



VALUE REPORT 2019

**INNOVATING
CURE AND CARE
TO MAKE PATIENTS'
LIVES BETTER.**

VALUE REPORT 2019



A photograph of a modern hospital interior. On the left, there is a row of wooden lockers with green cushioned benches in front of them. The lockers have small circular numbers on them, including 37, 36, 35, 43, 42, 41, and 40. On the right, there is a curved wooden bookshelf filled with books. The ceiling features large, exposed silver ductwork and several cylindrical pendant lights. The floor is made of light-colored wood. In the background, there is a glass-walled area with a white chair and a red ottoman.

INNOVATING CURE & CARE TO MAKE PATIENTS' LIVES BETTER

Z-LIFE

OUR NEW HOME

Z-LIFE, the new home of Zambon, was created within the OpenZone campus to promote our approach based on sharing without boundaries and on our ability to transform ideas into tangible opportunities for patients.

The building was designed by two internationally acclaimed architects, Michele De Lucchi and Carlo Ratti, who respectively oversaw the architectural and interior design.

They set out three objectives:

- Creating a space where people can feel so well that they may work to their greatest ability and conquer unimaginable challenges.
- Developing a positive relationship with both surroundings and nature, while respecting the balance between the two.
- Promoting an approach characterised by open innovation. Z-LIFE was created within OpenZone, the campus focused on health that is home to 27 businesses, including some of the foremost national and international biotech, pharmaceutical and advanced gene therapy companies.

Z-LIFE was designed from the ruins of the previous industrial building, requiring 426 days of work, 3,000 square metres of glass, 250 thousand kilograms of steel and 70 kilometres of electrical wiring.

The building meets the highest sustainability criteria and envisages technologically advanced solutions thanks to BMS (Building Management System), a system that enables monitoring and managing of air conditioning, lights and security through detectors.

Z-LIFE represents the practical implementation of Zambon's identity, a company that faces important global challenges while keeping its 'family ethos' and a unique 'human touch' in taking care of people. Inside the building, there are no walls, and the glass perimeter enhances the flair for open and bright spaces. Workstations open out onto large tables that connect the interior to the exterior while some greenery enters the office space through hydroponic cultivation, fully embracing the biophilia concept.

The construction of the building is an important step of the OpenZone development plan, which will increase the campus to 37,000 square metres by 2021. OpenZone currently encompasses 16,500 square metres of office space, 10,500 square metres of laboratories (of which 1,600 are allocated to *Good Manufacturing Practices*) and is home to 600 people, which will increase to 1,200 in the next two years.





MESSAGE FROM THE PRESIDENT

We value years of growth like 2019 more than ever during this 'strange', almost 'suspended' time; this positive energy helps us to face the delicate situation brought about by Covid-19 with courage, and allows us to look towards the future with confidence.

In the last few months we have had the opportunity to reflect on how a company is, above all, **a community of people who share the same values and a common purpose**. Now we look ahead with a sense of responsibility, in order to measure ourselves also in planning bravely for the future and learning from what we are experiencing. We have **a chance to review and renew ourselves and our role too**.

The credit for these remarkable results goes to the 2,828 Zambon people worldwide, who, through dedication, expertise and spirit of initiative have made our vision come true every day;

'Innovating Cure & Care to make patients' lives better.'

We confidently renew our commitment to improving patients' lives, combining 'cure and care' with a multidisciplinary approach, experimenting with new solutions, more and more

digital, to tackle the health challenges ahead of us.

2019 leads us in this direction; the group's total turnover increases to 769 million euros with an EBIT of 94 million euros. Investments in innovation also increase, towards a stable and promising future.

Zambon Pharma's success continues and is further reinforced through important strategic deals such as the acquisition of Breath Therapeutics in the respiratory field and the exclusive licence deal with Acquestive Therapeutics to address a rare central nervous system condition.

To support the growth of the group, our investments in Research and Development become increasingly significant, along with the strengthening of our industrial plants with sophisticated technological equipment.

Our chemical expertise is internationally recognised thanks to **Zach, Zambon Chemical**, which shows major business development through the acquisition of several projects for scientific innovation and allows us to invest significantly in our plant in Avrillé, France.

ZetaCube's activities also

continue. The group created this research venture in the early 2000's with a pioneering spirit, to identify and develop new solutions through the application of digital technology in the health field. The **ParkinsonCare** project shows the value of making disease treatment a caring experience for the individual through a specialised telenursing service.

In 2019 the community of **OpenZone**, our campus focused on Healthcare, expanded with the arrival of four new enterprises and the launch of several activities aimed at keeping the dialogue alive promoting communication and creating value in a field that is constantly challenged by innovation. The Campus' development plan marks an important step forward with the opening of Z-LIFE, a new home for Zambon created to showcase our way of working based on open innovation and sharing without boundaries.

Within the Campus, our home care division **ItaliAssistenza** is flourishing. Its Patient Support programme activities – developed in collaboration with major pharmaceutical corporations – and the numerous centres engaged in home care have become increasingly well-established and successful.

Taking care of people's health remains our greatest responsibility; we value the individual through our distinctive Human Touch that embodies the way we are, anchored to strong ethical values since 1906;

'Innovation to address Global Health Challenges. Family feeling and a Human Touch to take care.'

The Zoé Foundation, Zambon Open Education, celebrates its 10th year of activity with two challenging projects that promote the Human Touch in healthcare, an approach towards individuals and their relationships becoming central to their treatment.

What we have accomplished in 2019 allows us to rediscover yet again, how drive and determination are powerful inner qualities that guide us towards the future. My wish is that the beginning of 2020 will be **a turning point for a different, better future, which we can build together**.

Have a good journey,

Elena Zambon
President, Zambon S.p.A.





MESSAGE FROM THE CEO



2019 was yet another year where we saw **excellent results and new achievements** for Zambon Pharma.

I am pleased with our performance and the **skill that allowed us to effectively achieve** our ambitious **strategic plan**. Our constant commitment leads us to **innovative responses for patients, researchers, doctors and caregivers**, despite the complexity of the present situation, in which we face the changes dictated by this worldwide coronavirus pandemic on a daily basis.

In 2019, **turnover increased by 6% compared to 2018, reaching 724 million euros**. **EBIT** (Earnings Before Interest and Taxes) **grew by 12%** compared to 2018, hitting **101 million euros**. In addition to its significant financial performance, 2019 will be remembered for the **investment and progress made in our pipeline**. We achieved significant results with PROMIS-1, PROMIS-2, and many more clinical trials all over the world thanks to our **R&D**. We also signed **two valuable deals** that mark a significant transformation for Zambon Pharma. I am referring in particular to the

largest **acquisition** in our history, that of **Breath Therapeutics**, which allowed us to enrich our advanced phase pipeline with trials related to Bronchiolitis Obliterans Syndrome (BOS) – a disease without approved cure – and to become pioneers in the severe respiratory diseases area. Furthermore, we signed an important deal with **Aquestive Therapeutics** to market and distribute an innovative oral film formula of *riluzole* for patients affected by Amyotrophic Lateral Sclerosis (ALS): another sign of our **commitment to research** innovative solutions for people suffering from **rare diseases**.

The focus of our investments is also the quality of our industrial manufacturing. In 2019 we allocated **25.7 million euros** to upgrade our plants with state-of-the-art facilities at the highest technological level. We opened our new plant in Barueri (Brazil), continued to upgrade the one in Haikou (China) by now completely renovated, and created a new strategic manufacturing area in our Open Factory in Vicenza (Italy).

The opening of **Z-LIFE**, a 'new home' for Zambon Pharma, makes me particularly proud. Z-LIFE is the practical

implementation of our vision: a stable and transparent company, ready to take on important global challenges while keeping its 'family ethos' and a unique 'human touch' that holds human relationships at heart.

This year too, our **investments** focused on our most important resource, our **people**, through activities and training courses aimed at achieving our plans of globalisation.

Zambon is a company made by colleagues and now, more than ever, I wish to thank them, not just for their excellent performance and valuable skill, but for their passion, dedication and adaptability to the continuous and ever-changing challenges we face together every day.

Roberto Tascione
CEO, Zambon S.p.A.



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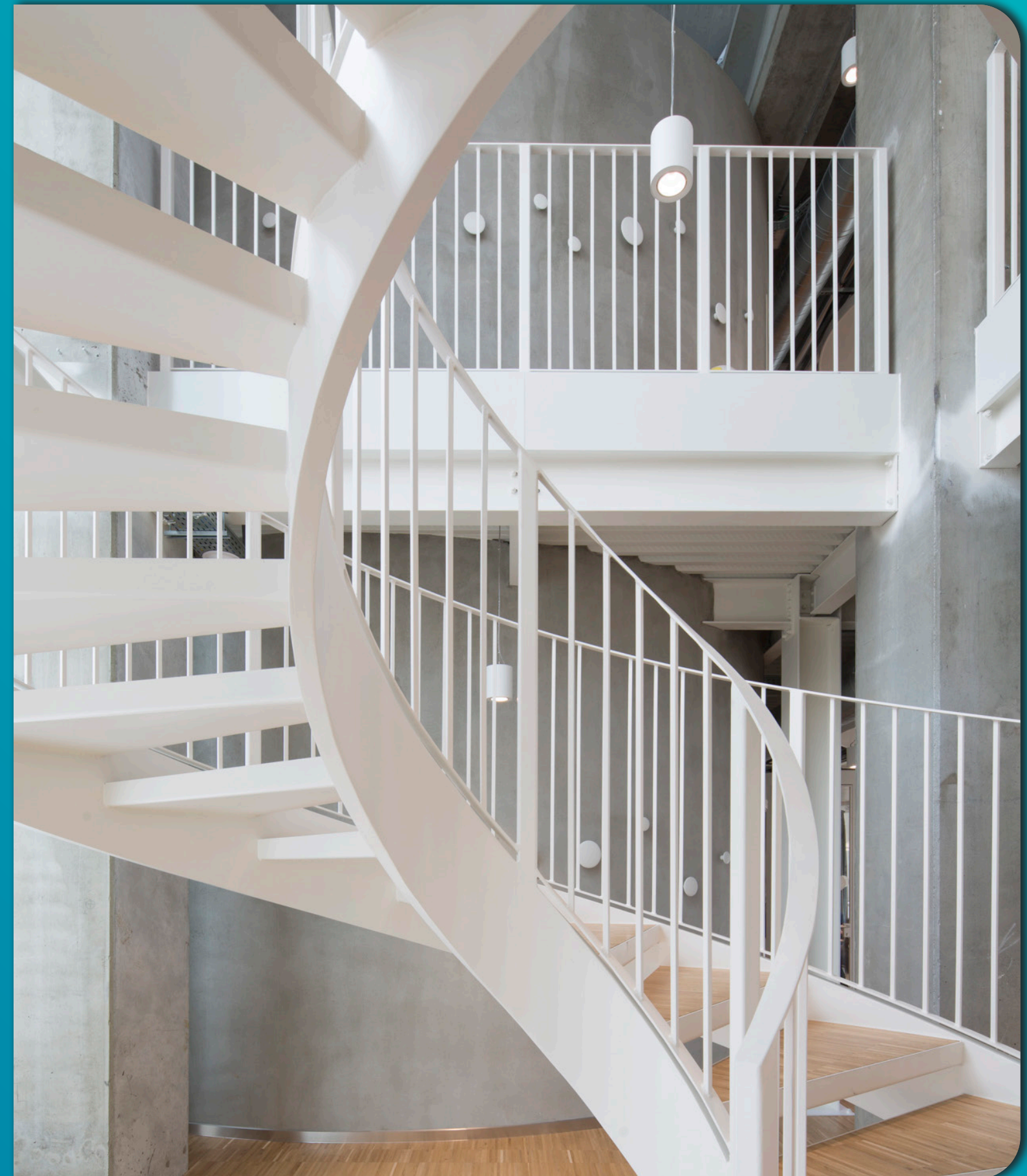
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BUSINESS RESULTS

TOTAL
PHARMA
REVENUES



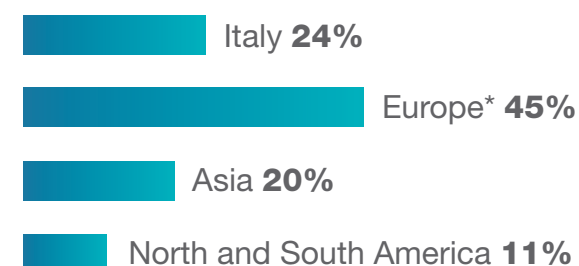
EBITDA



NET
INCOME



SALES BY GEOGRAPHICAL AREA



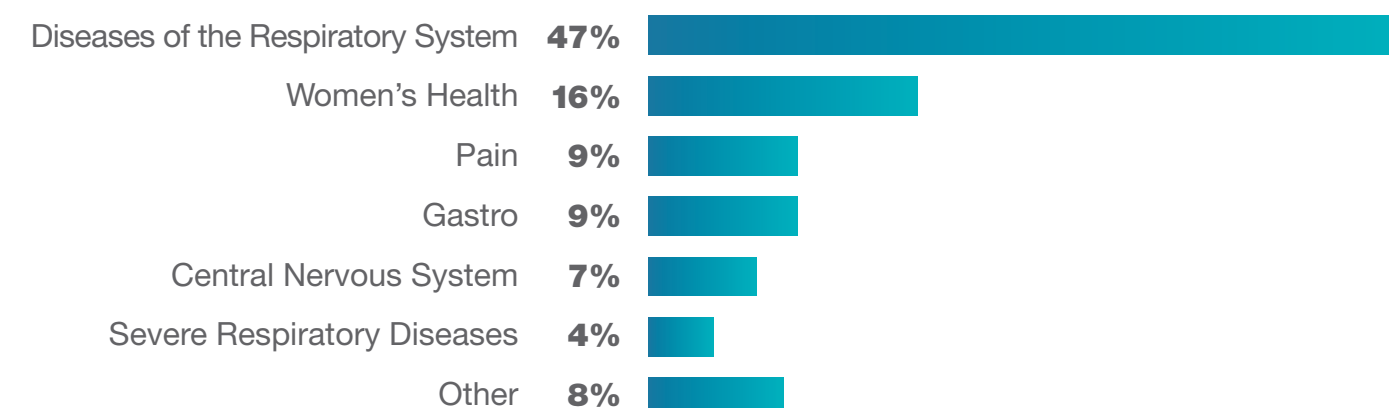
*Italy excluded

#PHARMA PEOPLE



TOTAL **2,533**

PHARMA THERAPEUTIC AREAS



**20 BRANCHES LOCATED IN VARIOUS COUNTRIES INCLUDING SOUTH AMERICA, EUROPE AND ASIA
COMMERCIALISATION IN 87 COUNTRIES WORLDWIDE**

CENTRAL NERVOUS SYSTEM

PARKINSON'S DISEASE

Parkinson's is a neurodegenerative disease that affects the nervous brain cells that control movement. It develops progressively and its symptoms appear gradually and evolve slowly.

It is associated with both **motor symptoms** connected to movement, and **non motor symptoms**, such as fatigue, depression and pain. These symptoms may appear at any stage, even before the motor symptoms¹.

It is a **debilitating condition** with a **high impact on the quality of life** of those affected.

It currently affects 1-2% of the population over 60, reaching 3-5% in the over 85 age range². In addition, there is a progressive increase in its expansion due to the ageing of population and its related medical conditions.

OUR CONTRIBUTION

Our commitment to Parkinson's **started in 2015** when we introduced *safinamide*, firstly in Europe and later in North America, South America and Australia. Over the years we have set up different departments, both locally and globally, focused on allowing access to *safinamide* for an even greater number of patients and also supporting the scientific community and HCPs.

Thanks to its **dual action**, *safinamide* combines a dopaminergic and non-dopaminergic action, thus acting on motor and non-motor symptoms and improving patients' quality of life.

In addition, during these five years of strong involvement, we have contributed to supporting the scientific and medical community through research and training events, and patients through cooperation with their representative groups.

OUR GROWTH PROSPECTS

Since 2015, over **60 thousand patients** in Europe, North America, South America and Australia have benefited from the use of Xadago®. **Geographic expansion** is one of our key objectives. In 2020, we will launch in Brazil, Israel and the United Arab Emirates, with many more countries to follow in the next few years.

By supporting various trials, we are continuing to **produce scientific evidence** which will support treatment options that will deliver increased benefit for patients. Our research is focused on finding increasingly innovative treatment solutions for Parkinson's and other neurodegenerative diseases.

In 2019, we finalised a deal with Aquestive for the distribution in Europe of a **new oral film formula of riluzole** for the treatment of patients with **Amyotrophic Lateral Sclerosis (ALS)**. Our aim is to distribute it as soon as possible in order to improve the quality of life of those affected by this highly debilitating condition.

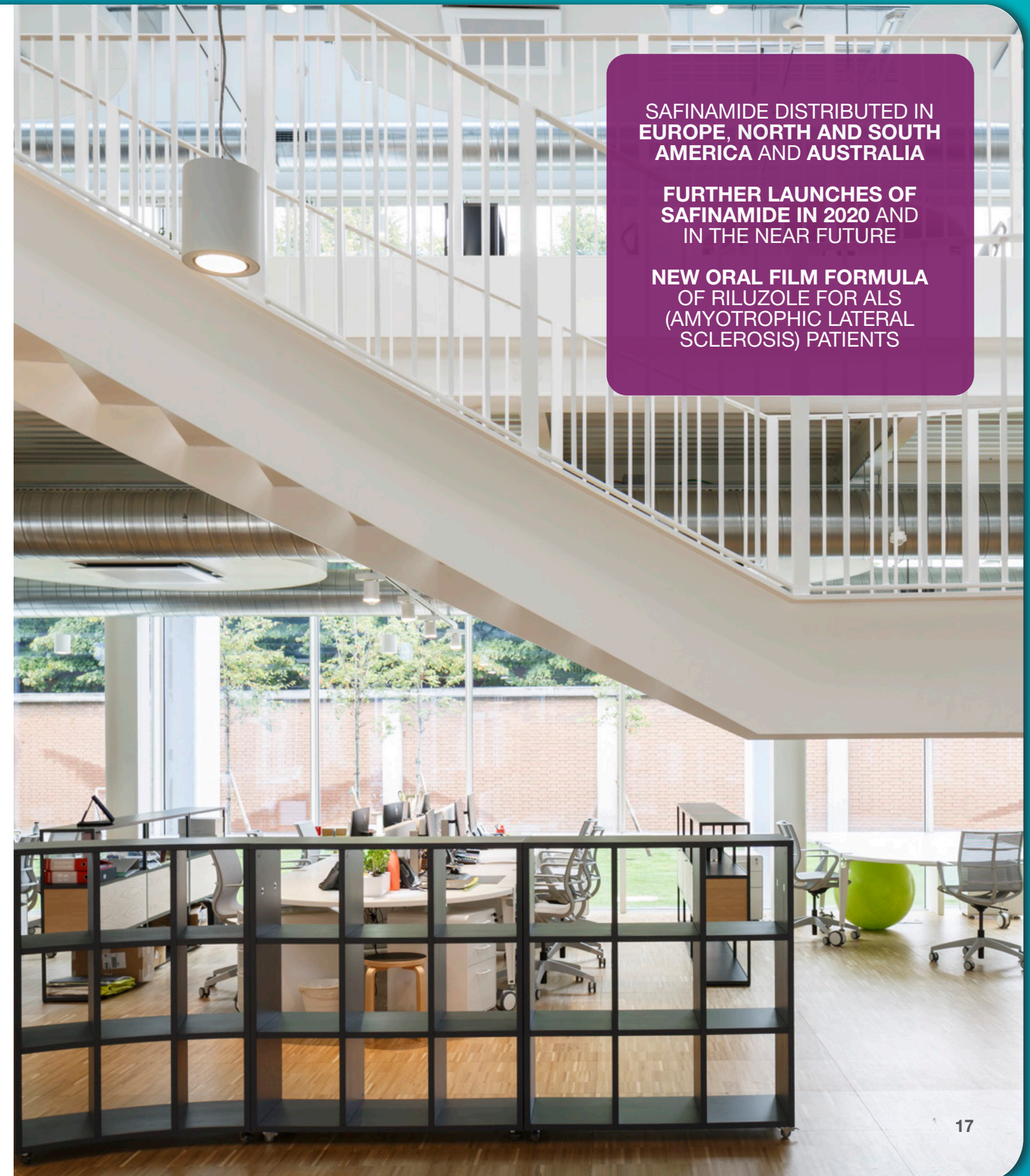
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2. www.parkinson.it/morbo-di-parkinson.html

SAFINAMIDE DISTRIBUTED IN
EUROPE, NORTH AND SOUTH
AMERICA AND AUSTRALIA

FURTHER LAUNCHES OF
SAFINAMIDE IN 2020 AND
IN THE NEAR FUTURE

NEW ORAL FILM FORMULA
OF RILUZOLE FOR ALS
(AMYOTROPHIC LATERAL
SCLEROSIS) PATIENTS



SEVERE RESPIRATORY DISEASES

SEVERE RESPIRATORY DISEASES

Cystic Fibrosis (CF) is the most common **severe genetic disease** and affects approximately **70 thousand people worldwide**. It is characterised by chronic infection of the respiratory tract and causes progressive deterioration of pulmonary function greatly impacting on the quality of life of those affected. Life expectancy in people suffering from CF has experienced a significant increase over the years; a patient born in 2016 has a life expectancy of 47.7 years, compared to just 5 years in the 50's.

This considerable achievement was made possible by ongoing progress in the medical and pharmaceutical fields, the use of antibiotics for chronic infection, and improvement in the dietary field¹.

INNOVATION: OUR SOLUTION FOR PATIENTS

Zambon combines investments in the development of innovative treatments with constant commitment to researching **new solutions to improve the lives of those affected by Cystic Fibrosis**. A prime example is **I-neb® Adaptive Aerosol Delivery (AAD)**, a device developed in partnership with Philips. Thanks to third generation AAD technology and to the possibility of monitoring accurate adherence data, it may offer substantial support to doctors, healthcare professionals and patients.

The two ongoing clinical trials for patients affected by Bronchiectasis validate Zambon's commitment to the research of innovative solutions in the care and management of severe respiratory diseases that require specific needs which remain unmet. Bronchiectasis is a severe orphan disease that is on the increase, yet it lacks dedicated treatment².

TOWARDS NEW GOALS

In 2019, Zambon reinforced its commitment in the field of severe respiratory diseases. In particular, we continue working on the development of **colistimethate sodium (Promixin®)** for the treatment of chronic pulmonary infections caused by *Pseudomonas aeruginosa*.

PROMIS-1 and 2, initiated respectively in 2017 and 2018, are the **only two phase III studies in the world** focused on developing treatment for **Bronchiectasis** and stand out for the significant recruitment carried out in Europe, Australia, New Zealand, United States and Latin America. The two trials involve over 800 patients worldwide.

SOURCES

1. Natalie E. West, Patrick A. Flume. Unmet needs in cystic fibrosis: the next steps in improving outcomes, Expert Rev Respir Med. 2018 July; 12(7):585-593
2. Gregory Tino, M.D. Bronchiectasis: Phenotyping an Orphan Disease, American Journal of Respiratory and Critical Care Medicine 2018; 197:1371-1372

**CYSTIC FIBROSIS IS
THE MOST COMMON
SEVERE GENETIC DISEASE**

**IT AFFECTS APPROXIMATELY
70 THOUSAND PEOPLE
WORLDWIDE¹**

**PROMIS-1 AND PROMIS-2
TRIALS INVOLVE OVER 800
PATIENTS WORLDWIDE**



DISEASES
OF THE
RESPIRATORY
SYSTEM

RESPIRATORY
DISEASES

Respiratory diseases include a wide range of illnesses, from acute seasonal conditions to chronic respiratory diseases such as Chronic Obstructive Pulmonary Disease (COPD) and Bronchiectasis.

According to the WHO, 1 billion people contract the flu every year, and between 3 and 5 million people contract severe flu¹.

OUR GOAL:
STEADY GROWTH

The respiratory therapeutic area represents 47% of the company turnover and is constantly growing. The core product for this area is Fluimucil®, which again this year registered a significant growth (+19%) compared to the previous year. Such results can be attributed to the performance of

the Chinese market – especially in the distribution of ampoules – and to the 7% growth registered in other markets compared to 2018.

Alongside Fluimucil®, a wide range of products in the respiratory area led to a performance aligned with that of the previous year.

COMMITMENT
TOWARDS THE
SCIENTIFIC
COMMUNITY

Fluimucil® is a long-standing Company product, yet investments in the molecule are ongoing. In 2019, Zambon focused on the role of Fluimucil® as an antioxidant for long-term intake. The Company's ongoing commitment towards the scientific community allowed for the organisation of a multidisciplinary Advisory Board focused on the antioxidant activity of NAC (*N-Acetylcysteine*) beyond the respiratory area. A symposium was held at the ERS International Congress where the first edition of *'Break the loop, Breathe free'*, an event dedicated to KOLs (Key Opinion Leaders) and pneumologists around the world, took place. Finally, we continued to invest in China, supporting a clinical study² focused on a new indication of usage for Fluimucil®, which would allow for an improvement in the quality of life for many patients.

SOURCE

- 1. WHO: Global Influenza Strategy 2019-2030, <https://apps.who.int/iris/bitstream/handle/10665/311184/9789241515320-eng.pdf?ua=1>
- 2. A Phase III, multi-centre, randomized, rater- and patient-blind, placebo- and active-controlled, parallel group clinical trial to compare the efficacy and safety of 1-week treatment with intravenous n-acetylcysteine (nac) 600 mg twice daily (active test treatment), ambroxol hydrochloride 30 mg twice daily (active control treatment) and placebo as expectorant therapies in adult Chinese patients with respiratory tract diseases and abnormal mucus secretions

ONGOING COMMITMENT
TOWARDS THE **SCIENTIFIC
COMMUNITY**

**'BREAK THE LOOP,
BREATHE FREE'**
1ST INTERNATIONAL EVENT
DEDICATED TO KOLs AND
PNEUMOLOGISTS

FLUIMUCIL® **+19%**
COMPARED TO 2018

ZAMBON'S SOLUTION

Spidifen® is a **non-steroidal anti-inflammatory drug containing *ibuprofen and arginine salt***. It provides a multi-purpose comprehensive solution for prime treatment of low to moderate acute pain. Available in different formats, it is distributed in **47 countries** in Europe, Asia and South America.

SPIDIFEN®; A TARGETED STRATEGY

THE IMPACT OF ACUTE PAIN

Low to moderate acute pain is a debilitating condition that affects a significant portion of the world's population (85%) especially with regard to **headaches** and musculoskeletal pain¹.

Such symptoms affect over half of the world's population (56%) on a **weekly basis**¹.

Acute pain (low or moderate) often has a psychological impact, in fact, approximately half of the people affected experience an actual psychophysical alteration that makes daily activities unbearable and leads to self-isolation¹.

In 2019, Spidifen® continued the growth trend of previous years achieving revenue of **65 million euros**, and **grew by 13.6% compared to 2018**. This result stems from the significant performance of **China (+26%), Italy (+27%) and Spain (+25%)**. The success and growth of Spidifen® are due to the remarkable results of several markets and a **targeted strategy based on two key factors; growth in the OTC segment and new communication tools** – with contents developed in collaboration with influential characters from the scientific community – **targeted directly at healthcare professionals**.

SOURCE

1. Fonte: GfK Global Pain Index 2017

**56% OF THE WORLD'S
POPULATION SUFFERS
FROM GENERAL PAIN
AT LEAST ONCE A WEEK¹**

**SPIDIFEN® +13%
COMPARED TO 2018**

**COMMUNICATION
WITH PATIENTS USING DIGITAL
CHANNELS**



WOMEN'S HEALTH

A COMMON CONDITION

Urinary tract infections (UTIs) are extremely common; it is estimated that approximately 150 million women are affected each year¹, this figure represents 12.6% of all women¹. 76.7% of these infections are caused by *Escherichia coli*².

Treatment for UTIs is mainly managed with antibiotics. However, in the last few years, traditionally prescribed antibiotics for urinary tract infections have increasingly been associated with anti-microbial resistance and many of them are no longer recommended^{3,4} as first-line treatment.

THE ADDED VALUE IN OUR HISTORY

Zambon's response to urinary tract infections is Monuril® (*fosfomycin trometamol*) which has been used by women all over the world for over 30 years. It is

estimated that from January 2000 to the present day approximately 272 million patients have received it as an oral treatment⁵.

Fosfomycin trometamol is one of the first-line antibiotic treatments recommended by the European Association of Urology (EAU) guidelines and one of its most interesting features is that bacteria resistant to other antibiotics are less likely to be resistant to *fosfomycin trometamol*⁶.

In this respect 'REWIND' (REal World INternational Database), a significant study that analysed data from over 50,000 patients⁷ (Italy, Belgium, Russia and Brazil), is worth mentioning.

Despite the use of different methods for analysing data and sources, *fosfomycin trometamol* turned out to be the most prescribed antibiotic in all four countries. Associated with a high rate of anti-microbial sensitivity to uropatogens² and an effective safety profile^{8,9}, *fosfomycin trometamol* is recommended as first-line treatment for uncomplicated and community-acquired UTIs in both international and European guidelines⁸.

MONURIL®: A STORY OF SUCCESS

In 2019, Monuril® was second in terms of contribution to the company turnover, registering growth of 3% compared to the previous year, and reaching total sales of 92.3 million euros.

Despite competition of the generic products market and price pressure, these results

further reinforce our market leadership in key European countries; Italy, Russia, Spain, Brazil and Belgium had a significant role in contributing to 63% of total sales.

Italy and Brazil in particular, have registered an increase in sales of 6% and 5% respectively, while distributors have seen an increase of 9% compared to the previous year.

This global success is also possible thanks to the contribution of Zambon Switzerland, which in the Cadempino plant manufactures over 19 million units a year for worldwide distribution.

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7. Cai, T., Palagin, I., Brunelli, R., Cipelli, R., Pellini, E., Truzzi, J.C., and Van Bruwaene, S. (2020). Office-based approach to urinary tract infections on 50000 patients: results from the REWIND study. International Journal of Antimicrobial Agents 105966
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MONURIL®: ON THE MARKET
FOR OVER 30 YEARS

OVER 19 MILLION UNITS
MANUFACTURED EVERY YEAR
IN CADEMPINO

MONURIL® +3%
COMPARED TO 2018



ZAMBON PHARMA

INDUSTRIAL BUSINESS OPERATIONS

EFFICIENCY, INNOVATION AND INCREASED COMPETITIVENESS

2019 was a year of great progress for Industrial Business Operations with **significant investment made in all plants**. Today Zambon's plants all work in the same manner, with the same high-quality standards and technological levels worldwide, thus playing an important role in

the success of the strategic plan. In November, we **opened a new production site in Barueri** (São Paulo), **Brazil** which obtained all the necessary permits. This accomplishment is a result of hard work and considerable investments – i.e. **one million euros** allocated to grant higher levels of compliance within the plant – and it makes us particularly proud.

In **Haikou, China**, we carried out the **reengineering of an extensive portion of the manufacturing area of the plant**. This significant investment in technological advancement allowed **production to double** to 40 thousand units per year. In **Cadempino, Switzerland**, we endorsed **investments** targeted at **training** and **process optimisation**. In particular, the 'autonomous maintenance' project, allows staff to operate directly on machinery, resulting in productivity increase and a reduction of interventions.

In **Vicenza, Italy**, it continues the construction of the **new Marco Polo building** for the production of Fluimucil® ampoules 300 mg

for the Chinese market. The IPU2 (Industrial Production Unit) was completed, obtained licences from AIFA (Agenzia Italiana del Farmaco – *Italian Pharmaceutical Agency*) and CFDA (China Food and Drug Administration) IPU2 increased the plant's production capacity from 15 to 40 million units.

The **Virtual Plant** (an organisational model for the centralised management of contract manufacturing of Zambon products) had a key role this year too and was an integral part of the programmes aimed at promoting smooth and increasingly inclusive synergies among plants.

CADEMPINO
Switzerland
70 mio
(units produced)

THIRD PARTIES
AND GENERICS
MANUFACTURERS OF
CARBAPENEMS
16 mio
(units produced)

VICENZA
Italy
73 mio
(units produced)

DEMONSTRATE
THE SITE'S
EXTRAORDINARY
COMPLEXITY
235 SKU

SÃO PAULO
Brazil
4.4 mio
(units produced)

HAIKOU
China
19 mio
(units produced)

**VIRTUAL
PLANT**
12.8 mio
units sold (including
Xadago® for 600K and
Proxinin® for 200K boxes)
141 mio€
global sales
(including Xadago® and
Promixin®)

CONSISTENCY
AMONG PLANTS

QUALITY
AND TRAINING

ADVANCED
TECHNOLOGY



BUSINESS DEVELOPMENT

TARGETED ACQUISITIONS AND GROWTH STRATEGY

The year 2019 will be remembered as the year of Zambon's key acquisitions that allowed us to become pioneers in treatment of both rare diseases and severe respiratory diseases.

The acquisition of Breath Therapeutics, the largest in Zambon's history, was particularly significant. Worth an initial 130 million euros, it will reach a total value of €500 million considering both regulatory and sales milestones.

Breath Therapeutics is a biotech company based in Munich (Germany) and in Menlo Park (USA). Its research is currently focusing on a novel patented liposomal formulation of Cyclosporine A (L-CsA-i) for inhalation administered through a customised device.

With this deal, Zambon broadened its portfolio in the severe respiratory diseases area and **enriched its advanced**

phase pipeline with trials related to **Bronchiolitis Obliterans Syndrome (BOS)**.

Thanks to our global presence, our R&D capabilities and our network within the scientific community, we aim to accelerate the development of a new potential treatment for this disease.

This operation marks the beginning of a new phase for Zambon, not just for the promising pipeline that the company acquired, but also for the new scientific knowledge it will be developing.

Our thorough scouting and evaluation of new opportunities **in the neurological area** allowed us to finalise another important business operation with the American company **Aquestive Therapeutics**.

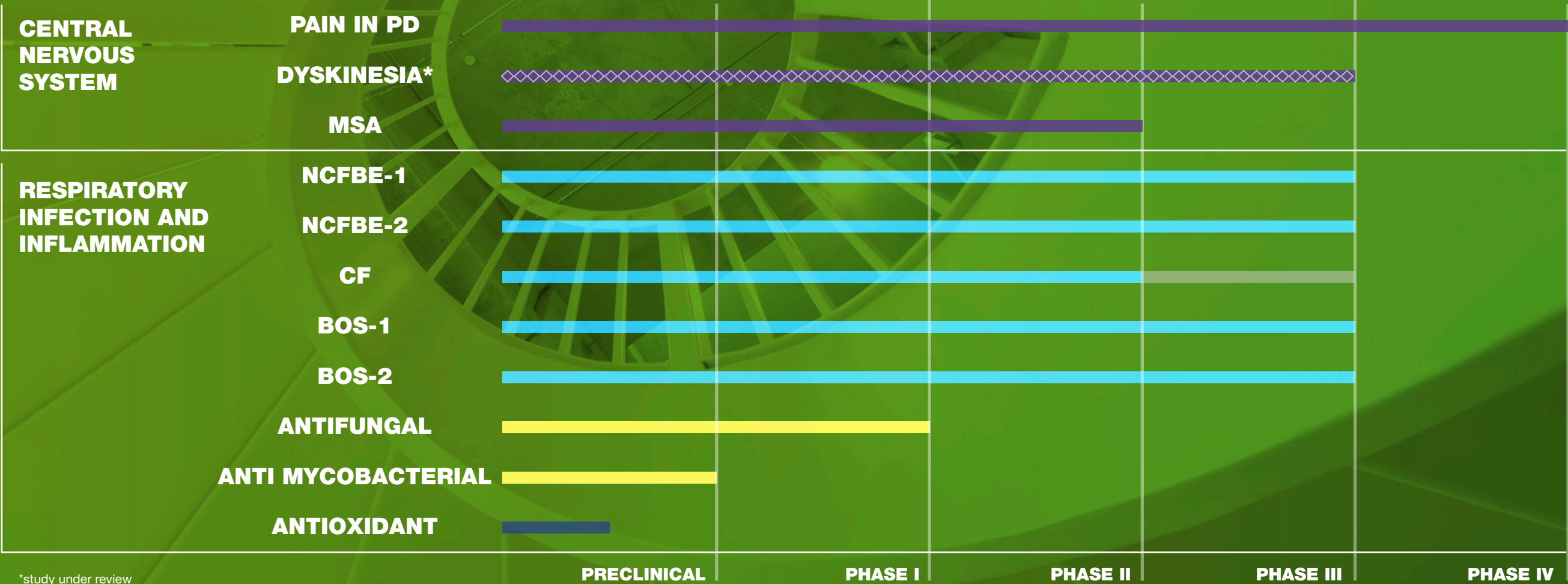
Zambon obtained rights to **distribute riluzole oral film in Europe** for patients affected by **Amyotrophic Lateral Sclerosis (ALS)**. This ground-breaking formula allows intake without water and promotes safety and treatment adherence, having a positive impact on patients' quality of life.

In the coming years, Zambon Business Development will remain focused on early (Next Generation Pharma Assets) and late stage assets in our strategic Therapeutic Areas, CNS and Severe Respiratory Diseases.

ACQUISITION OF
BREATH THERAPEUTICS
DEAL WITH
AQUESTIVE THERAPEUTICS
TARGETED ACQUISITIONS AND
GROWTH STRATEGY



PIPELINE



*study under review

GOOD SCIENCE

INNOVATION AT OUR SERVICE FOR A BETTER FUTURE

In 2019 Zambon continues to show significant progress in Research & Development and successfully reinforces its collaborations with the international scientific community and representative patient groups by participating in international congresses and publishing data in leading journals.

NEURODEGENERATIVE DISEASES

In 2019, the non-clinical programme that supports the dual mechanism of action of *safinamide* progressed, as did the Phase IV trial in Parkinson's Disease related pain (a major non motor symptom of PD) and the Phase I A study in MSA (Multiple System Atrophy) a rare neurodegenerative disorder with a pathogenesis similar to Parkinson's Disease. Results for both these studies are expected in 2021.

The Phase IV observational study 'Synapses' was successfully completed confirming the

safety profile of *safinamide* in routine clinical use. A new phase IV European observational study titled 'Success' started, comparing for the first time the effects of *safinamide* vs *rasagiline* with the aim of evaluating the impact of treatment on patients' quality of life, chronic pain and on direct and indirect healthcare costs.

Three IIT (Investor Initiated Trials) studies are ongoing on the effects of *safinamide* on non-motor symptoms, apathy and chronic pain in Parkinson's Disease.

RESPIRATORY INFECTIONS AND INFLAMMATIONS

Significant progress has been made in the global registration programme for ***colistimethate sodium* administered by the I-neb®** nebuliser for the treatment of Non-Cystic Fibrosis Bronchiectasis (NCFB) patients chronically colonised with Gram negative bacteria *Pseudomonas aeruginosa*. Both studies (PROMIS-1 and PROMIS-2) have continued their patient enrolment, with enrolment for PROMIS-1 due to be completed in 2020 and for PROMIS-2 in 2021.

With the acquisition of Breath Therapeutics, Zambon further strengthened its **advanced phase pipeline in severe respiratory diseases. Bronchiolitis Obliterans Syndrome (BOS)** is a rapidly progressive disease caused by an inflammatory and fibrotic process, commonly affecting patients who have received lung transplantation.

L-CsA-i is a novel liposomal formulation of the immunosuppressive drug ***Cyclosporine-A*** designed for

inhalation and administered through a customised Investigational **eFlow® Technology nebulizer** from PARI Pharma GmbH.

It is administered locally and designed to potentially **slow progression of the disease**, minimising the negative effects derived from systemic administration.

Specifically, two pivotal studies (BOSTON-1 and BOSTON-2) in patients with Bronchiolitis Obliterans Syndrome following lung transplantation are ongoing. All eligible patients included in the trials will be recruited in the open-label extension study (BOSTON-3).

RESPIRATORY INFECTIONS AND INFLAMMATIONS: PROJECTS IN EARLY STAGE OF DEVELOPMENT

In 2019, the development programme of a new dry powder inhaled formulation of *Voriconazole* obtained through the proprietary E-dry® technology has finalised all the non-clinical and pharmaceutical development activity enabling starting of clinical trials and progressed to first in man Phase I studies. E-dry® *Voriconazole* is intended for the treatment of *Allergic Bronchopulmonary Aspergillosis (ABPA)* in asthmatic patients suffering from hyper-sensitivity to *Aspergillus fumigatus*.

E-dry® technology is the basis of two other pipeline projects, both in preclinical development.

The first aims to develop an inhaled antibiotic formulation to treat pulmonary infections due to non-tuberculous mycobacteria, a condition that significantly

complicates the clinical condition of patients suffering from severe respiratory diseases such as Bronchiectasis or Cystic Fibrosis. During 2019, the clinical candidate molecule was identified.

The second development project concerns a new inhaled formulation of an antioxidant molecule to potentially address exposure to toxic particles and chemicals. In 2019, both *in vitro* and *in vivo* tests have been carried out with encouraging results.

FLUIMUCIL® (N-ACETYLCYSTEINE, NAC)

Fluimucil® one of the long-standing products of the company continues to be studied by Zambon. In January an Expert Panel Meeting was held to share, for the first time ever, the clinical practice experiences of world-renowned experts on clinical use of NAC. Furthermore, during the ERS (European Respiratory Society) International Congress in Madrid, Zambon sponsored a symposium on NAC's role in the treatment of chronic diseases of prevalent respiratory interest.

In 2019, NAC registered significant development in the clinical trial field.

In March, the Investigator Meeting for the recruitment of patients for a Phase I and Phase III study was held in Shanghai for the registration in China of intravenous NAC in patients with mucus hypersecretion.

A Phase I study on NAC 600 mg ended in September and demonstrated the absence of differences in terms of pharmacokinetics between

the Chinese and Caucasian ethnicities.

This study represents an important step in the approval process for the use of NAC in COPD, which will engage the Company in 2020.

In terms of 'Investigator Initiated Trials', two studies involving Chinese Investigators (Prof Wen, Prof Li) are being approved by the local ethics committees. They will evaluate the benefit of NAC in Idiopathic Pulmonary Fibrosis and in Non-Cystic Fibrosis Bronchiectasis.

At the end of the year, the NIH (National Heart, Lung, and Blood Institute) approved funding for a study (PRECISIONS) that will evaluate the clinical efficacy of NAC in patients with Idiopathic Pulmonary Fibrosis carrying a gene variant (TOLLIP rs3750920 TT genotype). This two-year study will seek to clarify the benefit of NAC in a particular type of disease, which requires genetic diagnosis for identification.

N-ACETYLCYSTEINE IN PATIENTS WITH RETINITIS PIGMENTOSA

In the United States, a study was concluded on the use of *N-acetylcysteine* in patients with retinitis pigmentosa, a rare and severe genetic orphan disease that affects the pigmented epithelium and retina, leading to a gradual and progressive vision loss. The first results of the study were published in the Journal of Clinical Investigation and confirm the benefit of NAC in patients with moderate to advanced forms of the disease.

Based on these promising results, an extension phase of the previous study was approved.

It will last two years and will evaluate the benefits of NAC in long-term treatment of retinitis pigmentosa.

MONURIL® (FOSFOMYCIN TROMETAMOL)

In 2019, the international SURF study aimed at assessing the rate of antibiotic resistance to *fosfomycin* and other antibiotics commonly used in urinary tract infections finished its data collection, with the ultimate goal of detecting a lower resistance to *fosfomycin* compared to other antibiotics.

In June 2019, the second Advisory Board was held with various international KOLs participating in an epidemiological study aimed at understanding the discrepancies between international and local guidelines, and clinical practice in the treatment of urinary tract infections. This study called REWIND (REal World International Database) analysed data from over 50,000 patients. The results of this international study will be published in a peer-reviewed journal in 2020.



ZACH

BUSINESS RESULTS 40

ZACH 40



ZACH

PROGRESS IN THE DEVELOPMENT OF CHEMICAL BUSINESS

Zach is the chemical division of the Zambon Group focused on producing Active Pharmaceutical Ingredients (API) and advanced intermediates for the pharmaceutical industry.

Today, Zach's headquarters are located in Bresso and its manufacturing in Avri  , France. Its activities are mainly focused on Custom Synthesis and some output for the generic products market.

Within this framework – and in synergy with Zambon's pharmaceutical business – through an ongoing investment plan we are updating the chemical plant, increasing its quality and performance standards and improving its competitiveness.

'In 2018 we introduced a five-year plan which we put into practice in 2019. We started off with a detailed operational plan and continued with investments, targeting plant modernisation. We finalised the revamping of R&D laboratories, started the digitalisation process of Quality Control Laboratories, and continued with equipment automation activities. We also launched the restructuring of the company's main functions, which will allow us to undergo the complete modernisation process that we have envisaged.'

The results we achieved in 2019 have been exceptional. Thanks to new projects developed with key startups and to the crucial contribution of R&D services provided to third parties, we were able to close the year with an EBITDA 58% higher than predicted.'

Lucio Lavacchielli
CEO Zach System S.p.A. and S.A.

BUSINESS RESULTS

EBITDA

4.5
mio  

NET INCOME

2.1
mio  

SALES REVENUES



33
mio  

#ZACH PEOPLE

Production	155
R&D	19
G&A	13
Sales & Marketing	3
TOTAL	190

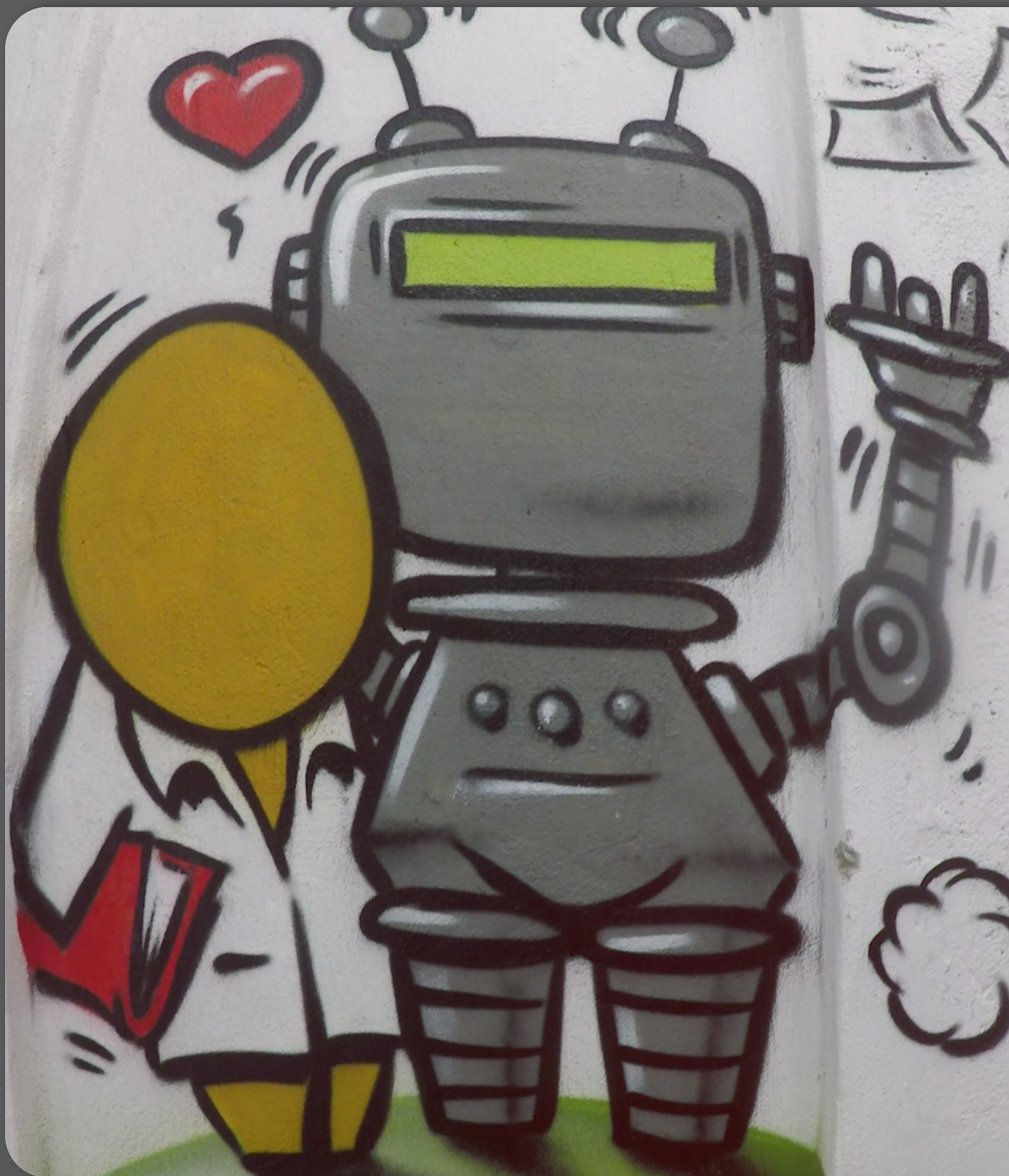


% REVENUES BY SEGMENT



% REVENUES BY GEOGRAPHIC AREA





ZCUBE

ZCUBE 46
OPEN ACCELERATOR 48
CAREAPT 50



WE EXPLORE THE WORLD OF INNOVATION

Zcube is the Research Venture of the Zambon Group. It was established in 2003 to explore innovation and research in the Life Science field on a global level and is **specialised in supporting the development and acceleration of innovative startups** involved in areas of interest such as issues linked to respiratory or neurodegenerative conditions.

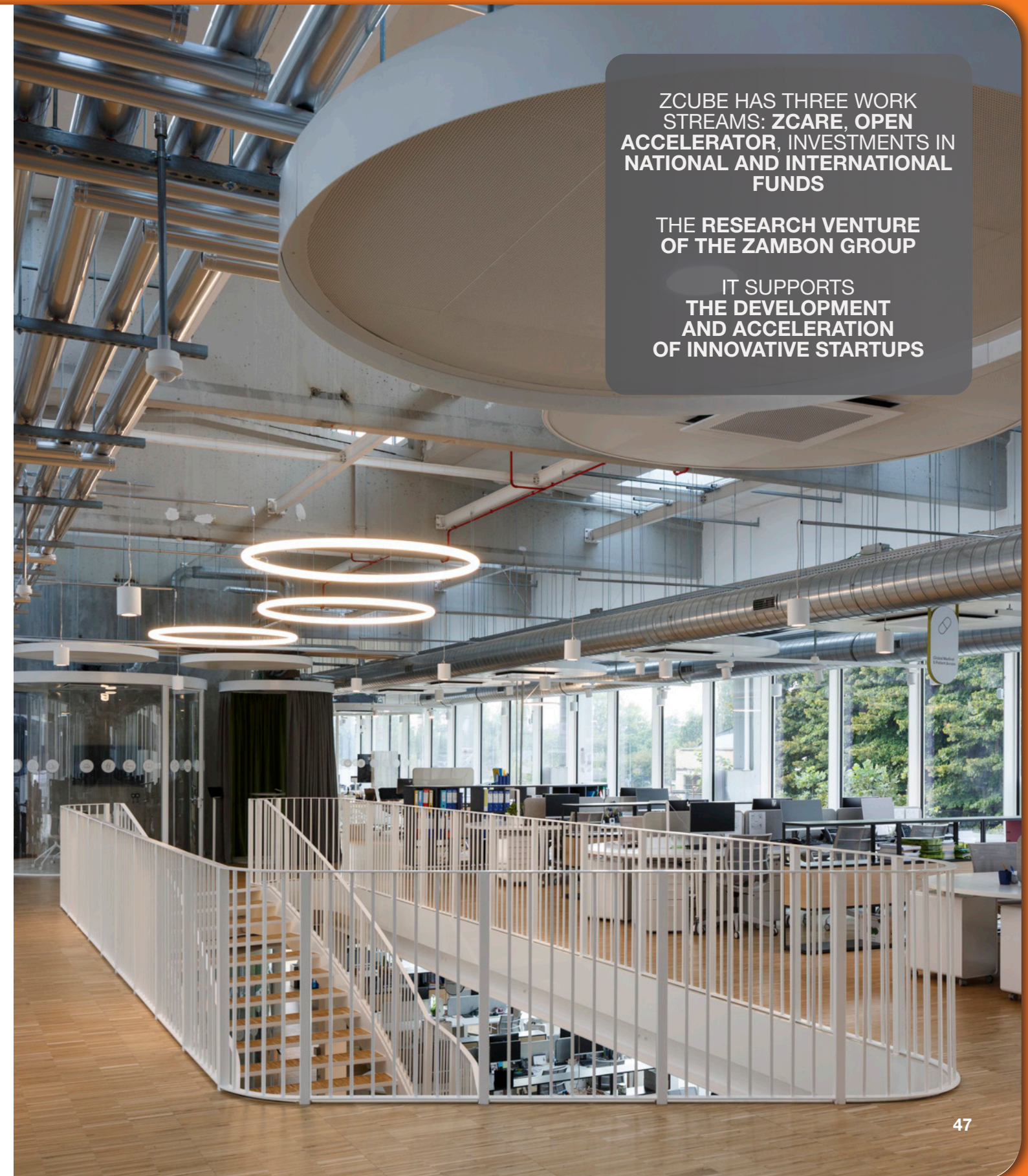
Zcube has three work streams:

- **Zcare** – a division focused on the development of innovative solutions inspired by the principles of value-based healthcare established to meet the needs of all stakeholders in the healthcare ecosystem, from patients to caregivers. Over the years, this division has become increasingly important, so as to create the newco Careapt.
- **Open Accelerator** – a business acceleration venture created to identify and support companies involved in patient management (Care) before and after treatment (Cure), which offer innovative products and services in the fields of diagnostics, digital health, biomedical devices and value-added services.
- **Investments in national and International funds** engaged mainly in the Life Science field.

ZCUBE HAS THREE WORK
STREAMS: **ZCARE, OPEN
ACCELERATOR, INVESTMENTS IN
NATIONAL AND INTERNATIONAL
FUNDS**

**THE RESEARCH VENTURE
OF THE ZAMBON GROUP**

IT SUPPORTS
**THE DEVELOPMENT
AND ACCELERATION
OF INNOVATIVE STARTUPS**



OPEN ACCELERATOR

SOLUTIONS FOR THE FUTURE OF HEALTH

Open Accelerator is an international acceleration programme for startups in the Life Science field. Launched in 2016, it marked its third year in 2018, and has attracted the participation of hundreds of startups through international calls. In the latest Open Accelerator edition, in line with Zambon's strategy, we specifically addressed the therapeutic areas of the Central Nervous System and Respiratory, including rare diseases in both areas. **In 2019, the Open Accelerator team focused on strengthening its relationship with award-winning startups from previous years, finalising seed investments and supporting follow up activities.** In particular, we launched the 'Partnership Engagement' project for three of the winning startups in 2018: Vilimball, Mobile GaitLab (involved in the Parkinson's/CNS fields) and LungPass (involved in the COPD/respiratory field). Thanks to our cooperation with a leading consulting company, **we built a business case for each of the three startups to assess the best strategic fit with Zambon** and identified tangible cooperation opportunities.

OPEN ACCELERATOR IS AN
INTERNATIONAL FAST TRACK
ACCELERATION PROGRAMME
FOR STARTUPS IN THE LIFE
SCIENCE FIELD

BUSINESS CASE AND
STRATEGIC FIT WITH ZAMBON
FOR THE WINNERS FROM THE
THIRD EDITION

SEED INVESTMENTS FOR
WINNING STARTUPS FINALISED



CAREAPT

FROM DISEASE MANAGEMENT TO PERSONALISED CARE

Careapt is the newco, established in 2018 and fully owned by Zcube, which develops integrated Hi-Tech/Hi-Touch solutions for chronic disease management.

Careapt brings digital and social innovation together to transform chronic disease treatment into a person-centered **experience of human relation and care.**

With its specialist expertise in chronic neurodegenerative and respiratory diseases, Careapt combines digital technologies and nursing skills with the aim of providing continuity of care to people with chronic diseases by fostering the empowerment of patients and their caregivers, and strengthening coordination among health professionals who support them, in a way that is sustainable for the healthcare system.

The first solution developed by Careapt is ParkinsonCare; a dedicated telenursing service that delivers specialised assistance to people with Parkinson's Disease, to their caregivers and to their healthcare team.

Through a collaboration platform coordinated by a case manager, ParkinsonCare provides daily support to patients and caregivers in the management of symptoms, while sharing with other professionals in the healthcare team the clinical information that promotes evidence-based, concerted and prompt action. With this service,

each patient and their caregivers are assigned two specialised nurses who provide nursing assistance for the management of characteristic symptoms of Parkinson's Disease. The skill profile of ParkinsonCare nurses and the clinical algorithms guiding their operations are designed by an international team headed by Professor Sue Thomas from Parkinson's Academy.

The assistance programme is designed to guarantee ease of access, appropriate clinical monitoring and emotional support in the difficult task of dealing with numerous symptoms of the disease. To this end, the nurse uses a digital platform to accelerate and facilitate the physician's access to clinical data required to support the suitability of therapeutic decisions taken remotely.



DIGITAL AND SOCIAL INNOVATION BROUGHT TOGETHER

PARKINSONCARE: SPECIALISED TELENURSING SERVICE FOR PEOPLE WITH PARKINSON'S DISEASE AND THEIR CAREGIVERS

EASY ACCESS, APPROPRIATE CLINICAL MONITORING AND EMOTIONAL SUPPORT



OPENZONE

OPENZONE 56



OPENZONE

WHERE INNOVATION AND RESEARCH ARE TURNED INTO ENTERPRISE

Taking care of people's health is a great responsibility and, in a field constantly challenged by innovation, it is important to maintain an ongoing dialogue. In 2001, the Group became aware that communication was essential in ensuring that intuition, ideas and solutions could turn into tangible opportunities for patients. Our commitment is to establish a new shared way to promote high-quality research while continuing to create value by promoting business initiatives with fast and easy access to expertise and capital.

OpenZone was created for this reason, and through ongoing and increasing investments it continues to play a solid and substantial part in the development of Life Sciences in Italy. In 2018, we devised a development plan with an investment of over 60 million euros which will increase the campus to 37,000 square metres. Currently, the campus is home to 27 businesses, including some of the foremost national and international biotechnology, pharmaceutical and advanced gene therapy companies.

2019 was a very busy year for OpenZone as four new businesses joined the 'Zoners': Careapt, FlowMetric Europe, Apply and Diadem. This expansion of the community, in conjunction with the ongoing development plan, took an important step forward with the launch of Z-LIFE, Zambon's new

home, a 4,000 square metre open space. AmdI Circle took care of the architectural design, while the interior design was assigned to Carlo Ratti Associati.

OpenZone, in cooperation with Assobiotech and Italian Angels for Biotech, also hosted the opening event for Biotech Week, where the role of Lombardy as a Life Science Hub for Italy and Europe was discussed.

Over the year many guests participated in the OpenZone Talks – meetings with innovation leaders and international experts of the scientific, economic and institutional fields.

Among the many speakers in 2019, some of the highlights were: Luca De Biase (Innovation Editor for Il Sole 24 Ore), Roberto Ascione (CEO and Founder of Healthware International), Marta Gaia Zanchi (Founder and Managing Partner of Nina Capital), Daniele Manca (Assistant Manager for Corriere della Sera) and Beniamino Pagliaro (CEO and Founder of Good Morning Italia).

ONGOING INVESTMENTS TO FOSTER THE DEVELOPMENT OF LIFE SCIENCES FIELD IN ITALY

A SIGNIFICANT STEP IN OUR DEVELOPMENT PLAN: Z-LIFE, A NEW HOME FOR ZAMBON

4 NEW ZONERS IN OUR COMMUNITY AND INCREASING PARTICIPATION IN OUR OPENZONE TALKS





ITALIASSISTENZA

ITALIASSISTENZA 62



ITALIASSISTENZA HOME CARE THAT GOES BEYOND TREATMENT

ItaliAssistenza S.p.A. is a subsidiary of Zambon Company S.p.A. and provides private home care in Italy and Switzerland to patients suffering from chronic diseases, in total compliance with the Human Assist Care spirit.

Human Assist Care is the new Group brand aimed at innovating the home care sector in Italy and Europe. In 2019, ItaliAssistenza registered revenues of 9.8 million euros.

Individuals and their well-being lie at the heart of this project (**Human**) which, through highly qualified assistance (**Assist**), takes care of the patient (**Care**).

Launched in 2017, Human Assist Care also represents the first strategic step that will allow ItaliAssistenza to become an increasingly international brand. In fact, our first directly managed Home Care Centre based in Lugano (Switzerland) is up and running servicing the entire Canton Ticino area.

ItaliAssistenza is a market leader in Italy for promoting home care management of chronic disease treatment through **Patient Support Programmes** (PSPs) that support pharmaceutical treatment developed in collaboration with major pharmaceutical corporations.

PSPs seek to ensure adherence to and efficacy of pharmaceutical treatment, and require planning a system of home assistance, telephone and technological services, that meet chronic

patients' needs for the duration of treatment.

Poor adherence is in fact the main cause for ineffective treatment. Studies have shown that **adherence rates are lower than 50%** in many chronic diseases, with severe outcomes for patients and the health system. PSPs ensure an increase in such rates, achieving optimum adherence in numerous cases.

In order to develop such programmes, ItaliAssistenza relies on a **team of professionals from the sector** who design, set up and coordinate all the activities necessary to satisfy specific needs for patients and their treatment.

The company has been running in Italy since 1993 thanks to **Privatassistenza**, a national market-leading network that currently has over 200 home care centres in its membership. Such centres offer social welfare and healthcare activities provided by qualified professionals.

REVENUES OF
9.8 MILLION EUROS

MARKET LEADER IN ITALY
FOR SUPPORT IN HOME CARE
TREATMENT OF CHRONIC
DISEASES THROUGH **PATIENT
SUPPORT PROGRAMMES**

PRIVATASSISTENZA:
A NATIONAL NETWORK THAT
CURRENTLY HAS OVER 220
HOME CARE CENTRES IN ITS
MEMBERSHIP





THE GROUP

BUSINESS RESULTS 68

PEOPLE & CULTURE 70

ZOÉ FOUNDATION 72

ZAMBON AROUND THE WORLD 76



▶ THE GROUP

BUSINESS RESULTS

EBITDA*



NET INCOME*



TOTAL REVENUES

data in mio€



* Italiassistenza S.p.A. (+ Privatassistenza SA), Zambon Group S.p.A., Zambon S.p.A., Openzone S.p.A., Zetacube S.r.l. (con Careapt Srl), Zach System Spa

** restated data in order to make a better comparability of the information reported

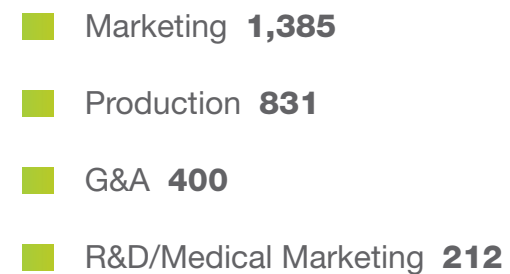


50%
women



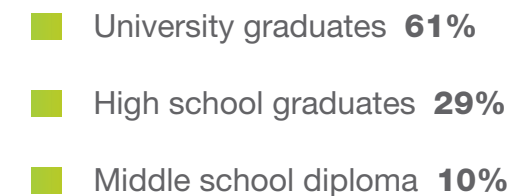
50%
men

#OUR PEOPLE



TOTAL **2,828**

EDUCATION



THE GROUP

PEOPLE & CULTURE

TOWARDS EXCELLENCE THANKS TO OUR PEOPLE

The ambitious results achieved in 2019 are not just the outcome of our long-term company strategy, but are also a result of passion, expertise and strong sense of belonging shared by our people.

ONGOING EVOLUTION FOR OUR COMPANY

In 2019, our organisation evolved both globally and locally. To ensure business sustainability, we strengthened the organisational structures, reinforced the expertise and introduced new skills, in particular in the Open R&D, Finance, ICT, Region RoW and Commercial Excellence areas. Over the year, we also worked on the acquisition of Breath Therapeutics, thus enriching Zambon by integrating new professional skills into the company thanks to workflows

defined in cooperation with our new colleagues. At the same time, we continued to focus on our partnership with AstraZeneca in China. This venture had a significant impact in 2019 on the organisation of our manufacturing plant in Vicenza where we hired new staff members and defined training paths to encourage skill development.

People Management was fundamental in supporting this transformation as it managed to consolidate and develop our staff's technical and managerial skills, as well as guide their commitment towards the accomplishment of our business goals.

LEARNING & DEVELOPMENT

In 2019, in terms of development, we worked on the up-skilling of all company functions to allow our employees reach increasingly challenging goals and higher positions within the company. In order to do so, we defined a skill chart with the requirements of each professional area. We also created a series of 'professional communities' projects, such as the up-skilling of World Medical Directors and the Global Marketing Academy (which focused on the development of skills used to define an omnichannel marketing strategy).

In addition, in 2019 we designed over 600 Learning Programmes, managed almost 2,000 training courses with the participation of approximately 2,800 staff members and provided approximately 20 hours of training per person. We also strengthened the activities of our Digital School, a programme focused on digital literacy and mindset change, involving

approximately 1,350 people from offices, manufacturing plants and sales in Italy, Spain, Switzerland and France. Finally, in 2019 the language-based programme 'Becoming Global', which was also made available worldwide, saw the participation of 60% of our Corporate team.

YOUNG TALENTS

In 2019, Zambon continued investing in its young talents as 17 young staff members from different Zambon locations participated in the third Up-Days event.

The programme included participation in the 2019 World Business Forum, as well as training and engagement activities featuring one of the key principles of Zambon's leadership 'Be Supportive!'. 'Z-Gen', our recruitment programme, also continued for 24 months, focusing on three strategic areas within the company (one of which is international), to hire the best talent on the market. In 2019, we added some new young team members in the fields of Global Strategic Planning & Commercial Excellence, Open R&D and ICT and hired young employees from previous Up-Days events.

BENVIVERE

Launched over a decade ago, **Benvivere** embodies the Zambon mindset 'taking care of our people'. It contributes through a number of projects, activities and services, to the creation of a community with a strong identity and a shared sense of belonging.

In this spirit, we have provided training for our people to encourage their curiosity and openness to communication and to promote personal interaction amongst themselves. We also organised several sporting events to further promote wellbeing and a sense of community.

Benvivere also means taking care of our people's families, and this is why we offer training courses and support the education and employment of our employees' children.

Taking care of our people's health is also a priority, and this is provided with medical check-ups and specialist appointments.

Finally, Benvivere supports several local non-profit organizations through solidarity campaigns designed to give constant support to those in need.

LEARNING & DEVELOPMENT:
OVER 600 LEARNING PROGRAMMES, 2,000 TRAINING COURSES, PARTICIPATION OF APPROXIMATELY 2,800 STAFF MEMBERS

DIGITAL SCHOOL: 1,350 PEOPLE INVOLVED IN ITALY, SPAIN, SWITZERLAND AND FRANCE

BECOMING GLOBAL:
WORLDWIDE LANGUAGE PROGRAMME

THE GROUP

ZOÉ FOUNDATION – ZAMBON OPEN EDUCATION

TEN YEARS TOGETHER

In 2019, the Zoé Foundation celebrated its tenth year of activity in the Vicenza area. Ten years characterised by commitment, dedication and passion, with the goal of contributing to the development of knowledge, information sharing and improved communication with those in the healthcare field.

In ten years of the autumn event **'Vivere Sani, Vivere bene'** (*Live healthily, Live well*) we have talked about health to 75,000 people of all ages, through conferences featuring over 350 nationally and internationally acclaimed experts, stage productions, concerts and workshops. In 2019, under the title of **Gli Orizzonti della Salute** (*Healthcare Horizons*), the Zoé Foundation addressed topics such as breathing, human relationships and mental health, portraying health, both physical and mental, as an integral part of daily life, but also as something

that evolves and needs to be nurtured while looking ahead, into the future.

Following this approach, in December the Zoé Foundation launched two new projects; the **Human Touch Academy**, which is a range of courses targeted at professionals and caregivers that focus on the relationship between patients and healthcare professionals as a means of treatment; and **Home Care Design for Parkinson's Disease**, which offers guidelines for the design and implementation of a safe, accessible home environment and improves the quality of life for Parkinson's patients, those with other motor disorders and the elderly.

The Foundation, through our branch in Bresso, launched a season full of events in Oxy.gen, managed in cooperation with the town of Bresso and Parco Nord Milano, dedicated to sciences, health and the environment.

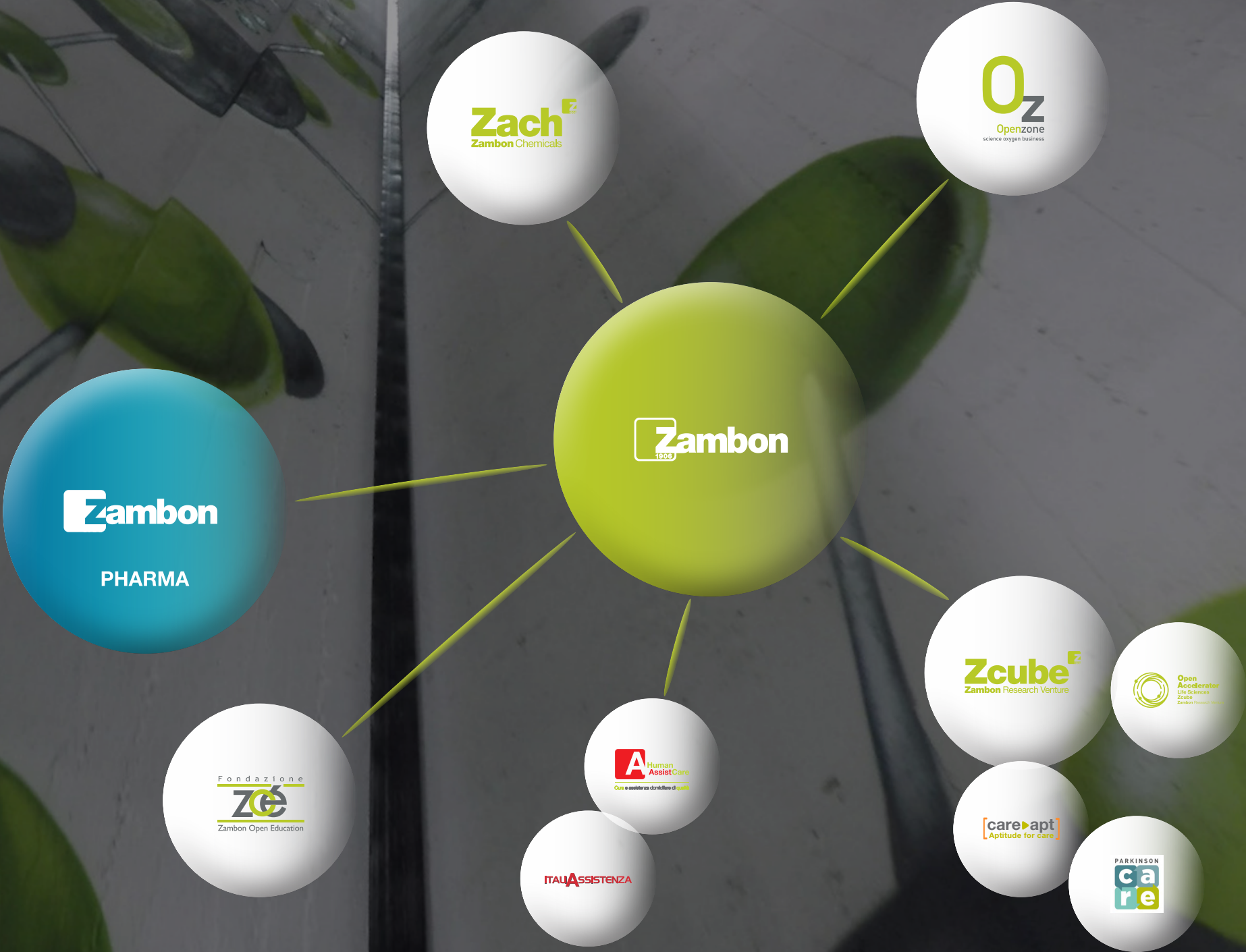
TENTH YEAR OF ACTIVITIES

IN TEN EDITIONS OF **'VIVERE SANI, VIVERE BENE'** (*LIVE HEALTHILY, LIVE WELL*) WE HAVE SPOKEN ABOUT HEALTH TO 75 THOUSAND PEOPLE AND HELD CONFERENCES WITH OVER 350 NATIONALLY AND INTERNATIONALLY ACCLAIMED EXPERTS

OXY.GEN: SEASON FULL OF EVENTS FOCUSED ON SCIENCE, HEALTH AND ENVIRONMENT

'Only the broadening of one's scientific knowledge and the tireless study of social and organisational issues enables one to rise above mediocrity and become truly useful and almost indispensable.'

– **Gaetano Zambon**, July 1938



THE
GROUP

AROUND
THE WORLD

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