

ACTIVE PHARMACEUTICAL INGREDIENTS API | CDMO | CHEMISTRY | HPAPI | BIOTECHNOLOGY END TO END SERVICE



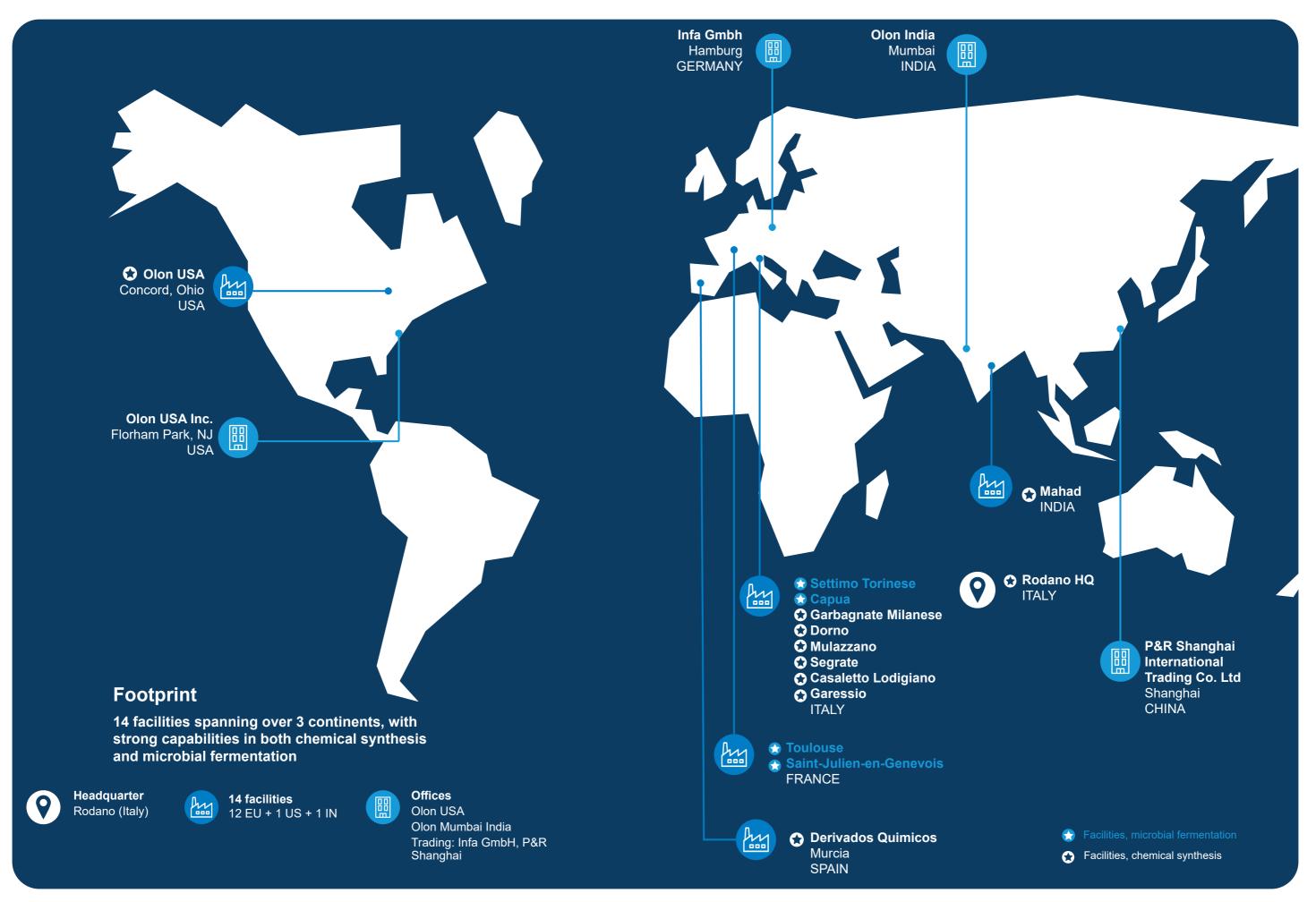
Olon Group is a global leader in the development and production of active pharmaceutical ingredients (APIs) for CDMO and generic markets, integrating chemical synthesis and biological processes while always embracing the highest international safety, quality and environmental standards.

With one of the longest track records of the API industry, having deep development expertise and a broad set of advanced technologies, we are the partner of choice which enables our client's molecules to enter the market successfully.

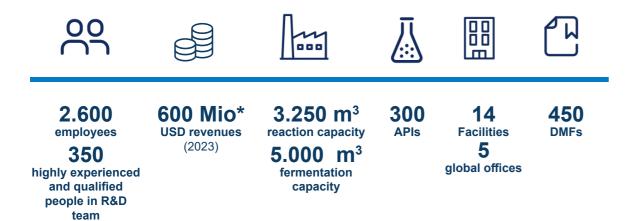
Olon has a global network of **14 manufacturing sites and 9 R&D centers** across the globe. Thanks to our 2,600 employees, including 350 highly experienced and qualified R&D experts, we represent a highly innovative and reliable partner.

At Olon, expertise and competent flexibility throughout the organization help build successful outcomes for our clients in custom chemical synthesis and microbial fermentation, while always maintaining the highest levels of safety, quality and environmental compliance





# Olon at a glance

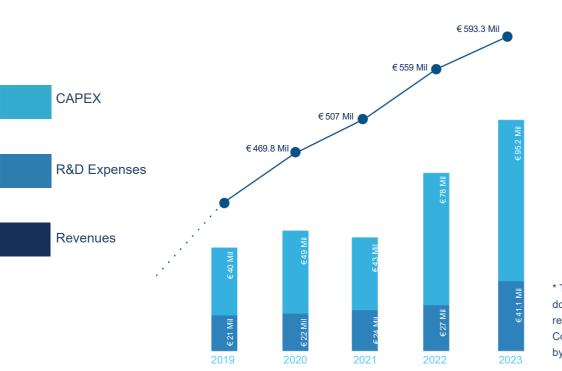


## Investments

We constantly develop technological platforms: a long-term program in which the Group has invested substantial human and economic resources, in order to explore new technologies or new applications for existing technologies.

The aim is to facilitate introduction of **environmental and economical sustainable production** of new pharmaceuticals and improve the quality and sustainability of the manufacturing process for those which we already produce.

We constantly invest in our sites to upgrade the facilities in terms of GMP and technology standard, and to increase the manufacturing capacity, innovation and sustainability of our facilities.



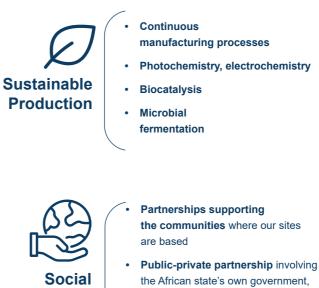
\* The financial data do not include the revenues of the Companies acquired by Olon in 2024 We are deeply aware that sustainability is not just an objective measurement based on reducing consumption and adopting greener technologies. It directly involves people and the surrounding social contexts. Only through coordinated, integrated development of this aspects we can expect to achieve significant goals, producing positive impacts for the Company and for society as a whole.

We are promoting environmental sustainability and energy transition, with significant investment in systems that harness alternative energy sources, and social and economic involvement and support for the communities in which we operate.

Our commitment to creating an increasingly sustainable and certified supply and production chain by transferring our values and standards to our global suppliers, and we continued our efforts to develop innovative production processes with an ever-decreasing environmental impact through research and development projects

### **ENVIRONMENTAL TARGETS**

Responsibility



the African state's own government, aimed at helping the local population suffering from sickle cell disease









# **OLON CDMO SERVICES**

Through chemical synthesis, microbial biomanufacturing or a semi-synthesis approach, we offer, under GMP, dedicated solutions for the development and manufacturing of NCEs, advanced intermediates, building blocks, enzymes & proteins, peptides of rDNA origin, high potency drugs, controlled substances and food bio manufacturing.

We guarantee customer support from the CDMO pharma R&D lab up to full-scale commercial manufacturing and strong regulatory support.

Our experience and global footprint allow us to follow the entire process in house, with a single point of contact for the customer and complete accountability.

## **Small Molecules**

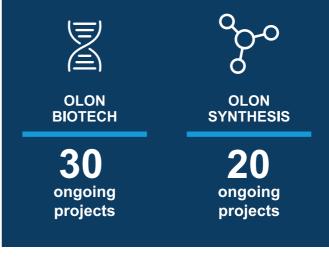
Small molecules represent a vast range of low molecular weight organic molecules that are essential for the development of numerous drugs.

Leveraging cutting-edge technology and a team of dedicated researchers, Olon continuously innovates in this domain, positioning itself as a leader in the manufacturing and development of these essential molecules, ensuring high-quality standards and tailored solutions for client needs.

The allure of small molecules stems from their unique physicochemical properties, which not only make them amenable to drug development but also allow for custom drug design. This adaptability results in targeted mechanisms of action, increased specificity, and reduced side effects, thereby improving patient outcomes.













## **Olon Biotech**

**Olon is a global partner of CDMO services in the field of microbial fermentation.** With more than 50 years experience in microbial fermentation, Olon has developed extensive know how which it applies to both CDMO and Proprietary Product production, including High Potent or Toxic Compounds requiring high containment systems.

Our experience in microbial fermentation embraces a broad range of bacteria, yeast and fungi. We offer a wide range of expertise from small molecules to large molecules – peptides, enzymes, proteins. We are able to support every stage of the lifecycle, from R&D and preclinical phases to industrialization, through microbial and mammalian fermentation and biotherapeutics.

We are an industry leader in applied biotechnology at industrial scale, able to manage the complexities often associated with the technical transfer and scale up stages. Due to our wide range of fermenter sizes (from 1 to 5, from 35 to 60 from 112 to 255 metric cubes) we offer a total fermentation capacity 5000 m3, making Olon Biotech one of the largest companies providing manufacturing services for third parties via microbial fermentation in Europe.

We are an **industry leader** in applied biotechnology to industrialization and commercialization, **able to manage the strong complexity** implied in the tech transfer and in the scale up of biotech process.

Endorsed by a strong experience in developing the production process from pilot to commercial scale, our experience in fermentation embraces managing broad range of microorganisms as bacteria, yeast and fungi. We offer a strong expertise from small molecules to large molecules – peptides, enzymes, proteins and rely on a highly skilled team of operators. **Olon expertise gained over more than 50 years**, represents one of the most extensive know how of microbial fermentation in Europe.

We have **four Biotech Centers**, bbased in Italy and France, that represent centers of **excellence in the microbial fermentation field**, meeting the **highest global quality standard**. Our Biotech Centers are multipurpose and able to manage the highest complexity; they are endowed with a unique flexibility and diverse capabilities thanks to the competencies gained by applying different manufacturing processes to different product and reach a total fermentation capacity of 5.000 m<sup>3</sup>.

Olon is also developing **one of the market's most innovative technological platforms**, capable of offering high-quality peptides. We are one **of the few companies able to integrate expertise in the two areas of chemistry and biotechnology**, in both of which we have extensive experience, to offer seamless platforms combining two processes meeting the needs of our Partner.

At the heart of Olon Biotech are the two bio-hubs based in Settimo Torinese and Capua, Italy. Our Biotech Centres are multipurpose and can handle production process with high level of complexity. They boast unparalleled flexibility and diverse capabilities thanks to the competencies acquired by applying different manufacturing processes to different products.

Our expertise in high containment processes goes back a long way.

In the 1970s our plant in Settimo Torinese was one of the first sites worldwide to operate in containment via microbial fermentation.

Since then, we have been investing in HPAPI production expertise to support our customers.

Our Biotech networking includes also Olon India, based in Mahad. Although it is not its prior asset, the site leverages on microbial fermentation facilities and expertise, managing the entire process flow of fermentation. With more than 50 years of experience, Olon Biotech represents one the most extensive know how of microbial fermentation applied to CDMO and Proprietary Product production, including High Potent or Toxic Compound thanks to high containment systems.

Our experience in fermentation embraces managing broad range of microorganisms as bacteria, yeast and fungi. We offer a strong expertise from small molecules to large molecules – peptides, enzymes, proteins.

We are an industry leader in applied biotechnology to industrialization, able to manage the strong complexity implied in the tech transfer and in the scale up of biotech process. We are endorsed by a strong experience in developing the production process from pilot to commercial scale.

Our global footprint led us to be one of the biggest companies producing via microbial fermentation for third parties in Europe, thanks to our fermenter's sizes (from 1 to 5, from 35 to 60 from 112 to 255 mc) and total fermentation capacity 5,000m<sup>3</sup>.

We are always driven by customer focused attitude. We can adapt project management approach in a flexible manner in terms of customising both the process and its timeframe of execution as well, to meet customer needs.

In the last three years we have invested over 130 million euro in our Biotech Centers. We have allocated an investment plan of over 50 million over 2024 / 25.

The investments have generated a significant increase of our capacity, new purifications departments, some of which from greenfield investments, modernization and upgrading of existing areas, further than improvement and efficiency enhancement of production processes. We have invested in the sites, making them more sustainable and lessening their environmental impact. We recently presented the two-year plan for investment in the Settimo Torinese Biotech Centre. The plan, worth €30 million, is significantly expanding the capacity and expertise of developing and producing therapeutic peptides obtained through biotechnology.



# **Generic API supplier**

We manufacture API via chemical as well as biological synthesis, relying on extended internal technical expertise while meeting the highest standards of quality and reliability, being competitive and cost-effective.

With a portfolio of 200 Generic APIs, we offer one of the most extensive track records in the industry, and we manage more than 450 Drug Master Files WW. Our portfolio embraces all the major therapeutic areas including oncology, CNS, infectious disease, immunology, dermatology, cardiovascular and many others.

Being an early adopter of the most advanced technology and processes, and handling the broadest range of analytical capabilities, we represent a partner enhancing competitiveness and time to market.

We have diversified and backed investments across several lines and multiple facilities to be able to manage various high-containment molecules at different scales and guarantee flexibility on a significant scale. We represent an agile and versatile API provider able to meet the needs of the most demanding clients. We customize our API from a chemical and physical viewpoint to match the specific and stringent project requirements of our customers; furthermore, our strong quality and regulatory expertise allow us to manage at best the approvals from the most demanding local authorities.



We are longstanding leader of the retinoid market, thanks to a product portfolio that includes all the main active ingredients in this class, as Tretinoin, Etretinate, Fenretinide, Isotretinoin, Alitretinoin, Tazarotene, Acitretin, and Trifarotene.

Olon also recorded a significant strengthening of its active ingredients for respiratory use which has been driven by the focus on innovative product applications to niche therapeutic areas with great unmet needs, and on developing specific physical properties of molecules for the administration via innovative inhalers.

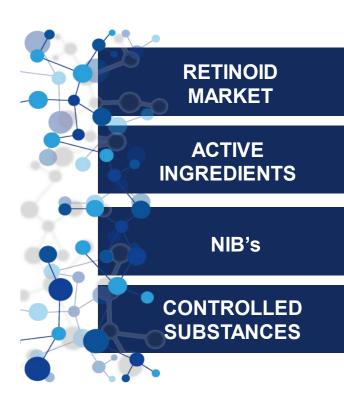
In continuity with the latest developments, we have developed several new 'NIBs' with proprietary technology and patent filings.

We are licensed to import narcotic raw materials on a commercial scale and routinely manufacture and distribute controlled substances such as psychotropics and intermediate lysergic acid throughout the world. Schedule III and IV APIs are currently licensed: Diethylpropion HCI, Phendimetrazine Tartrate, Phentermine HCI, Benzphetamine HCI.

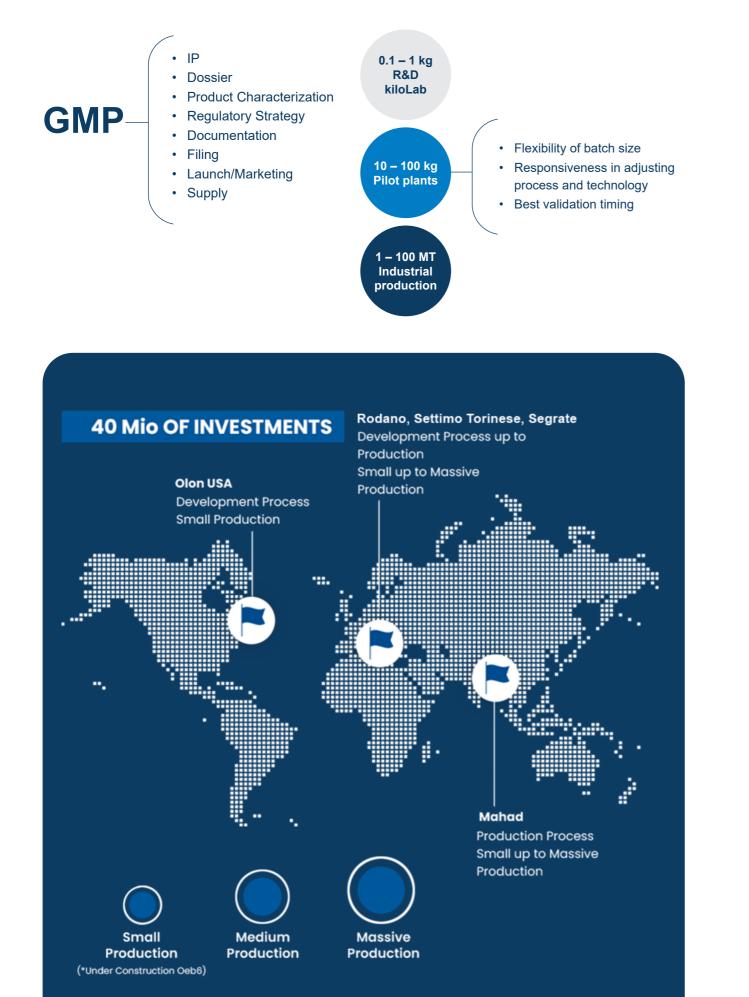
Being an early adopter of the most advanced technology and processes, and handling the broadest range of analytical capabilities, we represent a partner enhancing competitiveness and time to market.



## partnership with customer from lab up to commercial manufacturing



We represent an agile and versatile API provider able to meet the needs of the most demanding clients.



Taking advantage of the multisite footprint and a large technological portfolio available, Olon can be considered a real one-stop shop supporting all the phases of the development of a new drug starting from preclinical material up to the product required for the launch and commercial. In addition, we represent a one-stop shop from operational standpoint since that we can be involved in the production of an API starting from basic raw materials through regulatory starting materials, GMP-intermediates to the final API.

We constantly invest in our sites to upgrade the facilities in terms of GMP and technology standard, and to increase the manufacturing capacity.

We are working on the cutting edge of R&D applied both to chemistry, with flow chemistry, photochemistry and electrochemistry, and to biotechnologies.

High-level expertise and know-how applied to specific processes, consolidated in the 14 Olon plants worldwide and 9 research centres, are connected, shared, and extensively applied across the whole of the group's manufacturing network.

We offer seamless transition of the technology and scale-up, advanced control and in-depth understanding of out customers' processes from the outset, engaging the best in-house talent specialized in the specific process or technology.

The constant investment in innovation is strictly integrated with the protection of intellectual and technological property, in which the company invests heavily, and which represents a strategic asset of the Group.

The management and protection of proprietary know-how takes place according to consolidated company policies that regulate confidential information, including those owned by third parties.

As regards Olon's patent portfolio, it currently includes approximately 65 patent families, equal to approximately 256 patents, between patent applications and granted patents.

For the protection of the research and innovation generated in Olon, the IP function is committed to identifying and protecting them, including through either the filing of patent applications for Olon owned IP or the support to our customers for the filing of their patent application.

Olon guarantees that each product and related synthesis processes do not violate the IP rights of third parties. This occurs through constant and continuous work of analysis, evaluation and updating of the opinions develop.

## **High Containment Platform / Payloads**

We offer the capacity to develop and produce highly potent APIs, from very small to large scale, along the entire development chain.

We have completed the new extremely high containment production line with reactors that allow us to produce highly potent APIs in large-scale product batches ranging from 30 to 150 kg that enables us to serve the customer along all the stages of the scale up.

We are building a new facility which will be entirely dedicated to managing and producing Ultra-Potent compounds, used for example as payloads and payload-linkers for antibody-drug conjugates. The ultra-highcontainment production line will produce high-potency and toxic products and will therefore reach containment level OEB6 (target OEL 10 ng/m3).

# Next level technology

Olon is one of the few API suppliers to offer the range of specific integrated capabilities necessary to support the customer from the first clinical phase up to industrialization, regardless of the quantity of product needed and batch size required and regardless of the ongoing molecule development phase. From a few grams to hundreds of kilograms.



### **Technologies**

One of the widest range of leading-edge technologies chemistry and biotechnology expertise.

- High Potent Compound handling capabilities
- Filter driers, isolators and hightech segregated areas
- Photochemical conversions
- Chromatographic purification
- High pressure hydrogenations
- Cryogenic reactions, Hydrogenation also for acidic substances, Fluorination
- Distillation column
- Biocatalytic transformation
- Controlled substances as psychotropic, lysergic acid intermediate
- Micronization
- Biotechnology expertise Gene Synthesis, Protein Expression & Production, Recombinant Peptides



### Hazardous Chemistry

- Hydride Chemistry (Lithium Aluminium hydride and Borane complex up to hundreds of kg of active)
- Cyanation (hundreds of kgs of cyanide/batch)
- Fluorination with either Electrophilic or Nucleophilic fluorinating agent (not F<sub>2</sub>)
- Large scale oxidations even in organic solvents (e.g.H<sub>2</sub>O<sub>2</sub>, HCIO, Peracetic acid...)
- Bromination (up to 1,500 kg/batch)
- Carbonylation
- Organometallic reagent such as Lithium Reagents (up to hundreds of kg of active)
- Reaction with Sodium metal
  (up to 150 kg per production batch)
- Hydrazine/Hydroxylamine
- Isolation

GC

• NMR

• X-ray

LC/MS, GC/MS

Thermal Analysis

Physical Testing

surface tension

Semai-prep chromatography

Analytical capabilities

Our level of manufacturing

We are one of the few able

needs and objectives.

to implement in house

Nitrosamine analysis.

Atomic Spectroscopy

• UPLCs, HPLCs, prep-HPLCs,

Molecular Spectroscopy

Particle size, microscopy,

osmometry, dissolution,

hygroscopicity, viscosity,

capacity, customized on your

Stability Reach-in and walk-in sized stability chambers, forced degradation, photostability

## R&D Hub, Rodano

Intended to form the cornerstone of and reinforce the company's global research network, which has 9 other similar centres located in its 14 production sites in Italy, Spain, the USA and India, and according to a strategy of diversification of skills and applied technologies, it is mainly dedicated to the development of APIs for Contract Development and Manufacturing Organization and generic markets.

The new hub represents an expansion in terms of people to achieve faster scale-up and tech transfer processes both from customers to Olon's production sites and internal transfers from one site to another; and finally, to achieve more competitive levels of process safety standards, consistent product quality and guaranteed business continuity.

The hub will include a laboratory for process safety and the study of scale-up and process transfer; an analytical R&D area; a process development laboratory with working groups dedicated to the development of advanced processes.



## **Facilities**

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