

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 **Farmaceutici Italiani Derivati Industriali Affini** (*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. In fact, over 20 million patients worldwide have been treated with intra-articular injections from the launch of the first product in 1987, and more than 25,000 subjects have been involved in +310 international clinical studies on hyaluronic acid (*Company Data 2020*).

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, uro-gynecology**, 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 2020 a turnover of over 320 million Euros, 40% 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 uro-gynecology, applying platelet-rich plasma (PRP) technology and using adipose tissue, which is a major source of cells and other factors with regenerative potential.

The Fidia Group also includes:

- **HQ** – Abano Terme, Italy
- **R&D Unit** in Noto, Italy
- **Specialized Manufacturing 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 Dubai
- **Fidia Pharma Egypt for Marketing** in Egypt
- **Biosoft Company S.r.l.** in Romania

Our Values

Fidia Farmaceutici has continued its commitment to research and development for several decades since its foundation in 1946, with the aim to offer integrated, effective and safe products and services to healthcare professionals, patients, and global partners, with the best cost/benefit ratio.

Every day, the group works keeping its objectives clear, i.e. high quality and technological competence, and focus on its people, ideas and values.

INNOVATION is the result of the continuous commitment to research and development of new therapeutic opportunities. This translates into product lines for the treatment of known pathologies with a high social impact, offering innovative and integrated solutions that take the need to maintain a constant level of product quality and reliability into account.

QUALITY is monitored during each phase of the production process - from the API (Active Pharmaceutical Ingredient) to the finished product - according to control plans complying with quality procedures, to guarantee performance and safety standards. The company has invested in its production capacity by adding new technologies and improving those existing, thus increasing flexibility for partners and customers.

COMPETITIVENESS is sustained by specialized, high-quality products, proprietary know-how and manufacturing technologies, which allow Fidia to successfully identify opportunities in global markets and respond to the new healthcare environment. Effective use of knowledge and a strong spirit of collaboration are fundamental requirements for a company like Fidia. The high level of professionalism, experience, skills, and commitment of its employees are the foundation of the excellent quality levels and competitiveness of Fidia products.

INTERNATIONALIZATION has enabled Fidia to expand its global reach and successfully distribute its products worldwide through an established network of partners and distributors operating in the pharmaceutical and biomedical sectors, both on a global and local scale, as well a direct presence with wholly owned affiliated companies, while maintaining a strong foothold in the national market.

A Fully Integrated Company

With more than 1,400 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's 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

Fidia Farmaceutici's quality system

- 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
- 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 physico-chemical 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.

Nearly 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 2021*).

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. **WOUND 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**, a debilitating condition that is becoming increasingly common and can negatively affect an individual's quality of life.
3. **OPHTHALMOLOGY** - 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).

4. **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.

5. **NEUROSCIENCE** - Fidia has been actively engaged in the neuroscience field over the past few decades. The company 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.
6. **URO-GYNECOLOGY** - Thanks to its knowledge of the hyaluronic acid molecule, Fidia has developed an exclusive and patented hyaluronic acid derivative, specific for mucosal application and useful in the treatment of uro-genital diseases, such as **interstitial cystitis** and **vulvo-vaginal atrophy**.
7. **ANTI-INFECTIVES** - Fidia offers medical treatment options to the healthcare professionals 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**.
8. **REGENERATIVE MEDICINE** - 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 Medicine, 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.
9. **CARDIOVASCULAR HEALTH** - 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.

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, Egypt, and META (Middle East, Turkey and Africa).

YEAR CONSTITUTION	1946
HEADQUARTER	Abano Terme (PD), Italy
2020 TURNOVER	+320 million euros (of which 40% is generated in foreign markets)
GLOBAL PRESENCE	+100 countries worldwide through wholly owned subsidiaries and partnerships with international pharmaceutical and biomedical companies
EMPLOYEES	+1,400 worldwide
PATENTS	+1,300 of which +1,100 involve hyaluronic acid with different molecular weights, industrial processes, pharmaceutical formulations, compositions, and applications
FACILITIES	<ul style="list-style-type: none"> • Abano Terme (HQ) 215,000 m² • Noto Unit in Sicily 21,000 m² • Paderno Dugnano unit (former Biofarmitalia) 6,855 m² • Local Unit in Monte Giberto 3,200 m²
R&D	<p>2 research centres in Italy (R&D laboratories in Abano Terme, and R&D Unit in Noto, Sicily)</p> <p>Collaboration with Italian and international centres of excellence</p> <p>+55 years of R&D into hyaluronic acid</p> <p>+310 published international clinical studies on hyaluronic acid, involving +25,000 subjects</p> <p>+20 million patients treated with <u>intra-articular</u> hyaluronic acid since launch of first product in 1987</p>
THERAPEUTIC AREAS	<p>Joint Care</p> <p>Advanced Wound Care</p> <p>Ophthalmology</p> <p>Aesthetic Medicine & Cosmetics</p> <p>Neuroscience</p> <p>Uro-Gynecology</p> <p>Anti-infectives</p> <p>Regenerative Medicine (Autologous Biological Therapy)</p> <p>Cardiovascular Health</p>

(Company Data 2020)

Company photo gallery

All files are available in the MEDIA ROOM - Gallery section of 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.**

BUILDINGS AND INDUSTRIAL SITE

OUTDOOR

PRINTING: HIGH RES - WEB: LOW RES



Fidia_outdoor_entrance



Fidia_outdoor_logo and flags



Fidia_outdoor_logo and façade

INDOOR

Printing: HIGH RES - WEB: LOW RES



Fidia_Warehouse_1

PRODUCTION ACTIVITIES**INDOOR - PRODUCTION****PRINTING: HIGH RES - WEB: LOW RES****Fidia_API_7****Fidia_API_11****Fidia_API_13****Fidia_Lyophil_9****Fidia_Lyophil_13****Fidia_Lyophil_16****Fidia_Quality Control_5****INDOOR - PACKAGING****PRINTING: HIGH RES - WEB: LOW RES****Fidia_Packaging cardbox_8****Fidia_Packaging injectables_3****Fidia_Connettivina_1**

MANAGEMENT

CEO – CARLO PIZZOCARO

PRINTING: HIGH RES – WEB: LOW RES



CEO_C. Pizzocaro



CEO_C. Pizzocaro 2