



BioManufacturing Eurocluster for Recovery and Resilience in EU

D3.6 The Financial support scheme execution report

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Grant Agreement : No. 101074495



Funded by
the European Union

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BioRegioSTERN 



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Document Information

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|-------------------------|---|---|--|-------------|
| Grant Agreement Number | 101074495 | Acronym | BioMan4R2 | |
| Full title | BioManufacturing Eurocluster for Recovery and Resilience in EU | | | |
| Project URL | https://bioman4r2-biomanufacturing-eurocluster.b2match.io/home | | | |
| Project Officer | Arianna DELLACA | | | |
| Deliverable number: 3.6 | Title | Evaluation and Impact Assessment of the SME Support Programme | | |
| Work Package number:3 | Title | SME Support Programme Implementation | | |
| Delivery date | Contractual | 31 Aug 2024 | Actual | 31 Aug 2024 |
| Status | Final | Version number: 1 | Final | |
| Nature | R – Document, report | | | |
| Dissemination level | PU – Public | | | |
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| Partner | Turku Science Park Oy Ab | | | |

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|-------------------------|---|--|--|--|
| Deliverable description | An overview and evaluation of the distributed financial support schemes (Innovation Financial Support/Business Transformation Financial Support) to SMEs in regard to provided KPIs and based on the received reporting forms from the SMEs. Language – English, Estimated length – 5 pages per voucher type, Estimated number of SMEs to participate – at least 10 SMEs | | | |
| Key words | Financial support scheme, Voucher, Innovation, Business Transformation | | | |

History of Versions

| Version | Date | Changes | Page (if applicable) |
|-----------|----------|--|----------------------|
| V0 | 20/03/24 | Initial draft generated | N/A |
| V1 | 12/08/24 | Final version | N/A |
| V2 | 29/08/24 | Clarification - number of companies/projects awarded | 2 |

Disclaimer

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Executive Summary

As part of WP3 – SME Support Programme Implementation / Task 3.3 – Evaluation and Impact Assessment of the SME Support Programme, the success of this programme was evaluated.

In April 2023, BioMan4R2 launched a call for applications to contribute to the forging of more sustainable and resilient European ecosystems. BioMan4R2 provided financial support to small and medium-sized companies (SME) in the life sciences and medical technologies sector that can be used in activities related to collaborative innovation projects, such as:

- business transformation (e.g. training plans),
- support for travel to explore markets in other countries,
- business continuity and resilience plans.

European SMEs from Biomanufacturing and MedTech sector can benefit from various service providers and experts to improve their effectiveness or level of innovation, valorisation and/or marketing of products and/or services and increase their competitiveness by removing barriers or complications in the following areas: Regulatory, Funding, Infrastructure, Technology, Supply Chain, Market Access.

The call closed in July 2023 with 118 applications submitted from different European countries. In the end, 26 projects were funded:

- 15 IFS – Innovation Financial Support
- 11 BTFS – Business Transformation Financial Support

Of these 26 funded projects, 25 companies benefited from BioMan4R2 grants:

- The company Egerton sp. z. o. o. received 3 BTFS

| Innovation Financial Support (IFS) | | Business Transformation Financial Support (BTFS) | |
|---|-------------|---|---------------|
| Robeauté | France | SITEC pharmabio | Spain |
| Plantibodies | France | Zeisberg GmbH | Germany |
| InSpek SAS | France | Egerton sp. z o.o. | Poland |
| Antleron NV | Belgium | Manitty | France |
| Fibrothelium GmbH | Germany | JAFRAL d.o.o. | Slovenia |
| ATTOM | France | Breaz Medical SL | Spain |
| MindAhead UG | Germany | Earlab GmbH | Germany |
| ALTA sp. z o.o. | Poland | Egerton sp. z o.o. | Poland |
| MIRA Vision Microscopy GmbH | Germany | Gate2Brain S.L. | Spain |
| Time is Brain SL | Spain | ONIRIA THERAPEUTICS, S.L | Spain |
| MAGIC GENOMIX | France | Egerton sp. z o.o. | Poland |
| PolyAn GmbH | Germany | | |
| IntegraSkin GmbH | Germany | | |
| Basic Pharma | Netherlands | | |
| Care4living Oy | Finland | | |

Figure 1 - List of the BioMan4R2 winners

BioRegio STERN, responsible for the management of these Financial Support for Third Parties (FSTP), followed each project leader over the last few months. To this end, the cluster :

- conducted telephone / video exchanges with the awarded companies,
- asked project leaders to write technical reports (at mid-term and at the end of the project) to check on project progress and development.

Moreover, during S1 2024, BioRegioSTERN contacted each beneficiary and asked for feedback on their participation in the BioMan4R2 project. They received 24 responses, which will be developed in this deliverable D3.6.

1. Financial Support for Innovation (IFS)

Financial Support for Innovation (IFS) aims to help SMEs and collaborators from different sectors to deliver new products and services to business, focusing on technological, production or process innovation aimed at making the production processes of SMEs in the field of biomanufacturing and medical technology (BMT) more resilient, sustainable and digitised. IFS targets SMEs by bringing innovative changes to specific elements of the biomanufacturing value chain.



Innovation Financial Support (IFS)

The financial support can be used for one of the following actions:

1. Collaborative projects between SMEs and collaborators of different sectors with common resilience, green or digital transformation challenges.
2. Projects targeting joint supply chain optimization, prototyping, valorization of existing products by implementation of resilience, green or digital strategies. Validation of novel supply chain products or processes across ecosystems are also within scope.

What you receive

- Support from your regional ecosystem support organisation.
- Find collaborators from any stakeholder type in our database.
- €60.000 financial support.

Figure 2 - Financial Support Scheme Overview - IFS

As planned, BioRegioSTERN received reports & feedbacks from the 15 laureates. Their responses will be analysed and detailed in the following 3 sub-sections.

1.1 Feedback on the impact of financial support on the company

The financial support provided by the BioMan4R2 project has contributed to the development of several companies, enabling significant advances in different sectors. Winners of innovation vouchers, such as Plantibodies and InSpek, have indicated that this funding has enabled them to develop and test their technologies (monoclonal antibody production, improved measurement sensors), improving their technological readiness and bringing them closer to commercialization.

It also facilitated crucial collaborations, such as the 3DHEK-CellGuide project with Antleron and KU Leuven, or Basic Pharma's joint supply chain project with Artes, enabling processes to be refined and

new strategies validated. Companies such as Time is Brain and PolyAn also highlighted the essential role of financing in the manufacture of necessary devices and the development of scalable production processes, respectively.

In addition, some companies have been able to allocate specialized staff, reduce risks and accelerate iterations, as for example with the manufacture of microdevices and the development of cancer treatment software. Ethical compliance, regulatory channels and market strategies have also been considerably strengthened, improving commercial viability and competitiveness in various markets, notably for the Polish e-health sector.

Overall, the funding acted as a catalyst for innovation, collaboration and market expansion, paving the way for future growth and investment opportunities.

| Company | Feedback - Impact of the financial support |
|-------------------|---|
| Robeauté - FR | <p><i>“The financial support we received made it possible for us to designate specific personnel to undertake tasks focused on improving the supply chain for our microdevice fabrication. It fostered a highly supportive environment and allowed the iteration on the manufacturing of microparts.”</i></p> |
| Plantibodies - FR | <p><i>“Financial support of BioMan4R2 has been key for Plantibodies. The company has shown the ability to produce and bioencapsulate monoclonal antibodies in plant cells, and to release them to the gastrointestinal mucosa. This opens opportunities for further development of Plantibodies delivery platform and is a step forward bringing drug candidates to the clinic, for the patients.”</i></p> |
| InSpek SAS - FR | <p><i>“The financial support from the BioMan4R2 project supported InSpek’s development by providing the opportunity to test and improve our sensors in a pilot study with URD ABI. The implementation in an actual bioproduction environment led to several improvements of our system. Overall, this project elevated our product’s technological readiness level, enhancing our ability to address complex industrial challenges and moving closer to commercialization.”</i></p> |
| Antleron NV - BE | <p><i>“The 3DHEK-CellGuide project allowed us to validate our CellGuide® platform towards applications in gene therapy production. A critical step in that process was having LVVC as beta-tester for our CellGuide® custom bioreactors at their lab facility at KU Leuven. Their input on the technology, user-experience, and technology transfer process, helped us to refine our internal processes and contract research and technology services. These streamlined procedures will allow us to serve a new segment of customers in the GT field. A continued collaboration will enable us to further increase our visibility and market better our bioprocessing innovations.”</i></p> |
| ATTOM - FR | <p><i>“Receiving BiOMAN4R2 financial support allowed us to allocate three full-time team members to this project and enhance our capacity for more iterations. This support reduces the risks associated with innovative projects and strengthens our collaboration with one leading cancer research institute.”</i></p> |
| MindAhead UG - GE | <p><i>“The grant enabled us to prepare the documents for the ethics committee and to vote in favor of the clinical trial.”</i></p> |

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| ALTA sp. z o.o. - PL | <p><i>“While the project aligns with the regional Smart Specialization Strategy and Regional Innovation Strategy, there is a lack of financial support from the Regional Operational Programme for projects involving international partners. Thanks to this project, we have been able to respond swiftly to market needs. Consequently, we aim to enhance our competitiveness in the Polish e-health market and expand our reach to other EU markets, particularly those within the EU-13. Additionally, we have established closer international cooperation with Prometriks in Bulgaria.”</i></p> |
| MIRA Vision Microscopy GmbH - GE | <p><i>“The financial support from Bioman4R2 and the EU was of great importance to us. It gave us the opportunity to take a step that we would have strategically postponed otherwise. The importance of this decision became evident this week when our self-hosted physical servers reached their capacity limits due to the significantly increased access by our potential interested parties and customers.”</i></p> |
| Time is Brain SL - ES | <p><i>“The financial support provided by the BioMan4R2 project has been the catalyst for Time is Brain to carry out the PROMISE GLOBAL study. The funds provided have allowed us to manufacture the devices and electrodes necessary to carry out the trial in three European hospitals, obtain the regulatory approval, and conduct activities for the recruitment and monitoring of acute stroke patients included.”</i></p> |
| MAGIC GENOMIX - FR | <p><i>“Financial support from BioMan4R2 will accelerate the development and commercialization of our MAGIC software, expanding our capacity to deliver personalized cancer treatment solutions. This support will also bolster our market position and enhance our ability to attract further investment.”</i></p> |
| PolyAn GmbH - GE | <p><i>“The financial support that PolyAn received from BioMan4R2 boosts the development of our production automation project. It helps PolyAn in establishing more resilient, robust, and scalable production processes. No automation solutions for PolyAn’s highly elaborate production processes were available on the European market to date, so the development of suitable concepts together with PolyAn’s engineering partners poses a major milestone for PolyAn.”</i></p> |
| IntegraSkin GmbH - GE | <p><i>“The financial backing markedly reinforced IntegraSkin by refining regulatory insights and market tactics for Ki-DERM. It boosted commercial viability and charted a clear regulatory pathway, simplifying compliance and market access. This funding has thus paved the way for enduring expansion and strengthened the company's aptitude to draw future investments, nurturing progress in tailored dermatological care.”</i></p> |
| Basic Pharma - NL | <p><i>“The financial support allowed and accelerated the development of our first European joint supply chain for the production of proteins between Basic Pharma (NL) and Artes (DE). In this initial project a typical supply chain development for biologicals (here human serum albumin) was covered, starting from strain development until fill&finish. For both companies this validates the strategy to work towards a new value chain for the efficient co-development of new (pharmaceutical) products. That can be translated to other protein products.”</i></p> |
| Care4living Oy - FI | <p><i>“Funding was crucial in completing the development of innovative production technology. It facilitated the recruitment of one graduate student and the allocation of sufficient resources to the project. The completed work was already on our to-do list earlier, but it only made sense to finish it with this short-term funding. Since we took production</i></p> |

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| | <i>costs into account in this project, we expect it to have a significant impact on the financial support to implement our growth plan as well.”</i> |
| Fibrothelium GmbH - GE | <i>“The BIOMAN4R2 project gave us the opportunity to elaborate and succeed on a proof-of-concept for the biotechnological production of our proprietary silk proteins, showing the potential of such synthetical materials to be used in our products and medical devices. The straightforward approach of the project in terms of application, approval as well as conduction was an unique experience and helped us short-cut an important company milestone that else would have been part of a long and administratively complex endeavour. With the help of BIOMAN4R2 we now can build a sustainable path towards integrating biotechnological production of silk proteins into our future value chain and adding strategic benefit to our stakeholders. Without the provided funding, this progress would not have been possible.”</i> |

1.2 Testimonial - Financial Support Programme

The BioMan4R2 financial support program has played a crucial role in advancing the technological and commercial capabilities of various companies in the European medical technology sector.

- For Robeauté, the funding has enabled a significant improvement in the precision of micro-parts for micro-robotic devices, accelerating their transition to clinical trials and strengthening the resilience of the European medical technology supply chain.
- Plantibodies has benefited from both crucial funding and strengthened collaboration with European partners, enabling it to significantly advance its technology and raise its profile.
- InSpek and Antleron emphasized the program's role in facilitating short-term breakthroughs, collaborative projects and extending the application of their innovative platforms to new customer segments.

The program's comprehensive access to EU funding and efficient administrative processes enabled companies to focus on delivering innovative solutions. The financial support also made it possible to bridge funding gaps that were too large for regional bids and not covered by bank loans, thus facilitating essential steps such as the start-up of clinical trials.

Participants appreciated the simplicity, clarity and efficiency of the grant-awarding process, with well-prepared information sessions and excellent communication throughout. The program has enabled collaborative innovation projects to be set up, promoting the resilience and competitiveness of the European healthcare ecosystem. It has been particularly beneficial for smaller companies, eliminating the need for costly consultancy services and large consortia, while underlining the importance of bringing pharmaceutical manufacturing back to Europe.

Overall, the BioMan4R2 financial support program has improved regulatory compliance, operational efficiency, market positioning, and fostered innovation and resilience across the sector.

| Company | Testimonial - Financial Support Programme |
|---------------|--|
| Robeauté - FR | <i>“BIOMAN's financial support has enabled Robeauté to significantly improve the precision of crucial microparts for our micro-robotic devices, fostering a European MedTech supply chain that meets stringent quality</i> |

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| | <p>standards. This funding has been vital in accelerating our progress towards clinical trials, enhancing the resilience of the European medical technology sector.</p> |
| Plantibodies - FR | <p><i>“The financial assistance provided by the BioMan4R2 Financial Support Programme has proven invaluable to Plantibodies. Not only has it provided crucial funding, but it has also facilitated collaborations with European partners, advancing our technology significantly. The unwavering support and dedication from the BioMan4R2 team throughout the program have been particularly noteworthy, enhancing Plantibodies visibility and impact.”</i></p> |
| InSpek SAS - FR | <p><i>“The financial support from BioMan4R2 has been instrumental in providing a framework to work with a partner (URD ABI) on the short-term advancement and demonstration of InSpek’s product. This funding allowed us to quickly set up a collaborative project and obtain results together, reaching important milestones in our product’s development.”</i></p> |
| Antleron NV - BE | <p><i>“The BioMan4R2 program enabled us to perform additional validation work for our CellGuide® platform and to extend its use to a new application and customer segment. The BioMan4R2 call provided comprehensible access to EU funding, meeting relevant needs of small companies, such as Antleron. The coordinators from the main office have been helpful throughout the process. The administration required was appropriate for this size of project, letting us focus on the main activity, i.e., delivering innovative solutions for customers active in bioprocesses and biomanufacturing.”</i></p> |
| ATTOM - FR | <p><i>“As a project aiming to industrialize a proof of concept, it can be difficult to find the right funding in France. For industrial development, the financial envelope is too high for this project to fit in (for example, “first factory” starting at €1 000 000). Bank loans cover industrial device acquisition, not development. The BIOMAN4R2 financial support completes perfectly regional offers.”</i></p> |
| MindAhead UG - GE | <p><i>“The financial support program came at a very important time for us and enabled us to reach an essential milestone: the start of the clinical trial, which had to meet the regulatory requirements before it could begin.”</i></p> |
| ALTA sp. z o.o. - PL | <p><i>“Summing up the advantages of the Financial Support Programme, we need to emphasize that it was an uncomplicated, clear, and efficient, time-effective process to obtain this grant. This is crucial in a rapidly changing business environment, especially in IT/digitally aided sectors. Additionally, we were aware from the very start of all conditions required for proper reporting and successful project closure. The Programme was well-prepared, starting with an informative seminar and maintaining efficient communication throughout its duration.”</i></p> |
| MIRA Vision Microscopy GmbH - GE | <p><i>“We are extraordinarily grateful. Not only for the straightforward processing, but especially for the excellent support from Dr. Margot Jehle and her entire team. We always felt well cared for and knew that we were welcome with all our concerns. I can only recommend anyone who has a worthy idea to apply.”</i></p> |
| Time is Brain SL - ES | <p><i>“The BioMan4R2 financial support offers the opportunity to conduct collaborative innovation projects to enable the transfer of disruptive medical technologies into BMT industry, and strengthen the</i></p> |

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| | <p>competitiveness and sustainability of the European healthcare ecosystem. Furthermore, it allows to collaborate with specialized service providers that could be incorporated into the value chain of a MedTech product.”</p> |
| MAGIC GENOMIX - FR | <p>“The financial support from BioMan4R2 has been instrumental in advancing our innovative theragnostic platform. It has enabled us to bridge critical gaps in cancer treatment, fostering resilience within the biomanufacturing and medical technology ecosystem.”</p> |
| PolyAn GmbH - GE | <p>“The Financial Support Programme has been excellently organized by BioRegio STERN and its international partners. Information regarding the call for applications were abundantly presented on the project website and in additional information webinars. Any questions that we had regarding the application or the project implementation were swiftly answered by the project coordinator.”</p> |
| IntegraSkin GmbH - GE | <p>“BioMan4R2 funding transformed IntegraSkin. It directly improved our regulatory compliance, operational efficiency, and market positioning. The program clarified our path to market, enabling faster, more cost-effective delivery of Ki-DERM. The insights gained will drive future growth and attract additional investment. More than just funding, BioMan4R2 fostered innovation and resilience, aligning us with our goal of revolutionizing dermatology.”</p> |
| Basic Pharma - NL | <p>“We were very pleased by the good level of support and communication of the BioMan support team. Moreover, we greatly appreciated the clear application process and evaluation reports.”</p> |
| Care4living Oy - FI | <p>“This program is particularly suitable and a great opportunity for a small business. When resources are very limited, it makes more sense to use this opportunity for financial support without expensive consulting to make an application. In addition, there was no need to establish a large consortium to apply for funding. What is particularly great is that the program is aimed at bringing manufacturing back to Europe. We finally understand that it is important to have manufacturing of pharmaceuticals in Europe, including fermentative APIs.”</p> |
| Fibrothelium GmbH - GE | <p>“We had a wonderful experience with the BIOMAN4R2 project and would recommend other start-ups to engage in future applications, too. The pragmatic conduction and implementation of the project was a welcome surprise compared to other funding schemes, which sometimes lack simplicity and applicability, particularly for small companies or start-ups.”</p> |

1.3 Feedback on the resilience for the regional Biomanufacturing & Medical technology ecosystem, and for company's business

The BioMan4R2 financial support program has played a key role in improving the resilience and competitiveness of Europe's medical technology and biomanufacturing ecosystems. Several major advances have been made possible thanks to this program, including the establishment of two independent European supply chains for micro-parts, which have strengthened the resilience of the MedTech sector.

- Plantibodies has used the funding to scale up the production of biotherapies in plants, offering stable room-temperature drugs that patients can take at home, reducing hospital visits and societal costs.
- InSpek's demonstration project has paved the way for local supply chains and bioprocess optimization, enhancing industrial competitiveness and ecological sustainability.
- Collaborative efforts with LVVC in the field of closed bioprocesses have elevated the Belgian biomanufacturing sector by fostering mutual knowledge exchange and problem-solving.
- The Brain20® project has filled market gaps in stroke treatment tools, improving access to EVT treatment and brain monitoring, leading to improved patient outcomes worldwide.
- PolyAn's production automation has strengthened the EU biomanufacturing ecosystem by facilitating local production of high-end consumables, supporting faster innovation cycles and promoting ecological optimization.
- Baden-Württemberg's status as Europe's leading innovation center, home to major corporations and a strong start-up ecosystem such as IntegraSkin, has further strengthened regional resilience.

Continued investment in R&D has enabled rapid adaptation to challenges such as an ageing society suffering from cognitive impairment. In the field of cancer research, certain projects have created more predictive in vitro models, starting with breast cancer, and facilitated collaborations to innovate and expand applications across all medical fields. AI-driven technological breakthroughs were highlighted as key to transforming and increasing industry resilience.

The knowledge gained from certain projects opens up opportunities for the co-development of new pharmaceutical proteins, which could help to establish a European knowledge platform for the manufacture of recombinant proteins, boost market competitiveness and enable cost-effective drug development.

The BioMan4R2 project also aimed to build resilience through product innovation, international expansion and the attraction of economic players, mainly SMEs. The Turku region, with its strong biotech manufacturing network and environmental-friendly technologies, provides fertile ground for biotech growth, supported by an expanding network of contract manufacturers and trained human resources.

| Company | Feedback - resilience for regional Biomanufacturing & Medical technology ecosystem / the company, the business |
|-------------------|--|
| Robeauté - FR | <i>“This project allowed us to create two European supply chain for microparts that MedTech players will be able to use independently. Hence, it increases the resilience of the medical technology ecosystem, specifically on microtechnologies for medical devices which are a strategic edge for medical devices companies.”</i> |
| Plantibodies - FR | <i>“Plantibodies has shown its ability to mass produce biotherapies at scale within plants, in a resilient and sustainable way. Moreover, by delivering biologics orally, Plantibodies drastically improves healthcare system resilience. Its drugs are stable at room temperature and can be taken at home by the patients, allowing to avoid burdensome hospital visits while drastically reducing cost for society.”</i> |
| InSpek SAS - FR | <i>“The demonstration showcased in this project enhances the resilience of the biomanufacturing ecosystem by paving the way for a local supply</i> |

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| | <p>chain and expertise in bioprocess monitoring and optimization. In turn, optimized processes improve companies' industrial competitiveness. The environmental benefits of implementing InSpek's solution also participates in preparing the ecosystem to tackle ecological challenges."</p> |
| Antleron NV - BE | <p>"By collaborating with the LVVC we've established a robust partnership, fostering mutual knowledge exchange and collaborative problem-solving. This strategic alliance enhances our position within the local ecosystem and contributes to the broader bioprocess and cell-production landscape by advancing and spreading expertise in closed bioprocessing. The refined processes and innovative methodologies, elevate both entities' standing as key contributors to Belgium's biomanufacturing sector, promoting resilience, knowledge dissemination, and reinforcing our role in driving advancements within the country's biomedical technology domain."</p> |
| ATTOM - FR | <p>"The project will significantly influence cancer research by creating more predictive in vitro models, beginning with breast cancer studies. As a R&D platform, it will facilitate collaboration with research institutions, startups, and industrial entities to innovate and broaden its application across various medical fields. ATTOM will also further explore the materials used in these supports. This initiative will strengthen ATTOM's role within the ecosystem."</p> |
| MindAhead UG - GE | <p>"Continuous investment in research and development allows for rapid adaptation to new challenges: in our case an aging society with increasing numbers of cognitive impairments."</p> |
| ALTA sp. z o.o. - PL | <p>"Through this project, beyond the primary goals such as creating a memory test and conducting validation research in the Balkans, we also aimed to build resilience for both our company and the regional BMT ecosystem. We have achieved or are in the process of achieving this through:</p> <ol style="list-style-type: none"> 1. Innovating the product itself, leading to autonomy. 2. Expanding internationally to enhance access to global supply and value chains. 3. Reaching out to attract economic actors, mainly SMEs, beyond Euroclusters' locations, leveraging synergy with other EU companies and Euroclusters." |
| MIRA Vision Microscopy GmbH - GE | <p>"With our focus on Artificial Intelligence, we are hitting the nerve of the times. We are convinced that our technological breakthroughs can trigger a significant transformation in the industry. This transformation will lead to a significantly increased resilience."</p> |
| Time is Brain SL - ES | <p>"Early and adequate stroke treatment saves lives and prevents disability. There is a need to fill the current market gap in tools that can facilitate access to the EVT treatment and improve its outcome. BrainN20® solves this problem by streamlining access to the EVT treatment, and providing brain real-time monitoring during the entire patient journey. Thanks to BIOMAN4R2, we have extended the BrainN20® implementation to global acute stroke patient populations. Our main goal is that each patient would receive the most effective and fastest care, independently of its living area."</p> |
| MAGIC GENOMIX - FR | <p>"The resilience our project brings is twofold: it enhances the accuracy of cancer therapies and facilitates the inclusion of precise biomarkers in</p> |

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| | <i>clinical trials. By doing so, it strengthens the regional BMT ecosystem's ability to deliver cutting-edge, effective medical solutions."</i> |
| PolyAn GmbH - GE | <i>"The production automation at PolyAn strengthens the resilience of the Biomanufacturing and Medical technology ecosystem in the EU by facilitating the production of key, high-end consumables for life science applications. Being able to source such materials locally supports faster innovation cycles in the European life science clusters and improves the overall resilience of the life science industry. Automated processes are less prone to disruptions by external factors and can also be optimized with respect to ecological aspects like chemical consumption."</i> |
| IntegraSkin GmbH - GE | <i>"The resilience of the regional Biomanufacturing and Medical technology ecosystem in Baden-Württemberg is bolstered by its status as Europe's leading innovation hub, particularly in fields like mobility, AI, quantum computing, and healthcare. This region, home to enterprises like Amazon, Mercedes-Benz and Bosch, benefits from a robust start-up ecosystem with strong cooperative networks, making it an attractive location for business growth. Our company seeks to benefit of it, which is proven to be a factor of success."</i> |
| Basic Pharma - NL | <i>"The knowledge gained in this project opens opportunities for the co-development of new proteins. It paves the way to act as a combined CDMO partner for the development and production of the next generation (pharmaceutical) recombinant proteins. Ultimately, this partnership could result in a European Knowledge platform for the manufacturing of pharmaceutical recombinant proteins. Resulting in a strengthened competitive market position, and a more cost-effective supply chain for biological drug development."</i> |
| Care4living Oy - FI | <i>"Around 100 technology companies operate in the Turku region, which develop or utilize ecologically friendly technologies, processes, services and products. Therefore, our area offers good opportunities for biotech manufacturing. Contract manufacturers are growing considerably, giving good examples of production business in this area. The biotech and pharma industry network between companies and universities enables trained human resources for companies. Microbial fermentation can utilize the available infrastructure and resources on a large scale."</i> |
| Fibrothelium GmbH - GE | <i>"The BIOMAN4R2 project not only helped us as a small medical device start-up, but also the regional biomanufacturing and medical technology ecosystem, to gain more resilience. The transition of materials used in medical devices is high in effort and time-consuming, particularly due to recent changes in regulations for medical devices, such as the MDR. Furthermore, natural sources are drying up and environmental as well as geopolitical imponderables make third party sourcing across borders increasingly risky for technology driven companies. Being able to strategically replace natural materials with biotechnologically sourced solutions, while still relying on the original nature's blueprint, enables us and the whole regional ecosystem to pivot and react on external uncertainties. Our proof-of-concept has successfully shown that resilience is not always a matter of years and significant financial resources, but can be facilitated even in small companies."</i> |

1.4 Synthesis

In summary, the BioMan4R2 financial support program helped stimulate innovation and strengthen the resilience and competitiveness of Europe's MedTech and biomanufacturing ecosystems. Through targeted funding and support, the program has enabled the creation of independent European supply chains for micro-parts, strengthening the MedTech sector's resilience and business capabilities. This approach significantly improves the resilience of the healthcare system by enabling patients to take their medicines at home.

Continuous investment in R&D, driven by the program, has enabled companies to adapt quickly to new challenges, such as an aging society and increasing cognitive impairment. AI-driven technological breakthroughs have also taken center stage, promising significant industry transformation and increased resilience.

The program also highlighted the importance of regional groupings such as health clusters (consortium members, Baden-Württemberg...), bringing together a wide range of innovation players from major companies and a solid ecosystem of start-ups in Europe. The region's strong cooperation networks and innovation capabilities have strengthened the resilience of the local biomanufacturing and medical technology sectors.

The knowledge gained from the program has opened up opportunities for the co-development of new pharmaceutical proteins, potentially establishing a European knowledge platform for the manufacture of recombinant proteins. This initiative aims to boost market competitiveness and create a more cost-effective supply chain for the development of biological drugs. In addition, regions like Turku, with a strong biotech manufacturing network and a focus on green technologies, provide fertile ground for biotech growth, supported by an expanding network of contract manufacturers and skilled human resources.

Overall, the BioMan4R2 financial support program has been a catalyst for innovation, collaboration and market expansion, paving the way for future growth and investment opportunities in Europe's medical technology and biomanufacturing sectors. It has enabled companies to achieve important milestones, strengthen their technological capabilities and improve their competitive position, while promoting resilience and sustainability within the healthcare ecosystem.

2. Business Transformation Financial Support (BTFS)

Business Transformation Financial Support (BTFS) aims to support SMEs by training them in technology adoption, digitization and sustainable supplier business models, and by developing training programs for SMEs in digitization and digital skills.

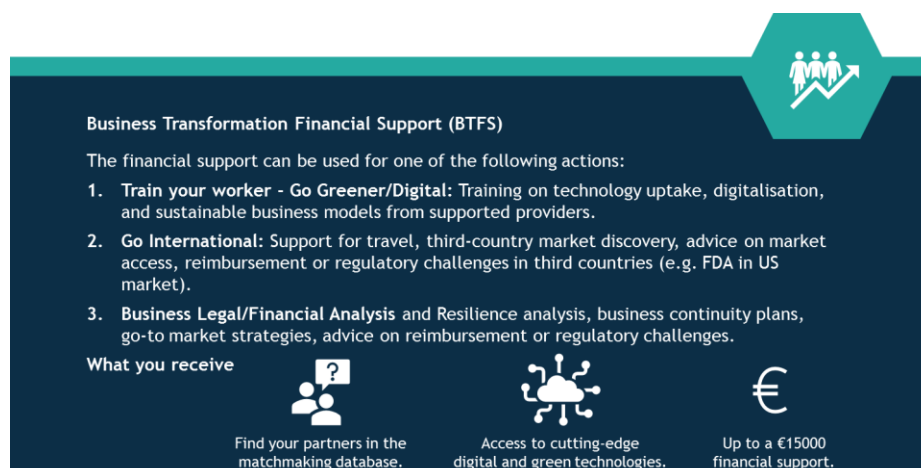


Figure 3 - Financial Support Scheme Overview - BTFS

As planned, BioRegio STERN received reports & feedback from the 9 laureates. Their responses will be analysed and detailed in the following 3 sub-sections.

2.1 Feedback on the impact of financial support on the company

The BioMan4R2 financial support program has been an important catalyst for the growth and development of several European companies, enabling them to advance their projects and improve their market presence. SITEC has used this support to develop a business continuity plan, define strategic R&D priorities and attract CDMOs willing to invest in its technology.

Funding has also facilitated companies' expansion into new markets, as illustrated by the case of a company that took advantage of support to penetrate the US market, establish links with researchers and obtain regulatory approvals efficiently, such as Oniria or Zeisberg. Egerton improved its medical device portfolio by collaborating with Novineon CRO GmbH and ELZAB S.A., boosting EMC testing and regulatory compliance, which strengthened its market position and reduced its dependence global suppliers. Manitty has drawn up a regulatory strategy roadmap to ensure that its medical headband complies with European standards, which is essential for obtaining approvals and integrating into hospital environments. In addition, companies like Jafral, with their 'Janet' software have improved the digitalisation of their processes.

BioMan4R2 support has enabled collaborations with CROs, facilitating effective regulatory planning and market entry:

- EARLAB has implemented a quality management system and is preparing for ISO 13485 certification, hence enhancing their attractiveness to investors.

- For Gate2Brain, the funding has helped investigate EAPs programs and market access, which could lead to early investment and market penetration through designated patient programs.
- Oniria have used the funding to advance their roadmaps, gather detailed market information and prepare for future European funding proposals, particularly for cancer-specific markets.

Overall, the BioMan4R2 financial support program has enabled companies to strengthen their regulatory compliance, improve their internal processes and achieve important milestones in their market development and expansion efforts.

| Company | Feedback - Impact of the financial support |
|-------------------------|---|
| SITEC Pharmabio - ES | <i>“Financial support helped SITEC to work with an expert provider and develop a business continuity plan. We defined strategic priorities on profitable R&D activities for clients, and on projects that can attract funds for specific products development in high-value therapeutic areas. We prioritized funding search towards attracting CDMOs interested in directly investing in SITEC’s technology and include it in their portfolio under licensing agreement.”</i> |
| Zeisberg GmbH - GE | <i>“The financial support will significantly impact our company by enabling our expansion into the US market. Additionally, this support facilitates the establishment of crucial connections with US-based researchers and potential partners, fostering collaborative opportunities and enhancing our market presence. Furthermore, the financial backing provides invaluable assistance in navigating the regulatory approval process, ensuring smoother and more efficient market entry.”</i> |
| Egerton sp. z o.o. - PL | <i>“The BioMan4R2 grant empowered Egerton to enhance our medical device portfolio, particularly in MDR-compliant technical documentation and clinical evaluation. Collaborating with Novineon CRO GmbH and ELZAB S.A. has amplified our capabilities in EMC testing and regulatory compliance, vital for market expansion. This strategic development not only boosts our internal process efficiency but also strengthens our role as a competitive European manufacturer, reducing dependence on non-European suppliers & fortifying our market position.”</i> |
| Manitty - FR | <i>“The regulatory strategy study and corresponding roadmap, funded by the grant, play a vital role in initiating the regulator compliance process and ensuring that Manitty’s medical headband complies with European regulatory standards. Meeting these standards is essential for obtaining necessary approvals, ensuring patient safety, and facilitating the integration of the device into hospital environments.”</i> |
| JAFRAL d.o.o. - SL | <i>“Financial support has impacted our company by enabling us to upgrade our production solution, Janet, which means an investment in new technologies, and enhance workforce skills. With that, we improved our competitive position, accelerated growth, and allowed us to ensure higher quality of our products.”</i> |
| Breaz Medical SL - ES | <i>“The support allows us to work in collaboration with a CRO which would otherwise not be available at our stage of development. This allows us to choose our regulatory paths and plan the resources we will need to get there. It allows us to get to market entry more efficiently so we can start making an impact earlier, as well as planning for future markets.”</i> |
| Earlab GmbH - GE | <i>“The financial support empowers us to implement the necessary QMS and integrate regulatory thinking into our company’s approach. This enhancement significantly refines our internal processes, removing barriers and mitigating complications associated with regulatory</i> |

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| | <i>requirements and market access. Furthermore, it boosts efficiency in the research and development of our products. By preparing EARLAB for ISO 13485 certification, the project makes our company more appealing to investors.”</i> |
| Gate2Brain S.L - ES | <i>“Studying EAPs programs and Market Access of G2B-002, which has been validated in a preclinical setting, will have a huge impact after clinical validation. This approach, considering investor’s opinion, may lead to an early investment for G2B-002 development. The inclusion of G2B-002 in an EAPs will have a huge financial benefit. EAPs can earn early revenues in the countries where early access through named patient programs can be charged by the countries. EAPs can be immensely useful in early market penetration leading to increased acceptance and uptake by physicians and patients after the commercial launch of the product.”</i> |
| ONIRIA THERAPEUTICS, S.L. - ES | <i>“As a start-up, this type of funding is essential to move forward into the planned roadmap. It helped Oniria to cover the needs explained before, but also to have more information to fill the next European funding proposal to have more details about the market for specific countries and types of cancer.”</i> |

2.2 Testimonial - Financial Support Programme

The BioMan4R2 financial support program has been decisive for a number of innovative SMEs, providing direct, practical assistance tailored to their immediate needs. Companies like SITEC have benefited from ad hoc collaborations with expert suppliers, facilitated by a clear and simple application process. Advance payment of a substantial part of the grant is particularly advantageous for SMEs, as it gives them the funds they need to get their projects off the ground quickly. For companies navigating the complex US regulatory landscape, funding has been key. It has enabled efficient deployment of technical expertise to overcome regulatory challenges, reduce time-to-market and accelerate revenue generation. Financial support also helped establish vital networks of contacts in the U.S., essential for small companies to establish partnerships and share resources.

- Egerton has gone from importer to manufacturer. This transition has strengthened its competitiveness in the market, reduced logistics costs and reduced its carbon footprint. The focus on MDR compliance and training with novineon CRO GmbH has enabled Egerton to position itself as a major player in the European medical sector, challenging the dominance of US companies and contributing to the resilience of the regional economy.
- Manitty's project has progressed significantly thanks to the grant, ensuring regulatory compliance, encouraging multidisciplinary collaboration and strengthening future market integration and credibility. This support has accelerated the development of a cutting-edge healthcare technology with far-reaching implications.

The BioMan4R2 program has also enabled a number of companies to modernize and adopt technologies, increase operational efficiency and upgrade staff skills to meet industry standards. Access to key resources has enabled companies to avoid early mistakes and save money, by strengthening internal knowledge and developing European collaborations. The BTFS component stands out for its transparent application process, which connects startups and small businesses with experienced service providers and partners. This fosters collaboration, knowledge exchange and networking opportunities that should continue beyond the conclusion of the project.

- Gate2Brain benefited from this financial support by analysing and understanding the requirements for applying for EAPs in the EU, which is crucial for rapidly translating clinical trial results into clinical practice. This support has had a significant impact on their market access strategy.
- Oniria Therapeutics has acquired in-depth knowledge of the main melanoma markets in Europe and the UK, which has helped it prepare for a new funding round and plan its strategy for accessing the US market.

Overall, the BioMan4R2 program has been a crucial resource for SMEs, enabling significant advances in technology, regulatory compliance, market integration and operational efficiency. It has fostered collaboration and knowledge exchange, contributing to the resilience and competitiveness of Europe's medical technology and biomanufacturing sectors.

| Company | Testimonial - Financial Support Programme |
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| SITEC Pharmabio - ES | <p><i>“We consider BioMan4R2 a very direct and lean Financial Support program for innovative SMEs like SITEC. It focuses on immediate and practical needs that companies have, and facilitates the establishment of ad-hoc collaborations with expert providers. It is based on a very practical approach in the presentation and discussion of the proposal and of the project results with the evaluators, which makes the project easy to understand, and to implement. The upfront payment of a substantial amount of the grant fund is obviously helpful for SMEs.”</i></p> |
| Zeisberg GmbH - GE | <p><i>“The funding was instrumental in navigating the US regulatory hurdles. The financial support allowed us to efficiently deploy the technical expertise to overcome these challenges. This will reduce our time to market, accelerating revenue generation and growth. The funding also facilitated building a vital network of US contacts. These connections are crucial for a small company like ours, enabling us to forge partnerships and share critical resources for market establishment. Without the financial support, gaining access to the necessary resources would have been much more difficult.”</i></p> |
| Egerton sp. z o.o. - PL | <p><i>“BioMan4R2's support was a game-changer for Egerton, fostering our transition from an importer to a manufacturer. This shift enhances our market competitiveness, decreases logistics costs, and reduces carbon footprint. The project's focus on MDR compliance and training with novineon CRO GmbH positions us as a key player in the European medical sector, breaking the monopoly of American companies and contributing to the regional economic resilience. The grant's impact extends beyond Egerton, catalyzing growth and stability in the local ecosystem.”</i></p> |
| Manitty - FR | <p><i>“The European grant played a pivotal role in advancing Manitty's project. It ensured regulatory compliance, fostered multidisciplinary collaboration, facilitated future market integration, enhanced credibility. This support accelerated the development of cutting-edge healthcare technology with far-reaching implications.”</i></p> |
| JAFRAL d.o.o. - SL | <p><i>“We are very grateful for the Financial Support Programme. With the funding received, we were able to modernize our software solution and adopt new technologies that significantly increased our operational efficiency. The program also supported us in training our staff, enhancing their skills to meet industry standards.”</i></p> |
| Brez Medical SL - ES | <p><i>“The program allows us access to key resources which would be difficult for us to justify without the financial support. This means we can avoid</i></p> |

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| | <i>making mistakes early on in our development process and save money to the company in the long run. It also allows us to build knowledge within the company and develop our European collaborations.”</i> |
| Earlab GmbH - GE | <i>“The BTFS offered by the BioMan4R2 program stands out for its straightforward and transparent application process, that connects startups and small companies with experienced service providers and partners. This program fosters collaboration, facilitates knowledge exchange, and promotes networking opportunities that are expected to continue well beyond the project's conclusion.”</i> |
| Gate2Brain S.L - ES | <i>“Gate2Brain platform technology will bring therapies closer to patients and clinical practice, going beyond societal and economic barriers to provide medicines for everyone, everywhere. Thus, Gate2Brain needed to analyze and understand the specific requirements for applying to EAP in the EU, in order to translate the clinical results obtained during the clinical trial to the clinical practice in the shortest period of time. The financial support received by BioMan4R2 had a great impact on the Market Access strategy of Gate2Brain.”</i> |
| ONIRIA THERAPEUTICS, S.L. - ES | <i>“The BioMan4R2 program has been a useful resource for Oniria Therapeutics, enabling a profound comprehension of the four major European markets and the UK, for Melanoma. This invaluable insight has helped our company to understand the access to the European market and to prepare a new funding call to achieve the next significant step for us: to know the market access strategy for the US market.”</i> |

2.3 Feedback on the resilience for the regional Biomanufacturing & Medical technology ecosystem, and for company's business

The BioMan4R2 financial support program has had a significant impact on several companies, fostering growth, innovation and resilience within Europe's medical technology and biomanufacturing ecosystems. For SITEC, the results of the project are expected to accelerate growth, attract investment and strengthen technical capabilities, particularly in Barcelona's thriving life sciences and biotechnology sector. SITEC's CryoXpand® technology aligns with sustainable development goals, promoting healthy living, sustainable industrialization and sustainable consumption.

Entering the US market offers strategic advantages by diversifying market presence and reducing dependence on European markets, ensuring continued growth despite market fluctuations. Egerton's participation in the program marks an important step in strengthening regional resilience by shifting production to Europe, mitigating the risks associated with geopolitical tensions and supporting economic sovereignty. This is in line with the European objective of a resilient economy, guaranteeing high-quality, on-time deliveries, and adapting to the needs of local markets.

This cascade funding has supported regional medical technology ecosystems by encouraging innovation, strengthening collaboration and ensuring regulatory compliance. It has provided vital support for research, development and market integration, catalysing significant contributions to the sector's growth and resilience. Slovenia's biomanufacturing and medical technology ecosystem, for example, has grown significantly, with the emergence of new companies and major investments planned by Novartis and Sandoz.

Support for medical device manufacturers has facilitated knowledge sharing through local networks, lowering barriers to entry for start-ups and stimulating innovation.

- The collaboration between EARLAB and MII is a model for other startups, promoting a culture of knowledge sharing and contributing to the resilience of the regional MedTech ecosystem. Their partnership with Tübingen University Hospital stimulates innovation in clinical research and facilitates the transfer of research findings to patient care.
- Gate2Brain is positioned as a mission-driven company that contributes to recovery and resilience by developing peptide-based technology for brain drug delivery, stimulating innovation in brain treatments and improving the resilience of the healthcare system. Its efforts improve the accessibility and effectiveness of treatments, thereby reducing the economic and social burden of brain diseases.

Efforts to improve social and economic sustainability through oral cancer treatments optimize patient outcomes and reduce treatment costs by eliminating the need for hospitalization. This approach strengthens the European healthcare system, improves patient care and prepares for future challenges.

Overall, the BioMan4R2 program has boosted growth, improved resilience and encouraged innovation in Europe's medical technology and biomanufacturing sectors, contributing to a more self-sufficient and robust ecosystem.

| Company | Feedback - resilience for regional Biomanufacturing & Medical technology ecosystem / the company, the business |
|-------------------------|---|
| SITEC Pharmabio - ES | <i>“The project outcome is expected to accelerate SITEC growth, and attract investments that will expand the company’s technical capability, facilitating the introduction of its technology to the EU markets. Barcelona area is one of the fastest growing Life Sciences-Biotech clusters in Europe with high visibility worldwide. Within this context SITEC, by mean of its CryoXpand® technology, can meet the demands of future sustainable pharmaceutical and nutraceuticals production, with a positive impact on SDG 3 (ensure healthy lives and promote well-being at all ages), SDG 9 (inclusive and sustainable industrialization) and SDG 12 (sustainable consumption and production).”</i> |
| Zeisberg GmbH - GE | <i>“Entering and obtaining product approval in the US market will strengthen our ability to withstand fluctuations in the European and German medical device markets. This strategic move diversifies our market presence, reducing reliance on a single market and ensuring ongoing growth in demand for our products.”</i> |
| Egerton sp. z o.o. - PL | <i>“Egerton’s participation in the BioMan4R2 project marks a significant step towards enhancing the resilience of the regional biomanufacturing and medical technology ecosystem. By shifting production to Europe, we’re mitigating risks from geopolitical tensions and supply chain disruptions. This strategic move not only strengthens our independence and economic sovereignty but also supports Europe’s medical sector to be more self-reliant and robust. Egerton’s commitment to local production aligns with the European goal of a resilient economy, ensuring high-quality, timely deliveries and adaptation to local market needs.”</i> |
| Manitty - FR | <i>“This funding bolstered the regional medical tech ecosystem by fostering innovation, enhancing collaboration, and ensuring regulatory compliance. For our company, it provided vital support for research,</i> |

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| | <i>development, and market integration, catalyzing impactful contributions to the sector's growth and resilience."</i> |
| JAFRAL d.o.o. - SL | "Slovenian biomanufacturing and medical technology ecosystem is growing in last 10-20 years. Where 20 years ago there hasn't been many companies apart from Novartis to do biomanufacturing or supporting biomanufacturing. Nowadays, there are quite few new companies that work (and expand) in this area. Also, Novartis & Sandoz are planning to invest around 500mio€ in their additional capabilities." |
| Breaz Medical SL - ES | "The project supports us, a hardware medical device manufacturer, of which there are few in our ecosystem. By supporting such companies the knowledge that is acquired can be shared through our local networks. This lowers the barrier to entry for other startups and drives innovation within the ecosystem." |
| Earlab GmbH - GE | "The collaboration between EARLAB and MII exemplifies a model for other startups and promotes a culture of knowledge sharing that contributes to the resilience of the regional MedTech ecosystem. As part of our engagement with MII, we are keen to share our hands-on experience in establishing a QMS. Being a medical device manufacturer, our robust partnership with the University Hospital Tübingen positions us to further drive innovation in clinical research and the MedTech sector, facilitating the transfer of basic research results to patient care." |
| Gate2Brain S.L - ES | "Gate2Brain team position itself as a mission-driven company with the goal to implement the pillars of the Recovery and Resilience Facility. Gate2Brain contributes by 1) Improving the treatment of brain diseases with the development of a peptide-based technology that helps drugs to reach the brain; 2) Boosting innovation in the field of brain drug delivery industry creating economic opportunities for EU companies developing brain treatments; and 3) Enhancing the resilience of the healthcare system offering a more effective and accessible treatment opportunities that will reduce economic and social burdens derived from brain diseases." |
| ONIRIA THERAPEUTICS, S.L. - ES | "We are trying to improve the social and economic sustainability, optimizing patient outcomes, and addressing potential barriers through the availability of a treatment against cancer, that can be taken orally. This presents an advantage that extends beyond enhancing quality of life since it can reduce treatment-related costs, as there is no requirement for hospitalization. By this way Europe can strengthen its healthcare system, enhance patient care, and effectively respond to future challenges." |

2.4 Synthesis

The BioMan4R2 financial support program has helped boost the growth, innovation and resilience of several European medical technology and biomanufacturing companies. Funding has enabled companies to accelerate their growth, attract investment and improve their technical capabilities, particularly within certain life sciences and biotechnology clusters.

For companies entering the US market, the program has brought strategic benefits by diversifying market presence and reducing dependence on European markets, ensuring continued growth despite potential market fluctuations.

Program support has strengthened regional medical technology ecosystems by encouraging innovation, reinforcing collaboration and ensuring regulatory compliance. This support has been vital for research, development and market integration, catalysing significant contributions to the sector's growth.

Support for medical device manufacturers has facilitated knowledge sharing through local networks, lowering barriers to entry for start-ups and stimulating innovation within the ecosystem.

Efforts to improve social and economic sustainability, such as the development of oral cancer treatments, optimize patient outcomes and reduce treatment costs by eliminating the need for hospitalization. This approach strengthens the European healthcare system, improves patient care and prepares for future challenges.

Overall, the BioMan4R2 financial support program has been a catalyst for growth, resilience and innovation in Europe's medical technology and biomanufacturing sectors. It has enabled companies to achieve important milestones, improve their competitive position and foster a more self-sufficient and robust ecosystem. The program's impact extends beyond individual companies, contributing to regional economic stability and the global competitiveness of Europe's healthcare and biomanufacturing industries.

3. Conclusion

The BioMan4R2 financial support program has been a transformative force for various European companies, significantly improving their growth, innovation and resilience in the medical technology and biomanufacturing sectors :

- The program has facilitated strategic breakthroughs, enabling companies to increase production, penetrate new markets and improve regulatory compliance.
- The support has also had a significant regional impact.
- Collaboration has been the cornerstone of the program, facilitating partnerships that stimulate innovation and knowledge sharing.
- In addition, the program has supported the modernization and adoption of technologies, improving operational efficiency and enhancing staff skills to meet industry standards. It has enabled companies to strengthen their internal knowledge, develop European collaborations and prepare for future funding opportunities.

Overall, the BioMan4R2 program has enabled companies to achieve significant milestones, improve their competitive position and foster a more self-sustaining and robust ecosystem. The program's impact extends beyond individual companies, contributing to regional economic stability and the global competitiveness of Europe's healthcare and biomanufacturing industries. It has provided a vital platform for innovation, collaboration and sustainable growth, ensuring the resilience and progress of Europe's medical technology and biomanufacturing sectors.

Given the response to this type of funding, it would be appropriate to offer a similar support programme to other innovation players who also want to work on the digital, resilient and green aspects of their projects.