



# REGENERATE & EVOLVE.

Starting from life to improve people's life quality



## **Corporate Press Kit**

# **Fidia Farmaceutici: Italian excellence around the world**

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## **Fidia Farmaceutici: an overview**

Founded in **1946** in Bologna (Italy) and subsequently transferred to Abano Terme (PD - Italy) in 1959, its name stems from the acronym of **F**armaceutici **I**taliani **D**erivati **I**ndustriali **A**ffini (*Italian Pharmaceuticals Related Industrial Derivatives*).

Since the early 1960s Fidia has been manufacturing high-quality, pharmaceutical grade **hyaluronic acid** and its derivatives. The company has assumed leadership in **wound care** and intra-articular injection therapy (viscosupplementation) for the treatment of **osteoarthritis**, the result of a long-standing and continuous commitment to R&D.

Over time, the extensive scientific and industrial know-how in the production of hyaluronic acid has led the company to focus on other areas of personal care, such as **skin care**, **urogynecology**, and **aesthetic medicine**, in addition to **neuroscience** and **ophthalmology**. More recently, Fidia has entered the **regenerative medicine (Autologous Biological Therapy)** sector, with innovative technologies that allow doctors and specialists to offer a "tailored" approach to each individual patient.

### ***The growth strategy: internationalisation, consolidation of core business and entry into new areas***

Over the years, Fidia has been able to identify and seize opportunities offered in the global marketplace, thereby expanding its commercial presence in **+100 countries worldwide**, thanks to a consolidated network of wholly owned affiliates, as well as commercial partners and distributors in the pharmaceutical and biomedical sectors. The company has ambitious plans for growth, that include opening new affiliates in strategic markets, expanding its presence worldwide and engaging in new business areas.

This global presence provided in 2022 a turnover of over 412 million Euros, 48% generated in foreign markets.

To further strengthen its leadership in pharmaceutical innovation, in 2016 Fidia acquired Biofarmitalia, an Italian company founded in 1992 and based in Paderno Dugnano (Milan province). Now an integral part of Fidia following a merger by incorporation (December 2019), it has enabled the company to gain expertise in developing and manufacturing new technologies for cosmetic applications and dynamic devices designed for oral, dermal and transdermal, **controlled-release formulations of active ingredients**.

The acquisition of Sooft in 2017 has enabled Fidia, who was active in the eye care segment in previous years, to re-gain market share and strengthen its position in this area, offering a wide array of products, such as eye drops, medical devices and food supplements. With a robust product portfolio that includes several well-known brands, Sooft was founded in 2000 and is now an integral part of Fidia.

The acquisition of the Spanish company Soluciones Bioregenerativas in 2018, enabled Fidia to consolidate its know-how and global presence in the field of **regenerative medicine**, specifically, in joint care, wound care, aesthetic medicine and urogynecology, applying platelet-rich plasma



(PRP) technology and using adipose tissue, which is a major source of cells and other factors with regenerative potential.

In 2023 Fidia acquired some **eye care** products and a **Vitamin D-based** nutritional supplement along with a branch of the Polish affiliate of **Unipharm**, privately owned pharmaceutical company headquartered in the U.S.

*The Fidia Group also includes:*

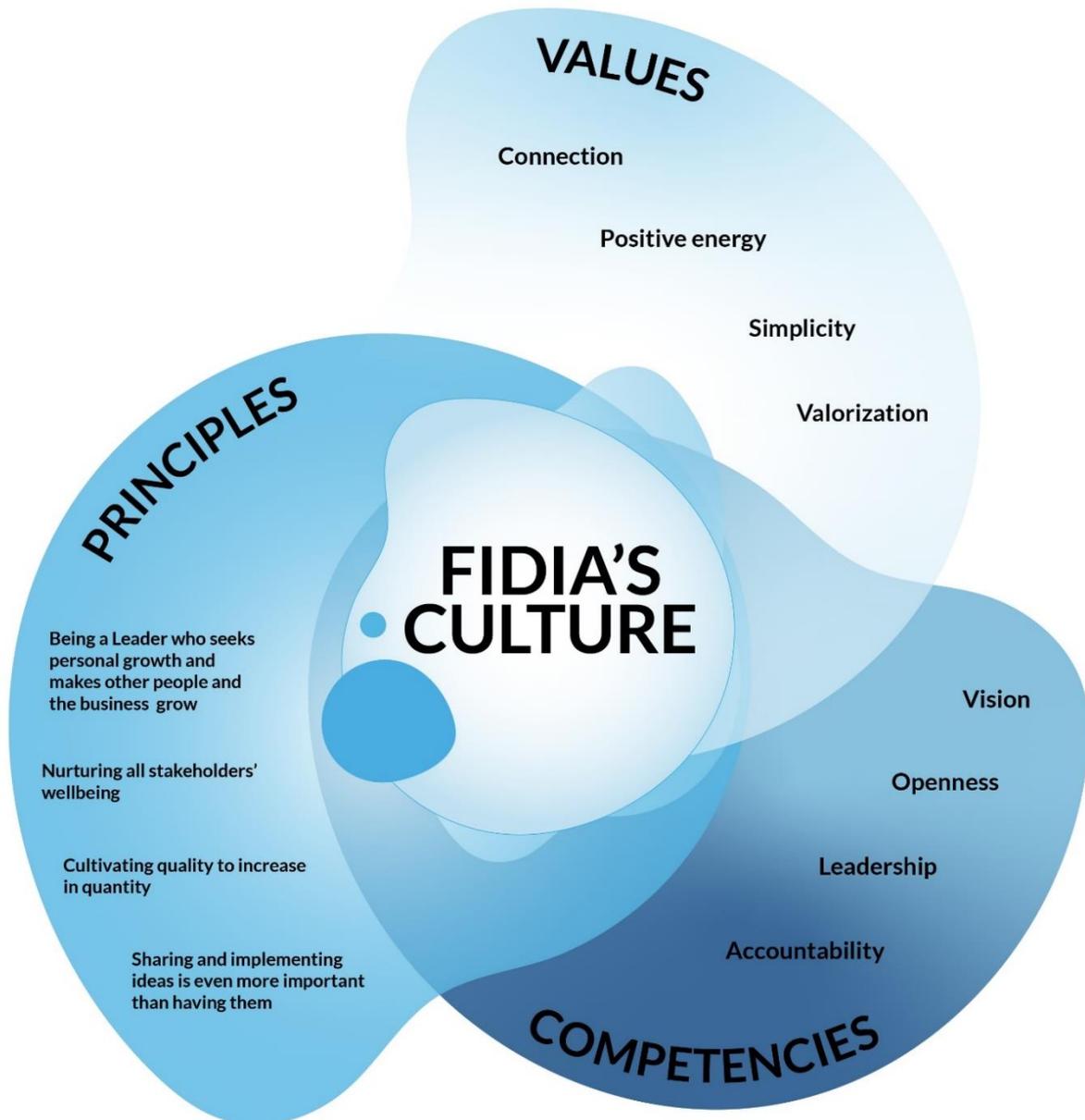
- **HQ** – Abano Terme, Italy
- **R&D Unit** in Noto, Italy
- **Local Unit** in Paderno Dugnano, Italy
- **Local Unit** in Monte Giberto, Italy
- **Fidia Pharma GmbH** in Germany
- **Fidia Pharma Austria GmbH** in Austria
- **Laboratorios Fidia Farmacéutica S.L.U.** in Spain
- **Laboratoires Fidia SAS** in France
- **Fidia Pharma CZ s.r.o.** in the Czech Republic
- **Fidia Pharma Slovakia s.r.o.** in Slovakia
- **Fidia Pharma Russia LLC** in Russia
- **Fidia Pharma USA Inc.** in USA
- **Fidia Pharma Middle East F.Z.E.** based in UAE
- **Fidia Pharma Egypt for Marketing** in Egypt
- **Fidia Pharma Romania S.r.l** in Romania
- **Fidia Pharma Polska Sp. z o.o.** in Poland

## Fidia's Culture

Fidia's corporate culture is the result of an inclusive process that has involved all its employees and reflects its identity, as well as its approach to all its stakeholders.

The bottom-up genesis of the process makes it innovative: the Fidia people were asked to express their views on what they considered to be the values representative of the corporate culture they belong to, as well as the principles and skills that, acted upon daily, could support its development.

Fidia's values are therefore the basis of its corporate identity because, inspired by its principles, they give rise to the behaviours that characterise the work of each team, in a virtuous circle in which each element contributes to making the others stronger and more relevant.



## **A Fully Integrated Company**

With more than 1,500 employees, many of them engaged in such areas as research and development, manufacturing and marketing, Fidia is a fully integrated pharmaceutical company, capable of managing the entire lifecycle of a product and focused on the development of innovative treatment solutions that address unmet medical and patient needs.

## **Research and Development (R&D)**

The company concentrates its R&D activities - equally balanced across all stages of product development - DISCOVERY PHASE, PRECLINICAL PHASE and CLINICAL PHASE - in areas of high scientific and commercial promise, and has established many ongoing collaborations with Italian and international centres of excellence.

R&D activities focus on the study of the properties and characteristics of **hyaluronic acid (HA)**, a molecule that Fidia perceives as tradition, innovation and excellence. R&D projects are carried out both in **Abano Terme** laboratories and at the Research Unit in **Noto**. The latter's activities center on the optimization of biopolymer production (i.e., enzymes, recombinant proteins and polysaccharides), using non-pathogenic host strains of bacteria.

More recently, Noto laboratories have been successfully working on the optimization of HA production from new GRAS (*Generally Recognized As Safe*) bacterial sources, through biotech processes. These new processes have enabled the company to improve the yield of LMW-HA (LMW - *Low Molecular Weight*) remarkably and reduce the cost of the API, without affecting the high-quality standard of Fidia's HA.

## **Manufacturing Skills**

Since the early 1960s, Fidia has produced hyaluronic acid (from extractive origin or through fermentation and biotech processes) with different molecular weights, depending on the indications and properties desired for the finished product.

The Abano Terme facility hosts the entire production process. Inaugurated in 1978, this facility still represents excellence in the landscape of global pharmaceutical production, thanks to the remarkable quality levels reached in the development of its formulations. Other specialized productions are manufactured in Paderno Dugnano and Monte Giberto plants.

The company's production capacity includes **various pharmaceutical forms**, i.e., sterile injectable and lyophilized products, topical products (creams and ointments), eye drops (both single- and multi-dose) and solid orals, with diversified packaging, based on the requirements of the commercial partners. Thanks to the expertise gained over the years, to investments for in-house industrial development and manufacturing process efficiency, Fidia can offer excellent credentials to companies who wish to outsource and rationalize their own facilities with commissioned production (e.g., vaccines) to a reliable partner (CMO).

### **Quality Management System**

The quality system of Fidia Farmaceutici

- complies with European GMP requirements for the production of medicinal products and pharmacologically active substances. It is also certified according to ISO 13485 and ISO 9001 standards
- complies with 21 CFR Part 211 and 21 CFR Part 820 requirements for the production and marketing of medicinal products and medical devices in the United States
- holds ISO 9001:2015 and ISO 13485:2016 certifications
- has been annually audited since 2018, in line with the requirements of the Medical Device Single Audit Programme (MDSAP), in order to manufacture and market medical devices in the USA, Canada and Brazil.

Since Fidia commercializes its products in Italy and in international markets, it is periodically inspected by Italian (i.e., AIFA and Ministry of Health) and international (i.e., US FDA, KFDA and ANVISA) Authorities, as well as by several Notified Bodies (i.e., GMED, ISS, TUV, IMQ, Certiquality, Eurofins Biolab).

### **Health, Safety and Environment**

Health, safety and environment are top priorities for Fidia. The company pursues continuous improvement in **safety conditions, occupational health and environmental protection** through prevention, assessing risks and their elimination and reduction. In addition, Fidia promotes and spreads the culture of occupational health and safety, the protection of the territory and the environment, as well as the importance of complying with regulations, through the continuous example and systematic control of all significant aspects.

To this end, the company adheres to the core principles and objectives of **Responsible Care®**, to continuously improve the health, safety and environmental performance, do business responsibly and contribute to a better quality of life.

## Hyaluronic Acid

### ***A substance with countless biomedical applications in a 1,100 patent landscape***

For Fidia, hyaluronic acid (HA) represents both tradition and innovation. The company's first HA-based product was in fact launched in 1963 and today, Fidia has established its leadership in research, technological development and production.

First discovered in 1934 by Karl Meyer and John Palmer at Columbia University (NY, USA), hyaluronic acid is a fully biocompatible, non-immunogenic, and non-toxic polysaccharide naturally present in the human body. It is especially abundant in connective tissues, where it confers elasticity and resistance to the skin, and in joints, where it plays a key role in cushioning and lubrication. It is also present in large quantities in the eye (vitreous) and in heart valves. Thanks to its unique physicochemical properties, HA and its derivatives have numerous applications, namely the treatment of musculoskeletal disorders (e.g., osteoarthritis and tendinopathy), wound care (acute and chronic lesions), eye surgery, and aesthetic medicine, and can be used as a carrier for the administration of pharmacologically active molecules, e.g. chemotherapeutic drugs.

The body's ability to naturally produce hyaluronic acid decreases with age, thereby causing difficulty in the repair and regeneration after an injury, the appearance of wrinkles, and more effort required for joint function and mobility. Fortunately, hyaluronic acid can be reintroduced by injection therapy in order to slow or delay joint damage and applied topically to promote tissue hydration and repair.

More than 60 years of research into this molecule have placed Fidia at the forefront in the production of both **natural and functionalized hyaluronic acid** (of extractive origin or through fermentation and biotech processes), with different ranges of molecular weight, depending on the indications and properties desired for the finished product.

Fidia has a **robust patent portfolio** (+1,300) worldwide, over 1,100 of which involve HA with different molecular weights, industrial processes, formulations, compositions, and applications (*Company Data 2023*).

Fidia is also able to chemically modify the molecule to obtain **patented derivatives** with different characteristics, e.g., improved mucosal adhesion and resistance to degradation, improved mechanical properties, diversified bioavailability timing, longer residence time, and remarkable rheological properties.

Fidia's pharma-grade hyaluronic acid is also commercially available in powder bulk in ready-to-use or tailor-made viscosities, according to customer's requirements and final use. Fidia has obtained the Certificate of Suitability to the European Pharmacopeia - **CEP certificate R0-CEP 2017-220-Rev 00** - granted by EDQM - for Sodium hyaluronate from fermentation for cutaneous and parenteral administration, including intra-articular administration, and for intra-ocular use.

## Fidia's Commitment

For over 70 years, Fidia Farmaceutici has been at the forefront in the development of diversified therapeutic solutions for commonly occurring pathologies with serious social and economic impact, age-related disorders and other health-related conditions, as life expectancy lengthens and chronic, disabling diseases increase as a result, to give effective and differentiated responses to the needs of healthcare professionals and patients. Specifically, the company has chosen to concentrate its efforts in key therapeutic areas, with the goal to enhance and consolidate each asset:

1. **JOINT CARE** - Fidia offers innovative, integrated therapeutic solutions based on different approaches, for the treatment of **musculoskeletal disorders, cartilage damage and tendon pathology**:
  - the intra-articular administration of hyaluronic acid, which can slow down osteoarthritis progression and reduce cartilage damage, even due to acute trauma or damage subsequent to joint overuse (e.g., sports-related trauma)
  - the peritendinous injection of hyaluronic acid for the treatment of pain and stiffness in tendinopathy
  - oral chondroprotection to help maintain healthy joint and tendon function
  - local treatments for pain relief
2. **EYE CARE** - With the acquisition of Sooft in 2017 and then the complete merger with it in 2021, Fidia, who historically already played a leading role in this therapeutic area with viscoelastic products based on hyaluronic acid for ophthalmic surgery, has enriched its portfolio with specific solutions for the treatment of **various conditions that affect the eye**, such as dry eye, accommodative asthenopia, ocular infection and inflammation, corneal oedema, vitreous pathologies, macular degeneration, diabetic retinopathy, and glaucoma. Fidia's portfolio consists of pharmaceutical products, medical devices, and food supplements, as well as novel technologies for the treatment of keratoconus (progressive non-inflammatory disease of the cornea).
3. **SKIN CARE** - Hyaluronic acid has long been widely used to treat general wounds, ulcers, and burns, as well as difficult-to-heal wounds, such as diabetic foot ulcers. Fidia has developed a unique portfolio based on high-tech, hyaluronan bioactive treatments for the management of both **acute and chronic lesions**, but also to improve altered skin conditions through healing time reduction and derma quality enhancement.

4. **REGENERATIVE CARE** - Since 1963, Fidia has pioneered the clinical application of hyaluronic acid and has paved the way to the concept of **tissue regeneration**, as well as a novel medical approach. Today, Regenerative Care, more specifically Autologous Biological Therapy, offers Fidia the possibility to develop a full line of products, namely a PRP concentration system, a bone marrow concentrate (BMC) and a functionally closed system to obtain stromal vascular fraction (SVF)-enriched fat micrografts, thereby allowing physicians to tailor the best treatment to the individual patient, in areas such as musculoskeletal disorders, advanced wound care and aesthetic medicine.
5. **AESTHETIC CARE** - Hyaluronic acid is the preferred substance in most medical aesthetic procedures. Fidia has pioneered the concept of "bio-revitalisation" with its portfolio of **injectable products based on hyaluronic acid**, and continues to evolve, thereby responding to the ever-wider needs of biocompatible, biodegradable, and effective solutions for skin wellness and beauty, and the most advanced treatment protocols available to the aesthetic doctor, which preserve the person's unique identity.

Balancing the codes of premium skincare with the rigor of medical science, Fidia has recently entered the cosmetic treatment field with an innovative **skincare** line based on hyaluronic acid and its chemical, patented modifications.

6. **PRIMARY CARE and SPECIALTY CARE** - Fidia is also active in other therapeutic areas. For instance, it has been actively engaged in **neuroscience** over the past few decades and is currently focused on the management of **mood and sleep disorders** and peripheral neuropathies, thereby offering a variety of safe and effective treatment options to physicians, patients, caregivers, and healthcare professionals. Fidia also offers medical treatment options to the healthcare professionals in the **anti-infectives** field, in the areas of antibiotic therapy, antivirals, and products for immune prophylaxis, for the treatment of numerous **infectious diseases caused by bacteria, fungi, and viruses**. As far as **cardiovascular health** is concerned, Fidia offers nutraceutical compounds useful in the prevention of **cardiovascular disease risk**, that may reduce the occurrence of certain contributing factors such as cholesterol and uric acid levels. An exclusive and patented hyaluronic acid derivative opened the doors **to urogynecology** field and is now used specifically for mucosal application and in the treatment of uro-genital diseases, such as **interstitial cystitis** and **vulvo-vaginal atrophy**.

## Design to Innovate

Fidia's robust pipeline includes the development of pharmaceuticals, medical devices, and dietary supplements, by investing in its own R&D and building global scientific collaborations to deliver innovative solutions to physicians and patients.

Among the products under development worth mentioning is **Oncofid®P-B**, an innovative conjugate obtained thanks to decade-long scientific know-how of hyaluronic acid and the collaboration with Italian and international centres of excellence. Oncofid®P-B combines the anti-cancer properties of **paclitaxel**, a cytotoxic drug known for its inhibition of the cell cycle, which is poorly soluble in water, with **hyaluronic acid**, for the treatment of patients with carcinoma *in situ* (CIS) of the bladder. In comparison with the various technologies aimed at the controlled release of anticancer drugs, the ONCOFID platform, developed and patented by Fidia, offers competitive advantages: the conjugation of paclitaxel with hyaluronic acid makes the drug easily water-soluble, thereby improving tolerability and allowing more intense treatment schemes. More recently, the U.S. Food and Drug Administration has granted Orphan Drug Designation for Oncofid-P for the treatment of malignant mesothelioma, a rare and aggressive cancer with limited therapeutic options.

The company is also developing a comprehensive medical device portfolio for obtaining autologous biological products at the point of care, with high quality, safety and efficacy profile, that allow physicians to customize the best science-based regenerative therapies to the individual patients. Specifically, Fidia offers innovative, functionally closed-systems to rapidly concentrate and isolate the **Stromal-Vascular Fraction (SVF)** from adipose tissue, a rich source of mesenchymal stem cells that include adipogenic, osteogenic and chondrogenic cells, and to obtain **Platelet-Rich Plasma (PRP)** and **Bone Marrow Concentrate (BMC)**.

Fidia is also involved in other therapeutic areas, such as Dupuytren's contracture, for which it is developing a treatment based on hyaluronic acid and **collagenase from *Vibrio alginolyticus***, produced and purified in Fidia's R&D Unit in Noto, which received the Orphan Drug Designation by the US Food and Drug Administration (FDA). This treatment is proposed as a safe, non-surgical option, to address an important, unmet need, and improve the quality of life for people with this painful hand condition that pulls one or more fingers into a bent position, which can complicate everyday activities, such as placing your hands in your pocket, putting on gloves or shaking hands.

## Fidia at a Glance

Fidia is a very successful Italian entrepreneurial company that has achieved - and maintains - a leading position in the national market, while extending its global reach worldwide.

The company has also a direct presence with wholly owned subsidiaries in strategic markets, such as the United States, Germany, Austria, Spain, France, Russia, the Czech Republic, Slovakia, Romania, Poland, Egypt and META (Middle East, Turkey and Africa).

<b>YEAR CONSTITUTION</b>	1946
<b>HEADQUARTER</b>	Abano Terme (PD), Italy
<b>2022 TURNOVER</b>	+412 million euros (of which almost 50% is generated in foreign markets)
<b>GLOBAL PRESENCE</b>	+100 countries worldwide through wholly owned subsidiaries and partnerships with international pharmaceutical and biomedical companies
<b>EMPLOYEES</b>	+1,500 worldwide
<b>PATENTS</b>	+1,300 of which +1,100 involve hyaluronic acid with different molecular weights, industrial processes, pharmaceutical formulations, compositions, and applications
<b>FACILITIES</b>	<ul style="list-style-type: none"> <li>• Abano Terme [HQ] (PD) <span style="float: right;">214,000 m<sup>2</sup></span></li> <li>• Noto Unit in Sicily (SR) <span style="float: right;">21,000 m<sup>2</sup></span></li> <li>• Paderno Dugnano unit (MI) <span style="float: right;">7,500 m<sup>2</sup></span></li> <li>• Monte Giberto unit (FM) <span style="float: right;">3,200 m<sup>2</sup></span></li> </ul>
<b>R&amp;D</b>	<p>2 research centres in Italy (R&amp;D laboratories in Abano Terme, and R&amp;D Unit in Noto, Sicily)</p> <p>Collaboration with Italian and international centres of excellence</p> <p>+60 years of R&amp;D into hyaluronic acid</p> <p>+200 published international clinical studies on hyaluronic acid, involving</p> <p>+20 million patients treated with <u>intra-articular</u> hyaluronic acid since launch of first product in 1987</p>
<b>THERAPEUTIC AREAS</b>	<p>Joint Care</p> <p>Eye Care</p> <p>Skin Care</p> <p>Regenerative Care</p> <p>Aesthetic Care</p> <p>Primary Care</p> <p>Specialty care</p>

*(Company Data 2023)*



## Company photo gallery

All files are available in the MEDIA ROOM - Gallery section of [www.fidiapharma.com](http://www.fidiapharma.com) website.

The image gallery has been developed to support members of the media or other stakeholders interested in products and company.

The images are available in high- and low-resolution, JPEG formats and are Fidia Farmaceutici's property. In case of publication, **Fidia Farmaceutici S.p.A. shall be credited as the source, with link to the company website [www.fidiapharma.com](http://www.fidiapharma.com).**