



# COMPANY **OVERVIEW**



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# FIDIA FARMACEUTICI

Fidia and its subsidiaries operate across different therapeutic areas, focusing on commonly occurring pathologies with social and economic impact, age-related diseases and other health-related conditions, through partnerships with local distributors and wholly-owned subsidiaries



**+1,300** employees globally



**+300** million € (2019), nearly **50%** generated in foreign markets



Development of technology platforms, pharmaceutical products, medical devices and 'lifestyle products', mainly based on **hyaluronic acid (HA)** and its patented derivatives

# GLOBAL REACH

**+100**

COUNTRIES WORLDWIDE THROUGH

- local partners and distributors
- wholly-owned subsidiaries in strategic markets, such as **USA, Germany, Austria, Spain, France, Middle East, Egypt, Russia, Romania, Czech Republic and Slovakia.**



# BUSINESS CONSOLIDATION THROUGH ACQUISITIONS



## 2016: BIOFARMITALIA

Founded in 1992 and based in north of Milan (Italy), the company specializes in novel technologies for cosmetic and pharmaceutical applications. i.e. patches and dynamic devices designed for oral, dermal and transdermal **controlled-release formulations of active ingredients**. The company is now an integral part of Fidia following a merger by incorporation (2019).



## 2017: SOOFT

The acquisition of Sooft 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 an extensive portfolio that includes +100 well-known brands (nutraceuticals, drugs and medical devices) and +130 international patents.



## 2018: SOLUCIONES BIOREGENERATIVAS

The acquisition of the Spanish company operating through its proprietary trademark Proteal, will enable Fidia to consolidate its know-how and global presence in the field of **regenerative medicine**, specifically, in joint care, aesthetic dermatology and veterinary, applying Platelet-Rich Plasma (PRP) and using adipose tissue, which is a major source of cells and other factors with regenerative potential.

# FIDIA FARMACEUTICI



**Founded in Bologna (Italy) in 1946**, relocated to Abano Terme (Italy) in 1959. Acquired by the P&R Group in 1999. Italian healthcare company, fully integrated, with R&D, production, marketing and sales capabilities.



## **+55 years of research into hyaluronic acid (HA)**

Fidia is currently at the forefront in the production of both natural and functionalized hyaluronic acid, using proprietary and validated manufacturing processes.



**1,300 international patents, of which nearly 1,100 involve HA** with different molecular weights, industrial processes, formulations, compositions, derivatives, and applications.



# MISSION

Establishing the leadership of Fidia's hyaluronic acid (HA) in the following strategic areas



**Joint Care**



**Wound Healing**



**Ophthalmology**



**Aesthetic Medicine**

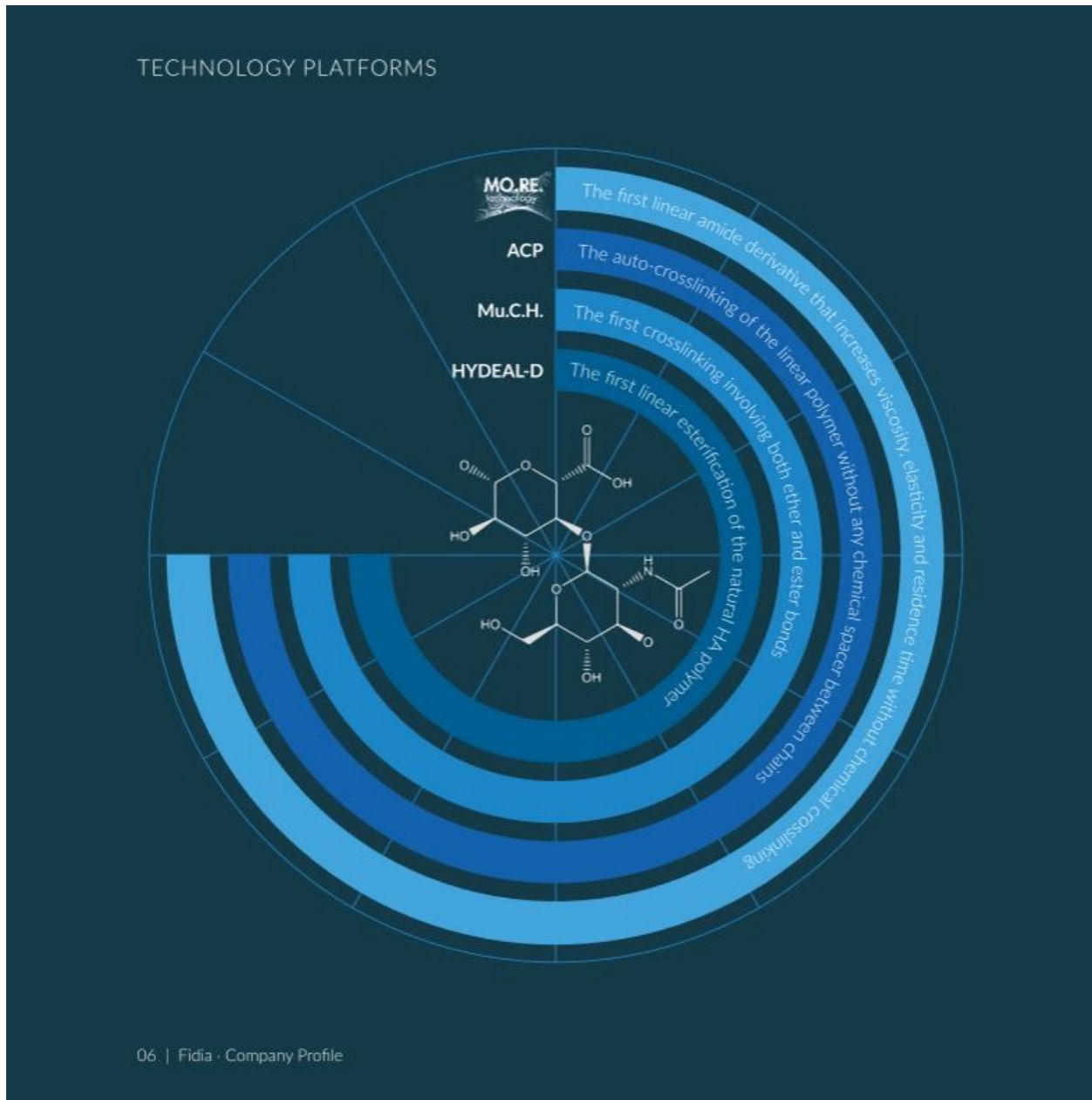
through researching, developing and marketing

- technology platforms
- pharmaceutical products
- medical devices
- 'lifestyle' products



# KNOW-HOW

Fidia's know-how of **hyaluronic acid** has enabled the company to obtain a variety of **patented chemical modifications** of the native molecule, among them



## HYDEAL-D

- improves mucosal adhesion
  - improves resistance to degradation,
  - provides slow and **continuous release of hyaluronic acid**.
- (first to file: 1985)

### Auto-Crosslinked Polymer

## ACP

- auto-crosslinking with no chemical spacer between chains
  - used where there is a need for a biocompatible, biodegradable, viscoelastic material with **improved mechanical properties**.
- (first to file: 1988)

### MULTI Crosslinked Hyaluronan

## Mu.C.H

- perfect physical association of two crosslinked derivatives
  - **diversified bioavailability timing**.
- (first to file: 2009)

### MOBILE Reticulum

- first linear, HA amide derivative
  - **longer residence time**
  - **remarkable rheological properties**
- (first to file: 1998)



06 | Fidia - Company Profile



# SKILLS AND EXCELLENCE

Fidia has several decades of unparalleled experience developing innovative solutions in key therapeutic areas where hyaluronic acid properties can be effectively, efficiently, and rationally exploited, such as **joint care** and **wound healing**.

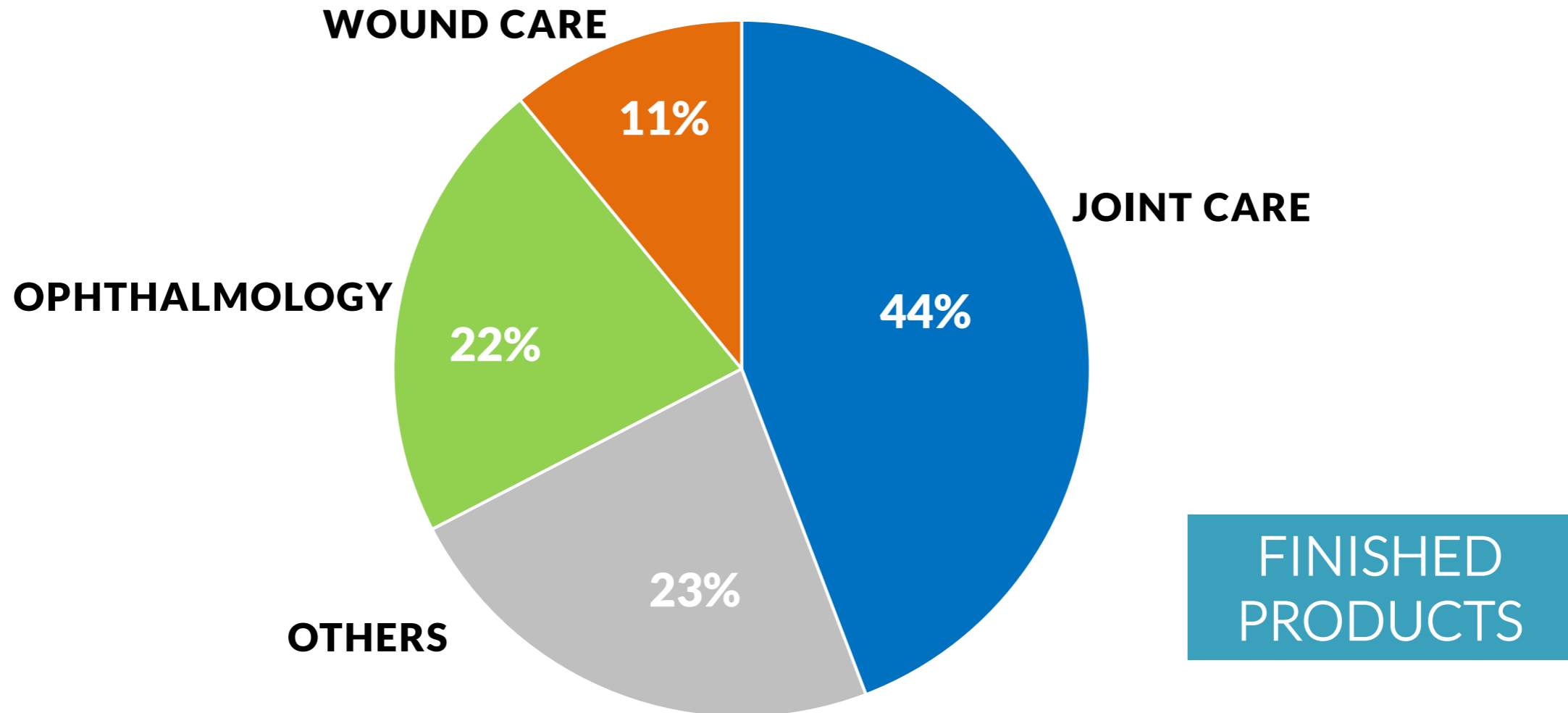
The company is also expanding its portfolio, including products and line extensions in **women's health, urology, aesthetic medicine** and **cosmetics**.

Fidia continues to be strongly focused on the **neuroscience** and **ophthalmic** therapeutic areas, with important R&D projects at various stages of development.

More recently, Fidia has announced its entry into the **autologous biological therapy** market segment, with innovative technologies that allow physicians to tailor the best treatment to the individual patient.

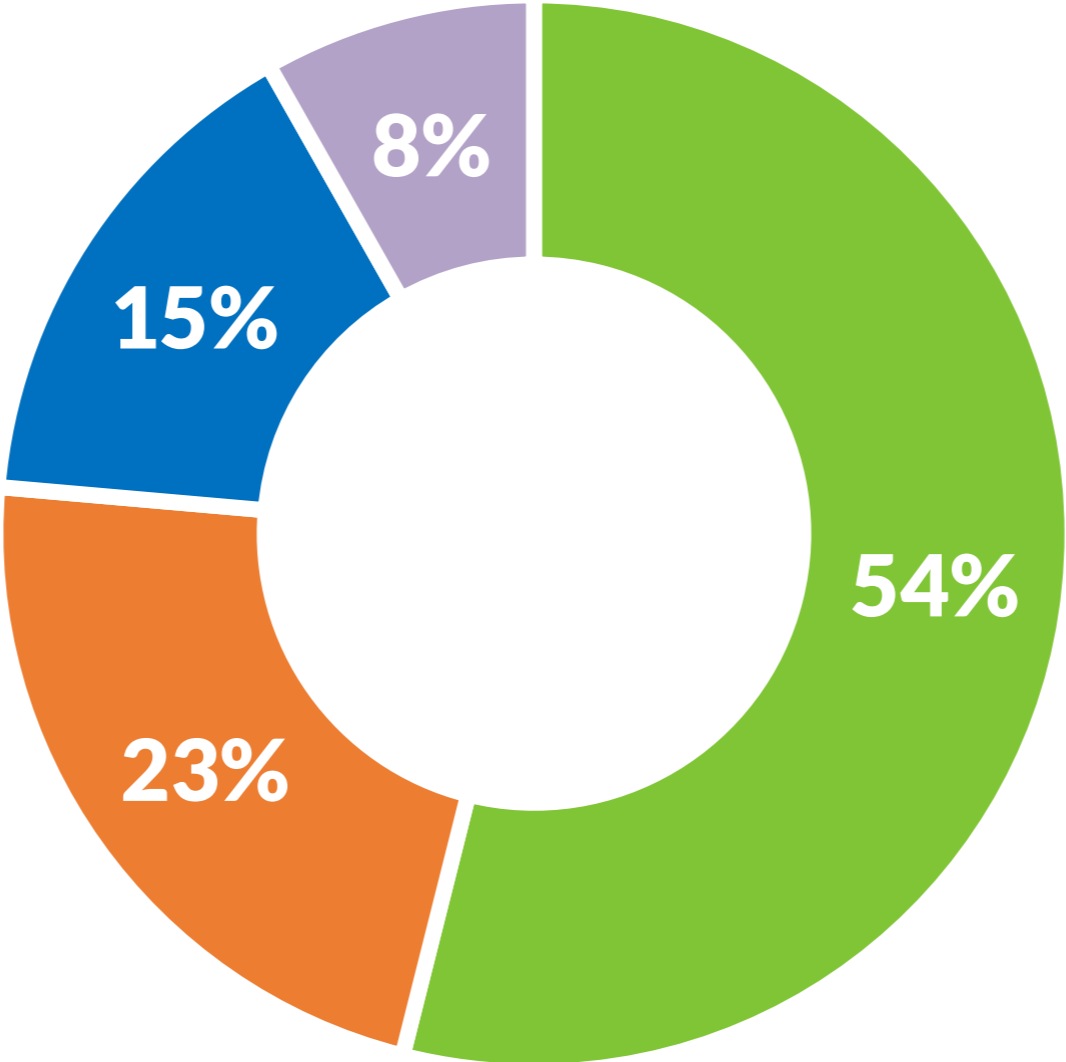


# GLOBAL PORTFOLIO



Fidia's global product portfolio focuses on strategic areas such as Joint Care Ophthalmology and Wound Care, with a variety of products resulting from its R&D activities.

# REVENUES PER GEOGRAPHIC AREA



■ Italy ■ EU (EEC) ■ USA ■ RoW

(%)

# STRONG MANUFACTURING FOCUS



**GMP-compliant manufacturing plant** (214,000 sqm) in Abano Terme (Italy) and a 21,000 sqm **Research Unit** in **Noto** (Sicily, Italy), the latter specialized in the optimization of biopolymer production by fermentation processes (i.e., enzymes, recombinant proteins and polysaccharides) from non-pathogenic bacteria strains.

**CEP certificate R0-CEP 2017-220-Rev 00 for Sodium hyaluronate** from fermentation for cutaneous and parenteral administration, including intra-articular administration, and for intra-ocular use



All stages of raw material production processes, as well as finished product manufacturing, are thoroughly and constantly supervised. This adds to the excellent credentials Fidia can offer to companies who wish to rationalize their own facilities with commissioned production (**CMO**).



All facilities and services are constantly updated, thereby anticipating any future **regulatory and quality standard requirements**.

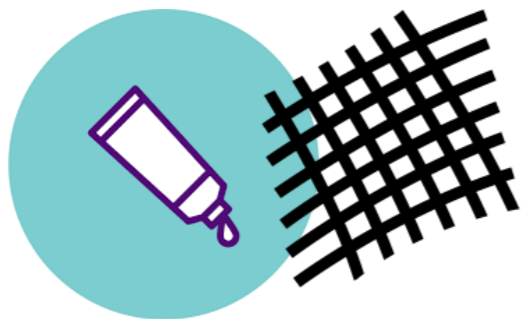


# MANUFACTURING CAPABILITIES (YR 2019)

**Wide range of pharmaceutical forms:** sterile, lyophilized and injectable products, topical formulations, eye-drops, and solid orals, offering diversified packaging solutions to meet the requirements of Fidia's clients and partners.



OVER **22 MILLION**  
STERILE INJECTABLES AND EYE DROP UNITS  
>4 MILLION PREFILLED SYRINGES



OVER **22 MILLION**  
TOPICAL PRODUCTS  
(CREAM AND GAUZE PADS)



OVER **8 MILLION**  
SOLID ORALS



OVER **14 MILLION**  
LYOPHILIZED VACCINE  
VIALS

# A GLOBAL QUALITY SYSTEM

Regularly and successfully inspected by different **health authorities**, including the Italian AIFA, the American and Korean FDA (Food and Drug Administration), the Brazilian ANVISA, and the notified body G-MED.

Complies with the **strictest national and international regulation systems and the highest safety standards**, such as EU and US cGMP (including 21 CFR Part 211, 21 CFR Part 820, a pre-requisite to manufacture and export medical devices for the US market), Quality Assurance ISO 9001:2015 and ISO 13485:2016.

Strongly engaged in sustainable development, through the worldwide **Responsible Care® programme** the global chemical industry's voluntary initiative, which commits companies, national chemical industry associations and their partners.



# EXTENSIVE CLINICAL EXPERIENCE WITH IAHA

**+180**

STUDIES

INVESTIGATING INTRA-ARTICULAR HYALURONIC ACID WORLDWIDE

**+20 K**

SUBJECTS

INVOLVED IN STUDIES INVESTIGATING INTRA-ARTICULAR HA

**+20 MIO**

PATIENTS

TREATED WITH INTRA-ARTICULAR HA-BASED PRODUCTS SO FAR\*

**ONGOING  
CLINICAL  
TRIALS IN**

**North America**

United States

**Western Europe**

Belgium, France, Germany, Italy, The Netherlands, Spain, Sweden, UK

**Eastern Europe**

Czech Republic, Hungary, Romania, Slovakia

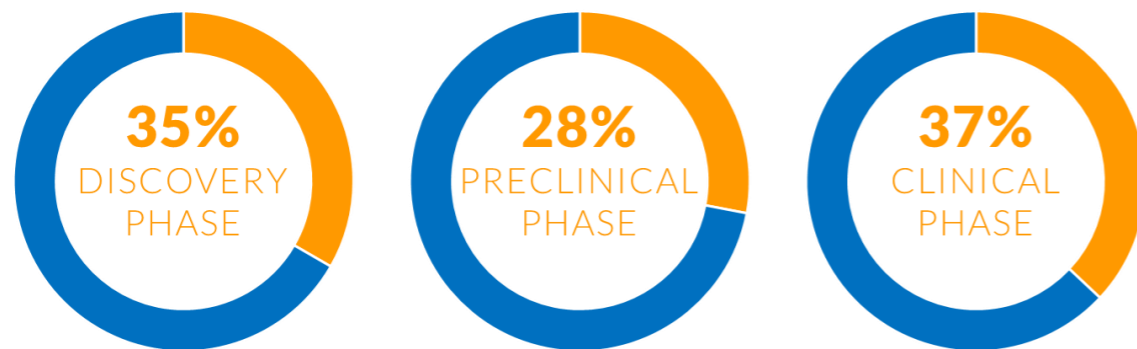
**Asia-Pacific**

Taiwan, Thailand

\* since launch of first product in 1987

# EXTENSIVE R&D EXPERIENCE

Fidia is prioritizing its R&D efforts in areas with the greatest scientific and commercial promise, such as **Joint Care, Wound Healing, Women's Health, Oncology, Aesthetic Medicine, Neuroscience, Ophthalmology**, also in collaboration with centers of excellence in Italy and worldwide, e.g, in Europe, USA and Australia.



R&D projects are carried out both in Abano Terme's laboratories and at the Research Unit in Noto (Sicily).





# SPECIALIZED PRODUCT PORTFOLIO FOR INTERNATIONAL MARKETS

Fidia has several decades of unparalleled experience developing innovative solutions in key therapeutic areas where **hyaluronic acid** properties can be effectively, efficiently, and rationally exploited, such as **intra-articular therapy** and **wound healing**.

More recently, based on its strong experience in the clinical applications of hyaluronic acid in the field of tissue regeneration, Fidia took up the challenge of promoting **autologous biological therapy**, thereby allowing physicians to tailor the best treatment to the individual patient.



# HIGHLY DIVERSIFIED PORTFOLIO FOR A LARGE NETWORK OF CONSUMERS

The company is also expanding its portfolio, including products and line extensions in **joint care**, **women's health** and **aesthetic medicine**, and continues to be strongly focused on the **CNS** and **ophthalmic** therapeutic areas, with important R&D projects at various stages of development.

**CartiJoint FORTE**

**CartiJoint D**

**CartiJoint D**  
1000

ITAMI

ITAMITRAUMA

Wet  
gel

Aciclinlabiale

HYALO *femme*

IAL-SYSTEM ACP<sup>®</sup>  
AUTO-CROSS-LINKED HYALURONIC ACID  
2.0%

IAL-SYSTEM DUO<sup>®</sup>  
CROSS-LINKED HYALURONIC ACID + ACP  
2.5%

IAL-SYSTEM<sup>®</sup>  
HYALURONIC ACID  
1.8%