoma, being close to start a phase 1 clinical trial. The proposed approach can be effective and extended against multiple tumors.

Context

It is estimated that globally about 20 M new cases of cancer are identified every year, of which 9 M in Europe and 0.5 M in Italy. In that regard, hepatocellular carcinoma (HCC) is the most common type of primary liver cancer, accounting for 80-90% of all cases, with 800k new cases each year and a high mortality. Tumor immunotherapy has revolutionized the cancer treatment, with unprecedented survival rates. However, the vast majority of cancer patients do not benefit from such treatment. Consequently, it is necessary to continue to develop new strategies, including cancer vaccines that have an enormous cost-effectiveness advantage. To date, therapeutic anti-tumor vaccines have not yet provided acceptable efficacy and new innovative strategies are essential, in particular capable of inducing more specific and powerful anti-tumor immune responses, also in combination with immunotherapy drugs (e.g. immune checkpoint inhibitors, ICI).

Value proposition

Microvaxxine is the result of ten years of R&D of anti-tumor vaccine models. It is developing vaccines based on antigens derived from microbes (viruses and bacteria - MoAs) with high homology to multiple tumor antigens - TAAs (Molecular Mimicry). MoAs are foreign non-self-antigens readily recognized by our immune system. On the contrary, TAAs are shared over-expressed self-antigens prevalently expressed by tumor cells but, at low levels, also by normal cells. Consequently, their immunogenicity may be hampered by the central tolerance, while MoAs are able to elicit a potent immune response, cross-reacting with the highly similar TAAs and killing tumor cells. The resulting off-the-shelf cancer vaccines will have an invaluable advantage over current pursued strategies, not requiring the high-costly procedures involved in the cancer vaccines based on patient-specific mutated neoantigens. Moreover, the devised approach can potentially be effective against multiple tumors, revolutionizing the cancer vaccine field.

Market overview

The therapeutic anti-cancer vaccines market is estimated to be around $ 9.7 Bn in 2024, expected to grow to $ 15.8 Bn in 2029, with a 10.3% CAGR. Hepatocellular carcinoma therapeutic market is estimated to grow from $ 800 M in 2023 to $ 1.5 Bn by 2034, at a 6.3% CAGR.

Pharma

Cancer vaccines

Microbes antigens

Hepatocellular carcinoma

https://www.microvaxxine.com/

OFTEN MEDICAL

Often Medical

Easy guide of needles and cathers in epidural space

Often Medical developed a novel system for guiding needles and catheters into the epidural space, a clinical practice still being fully manual with a 30% failure rate (also in veterinary use). The device can be used for loco-regional anesthesia, pain therapy and spinal cord stimulators implantation. The device is based on optical fiber probe measuring the force exerted on the epidural needle tip during tissue penetration, giving the physician a visual and acoustic feedback during the procedure, thus making identification of correct epidural needle placement fully reliable and accurate and minimizing procedure failure rate.

- *Incorporated*: 2018
- *Stage*: pre-clinical validation completed
- *IP*: 1 patent family
- *Funding need*: 5 M round A for clinical validation and CE-MD mark

Context

Every year about 22 M epidural procedures for pain relief (including spinal cord stimulator (SCS) implant procedure) are performed each year in Europe, doubling the US (11 M, worth $ 5 Bn/year), representing one of the fastest growing procedures worldwide. Despite the fact that these clinical practices are in such high demand, the current procedure for placing needle and catheters in the epidural space (Loss-of-Resistance Technique) is still a manual and 'blind' technique and its success depends on the expertise of the physician, with failure rates that can be as high as 30%. The same failure rate has also been estimated in the veterinary field in companion animals procedures.

Value proposition

OFTEN Medical developed a novel system for guiding needles in biological spaces based on an optical fiber probe acting as a strain sensor and measureing the force exerted on the epidural needle tip during tissue penetration. The device is then able to provide the physician a visual and acoustic feedback during the procedure, identifying the point at which needle enters the epidural space when the optical sensor measures an abrupt force drop, thus making identification of correct epidural needle placement fully reliable and accurate. The patented innovative system was tested in vivo in animal studies, providing a 100% accuracy. Market surveys were carried out among anaesthesiologists (86) and veterinary anaesthesiologists (39) from different EU countries, confirming the need for an epidural guidance system and the great safety in reaching the epidural space using the developed device. Compatibility with the standard of care, the active feedback, catheter control and the possibility of data registration & collection during the procedure are key competitive advantages of OFTEN solution.

Market overview

The Epidural Anesthesia Systems Market was valued $ 3 Bn in 2022 (1 Bn US, 2 Bn EU) and it is expected to grow at a 9% CAGR up to 2030. The market growth is mainly driven by rising number of surgeries across the globe and preference for epidurals by pregnant women. There is a huge potential market also for the SCS systems that is predicted to reach $ 4.12 Bns globally by 2027


Armando


Alberto


Gianfranco


Benito


Ezio


Marco


Andrea


Antonello

Medical device

Epidural procedure

Needle & cather guidance system

Pain relief

https://www.often-medical.com/

PoliRNA

PoliRNA

Polymer hybrid nanocarriers for RNA therapies

- *Incorporated*: February 2024
- *Stage*: preclinical studies in progress
- *IP*: 1 patent family
- *Funding need*: 1 M round A to complete platform validation and toxicology studies

PoliRNA develops novel hybrid nanocarriers for a new generation of safe and efficient cell-targeted RNA therapies, overcoming the limited stability, safety and lack of cell-targeting efficiency of gold-standard lipid nanoparticles (LNPs). First focus is cardiac regenerative medicine, with PoliRNA NPs showing target efficiency in preclinical trials, paving the way towards novel applications of RNA therapies in that and other fields.

Context

RNA therapies have emerged as promising strategies for the treatment of different diseases through correcting abnormal gene expression or reprogramming cell behavior. Approved RNA therapies, used as Covid-19 vaccines or treatments for liver-related diseases, make use of modified RNAs by N-Acetylgalactosamine (GalNAc) conjugation or are based on RNA-loaded lipid nanoparticles (LNPs). Such strategies have enhanced the *in vivo* stability of RNA molecules and allowed significant RNA accumulation in the liver, the target organ. Advanced LNPs are under investigation for new applications of RNA therapies. However, LNP are limited by their poor colloidal stability, *in vivo* short half-life, risk for immunogenicity and cytotoxicity at relatively low doses, and significant accumulation in the liver and the spleen leading to potential off-target effects. Hence, one relevant barrier in expanding the use of RNA molecules to novel therapeutic applications is the lack of safe and efficient delivery systems, with superior *in vitro* and *in vivo* stability and the ability for precise RNA delivery to target cells.

Value proposition

PoliRNA addresses critical limitations in RNA therapy delivery through hybrid polymer-lipid nanoparticles (NPs), designed to overcome the drawbacks of traditional LNPs. By integrating a lipid core for efficient RNA loading with a polymeric shell that enhances stability and controlled release, PoliRNA NPs offer superior stability, safety, and efficacy than currently used LNPs. Their ability for tunable decoration with surface ligands enables precise cell targeting, minimizing off-target effects and improving therapeutic outcomes. As a first therapeutic target, PoliRNA NPs have been developed for cardiac regenerative medicine applications, showing high RNA loading efficiency, biocompatibility, *in vitro* and *in vivo* stability, controlled and sustained RNA release, target cell internalization and transfection efficiency, and therapeutic efficacy in preclinical trials. The enhanced stability, safety and efficacy shown by PoliRNA NPs pave the way towards novel applications of RNA therapies in cardiac regenerative medicine and other fields (e.g. pulmonary and muscular field), currently under investigation.

Market overview

RNA Therapeutics market was estimated $ 13.7 Bn in 2023 and is expected to reach $ 18 Bn by 2028, growing at a 5.6% CAGR. Global lipid nanoparticles market was valued at $ 820 M in 2023 and projected to reach $ 2.4 Bn by 2032 at 13% CAGR.

Pharma

RNA therapies

Targeted RNA delivery

Polymeric hybrid nanoparticles

https://user-160435880-work.colibriwp.com/polirna/

Previeni

Portable AI-powered imaging device for timely diagnosis

- *Incorporated*: september 2024
- *Stage*: ex-vivo prototype validation achieved in hospital
- *IP*: 1 patent family
- *Funding need*: 400 k pre-seed for in-vivo demonstration

Previeni has developed a patented portable hardware device based on electromagnetic imaging enhanced by AI software, able to functionally identify patient tissues and fluids. The first focus is thoracic applications, in particular in emergency admissions, in which traditional chest X-rays provide information in only 4% of cases, leading to high misdiagnosis rates. The device can be used for early assessment of patient conditions and integrated into the current radiographic flow, generating anatomical images providing accurate information on fluid concentrations, their movement, tissues, or foreign objects, allowing timely diagnosis and proper treatment.

Context

The lack of devices to assess and monitor fluids - valuable indicators of inflammation - leads to inefficient hospital processes, increased mortality rates, and more extended hospital stays.
For instance, 10% of ER admissions are due to respiratory problems and the presence of lung water, yet current methods provide valuable insights in only 4% of cases. Moreover, no devices are available to assess patients directly at their location, whether in the ICU or at home. This deficiency results in high misdiagnosis rates, causing up to $2 billion in unnecessary costs and $5.7 billion in avoidable legal fees annually in the United States. Tragically, these issues contribute to permanent damage or death for 14 million people each year.

Value proposition

Previeni has developed a portable hardware device (patented technology, additional patents under filing) enhanced by AI software that uses electromagnetic imaging to safely detect and quantify fluids and tissues. The device can be integrated with existing X-rays to increase information content by integrating functional data and/or used independently for initial patient assessments or continuous monitoring (e.g., in ICU), even when patients cannot stay still. It generates anatomical images with a composition analysis, providing color-coded insights into fluid concentrations, fluid movement, tissue or foreign objects. The system represents a safe and easy-to-use tool for early detection of water in the lungs, allowing physicians to provide timely and accurate assessments, thus reducing the risk of misdiagnosis and significantly improving patient outcomes. Collaborations are ongoing in 3 hospitals. Interest has been expressed by >40 doctors interviewed across Europe. The technology can also find application in other anatomical districts and conditions.

Market overview

About 2 Bn chest X-ray examinations are carried out yearly worldwide. The Lung Fluid Status Monitor Market is projected to grow at a CAGR of 7.8% from 2024 to 2031. The global medical imaging market size was $ 40 Bn in 2023 and is expected to grow to $ 70 Bn in 2032, at a 6.4% CAGR.

Medical device

Diagnosis

Imaging

Portable device

https://www.previeni.org/

ScarTech
Biomedical device with modulated compression for the support and optimization of skin care

ScarTech

Modulated compression for effective skin scar healing

- *Incorporated*: Q1 2025
- *Stage*: working prototype
- *IP*: 1 patent
- *Funding need*: 750 k A for device optimization, validation, CE-MD mark (class I)

ScarTech aims to address wound healing scar through an innovative biomedical device able to modulate compression on tissues to optimize skin scar healing, enhancing tissue repair following surgery. The device applies mechanical loads to provide a dual compression effect on the scar, being customizable towards different anatomical districts, optimizing the scar healing process and preventing hypertrophic and keloidal healing, maximizing the aesthetic and functional results of wound healing. Main application in plastic surgery, both aesthetic and reconstructive (first focus brachioplasty).

Context

Pathological wound healing is a common challenge that arises from most surgical procedures. The process involves complex molecular signaling pathways, cellular interactions, and extracellular matrix remodeling, all of which influence the outcome of tissue restoration. Frequently, this phenomenon is characterized by irregular tissue repair mechanisms, leading to anomalous tissue healing, which can result in functional impairments such as limited mobility and working capability. This can affect the overall quality of life for individuals who are affected. The primary cause of this phenomenon is an inadequate biomechanical environment around the wound site, wherein traction forces fail to facilitate optimal healing dynamics, thereby predisposing the wound to structural disruption.

Value proposition

ScarTech developed and patented a biomedical device that is able to apply modulated compression to optimize skin scar healing. It can be worn by post-surgical patients and allows for customizing the intensity and direction of compressive forces on both the scar and surrounding soft tissues. The device applies mechanical loads to provide a dual compression effect on the scar. This innovative compressive sheath is customizable towards different anatomical districts, optimizing the scar healing process and preventing pathological issues. By gradually compressing the injured area, the device avoids hypertrophic and keloidal healing, maximizing the aesthetic and functional results of wound healing. Additionally, there are reinforcing elements that wrap the sheath, tailored to the specific body district and scar shape. Technological benefits encompass integrability within existing devices, lightness, wearability, and maneuverability while ensuring no direct contact with the scar, enhancing patient comfort. The system is a class I medical device. Its main application is plastic surgery, both aesthetic and reconstructive, in particular wound healing recovery after brachioplasty.

Market overview

The global wound care market was estimated at $ 21.4 Bn in 2023 and expected to grow to $ 28.6 Bn at a 5.9% CAGR by 2028. Brachioplasty market crossed $ 1.45 Bn in 2023 and is set to reach $ 2.7 Bn by 2032 at a 7.2% CAGR. Global plastic surgery market was valued at 70 Bn in 2022 and projected to reach 160 Bn by 2031.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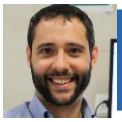
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Medical device

Plastic surgery

Wound healing

Brachioplasty

Unicorn

Unicorn

AI for advanced diagnostic solutions in ultrasound

UNICORN is an innovative startup focusing on applying artificial intelligence to ultrasound imaging. UNICORN has developed its first prototipe, USe (Ultrasound Steatosis Evaluator), an AI-based advanced, cost-effective and rapid diagnostic solution for liver steatosis (the most common liver disease) in ultrasound. Use is able to analyze a single US image and evaluate accurately the presence of fat above 7% in liver (current ultrasound limit is 19%, considered a severe steatosis state), similarly to the MRI gold standard, as verified in a prospective clinical trial. USe is rapid (20 sec), fully automated and represents the cheapest system to determine steatosis.

- *Incorporated*: July 2024
- *Stage*: prospective clinical trial completed
- *IP*: 1 patent pending
- *Funding need*: 500 k round A for CE-MD mark

Context

Hepatic Steatosis is the most common liver disease, affecting one third of global population and being an important risk factor for liver, methabolic and cardiovascular disease. Undiagnosed steatosis can lead to cirrhosis and hepatocarcinoma. The golden standards for accurate diagnosis are agobiopsy and magnetic resonance proton density fat fraction. This techniques are expensive and/or invasive. In the last 10 years ultrasound (US) examination established as an economic and non-invasive alternative but it has still some disadvantages in terms of precision and accuracy, being affected by human variability in execution of exam and in evaluation. In particular, it has been proven that human eye cannot accurately detect liver fat below 19% (a severe grade of steatosis).

Value proposition

UNICORN developed and patented USe (Ultrasound Steatosis evaluator), an explicable AI-powered tool able to analyze a single US image and evaluate accurately the presence of fat above 7% in liver in 20 seconds, as verified in a prospective clinical trial (published) compared to golden standard Magnetic Resonance Proton Density Fat Fraction. Currently, Use represents the only solution that can evaluate precisely and automatically the hepatorenal index (the index used to estimate steatosis by US). There are other solutions that use AI on US images, but providing a generic steatosis stage classification and not automatic. Moreover, USe work in post-processing and so it can be used also with images obtained by older ultrasound machines, enabling them to AI even in a cloud based environment. Use main advantages are speed (only 20 sec for the evaluation), cost (it's the cheapest accurate solution), automation (fully automated), allowing the possibility of mass screening for liver steatosis and cheaper follow up of patients. Customer targets are hospitals, US manufacturers, pharma companies developing steatosis treatments.

Market overview

US global market count 270k new US yearly, witn 1 - 2 M US devices already in hospitals and clinics. Liver Disease Diagnostics Market was valued at $ 39.5 Bn in 2023 and estimated to grow to $ 74.6 Bn at 7.3% CAGR. Nonalcoholic fatty liver disease (NAFLD) global prevalence is 32% on average, with peaks >40% in US and South-East Asia.

Medical device

Steatosis

Ultrasound enhancement

AI-powered hepatorenal index

https://www.unicornapulia.it/

STARTUP BREEZE

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