Science. People. Affordable and innovative medicines.
Synthon is a company committed to delivering quality medicines at sustainable pricing through innovative science.
Science-driven innovation

Good health is something we all desire and deserve. We believe that everyone on the planet is entitled to have access to quality medicines at sustainable pricing. We will put our cutting-edge science, ability to innovate and talented people into action to provide solutions to the healthcare challenges of today and tomorrow.

Innovation and continuous improvement are the heartbeat of our company. We work to develop therapies that address the needs of people worldwide and help improve their health and well-being. With our portfolio of innovative medicines, we will provide treatment options for patients in selected therapeutic areas with high unmet medical need. Through the provision of high-quality generic medicines we make treatments more affordable and increase access to important remedies. To make this happen, we hold ourselves to the highest standards of scientific and operational excellence in everything we do – from the discovery phase in R&D through production and to delivery of our products to our customers - across every technological platform.
A growing, global operation

Our products are currently approved by regulatory agencies in around 100 countries. We have globally-oriented API or drug product manufacturing facilities in the Czech Republic, Argentina, Chile and Spain. Furthermore, our facilities in Mexico and Chile manufacture and package products for the local markets. With our state-of-the-art biopharmaceutical laboratories and GMP facilities for the manufacture of monoclonal antibodies (mAbs) and the production of antibody-drug conjugates (ADCs) - up to Phase III clinical trials and early launches - in our main campus in the Netherlands, our worldwide infrastructure is fully rigged up, positioning us to deliver on our ambitions.

We continue to invest and expand globally and are continually looking to find partners for our products in all major markets. Synthon’s strategy from its inception included the development of a vertically integrated organization. Today, we control every facet of the development chain beginning with research, development and production of active pharmaceutical ingredients through to manufacture and sale of our drug products. This is, and has always been, one of our great strengths in enabling us to deliver high-quality medicines to the people most in need of them.
Our strategy

Synthon aims to become a recognized leader in specialty pharmaceuticals. The vertically-integrated model we developed for small-molecule generics is expanding as we continuously strive to improve our R&D capabilities, global regulatory and IP expertise, and world-class manufacturing and supply chain operations. We have extended this model to our new biological and new chemical entity technological platforms. Our innovative R&D and proven ability to manufacture and distribute high-quality pharmaceuticals position us well for our future in specialty pharmaceuticals.
Research and development remain vital to the overall value chain and are essential to our company. We therefore invest heavily in basic and applied research. In addition to chemical and (bio)pharmaceutical R&D, we carry out analytical and clinical research worldwide. We have our own fully-functional clinical drug development unit which is well-equipped to take our development phase compounds into clinical trials - up to and including Phase III.
Complex small-molecule generics and hybrids form the backbone of our product portfolio. Our generic product range covers many therapeutic areas with medicines to treat a large number of diverse indications. One common factor drives our business and that is the pursuit of innovative excellence with a clear preference for complex synthesis and sophisticated dosage forms. This results in first-rate medicines that meet market needs, supported by strong patents that guarantee a long product lifespan.

Our generic pipeline is rich with research projects and pending regulatory applications. As the only company to have performed a large-scale, multicenter Phase III study for glatiramer acetate 20 mg/ml and obtained regulatory clearance in Europe, we introduced this important product in many significant markets across Europe. Other recent product launches include sevelamer, for the treatment of chronic kidney failure, in several EU countries and ivabradine in the Czech Republic and Slovakia. Ivabradine is used to treat chronic stable angina pectoris and chronic heart failure. We also launched imatinib capsules for the indication chronic leukemia in Italy and Finland, while etoricoxib, a non-steroidal anti-inflammatory drug indicated for the treatment of inflammation and pain, was launched in several countries including Germany and Italy. Additionally we introduced anagrelide, as first-to-market generic for the treatment of thrombocythemia in our major markets, and clofarabine, which is used to treat children and young adults up to the age of 21 with acute lymphoblastic leukemia, in the United Kingdom.
Promising biopharmaceutical pipeline

Synthon started its biopharmaceutical franchise (the development of biopharmaceutical medicines based on therapeutic proteins) in 2007. Today, the franchise focuses on new molecular entity development. This highly innovative business covers a wide spectrum of very diverse technologies, including complex small-molecule chemistries, medicinal chemistry, cell line development, and recombinant protein production, protein purification and protein modification, including (site-specific) conjugation, analytics, formulation and development of novel medicines. Our well-equipped team of professionals, experts in in vitro pharmacology, in vivo pharmacology, protein interaction, companion diagnostics and toxicology, carries out the extensive pre-clinical R&D work for our innovative programs.

Our principal technologies include monoclonal antibody (mAb) technology, as well as antibody-drug conjugate (ADC) technology, including a unique linker-drug platform to generate novel ADC candidates.

In 2014, we brought our most advanced ADC candidate SYD985 to the clinic for a two-part first-in-human Phase I study. Since then, we have been successfully progressing the clinical evaluation of this anti-HER2 ADC in patients with HER2 positive metastatic breast cancer, as well as in patients in other indications where no effective anti-HER2 therapy is currently available.

Our pipeline of new molecular entities is well-positioned to encompass multiple clinical-stage programs in the coming years and reflects our focus and commitment to bring medicines for treating medically complex and serious conditions to patients with a high unmet medical need, notably in oncology and autoimmune diseases.
We believe in a collaborative model based upon strong partnerships with leading scientists, research institutions and marketing partners. Our strategy of developing robust business-to-business partnerships enables us to share knowledge with and draw upon the specialist skills of partner companies. This helps to manage costs, deliver short product development cycle times and bring much-needed products to market. Such has been the success of our efforts that we now have over 200 partner companies today.

In terms of commercializing our programs, Synthon will choose the optimum timing to partner each program. This might involve: taking a given product all the way to market, or, alternatively, partnering a technology or pipeline project at the appropriate stage or value inflection point.

Strength through collaborative partnerships
Intellectual property rights will remain a crucial factor in the pharmaceutical industry. We actively promote and defend our interests worldwide, particularly with regard to patent and regulatory issues. To this end, we have access to high-quality legal representation and employ in-house patent attorneys, information specialists and support staff. By having the right legal expertise at hand, we can proactively ensure that our interests are fully protected and a seamless and effective business operation is maintained.
In our Generics business, we provide our customers with a complete product, including all components necessary for trouble-free registration, wherever in the world. In practical terms, this means that our experts are familiar – down to the smallest detail – with increasingly stringent and ever-changing regulatory regimes in more than 100 countries. We compile registration files, compliant with the chemical, pharmaceutical and clinical requirements of regulatory authorities, such as the EMA, FDA and TGA. Generally, we out-license our biopharmaceuticals before regulatory submission, but our counterparts can count on detailed documentation and support that can eventually be used to build a dossier for submission.
## Our products

Our products are all high-quality, affordable medicines, supported by a dedicated patent portfolio, guaranteeing a long product lifespan.

### Our global commercial generic portfolio includes*

#### Allergy

- **Levocetirizine**
  - Urticaria / allergic rhinitis
  - tab 5 mg

- **Montelukast**
  - Asthma / allergy
  - tab 4.5 mg, tab 10 mg

#### Anti-infective

- **Linezolid**
  - Anti-infective
  - inf bag 2 mg/ml 300 ml, tab 600 mg

- **Voriconazole**
  - Anti-fungal
  - lyo 200 mg vial, tab 50/200 mg

#### Cardiovascular

- **Anagrelide**
  - Thrombocythemia
  - cap 0.5/1 mg

- **Bisoprolol**
  - Hypertension
  - tab 5/10 mg

- **Bisoprolol HCT**
  - Heart failure
  - tab 5+12.5/10+25 mg

- **Dobutamine**
  - Heart failure
  - inj 12.5 mg/ml - 20 ml

- **Doxazosin**
  - Hypertension / BPH
  - tab 2/4/8 mg

- **Eplerenone**
  - Congestive heart failure
  - tab 25/50 mg

- **Ivabradine**
  - Angina pectoris
  - tab 2.5/5/7.5 mg

- **Simvastatin**
  - Hypercholesteremia
  - tab 5/10/20/40/80 mg

#### Central Nervous System

- **Aripiprazole**
  - Schizophrenia
  - tab 5/10/15/20/30 mg; odt 10/15 mg

- **Clozapine**
  - Schizophrenia
  - tab 25/100 mg

- **Donepezil**
  - Alzheimer
  - tab 5/10 mg

- **Escitalopram**
  - Depression
  - tab 10/15/20 mg

- **Fluvaxamine**
  - Depression
  - tab 50/100 mg

- **Galatramer**
  - Relapsing remitting multiple sclerosis
  - syringe 20 mg/ml

- **Memantine**
  - Alzheimer
  - tab 20 mg; drops 20mg/20 drops – 20ml flask

- **Paroxetine**
  - Depression
  - tab 10/20/25/30/40/50 mg

- **Propofol (LCT)**
  - Anesthesia
  - inj 1%/ 20/50/100 ml, 2%/ 50 ml

- **Rasagiline**
  - Parkinson
  - tab 1 mg

- **Zolpidem**
  - Insomnia
  - tab 5/10 mg

- **Zopiclone**
  - Insomnia
  - tab 3.75/5/7.5 mg

#### Oncology

- **Anastrozole**
  - Breast cancer
  - tab 1 mg

- **Bendamustine**
  - Chronic lymphocytic leukemia
  - tab 25/50/100 mg/vial

- **Bortezomib**
  - Multiple myeloma
  - tab 1 mg/1.6 mg vial

- **Cisplatin**
  - Cancer chemotherapy
  - tab 25 mg

- **Exemestane**
  - Breast cancer
  - tab 25 mg

- **Ibendronate**
  - Bone metastases
  - tab 50 mg, vial 2mg/2ml, 6mg/6ml

- **Ibandronate**
  - Bone metastases
  - tab 100/400 mg; cap 100 mg

- **Ibritimumab**
  - Breast cancer
  - tab 2.5 mg

- **Lamotrigine**
  - Epilepsy
  - tab 50/100 mg

- **Letrozole**
  - Breast cancer
  - tab 25 mg

- **Nexavar**
  - Liver cancer
  - tab 100/200 mg

- **Pemetrexed**
  - Lung cancer
  - tab 100 mg

- **Zoledronic acid**
  - Bone metastases
  - tab 4 mg/6 ml

#### Musculoskeletal system

- **Celecoxib**
  - Arthritis
  - tab 200 mg

- **Etoricoxib**
  - Inflammation
  - tab 30/60/90/120 mg

- **Ibendronate**
  - Osteoporosis
  - tab 150 mg, vial 3mg/3ml

- **Ibuprofen**
  - Inflammation
  - tab 60 mg

- **Zoledronic acid**
  - Paget’s disease
  - tab 5 mg

#### Systemic

- **Cinacalcet**
  - Hyperparathyroidism
  - tab 30/60/90 mg

#### Urology

- **Doxazosin**
  - Hypertension / BPH
  - tab 2/4/8 mg

- **Sevelamer**
  - Chronic kidney failure
  - tab 200 mg sachet 2.4 g

- **Tamsulosin**
  - BPH
  - mr cap 0.4 mg; mr tab 0.4 mg

* Please note that the reference date for this product list is September 2017. Our portfolio of approved products differs from country to country. In addition to the above mentioned commercial products, Synthon owns a rich pipeline of research projects and pending regulatory applications for multiple products.
Leadership by example

Synthon was founded in 1991. Within two years, our creative vision and passion for making healthcare more affordable led to the development of a generic version of dobutamine, a sympathomimetic drug used in the treatment of heart failure and cardiogenic shock. The success of this first product marked the start of our rapid international growth. Synthon quickly grew from a small Nijmegen-based company employing fewer than a hundred people into the fully-fledged company it is today with a headcount of over 1,900 highly-educated people, and laboratories, offices and production plants in nine countries around the world. This would not have been possible without the right combination of technical expertise, business discipline and entrepreneurial capability at every level of management.

<table>
<thead>
<tr>
<th>Year</th>
<th>Event</th>
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<tbody>
<tr>
<td>1991</td>
<td>Founded in the Netherlands</td>
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<tr>
<td>1993</td>
<td>Launched first product: generic dobutamine</td>
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<tr>
<td>1997</td>
<td>Opened office in North Carolina, United States</td>
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<tr>
<td>1998</td>
<td>Acquired drug product manufacturing facility in Spain</td>
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<tr>
<td>2000</td>
<td>Acquired API production facility in Blansko, the Czech Republic</td>
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<tr>
<td>2001</td>
<td>Acquired API production facility in Argentina</td>
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<tr>
<td>2003</td>
<td>Introduced simvastatin</td>
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<tr>
<td>2006</td>
<td>Introduced tamsulosin</td>
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<tr>
<td>2007</td>
<td>Acquired Laboratorios Rider in Chile</td>
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<tr>
<td>2009</td>
<td>Opened new R&amp;D and production unit in the Czech Republic</td>
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<tr>
<td>2010</td>
<td>Opened office in Moscow, Russia</td>
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<tr>
<td>2011</td>
<td>Opened new biopharmaceutical lab in Nijmegen, the Netherlands</td>
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<tr>
<td>2012</td>
<td>Multi-purpose GMP drug product manufacturing facility in Chile in business</td>
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<tr>
<td>2013</td>
<td>Licensed biosimilar trastuzumab to Amgen/Watson (now Amgen/Allergan)</td>
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<tr>
<td>2014</td>
<td>Inauguration of R&amp;D pilot plant in Argentina</td>
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<tr>
<td>2015</td>
<td>New antibody-drug conjugation (ADC) facility with high-potent clean room suite and cutting edge QC laboratories operational</td>
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<td>2016</td>
<td>New monoclonal antibody production facility established in the Netherlands</td>
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<tr>
<td>2016</td>
<td>New plant dedicated to the manufacture of API to support our MS product line opens in Argentina</td>
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<tr>
<td>2016</td>
<td>Opened new facility for linker-drug production in Blansko, the Czech Republic</td>
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<tr>
<td>2016</td>
<td>Successful completion of our Phase III clinical trial with glatiramer acetate 20mg/mL in patients suffering from MS</td>
</tr>
<tr>
<td>2016</td>
<td>Approval obtained for glatiramer acetate 20 mg/mL in Europe</td>
</tr>
<tr>
<td>2016</td>
<td>Opened galenical laboratory dedicated to the development of high-potent molecules in Chile</td>
</tr>
<tr>
<td>2016</td>
<td>Advanced clinical evaluation of anti-HER2 ADC SYD985 in an expanded cohort of HER2-positive metastatic breast cancer patients</td>
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A core of talented people

Our continued success depends on the quality of our people. We openly seek to attract and reward talented men and women who share the same values and who are both entrepreneurial in attitude and able to work selflessly as part of a team for the good of our company and our ambitious goals. These are individuals with the drive to contribute to the creation of new and effective medicines. One of our core beliefs is that the people who work for Synthon do so with pride and real satisfaction in their work. We believe that success is not just what you achieve, but also how you achieve it. We want our colleagues to be able to see the bigger picture and think outside their own field of expertise. In short, we require people who are willing to share knowledge with other disciplines, who are prepared to work hard to produce commercially viable products, who are team players, but above all share our commitment to bringing important medicines – irrespective of whether they are complex generics or new molecular entities – to our ultimate focal point: the patient.
Contact

Would you like to learn more about Synthon? Please visit www.synthon.com

If you are interested in our product portfolio, please feel free to contact us.

Business Development Generics
Businessdevelopment@synthon.com
(+31) 24 37 27 700

Business Development Biopharmaceuticals
Biobusdev@synthon.com
(+31) 24 37 27 700

If you would like to know more about job opportunities, please visit www.synthon.com and click on Careers.

Editorial coordination
Synthon Holding BV
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Zuiderlicht
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