Pharma Zambon SpA 2016



Medicines to make patients' lives better



Giving back time to enjoy life

Parkinson's disease is the second most frequent chronic neurodegenerative disease after Alzheimer's disease: worldwide it affects up to 2% of people over the age of 65 and up to 5% of people over 85. In the future, Parkinson's patients are expected to grow globally, due to population aging and the increase of comorbidities.

Unfortunately, Parkinson's disease does not affect only the elderly: the so called "early on set" can affect people between 20 and 50 years of age - and "young onset" can affect people under the age of 20 due to purely genetic causes and range from 5% to 10% of the total patient population.

In Germany, **Wilfried** was diagnosed with Parkinson's disease at the age of **35**. "At first, considering my young age, I felt that the world collapsed upon me. I withdrew from social life, distancing myself even from my wife and daughter. The burden was so heavy that I didn't want to live anymore."

Diagnosis of Parkinson's disease is basically set on the manifestation of few symptoms, including: muscular rigidity, resting tremor, postural instability and slowness of movement. As stated by **Bruno**, an Italian patient, who was diagnosed at the age of **49**: "...I noticed that my left leg didn't respond properly causing a slight restrain in movement. At that time, I didn't realize what was happening: only two years later, as the discomfort continued to increase I decided to consult a neurologist."

Besides pharmacological treatments, patients approach to the disease has a great importance. **Fatima**, a Moroccan patient diagnosed with the disease at the age of **53**, likes to prepare couscous for the entire family: a small daily activity, a positive approach to life.

*Source: http://www.parkinson.it/morbo-di-parkinson.html

Zambon daily commitment: improving patients' lives Two questions to Wilfried, Bruno and Fatima

Q1. What would you do if you had an extra hour of "good ON time"?

Q2. What are your hopes for the coming years?



Wilfried

German patient, diagnosed with Parkinson's disease at the age of 35 **A1:** I would enjoy spending more time with my partner.

A2: I hope that my disease won't progress too quickly so that I will be able to carry on my volunteering activities for a long time. For me it is also important to get clarity on the future of young Parkinson's disease patients.

Bruno

Italian patient, diagnosed with Parkinson's disease at the age of 49 A1: I would make a 10 km run.

A2: I am an optimist therefore I hope to experience first-hand the victory over Parkinson's disease. Perhaps, I should have been born 30 years later to be able to benefit from the results of the research efforts in this field.

Fatima

Moroccan patient, diagnosed with Parkinson's disease at the age of 53 **A1:** I would cook a good couscous for my family and return to create small handcrafts.

A2: I would like my clinical symptoms to decrease, in particular tremors.

PHARMA

56 Zambon will continue to invest in research on Safinamide over the coming years Zambon reason for being can be summarized in a simple but challenging sentence: **developing medicines to improve patients' lives**. Under this principle, the company has fully entered into a **new phase**, focusing its effort in the **treatment of specialist diseases such as Parkinson's disease and Cystic Fibrosis**.Inthe Central Nervous

FDA approves Xadago®: a historic milestone for Zambon and for our Partners System therapeutic area, 2016 was the year of the launch of **Xadago**[®] in several European countries.

In addition to Germany, Xadago[®] is now available in Italy, Spain, Belgium, Denmark, Sweden, Norway, United Kingdom, Luxembourg, Netherlands, Switzerland and Portugal. Up until today, more than 30.000 patients have benefited from this innovative molecule, a step forward in the treatment of Parkinson's disease, an area that for over 10 years had not seen the introduction of new drugs. During the course of 2016, we signed an agreement with an American partner for the launch of Xadago® in the United States, scheduled for mid 2017.



Promixin®: a key drug for the treatment of Cystic Fibrosis

Promixin[®] continues to be a drug of key relevance for the treatment of Cvstic Fibrosis, a chronic condition that is highly debilitating. Thanks to the use of the I-Neb device, and the Insight Online software, Zambon continues to support patients and healthcare providers ensuring the adequate adherence to the therapy. In addition to research of innovative drugs, in a rare disease such as Cystic Fibrosis, patient support plays an important role. Zambon is evaluating and developing new devices that can respond to patients' needs. Moreover, we continue searching for innovative new therapies, mainly through an open network of partnerships with Universities and Research Centres. Zambon has also set two Phase III clinical studies (PROMIS1& PROMIS 2) in adult patients affected by bronchiectasis not associated to Cystic Fibrosis. The purpose

We fight against severe diseases

of the studies is to **evaluate the efficacy and safety of Promixin**[®] **in preventing exacerbations** of pulmonary infections due to chronic colonization by Pseudomonas aeruginosa, a bacteria that can cause serious infections significantly impacting on the quality of life and on the survival of patients.



Zambon has started two registration programs for non-Cystic Fibrosis bronchiectasis

99

PHARMA

Founded in 1906, Zambon is a modern multinational pharma company founded on the heritage and values of an innovative Italian family-owned enterprise.

A company oriented towards the future that preserves an ancient soul, built on fundamental ethical values: the integrity of its actions, honesty in its operations, modesty towards the surrounding world, caring for people of any level, order and grade.

Every day, through the work and actions of people, **these values** become substantial and tangible, **guiding the company in the continuous search for improvement, not only financial, but also for the community at large**.

Established in Italy, and throughout its long history, Zambon has always stood out for the ability to innovate and deliver a solid and organic growth of its **core products** while covering more and more **markets**

on a global level.

When talking about **core products** undoubtedly we refer to **Fluimucil**[®], **Spididol**[®] and **Monuril**[®]. The year 2016 marked a significant growth of **Fluimucil**[®] (+3%) led in particular by China with +57%, becoming the second largest market for sales of this drug. **Investments on scientific communication** of new data continued through dedicated scientific symposia and new publications addressed to pneumologists.

2016 has also seen Zambon continuous commitment in research aimed at developing further areas of application for N-acetylcysteine to improve the quality of life of patients with chronic respiratory diseases.

In 2016, Spididol[®] registered a significant growth (+8%). This goal has been headed by Spain, a country where Spididol[®] is considered the fast-acting analgesic par excellence. Several other countries reported positive results, mainly China and Russia. In 2016, the product family has been enhanced by the arrival of **Spididol[®] Care**, an innovative patch

The global expansion of Zambon core products continues



with a liposomal formula, which has been launched in 5 countries. With over 30 years in the market, and in spite of the availability of generic drugs, Monuril® achieved an overall growth of +2%. This represents the undeniable proof of its value and strong brand equity as the drug of choice for cystitis, especially in Italy where the product is the undisputed market leader. Brazil, Colombia and the USA lead the growth and maintain a positive trend with double digits growth (respectively +15%, +21% and +75%). Confirming the growing trend for the future Monuril® was launched last August in the UK.

NAC: a continuous source of evidence

With 50 years of history, N-acetylcysteine is increasingly proving to be a drug with multiple therapeutic applications.

Its distinctive antioxidant properties are directing research **towards the development of further potential areas in the treatment of rare and orphan diseases**, such as retinitis pigmentosa and idiopathic pulmonary fibrosis.



Today, Zambon is an increasingly global reality with branches in 84 countries of 5 continents"

Vicenza

Produced Units	52.6 M
#skus demonstrate the site's extraordinary complexity	218 sku

Cadempino

Produced Units	77.4 M
of which for third parties and generic carbapenems	28.2 M

Virtual Plant

Produced Units	11 M
Sales (including Xadago®)	95.9 M

Haikou

Produced Units 17.5 M

Produced Units 5.2 M

PHARMA

66

2016 showed good results for the Industrial Business Operation division, particularly for the Tolling & Trading Business which reached the record amount of 30 million Euros. The Vicenza facility focuses its efforts on the new partnerships with Otsuka for the production of Abilify - a sterile solution for the treatment of bipolar schizophrenia - and with IBSA, completing the production of registration batches of a sterile lyophilized biological product. The site is no longer just a production facility but is a new scientific **centre** promoting dialogue among universities, the world of research and the industry at large.

Cadempino strengthened its leadership with contractors in both the **carbapenems area** in the United States, with the consolidation of the relationship with ACSDobfar, and in **oral solids** with the increase of production volumes of granular for the main current contractor.

Zambon production facilities (Vicenza, Cadempino, China, Brazil and Virtual Plant) reached a total production of over 163 million packs, with an increase of +8% compared to the previous year, with a peak of +26% of the Chinese plant. Over the course of 2016, Zambon continued global development of the main brands, reaching 84 countries over 5 continents and launching Monuril® in Iran and Egypt. In addition, Monuril[®] dossier was deposited in Australia and the Baltic States and the dossiers for Fluimucil® and Monuril[®] have been deposited in Vietnam. Moreover, we reached an agreement for the distribution of Zambon products in the United Arab Emirates. The "Distribution Partners" sector registered a significant growth in sales, with peaks of +20% in Europe and +73% in North America.

The Industrial Business overview:

Europe 27% North America 13% South America 15% Asia 33% Africa 12%



2016 was a very important year for our Group; a year that confirmed the Pharmaceutical Business - with a turnover of more than 600 million Euros - as the main area in which our company has been operating for 110 years with conviction and success.

In 2016 Zambon entered into what we could define as a "new growth phase", a renewed path confirming our international mission and the willingness to support products that are the result of our research and the development of drugs which have a positive impact on patients' lives.

Consistently with our strategy, Xadago[®] (Safinamide), for the treatment of Parkinson's disease, was launched in 12 European countries, receiving also the approval by the FDA.

We believe that new growth opportunities are emerging for us in the US market that will reinforce our commitment to the development of therapies for patients with Parkinson's disease, for severe respiratory disorders and rare diseases.

The new Zambon management

team is strategically redirecting the company towards the world of specialties, thanks also to high profile and skilled competencies that make us look to the future with serenity and curiosity. A strongly motivated team that will pursue and consolidate the important path that will change Zambon's position within the international pharmaceutical market.

50

President

Zambon SpA

BUSINESS RESULTS





Sales by geographic area

Net revenues by country 2016**

*Licensees, distributors and production for third parties

**Values expressed in M €

Becoming a Global



Leadership team and our core behaviours

ACCOUNTABILITY

We perform with courage, trust and ownership

FOCUS

We concentrate on a few, sharp and high impact objectives

INNOVATION

We encourage new ways to address challenges

AMBITION

We dare to think big, act boldly and go beyond

Company



Zambon has always focused its energies on the **international expansion**. Among the many countries where we are currently present, undoubtedly **China** is an area of the world that we are **carefully considering**.

The consistent performances of the past years and a highly professional local management team are the starting point from which Zambon is planning **new** and ambitious objectives for the future. Thanks to a regulatory office in Beijing, a commercial office in Shanghai, a production facility in Hainan and over 350 employees, Zambon China is ready to meet the complex challenges of the Chinese market in a perspective of continuous growth. Therefore, we are all looking at the development of our subsidiary with great optimism and trust. "We believe that Zambon expansion in these markets constitutes a great growth opportunity

Vasily Pavlov, Head of Rest of the World & Distributors

PHARMA

Our new journey: a talk with the CEO

> **Roberto Tascione** CEO Zambon SpA

1 The mandatory first question is: why did you choose Zambon? And why did Zambon choose you?

Zambon is an Italian excellence in the pharmaceutical industry with a strong international vision that goes back to the 1950s and a portfolio of highly interesting products that have a significant growth outlook for the future. An Italian company that is now ready to transform itself into a **real global** multinational enterprise. I am very proud to lead the company in this new phase of growth, explore further business to opportunities and strengthen our international network. Zambon, with its 110 years history, is re-evaluating its role in **providing** innovative therapeutic solutions for patients. I believe that Zambon and I mutually choose each other, thanks to the **deep sharing of the** same values and the future vision for the company. I would define it as "natural" harmony.

What values characterise the company?

Integrity, honesty, caring for people and modesty. This is our DNA and determine the way we work, manage the business and grow. It is certainly important what people achieve but the way they do it is also key. Our goals cannot disregard the foundational values that have always guided Zambon business choices. We are at the same time ambitious and willing to build a larger, improved company, able to generate welfare over the short, medium and long term.

What changes have you implemented already?

Simplification and focus are the two key principles that guided my work over the first months. The primary objective was to have a central organisation totally focused on our strategic priorities and able to supply affiliates with clear guidelines, solid and gualified support. In order to achieve that, new corporate functions have been created: Global Marketing, Open **R&D, Global Medical Affairs and** Patient Access with responsibilities for defining and guiding the global strategy for our main products (Xadago[®], Promixin[®], Fluimucil[®], Monuril[®], Spididol[®]). The same approach was applied to all the other "classic" corporate functions. This is an organisational model similar to what you find in large multinationals where I had the privilege of spending the past 30 years.

4 What are the three things which will make the difference in Zambon in the next few years?

We are building an open and meritocratic company. Therefore the first point concerns **people**: the most important factor for the growth of our company. It is for this reason that we are highly committed to make the experience of working at Zambon stimulating, instructive and gratifying, creating an even more inclusive, participatory working environment where each person can give the best and where talent and professionalism are rewarded.

A second aspect concerns the **centrality of the patient**. In Zambon we strive **to improve the lives of patients** who take our drugs, letting us being guided by this mission for our daily choices and trying to offer more integrated solutions that can bring hope for a better life. **What we are doing is a real change of mentality: setting the patient at the centre**.

Thirdly, but not less important, the commitment to **respect our values**. The 110 years history of Zambon is a tangible evidence of the benefit of having strong and deep roots.

For us, this orientation won't ever change, not today nor in the future.

ITALY

Zambon Italia Srl Zambon SpA (Pharmaceutical)

Via Lillo del Duca, 10 20091 Bresso (Milano) Tel. +39 02 665241 Fax +39 02 66501492

Zambon SpA (Pharmaceutical) Pharmaceutical Plant Via della Chimica, 9 36100 Vicenza Tel. +39 0444 968911 Fax +39 0444 348049

Eratech s.r.l. Via Lillo del Duca, 10 20091 Bresso (Milano)

SWITZERLAND

Zambon Switzerland Ltd. Via Industria, 13 CH - 6814 Cadempino Tel. +41 91 9604111 Fax +41 91 9664351

FRANCE

Zambon France S.A. 13, Rue René Jacques 92138 Issy Les Moulineaux Cedex Tel. +33 | 58044141 Fax +33 1 58044100

BELGIUM

Zambon S.A./N.V. Av. E. Demunterlaan 1/9 1090 Brussells Tel. +32 2 7770200 Fax +32 2 7718570

UNITED KINGDOM

Profile Pharma Ltd. Suite 3 Ground Floor Bicentennial Building Southern Gate Chichester West Sussex PO19 8EZ

GERMANY

Zambon GmbH Lietzenburger Strasse 99 10707 Berlin Tel. +49 30 1202 12-0 Fax+49 30 1202 12-121

NETHERLANDS

Zambon Nederland B.V. Basicweg 14b 3821 BR Amersfoort Tel. +31 33 4504370 Fax +31 33 4561233

SPAIN

Zambon S.A. Poligon Industrial Bernades Subirà 08348 Calle Maresme 5 Santa Perpetua De la Mogoda Barcelona Tel. +34 93 5446400 Fax +34 93 574 04 36

PORTUGAL

Zambon - Produtos Farmacêuticos Lda. Rua Comandante Enrique Maya, 1 1500 - 192 Lisbon Tel. +351 21 7600952/54 Fax +351 21 7600975

RUSSIA

Zambon Pharma LLC Glazovsky Per. Building 7 119002 Moscow Tel. +74 95 9333830/32 Fax +74 95 9333831

BRAZIL

Zambon Laboratórios Farmacêuticos Ltda. Avenida Ibirapuera, 2332 12° Andar, Torre 1 Moema São Paolo - SP Tel. +55 11 30759300 Fax +55 11 30759322

COLOMBIA

Zambon Colombia S.A. Calle 124, No 45-15 Pysos 3 y 4 Santa Fe de Bogotà Tel. +57 1 6198558-47-69 Fax +57 1 6198669

CHINA

Hainan Zambon Pharmaceutical Co. (Plant) Hainan Haibon Pharmaceutical Co. (Trading Company) High & New Technology Development Zone Haikou City 570314 Hainan Tel. +86 898 6863 1288 Fax +86 898 6863 6121

Hainan Zambon Pharmaceutical Co. Shangai Branch Room 1606, No. 511 Weihai Road Shanghai Tel. +86 21 62387722

INDIA

Zambon (India) Pvt. Ltd. 15, Chelmesford Country Club Ghitorni, New Dehli - 110030 Tel. +91 1242804021/2/3 Fax +91 1242804024

INDONESIA

P.T. Zambon Indonesia Antam Office Park Tower B, 9th floor JI. Letjen TB Simatupang No. 1 Jakarta Selatan 12530 Indonesia Tel. +62 21 2904 8820 Fax +62 21 72904 8821

NORDICS

NORWAY

Nigaard Pharma AS (Registered head office) Bryggegata 6, NO-0250 Oslo - Norway Postboks 373 2001 Lillestrøm, Norway Tel: +47 815 300 30

SWEDEN

Nigaard Pharma AS, Norge filial (Branch Nigaard Pharma AS) Medicon Village, 223 81 Lund, Sweden Tel: +47 815 300 30

DENMARK

Nigaard Pharma Denmark (Branch Nigaard Pharma AS) Lyskær 3 C 2730 Herlev, Denmark Tel: +47 815 300 30

FINLAND

Nigaard Pharma OY (Registered head office) Hallonnasstranden 2 00210 Helsinki, Finland Tel: +47 815 300 30

Italy Switzerland France **Belgium United Kingdom** Germany **Netherlands** Spain **Portugal** Russia **Brazil** Colombia China India Indonesia Norway Sweden Denmark Finland



									1		





