



IMPACT REPORT 2024

Bios-Therapy,
Physiological Systems for Health S.p.A.



BIOS-THERAPY
PHYSIOLOGICAL SYSTEMS FOR HEALTH

IMPACT REPORT

2024

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LETTER FROM THE PRESIDENT

We are living in a historical period that is breaking with the past, a period of profound change. The implications of this transition are still not very clear in some respects, but what is certain is that these changes will have a profound impact on our lives and our way of doing things. Over the next few years, we will witness a genuine global realignment. There is nothing new or strange about this if we look carefully at human history. Over time we have gone through cyclical phases, even dramatic ones, and they have always been an expression of the need to find a new equilibrium.

This is happening again at the beginning of this third millennium, which is marked by the need to find a balance in many interrelated areas, from socio-economic to environmental, industrial-financial, and even health, which we have come to realise is the most important.

What is certain is that restoring harmony will not be easy or painless, given the magnitude of the changes that humans have wrought on our planet.

These changes are so significant that we have redefined our era as the 'Anthropocene' – an age in which humanity has established itself as the 'dominus naturae' and, as such, has absolute power over creation.

It is now clear that we need to look at things from a different perspective, a systemic perspective, which places humans within the system and not outside or above it, no longer as 'dominators' but as 'guardians of nature'.

A new Renaissance that offers us a vision of the future for humanity with concrete implications for the field that interests us most: health and medicine.

Adopting a systemic perspective in this context means, for example, moving from a reductionist approach focused on treating the symptom to a complex interpretation of the disease, which we can include in the new definitions of Systems Medicine and Systems Pharmacology. A systemic interpretation of disease and the patient also leads us to redefine pathophysiology, the physiological state and physiological actions.

A major turning point came with the Medical Device Regulation (EU) 2017/745 known as RECAST. The new RECAST regulation introduces several changes with respect to the previous legislation, including a significant change in Art. 2, 3rd indent, regarding the positioning of Medical Devices. In particular, the regulation emphasises that in exerting their therapeutic action, medical devices can modify the physiological state of the body in a way that is different to the actions typically attributed to drugs.

Therapeutic systems that are to be developed as Medical Devices can fall under the definition of Systems Pharmacology if they consist of many isolated chemicals, or under the definition of a 'physiological action' if they consist only of natural matrices.

The term 'physiological action' can be used as a substitute for a kinetic and dynamic activity on other metabolic networks such as those of the human body.

Nowadays, the term 'physiological' is almost always used to define a state, be it a state of homeostatic equilibrium or a state of pathophysiology. What we can expect as a result of RECAST is the advancement of research in these areas.

Bios-Therapy, Physiological Systems for Health S.p. A., has long anticipated this type of approach with an innovative platform that uses the latest techniques, including genomics, transcriptomics and proteomics. This has helped to move beyond the study of 'molecule-receptor' interactions to an understanding of the interaction between the complex natural substance and the body's metabolism. This wealth of knowledge can now be shared with the wider scientific community, contributing to the ongoing shift towards a truly systemic approach to medicine.

Valentino Mercati



INTRODUCTION

Bios-Therapy, Physiological Systems for Health S.p.A. is the systems biology laboratory that studies the interaction between complex natural substances and the body's metabolism. It is the only research platform in the world that does not apply the criteria of Pharmacology and its consequent practices.

Every health issue is addressed in a systemic manner. The researchers at Bios-Therapy not only analyse the organ or system directly involved, but look at the human body as a whole, taking into account all its interactions, in order to develop innovative health and therapeutic solutions.

Bios-Therapy is a strategic partner of Aboca S.p.A. Soc. Agr. in Preclinical and Clinical Research.

Bios-Therapy was founded in 2012 by Valentino Mercati, under the name "Natural Bio Medicine", to create an independent company that would scientifically study the interaction between humans and nature at a molecular level. The current name Bios-Therapy, Physiological Systems for Health S.p.A.¹ was adopted in 2022, when the company was converted into a Benefit Corporation.

Over the years, Bios-Therapy has specialised in providing services in the field of identification, evaluation and profiling of complex natural substances, naturally self-assembled structures extracted from plant raw materials, in order to promote the development of innovative products that can be used in the health and therapeutic sector. Bios-Therapy takes a systemic and non-reductionist approach to conducting in vitro and ex vivo experiments using advanced methods that are often unique in the world. These methodologies rely on dedicated platforms for high throughput screening, which is essential for assessing the efficacy and safety profile of natural materials. By their very nature, materials derived from living organisms require methods of study that do not take a reductionist approach that is based on the chemical quantification of the individual components of a product. While this approach can be used to study individual isolated substances, either alone or in combination, it does not capture the behaviour of a complex natural substance, which is the result of the interaction between its constituents and is known as the 'matrix effect'.

In particular, the company has developed platforms relying on the use of what are known as 'omic' technologies. When these technologies are applied to the appropriate cellular models and combined with a high interpretative capacity using bioinformatics, they are able to suggest the potential role of complex natural substances in the management of human health.

These platforms allow us to analyse the mechanisms through which a complex natural substance interacts with the human body, highlighting its physiological role and investigating its dynamics. These technologies allow us to gather detailed data on the interaction between the human body and the naturally self-assembled system, thus favouring the development of effective and sustainable solutions. The innovative approach of Bios-Therapy is a benchmark for research in this sector.

Bios-Therapy collaborates with numerous universities and research organisations, both in Italy and abroad. This network of partnerships ensures a constant advancement in applicable approaches and the maintenance of the highest operational standards.

Given the quantity and complexity of the analyses carried out every day, the Bios-Therapy laboratory has equipped itself with a 'Cell Bank' that makes use of cryogenic systems to store numerous cell lines from certified international suppliers. Bios-Therapy has been working for years on the development and validation of innovative technologies aimed at moving away from animal experimentation, and it is thanks to technological investments of this kind that they have been able to do so.

The company actively collaborates with European regulatory bodies to integrate the principles of systems biology into product authorisation protocols, thus contributing to a new way of treating disease using evidence produced with scientifically advanced methods, for the benefit of humans and all living things.

¹ From this point onwards, reference will be made to 'Bios-Therapy, Physiological Systems for Health S.p.A.' with the abbreviation 'Bios-Therapy'

BIOS-THERAPY IN NUMBERS

- 2,341,597.47 in turnover
- 98% of supplier spending is allocated to Italian companies
- Company staff: 22 people
- Average age: 40
- 91% of staff are actively involved in research
- Total hours worked: 37,293

(**68.2%** | **31.8%**)
WOMEN | MEN



KEY DATES:

2012

Founding of Natural
Bio Medicine

2014

Commissioning of
the new state-of-
the-art laboratory

2022

Adoption of a new
organisation and
company name together
with the Benefit
Corporation Statute

2024

The company
reaches 22
employees.

IMPACT REPORTING

In order to fulfil the obligations set out in Italian Law no. 208 of 28.12.2015 (Paragraphs 376-384) regarding Benefit Corporations, Bios-Therapy measures and reports its impact through the Annual Impact Report, which is made up of two parts:

PART 1

'Part 1' provides an evaluation of the overall impact of Bios-Therapy using a third-party standard: the Benefit Impact Assessment (BIA)

PART 2

'Part 2' outlines the results achieved by Bios-Therapy over the past year with reference to the specific aims of public benefit included in the company's statute, together with the objectives we have set ourselves for the year ahead

WHAT IS A BENEFIT CORPORATION?

Traditional companies exist for the sole purpose of distributing dividends to shareholders. **Benefit Corporations are the expression of a more advanced paradigm: they include the goal of having a positive impact on society into their business objective, in addition to the goal of profit-making.**

From this perspective, Benefit Corporations are an evolution in the very concept of a company, as they aim to achieve true economic, environmental and social sustainability. Benefit Corporations have the following key characteristics:

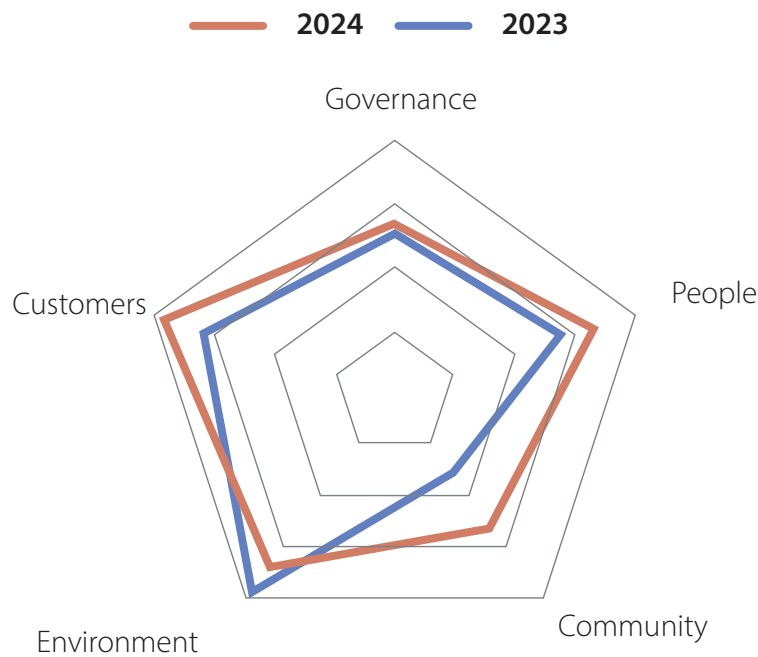
- They are committed to acting responsibly, sustainably and transparently towards the region, the environment and other stakeholders.
- They consider everyone, both shareholders and stakeholders, in their social object.
- They measure the company's results in terms of their positive impact on society and the environment with the same rigour and diligence as they do for their economic and financial results.

Italian Benefit Corporations voluntarily pursue one or more goals of public benefit as part of their business operations, in addition to the goal of profit-making. "Public benefit" refers to the pursuit of one or more positive effects on people, communities, regions, the environment, cultural and social assets and activities, organisations and associations, and other stakeholders. Benefit Corporations aim to achieve these public benefit goals in a responsible, sustainable and transparent way. This approach requires managers to balance the interests of members with the interests of the community. Benefit Corporations must appoint a person in management who is responsible for the impact of the company and who commits to transparently and comprehensively reporting on its activities through an annual impact report, describing both the activities carried out and the plans and commitments for the future. At the time of writing, Benefit Corporations do not enjoy any economic or tax incentives, so in addition to representing a value to society, they do not cost money to the taxpayer.

PART 1

OVERALL IMPACT

In order to report on the impact, the international Benefit Impact Assessment (BIA) standard was chosen to evaluate the qualitative and quantitative evolution of the impact profile, as required by the law governing Benefit Corporations. Below is the graph showing the results of the analysis for the year 2024.

**WHAT IS THE BIA?**

The Benefit Impact Assessment is a benchmark developed by the non-profit organisation, B Lab. This tool makes it possible to assess the social and environmental impact of a company in a quantitative and rigorous way. The BIA is conducted on an online platform, where the company is required to provide qualitative and quantitative information through a specially designed questionnaire. The tool adapts to the company during the analysis, as it uses a questionnaire made up of several hundred questions that can be accessed depending on the answers given. Because of this adaptability, each one of the five BIA areas (Governance, Environment, Community, Workers and Customers) have a maximum score that is different from the others and that varies according to the sector in which the company operates.

PART 2

RESULTS RELATING TO SPECIFIC PUBLIC BENEFIT GOALS

As a Benefit Corporation, Bios-Therapy incorporated three specific goals of public benefit into its statute. The company intends to pursue these goals in the exercise of its business activity, through measures whose aim is to generate a measurable positive impact on society and the environment, as well as creating the conditions for maintaining satisfactory economic results.

In particular, article 2 of the Bios-Therapy statute states:

As a Benefit Corporation, the company aims to pursue multiple goals of public benefit and to operate responsibly, sustainably and transparently towards individuals, the region, the environment and other stakeholders. [...]

THE THREE PUBLIC BENEFIT GOALS STATED IN THE BIOS-THERAPY STATUTE:

The company also pursues the following specific public benefit goals:

- 1** *Research and identify physiological therapeutic solutions that are intrinsically similar to the human body because they belong to the system of living things, are biodegradable and are thus part of the circularity of natural processes.*
- 2** *Create a positive working environment that focuses on the development and well-being of individuals, to realise each person's potential and constantly foster pride and satisfaction in working for the company.*
- 3** *Protect the natural balance in all business activities by promoting awareness of the interconnection between humans and nature.*

PRESENTATION OF THE RESULTS

In this section of the Impact Report we present the results Bios-Therapy has achieved over the last year, with reference to the three specific public benefit goals included in the Statute, together with the goals we set for 2024.

Each goal is presented by citing the original wording from our statute. There is a brief explanation of the most significant aspects of each goal.

Individual activities, data, indicators and results are presented schematically.

We believe that the presentation method exemplified on the next page can add clarity to our Report, a crucial requirement for a company that wants to give a true measure of the results achieved to its stakeholders.

READING GUIDE

LEVEL 1:

ACTIVITIES

Description of the activity promoted by Bios-Therapy.

LEVEL 2:

DATA/KPIS

The main qualitative and quantitative data regarding the initiative.

LEVEL 3:

RESULTS ACHIEVED

The impact produced in relation to the public benefit goal, represented where possible with indicators.
All the results reported contribute in achieving the impact generated by Bios-Therapy's activities, i.e. its public benefit goals.

ACTIVITIES
<div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div><div></div></div>
DATA/KPIS
<div><div></div><div></div><div></div><div></div></div>
RESULTS ACHIEVED
<div><div></div><div></div><div></div><div></div></div>

1 FIRST PUBLIC BENEFIT GOAL: RESEARCH AND DEVELOPMENT

From the statute:

Research and identify physiological therapeutic solutions that are intrinsically similar to the human body because they are part of the living system, are biodegradable and are therefore part of the circularity of natural processes.

ACTIVITIES	ACTIVITIES	ACTIVITIES
PEOPLE ACTIVE IN RESEARCH In addition to state-of-the-art equipment and facilities, our research relies on the advanced skills of the people who work for us and who dedicate their time to studying the relationship between humans and nature, in keeping with the spirit of the company.	INVESTMENT IN RESEARCH AND DEVELOPMENT The company is committed to its research activities every year, with the aim of reaching common goals and advancing knowledge on natural substances.	RESEARCH AREAS AND COLLABORATIONS At Bios-Therapy, research is a fundamental activity for the development of natural and biodegradable solutions. Research activities aim at constant innovation across several research areas and through collaborations with external organisations.
DATA/KPIS	DATA/KPIS	DATA/KPIS
20 people active in research and regulatory projects, 90% of the total workforce	Over 1.863.939,93 of investments in the form of tangible and intangible fixed assets	9 areas of research Active collaborations with 10 national universities
RESULTS ACHIEVED		
A contribution to the advancement of knowledge regarding the therapeutic potential of natural substances and their physiological interaction with the human body. <ul style="list-style-type: none"> • 3 research projects to identify new raw materials • 2 100% natural formulas in development • 3 product development projects underway • 1 publication in a scientific journal 		

OBJECTIVES, RESULTS AND FUTURE TARGETS

FIRST PUBLIC BENEFIT GOAL

Research and development

GOALS FOR 2024

People active in research:

we will keep the percentage of people actively involved in research above 80%

✓ 90% of people active in research.

Investment in research and development:

we will continue to invest in research and development in 2024.

✓ R&D investments reached 1.863.939,93 €

Research areas:

We will continue to focus our studies on at least 7 research areas

✓ There were 10 research areas under study.

GOALS FOR 2025

We will increase the number of people working in research and development.

We will continue to invest in R&D in 2025.

We will continue to focus our studies on at least seven research areas.

Key

✓ = Objective achieved ⏸ = Objective in progress ! = Objective partially achieved ✗ = Objective not achieved



2 SECOND PUBLIC BENEFIT GOAL: VALUING PEOPLE

From the statute:

Create a positive working environment that focuses on the development and well-being of individuals, to realise each person's potential and constantly foster pride and satisfaction in working for the company..

ACTIVITIES	RESULTS ACHIEVED	ACTIVITIES
BENEFITS AND INITIATIVES FOR PERSONNEL <p>In addition to agreements for purchases from local merchants, Bios-Therapy offers its employees and family members a range of free membership services, such as supplementary health insurance² whose costs are 80% covered by the company, and the supplementary pension fund³. In addition, various types of bonuses were paid to employees during the year, both individual bonuses concerning specific objectives and other types of extraordinary bonuses. Finally, to maintain internal cohesion even outside our laboratories, we have organised leisure activities for our collaborators.</p>	TRAINING AND DEVELOPMENT MANAGEMENT <p>Bios-Therapy believes that an essential requirement for the qualitative development of the company is the constant professional growth of its collaborators.</p> <p>We have introduced the Development Management System to ensure that people are managed in the best possible way, with a view to their improvement and development in a manner that benefits both the company and the individual. This is an ongoing process of assessing and developing transferable skills with the aim of enriching the professional experience of our employees through targeted training.</p>	RECRUITMENT AND PROMOTIONS <p>To support research activities and the expanding branches, the company has continued to create job opportunities, while at the same time promoting the internal growth of existing employees. Wherever possible, we have continued to offer the option of working remotely for several days a week, to help our employees achieve a better work-life balance.</p>
DATA/KPIS	DATA/KPIS	DATA/KPIS
<ul style="list-style-type: none"> • Over 80 agreements with retailers • 95.5% of people have joined at least one supplementary health or pension scheme • €89,616.00 in bonuses awarded • 2 corporate events 	<ul style="list-style-type: none"> • 22 people trained • 100% coverage rate • 145 training activities • 531 hours of training⁴ • 1.42% ratio of training hours to hours worked • 22 people involved in the Development Management system 	<ul style="list-style-type: none"> • 2 new recruits • 34 Employment relationships terminated⁵ • 4 internal promotions • 22 people took advantage of smart working for a total of 7,631 hours
RESULTS ACHIEVED	RESULTS ACHIEVED	RESULTS ACHIEVED
<p>On the basis of the data and the positive feedback received, it can be said that the Bios-Therapy ecosystem has provided its employees with the best possible working conditions, and has also met their needs.</p>	<p>Training opportunities are always welcomed by our employees, who recognise the importance of these experiences both as an opportunity for personal and professional growth and as a way of improving their work. Within the Development Management system, 100% of the evaluations have been completed and 100% of the feedback interviews have been carried out.</p>	<ul style="list-style-type: none"> • 18% internal promotion rate⁶ • 10% increase in job positions • The turnover of personnel leaving Bios- Therapy in 2023 is 0%.

² Through 2 Funds: EST Fund (supplementary health care for employees), qu.a.s. (supplementary health care for managers).

³ Supplementary pension fund for employees FON-TE

⁴ The data refers to training in the form of on-the-job courses, cross-disciplinary skills, internal or external specialisation and academic courses subsidised by the company.

OBJECTIVES, RESULTS AND FUTURE TARGETS

SECOND PUBLIC BENEFIT GOAL

Valuing people

GOALS FOR 2024

Training activities

We will continue to promote training activities for at least 80% of personnel.

✓ 100% of people participated in training activities.

Development Management:

100% of the company's staff will be evaluated as part of the Development Management programme in 2024 as well.

✓ 100% of the company's staff have been assessed as part of the Development Management programme.

Benefits and initiatives for the people of Bios-Therapy:

we will continue to promote social, leisure and benefit activities for the people who work for Bios-Therapy.

✓ Two social events were organised for the company's employees and agreements were maintained with local businesses and supplementary pension services.

GOALS FOR 2025

We will continue to promote training activities for at least 80% of personnel.

We will assess 100 per cent of the company population through the Development Management system.

We will continue to promote social, leisure and benefit activities for the people of Bios-Therapy.

Key

✓ = Objective achieved 🟢 = Objective in progress ⚠ = Objective partially achieved

✗ = Objective not achieved

⁵ 'Terminated relationships' refers to contract expirations, retirements, dismissals, resignations

⁶ Level changes, salary increases, transfers to permanent status

3 THIRD PUBLIC BENEFIT GOAL: PROTECTION OF THE NATURAL BALANCE

From the statute:

Protect the natural balance in all business activities by promoting awareness of the interconnection between humans and nature.

RESULTS ACHIEVED	ACTIVITIES
<p>CLEAN ELECTRICITY</p> <p>To power our production activities and offices at our sites, we purchase electricity from certified low-impact renewable sources with Guarantee of Origin (GO). Since its creation, the company has also purchased electricity from wind and solar power plants.</p> <p>Low-impact renewables ensure the least possible alteration of the ecosystems in which the systems are installed. Wind and solar power are typically low-impact sources of energy, unlike hydropower, which harnesses the power of large waterways.</p>	<p>OTHER ENVIRONMENTAL INDICATORS</p> <p>Our laboratories generate the most significant amount of waste: all of it is collected and disposed of responsibly, in accordance with current legislation. In addition, we have a separate collection system in place at all locations to allow staff to properly recycle waste.</p> <p>We have a closed tank, isolated from the rest of the environment to prevent accidental spillage, into which we pour all the water used in our laboratories. This tank is periodically emptied by an external company that ensures the proper management of the collected water in accordance with regulations.</p> <p>Attention to these details also influences the choice of goods, services and logistics suppliers.</p>
DATA/KPIS	DATA/KPIS
<ul style="list-style-type: none"> • 252,507.95 kWh used annually, taking into account electrical and thermal energy, which correspond to 6,196.36 GJ • 100% electricity from low impact renewable sources: wind and solar • 0.09 kWh OF ENERGY to make 1€ of turnover 	<ul style="list-style-type: none"> • 1.32 tonnes of solid waste • 0.44 tonnes of liquid waste • 0.94 tonnes of miscellaneous aqueous liquid waste (sink waste)
RESULTS ACHIEVED	RESULTS ACHIEVED
<p>Total emissions: 26.60 tonnes of CO₂</p> <p>Avoided emissions⁷ : 28 tonnes of CO₂</p>	<p>The approximately 2.7 tonnes of waste were disposed of by external companies according to the regulations in force⁸.</p> <p>Thanks to the use of biofuels by our transport provider, we have avoided the release of 21.34% of tonne CO₂ into the environment.</p>

⁷ Through the use of electricity from low-impact renewable sources, 28 tCO₂ less was emitted than if we had used energy from traditional energy sources: corresponding to a 51% reduction in emissions. The assessment was carried out using a calculation methodology provided by specialist consultants. Through consultations with authoritative sources such as the Ministry of Economic Development, the Ministry of the Environment and Protection of Land and Sea, and the Ministry of Infrastructure and Transport, the analysis took into account the main emissions for SCOPE 1 and SCOPE 2 of Bios-Therapy, Physiological Systems for Health S.p.A.

⁸ This type of waste is comparable to the category "hazardous waste".

OBJECTIVES, RESULTS AND FUTURE TARGETS

THIRD PUBLIC BENEFIT GOAL

Protecting the Natural Balance

GOALS FOR 2024

Electricity from renewable sources:

We will continue to use more than 80 per cent electricity from renewable sources.

✓ 100% electricity from renewable sources used.

GOALS FOR 2025

We will continue to use 100 per cent electricity from renewable sources.

Offsetting emissions from our shipments:

we will continue to offset part of our shipping emissions through our suppliers' offset programmes.

✓ 21.34% emissions generated (Well-to-Wheel) compared to the use of standard fuels for transport thanks to the use of biofuels

For our shipments we will rely on suppliers capable of reducing the emissions generated by transport activities.

Key

✓ = Objective achieved

≡ = Objective in progress

! = Objective partially achieved

✗ = Objective not achieved

A NOTE ON METHODOLOGY

The Impact Report plays a key role in terms of analysing the activities carried out and it is the result of the company's annual commitment to its stakeholders.

The process of drawing up this document is a complex and multi-faceted one, as it involves the different areas of the company making their own contribution, each in accordance with their areas of competence.

Our Impact Report is a piece of work that involves a multidisciplinary team of different professions, including 'Certified Impact Assessors'. These are members of the Register dedicated to this category.

Reporting takes approximately 4 months from January until the budget is approved. It is divided into five phases:

Data collection, verification and analysis

Drawing on the experience gained over the years, an internal data gathering system has been put in place that ensures complete traceability of the data used in this document to ensure its veracity and correctness, while at the same time guaranteeing complete compliance with the criterion of transparency: a key instrument in this system is the IT platform specially developed in-house and used by the entire company. All non-financial data is requested and gathered centrally by the reporting office and in parallel the accuracy of the financial data is verified by Management Control. Once the reliability of the data has been verified, an analysis is carried out in order to select the most appropriate indicators for measuring the impact of the company's actions in line with its public benefit goals.

Overall impact assessment

The data is also used to track the overall impact of the company, according to standards created by independent third parties, as required by the Benefit Corporation regulations. We currently use the Benefit Impact Assessment, which analyses the areas of Governance, Workers, Community, Environment and Customers, returning a single overall assessment;

Activation of internal offices

To help shape the content of the report, the persons responsible for pursuing the activities related to the specific public benefit goals were identified.

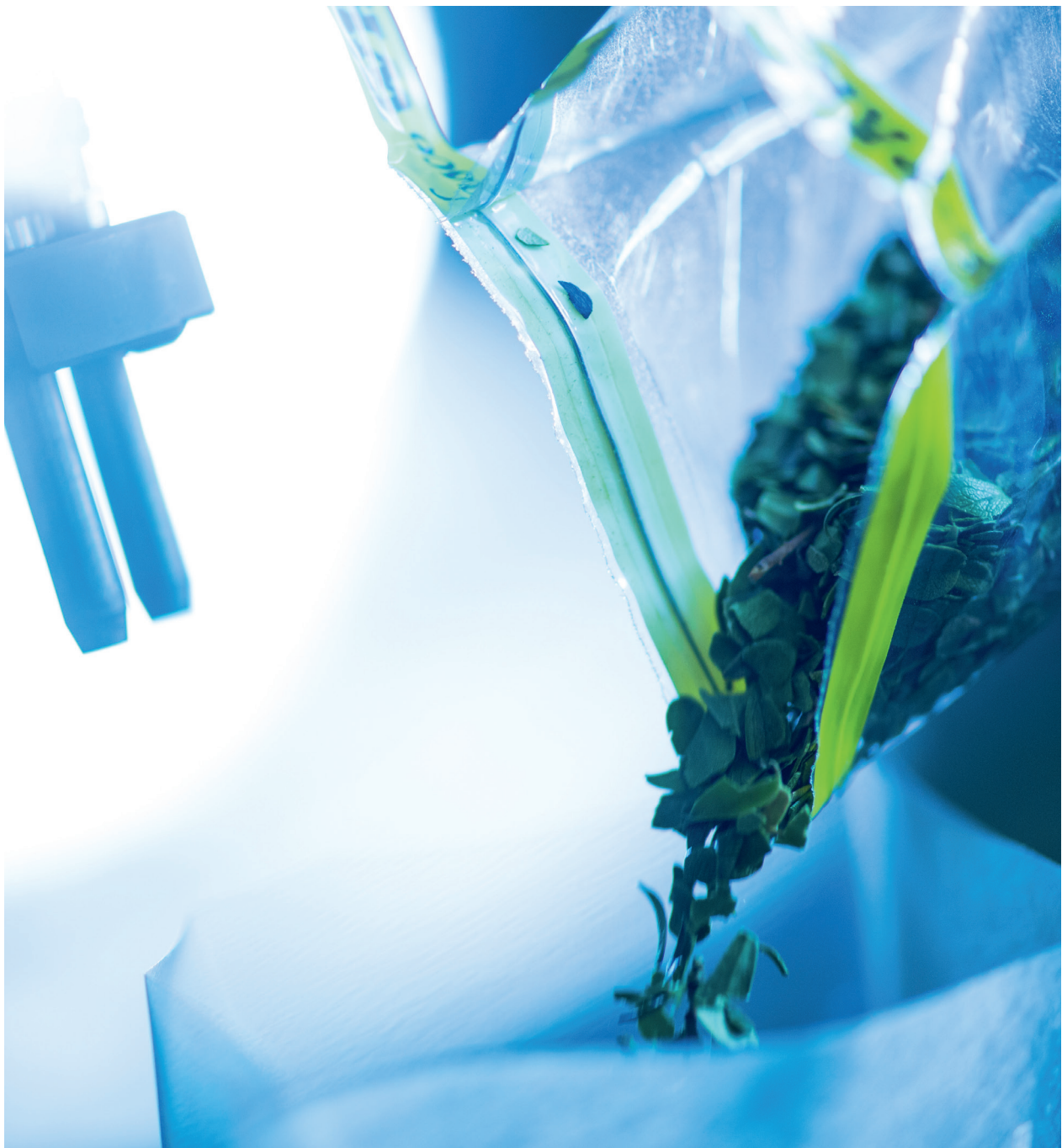
Drafting the report

In accordance with the legal requirements on Benefit Corporations, the report is drafted taking into account the latest developments in non-financial reporting.

Graphics and Copy Editing

In order to make the information in the report more intelligible, our in-house Creative Department works in coordination with the Impact & Sustainability function to produce a material that can be read at different levels.

It is a team effort that we take pride in, with the awareness that we always need to improve. Everything is designed to make this document a real exponent of the change that Aboca helps to generate on a daily basis, delivering the most complete and truthful image of its impact, in line with the legal disclosure requirements imposed on Benefit Corporations. A special thank you to all colleagues who again this year collaborated on this document and to all those who will devote time to our Impact Report.



THE BIOS-THERAPY LABORATORY,
Physiological Systems for Health S.p.a.







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