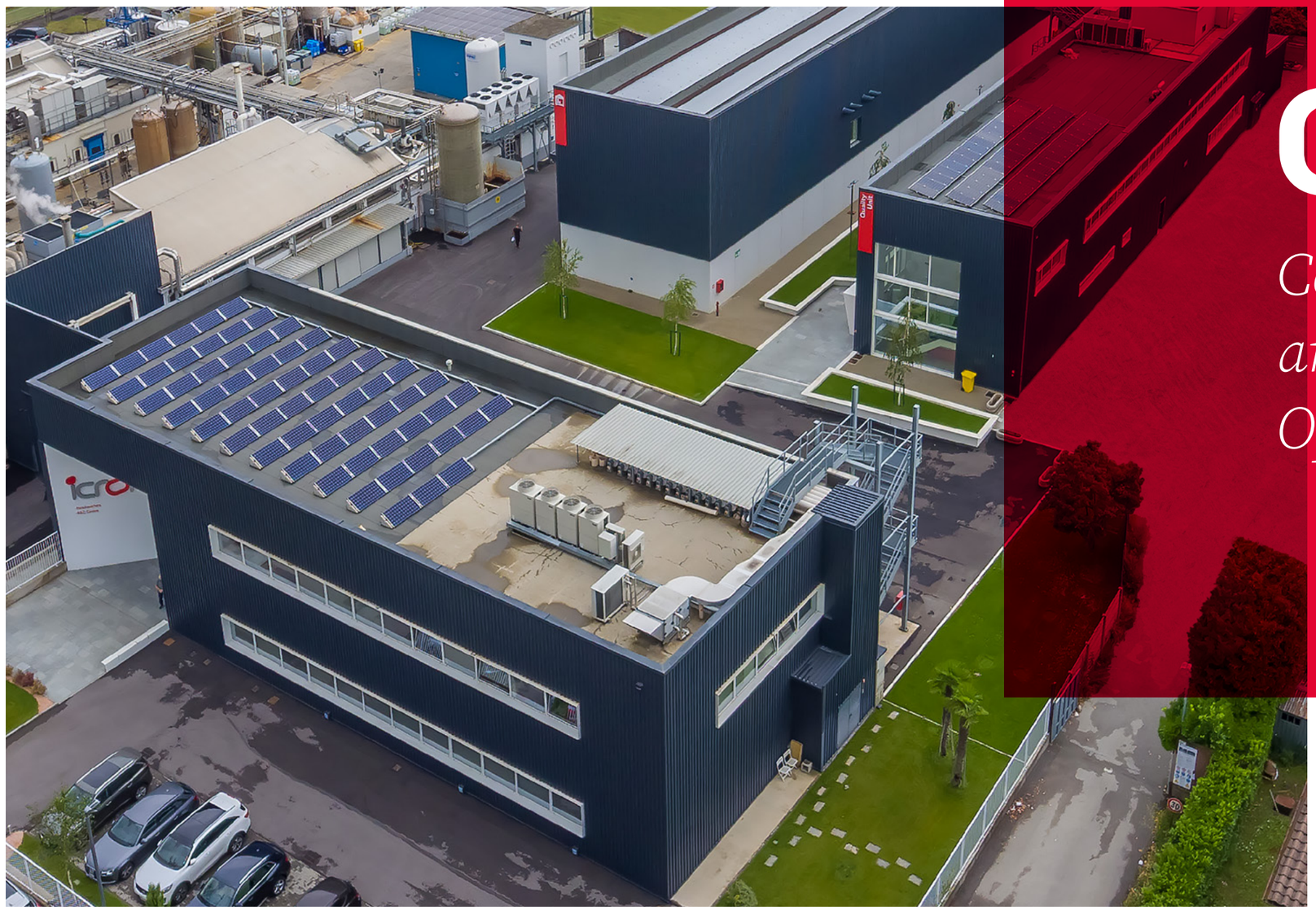
YOUR BOUTIQUE FOR HI-TECH APIS



CDMO

Contract Development and Manufacturing Operations for APIs

History

OVER 50 YEARS OF EXPERIENCE IN CHEMICAL DEVELOPMENT AND GMP MANUFACTURING ACTIVITIES

1969

Establishment by the founder Jean Epuran. CMO for Synthelabo (later Sanofi).

1996

Acquisition by the French group Protex International (Robert Moor).

2004

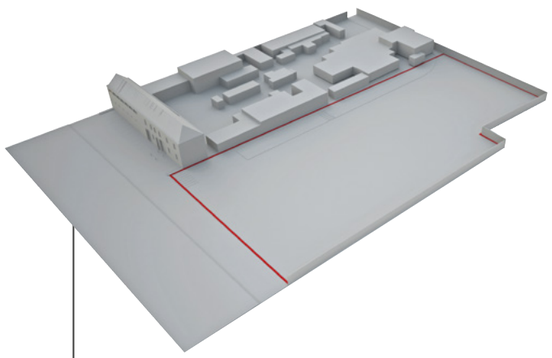
Establishment of Proxis Développement group as a spin-off of Protex. ICROM enters Proxis group held by Arnaud Moor (IIIrd generation). Strong investment period both in capabilities and technologies for development activities.

2014

Significant site expansion from 5’000 up to 20’000 sqm. Further investment in production workshops, warehouses, R&D capabilities

ICROM FACILITIES
YEAR 2004

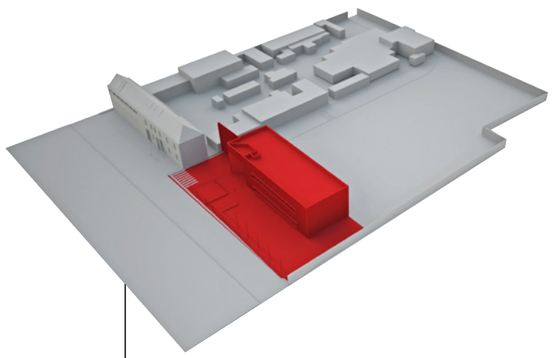
Investments to growth



2014

ACQUISITION OF A NEW EXPANSION AREA

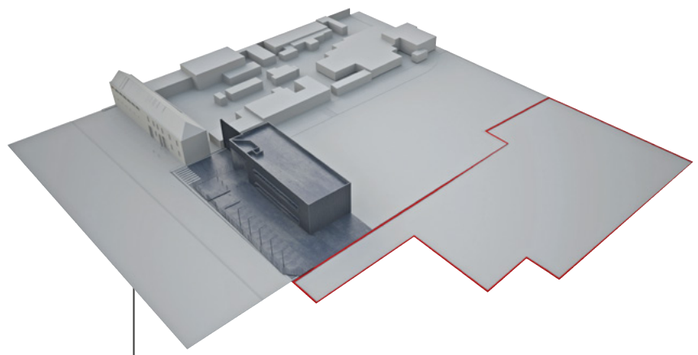
6,000 sqm at the south border.
Started a considerable capital investment program.



2017

NEW HQ BUILDING AND R&D CENTRE

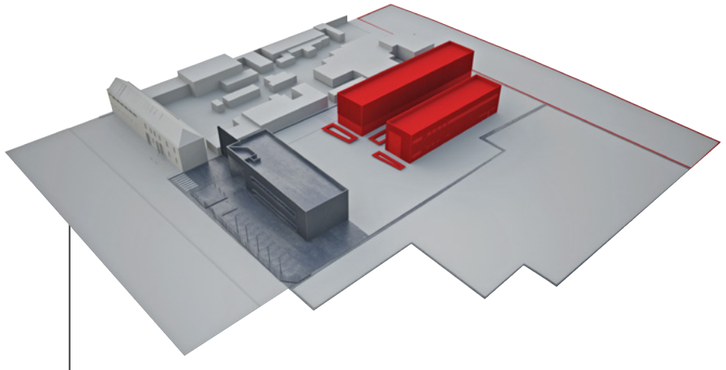
1,000 sqm surface.



2018

SECOND EXPANSION AREA ACQUISITION

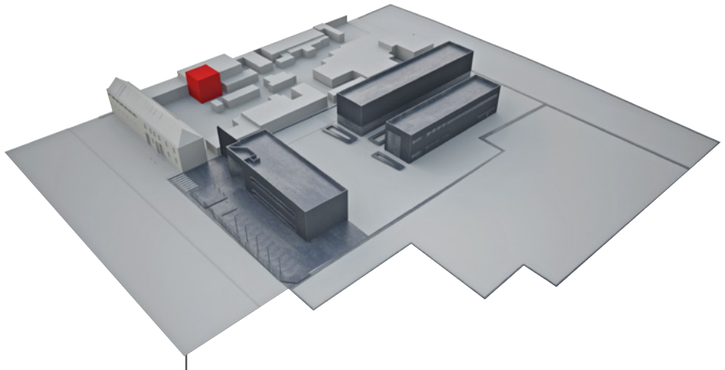
Further 3’500 sqm area are added to the Site layout.



2021

NEW WAREHOUSE AND QULITY UNIT BUILDING

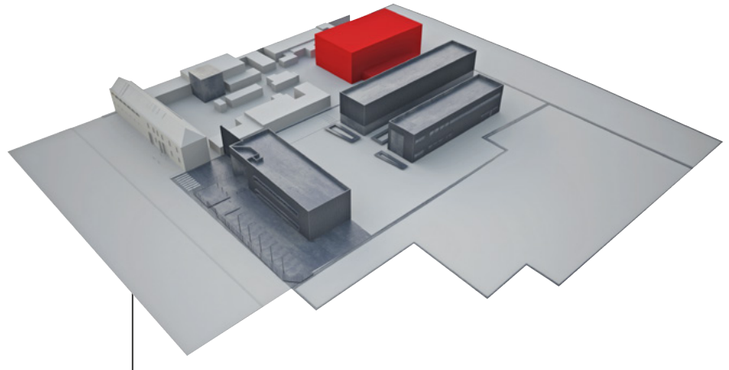
900 sqm warehouse equipped with semi-automatic shelves allocating over 1’600 pallets. Establishment of the quality building hosting brand new QC lab and QU offices. Acquisition of additional 2’500 sqm at the East boarder of the Site Area.



2022

CLINICAL SCALE API PLANT

Establishment of a new CMC building able to meet the requirements of small scale APIs for clinical programs.



2025

NEW PRODUCTION HUB

Scheduled the establishment of a large scale production building designed in compliance with the latest guidelines in terms of ecosustainability .

Our Core Services are your Solutions

We have the expertise and the technologies to support large Pharmaceutical innovators, as well as small Biotech companies, in the challenging development of their pipeline, from R&D till approval and commercial phase.

- Route scouting & Process Design
- Parallel Chemistry and Design of Experiment (DoE)
- Quality by Design
- Process Development, Scale-up & Optimzation
- Solid State Studies & Polymorphs Screening
- Analytical Methods development & validation
- Synthesis and Characterization of Impurities
- Dedicated Project Management
- Technology transfer and industrialization
- cGMP Clinical Scale & Industrial Scale Manufacturing

Custom Development

HIGH EXPERTISE IN COMPLEX CHEMISTRY

- Cross-coupling reactions
- Heterocyclic chemistry
- Chiral chemistry
- Organocatalysis
- Grignard chemistry
- Lithiation & Organolithium Reactions
- Chromatographic purifications
- Chemical technologies for conjugating cytotoxic payload with peptides and biomolecules
- Solid state chemistry
- Proprietary sterilization technologies

DEDICATED RESOURCES

Area of 500 sqm

– Integrated R&D Centre divided in 2 laboratories

Equipment

– 16 hoods
– 50 glass reactors for non-GMP synthesis up to 10L
– Semi-Automated Parallel Reactors
– Preparative Automated Chromatographic systems

Analytical equipment

– 10 HPLC
– 2 GC-HS
– 1 UPLC-Mass Spectrometer
– 1 DSC
– 1 Polarimeter
– 1 Particle Size Analyzer

Team R&D

– 10 Organic Chemists (5 with Ph.D.)
– 3 Analytical Chemists

Custom Manufacturing

DEDICATED TEAM FOR TECHNOLOGY-TRANSFER, SCALE-UP AND INDUSTRIALIZATION

– 1 Ph.D chemist

– 1 chemist

PRODUCTION OPERATORS

– 32 Technical Operators over 3 shifts, 5 days/week

– 60% of the operators holds a chemistry secondary school degree

MANUFACTURING TECHNOLOGIES

– High pressure catalytic hydrogenations

– Cryogenic and high T capabilities from -70°C to 200°C

– Manufacturing technologies of diagnostic dyes

– High potent API containment

– Ozonolysis technologies

– Micronization capabilities

– Permitted use of very corrosive and toxic reagents on industrial scale

ICROM's production units operate under European cGMP and are regularly inspected by AIFA.
ICROM is also approved by International Regulatory Agencies including US-FDA, JP-PMDA, KFDA.

ICROM's HSE and QA systems ensure full compliance to the strictest International regulatory guidelines.

cGMP Multi-scale manufacturing facilities

SMALL SCALE (0,5 Kg - 2 Kg)

- 4 x 25L glass-reactors,
- Buchner filters and static dryiers

CLINICAL SCALE (3 Kg - 6 kg)

- CMC building equipped with independent QC GMP lab. for IPC
- 2 x (100 L, 200 L, 400 L) glass lined and hastelloy reactors
- Hastelloy filter dryer
- Centrifuge and static dryer

MEDIUM SCALE (10 Kg - 50 Kg) and **LARGE SCALE** (up to 1-2 mT)

- Multi-scale reactors (500L - 6’000L) stainless-steel, glass-lined and Hastelloy
- Centrifuges stainless-steel
- Hydrogenation reactor (500L)
- Cryogenic system
- Paddle dryiers and biconical dryiers
- Jet-mill and conical mill

HIGH-POTENCY UNIT

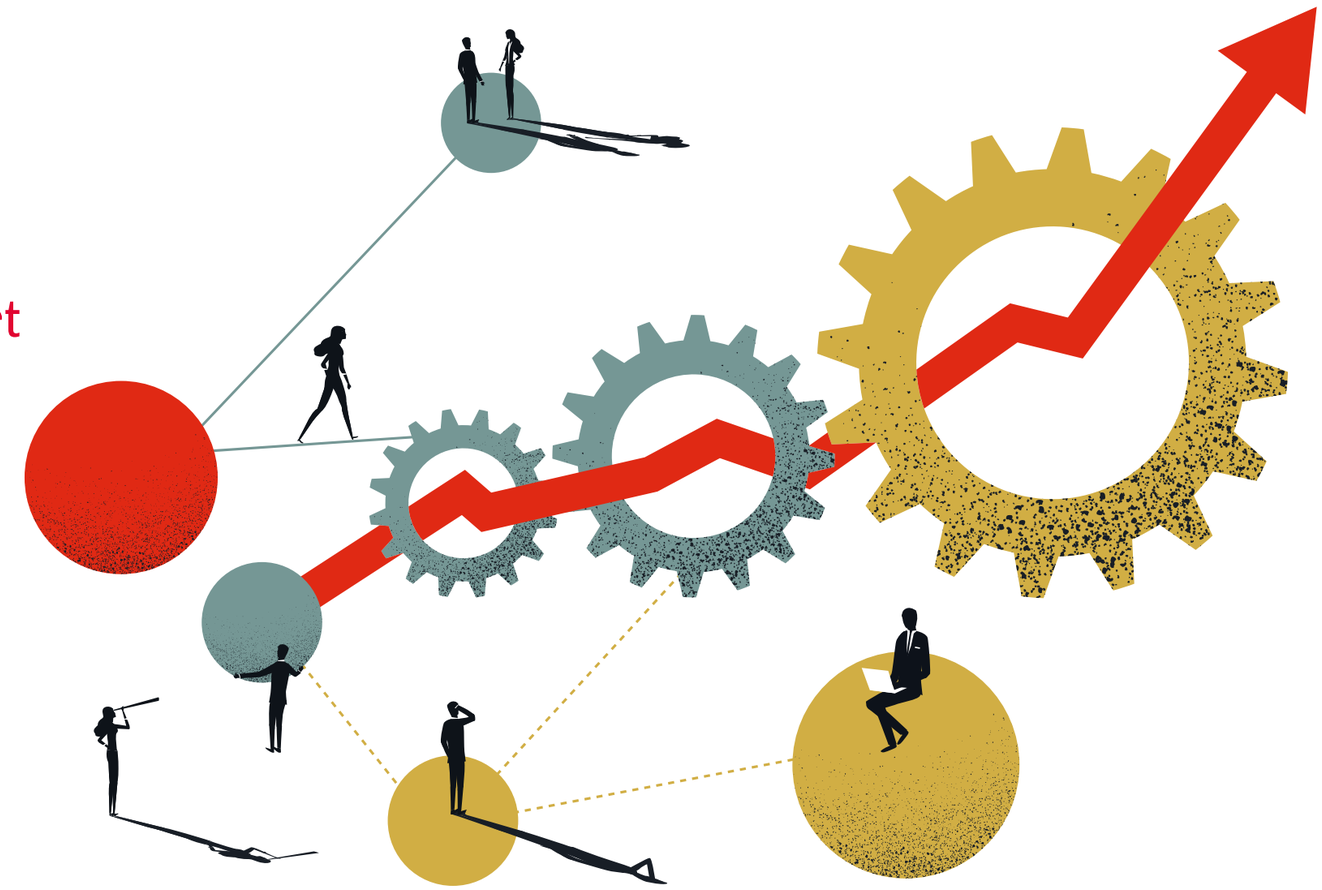
- High containment isolators for GMP manufacturing of highly potent and cytotoxic APIs
- OEL 0,1 µg/m3

Project management

ICROM's PM team will be able to support and coordinate the activities as API CDMO, also in connection with your CMC Team and your Partners, such as:

- CLINICAL RESEARCH ORGANIZATIONS
- DRUG PRODUCT CDMO
- REGULATORY ADVISORS

enabling a smooth progression of your drug development program



PLAN MANAGEMENT

- Project Plan definition : activities, responsibilities and GANTT chart
- Budget allocation and Project's proposal definition
- Assignment of Project's Team, functional managers and FTE resources

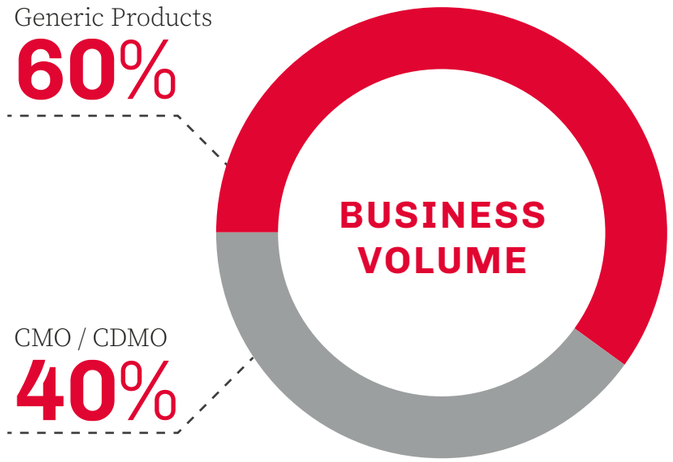
OPERATIONAL MANAGEMENT

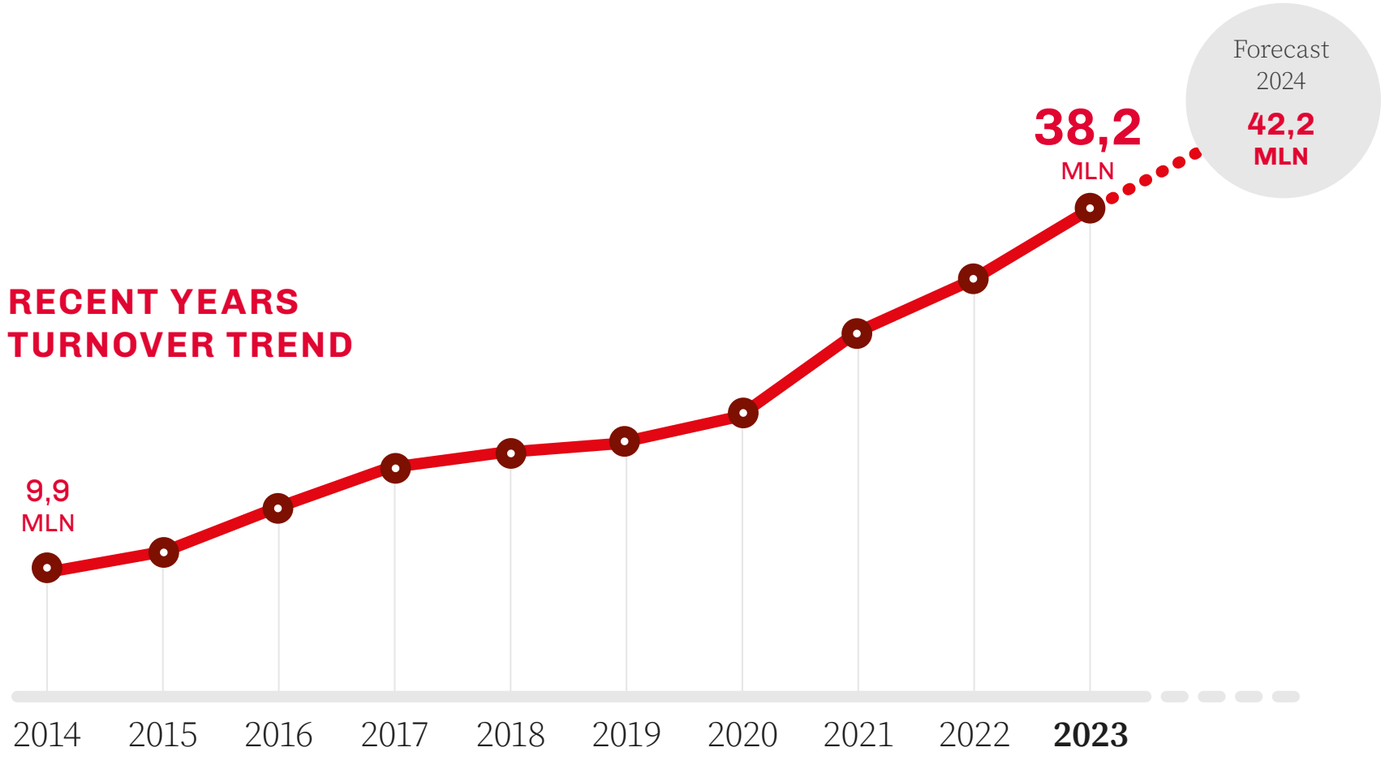
- Continuos operational planning
- Monitoring and Control of critical factors and progress estimations
- HSE, QA and Regulatory supervision from the project's baseline
- Dedicated Supply Chain management & control and integrated approach for risk management and prevention

THIRD-PARTIES INTERACTION AND COORDINATION

- High-level coordination and technical support
- Scientific advise and scientific plan to address the impact of API process with : formulation development, delivery system, bioavaillability, regulatory compliance & CMC

Business Operations





CLINICAL PROGRAMS SUPPORTED WW (2017 - 2022)

START DATE	TYPE	COUNTRY	EARLY STAGE DEVELOPMENT	CLINICAL DEVELOPMENT	UNDER SUBMISSION	PENDING FOR APPROVAL	APPROVED	LAUNCHED
2021	NCE	EUROPE	■					
2021	NDA	SOUTH KOREA	■	■				
2020	Branded generic	EUROPE	■					
2019	NDA	EUROPE	■	■				
2019	Branded generic	EUROPE	■	■	■			
2018	NCE	USA	■	■	■			
2018	Branded generic	EUROPE	■	■	■	■	■	
2017	NCE	USA	■	■	■	■	■	
2017	NDA	USA	■	■				
2015	NDA	JAPAN	■	■	■	■	■	■

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