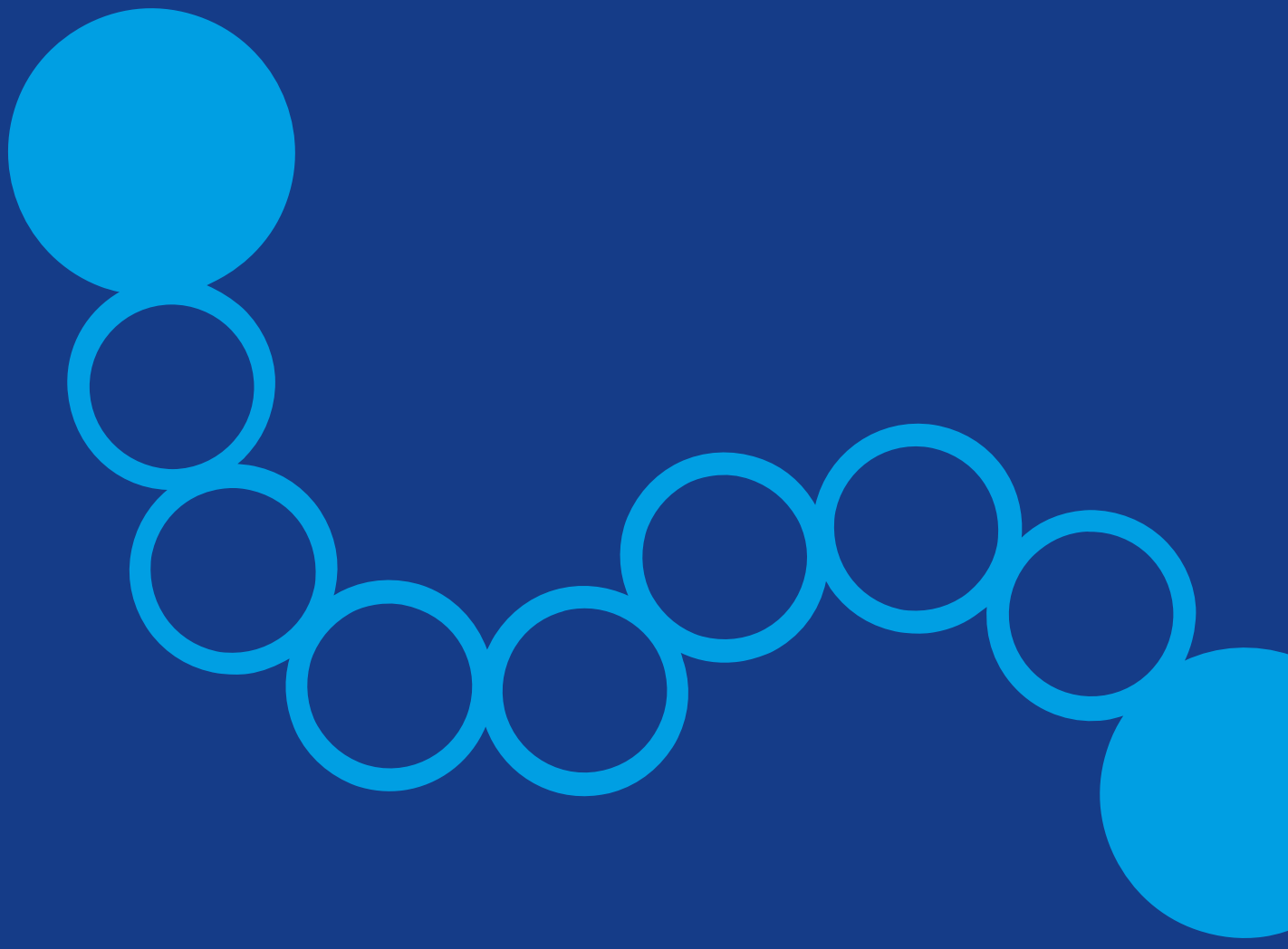
Corden Pharma

Peptides

Technology Platform



Need small quantities of GMP peptides at a reasonable price?

Looking for a complete, continual stability testing service?

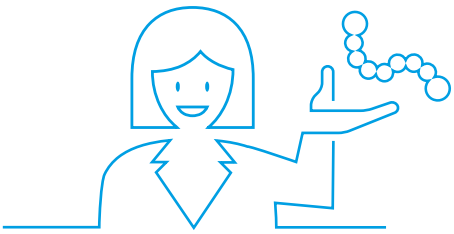
Seeking a more efficient, cost-effective way to manage several third party suppliers?

Aiming for fully-transparent documentation?

Expect guaranteed process knowledge from early phase to commercial?

Want to be up-to-date with recent regulation changes?

Care about green chemistry integrated into process development?



The right partner is one partner. Working and coordinating with several providers can be demanding and time consuming when outsourcing a project. No matter where your project starts, Cordenpharma is the partner you need for a fully-integrated solution spanning the complete product life cycle at all stages, from preclinical to commercial, supported by dedicated regulatory and project management services. A straightforward communication with one supplier alleviates the need for excess resources required to manage multiple providers. Our organizational structure provides you with one point of contact to help navigate your way to project completion. Through our network of integrated cGMP facilities across Europe and the US organized under six Technology Platforms, we have fostered an efficient exchange between API & Drug Product teams to decrease your development time to market.

Your Benefits — Our Strengths

Fast & Lean Process Development Approach

Scientific Expertise
Your project will benefit from our efficient, time-saving development of thousands of process steps using Quality by Design.

Meet Collective Sustainability Goals

Toxicology Knowledge
Gain assurance from our in-depth knowledge in handling a wide range of toxicological active compounds, including highly potent APIs, to protect people, products & the environment.

Foster Entre-preneurial Spirit

Flexibility & Transparency
Benefit from our collaborative commitment to react with flexibility & transparency to your changing needs.

Focus on Patient Safety

Our Motto is Quality
Rely on the integrity of our robust quality & regulatory compliance standards at the foundation of every step your project takes, from initial process development through product delivery and beyond.

Faster Time to Market with Reduced Cost

Streamlined Fully-Integrated Supply
Discover how our fully integrated supply services, ranging from GMP starting materials to Drug Substance, Fill & Finish Drug Products and Packaging, enable faster times to clinical trials & market with reduced costs.

Continuous Exchange & Knowledge Sharing

Transparent Communication
Work closely with our dedicated project management teams to receive regular project updates, gain continual access to your batch records and reach your defined target.

Proven Peptide Production

Over 130 Years of Combined Peptide Manufacturing Experience
Receive superior peptide API processes using both SPPS & LPPS technologies from gram-scale to the largest worldwide multi-ton peptide capacity available.

Go Green, Go Large

Unique Solvent Handling
Take advantage of our unique solvent recycling concept to enable the largest capacity of peptides available globally.

Expertise in Peptide Vaccines & Antigens

Peptides from APIs to Drug Product
Access to a wide range of peptide cocktails from gram-scale APIs to finished dosage Drug Product for clinical trials and commercialization.

Ingenuity at Work

Thinking Outside the Box
Grow from our scientific passion and ingenuity in finding new ways to solve complex problems that help you take the most efficient path to reach your project goals.

Your Goal is our Goal. We turn our strengths into your benefits by keeping in mind that your goal is our goal: to produce high quality pharmaceutical medicines through efficient, lean processes with reduced times to market.

Your Full-Service CDMO for a Global Market

Secure Your Supply Chain with our Fully-Integrated Solution

CordenPharma is the partner you need for a Fully Integrated Supply solution spanning your complete product life cycle at all stages, from sourcing of raw materials to secure your supply chain, through preclinical & commercial development and manufacturing of GMP starting materials, APIs, finished dosage Drug Products & Packaging > resulting in reduced time & cost. Your project is all the while supported by dedicated regulatory & project management expertise at every step along your outsourcing path.

Aseptic Fill & Finish at CordenPharma Caponago (IT).

The Backbone of Synthesis – Advanced Peptide APIs

Our scientists have mastered the core principles of synthesizing advanced Peptide APIs, and bring them to bear on every project, large or small. The Peptides platform supplies you with specialized combined expertise across multiple cGMP facilities from early stage to commercial supply of advanced Peptide APIs.

Proprietary process technologies provide access to a wide range of products for cost-effective manufacturing, with robust CMC dossiers that reduce the number of chemical steps required, increasing purity and decreasing raw material costs. An additional benefit includes our unique backward integration of key starting materials, which secures your supply chain in terms of cost & quality.

Furthermore, your benefit expands to the seamless tech transfer of your project within our facility network for the production of Drug Products & Packaging Services. The Injectables Platform provides Aseptic & Terminal Sterilization Fill & Finish in Pre-Filled Syringes (PFS), ampoules, liquid & lyophilized vials, as well as combination device products, packaging / labelling, and clinical trial kit management. We additionally supply peptides for oligonucleotide drug product capabilities as well as LNP formulation. Our Highly Potent & Oncology Platform offers oral & sterile highly potent drug products, packaging, labelling & distribution.

Peptide Centre of Excellence

The Intelligence of Peptides

Benefit from our streamlined process development, scale-up and small to large-scale manufacturing. Our successfully inspected cGMP facility, CordenPharma Colorado (USA), produces a wide range of Peptide products for various therapeutic indications. To increase your R&D throughput, our European R&D Center, based in Frankfurt, Germany, supports our integrated network of facilities with process design development, non-GMP synthesis and GMP manufacturing for supporting early clinical phase. This unique concept, combined with open, transparent communication, allows us to infuse your project with the highest degree of flexibility needed to guide you quickly through all clinical phases.

Our peptide development and scale-up approach is enhanced with Quality by Design (QbD) equipment engineering which mimics large-scale production to limit deviations associated with the equipment design. State-of-the-art equipment combined with innovative technologies efficiently respond to your needs at any scale and stage of development, ultimately resulting in cost-effective Peptide

Our Core Peptide Products & Services

- Complex peptides & peptidomimetics
- Proprietary process technologies for cost-effective manufacturing
- Peptide conjugations (PEGs, proteins, lipids, carbohydrates)
- Cyclic & multiple disulfide bridge peptides
- Short peptides (up to 12 residues), often without HPLC purification
- Arginine-rich peptides
- Green process design for REACH regulation trend & cosmetic market
- Design of Experiments (DoE) for peptide synthesis
- Scale-up know-how

Drying of the final crude API in a filter dryer.

Technologies of Proven Peptide Production

Solid Phase Peptide Synthesis (SPPS)

- → Gram to multi-100 kilogram quantities under cGMP with dedicated peptide lines
- → More than 10 commercial products & > 50 development projects
- → Large-volume solvent & waste-handling logistics
- → Precipitation & isolation of fragments and final APIs
- → Unique & efficient production of large-scale commercial peptides
  (e.g. Enfuvirtide (FUZEON®) with up to 920 kg of synthesized fragments per batch
  > the largest fully-synthetic peptide ever commercially manufactured)

Colorado (USA) and Frankfurt (DE) offer industry leading expertise in LPPS.

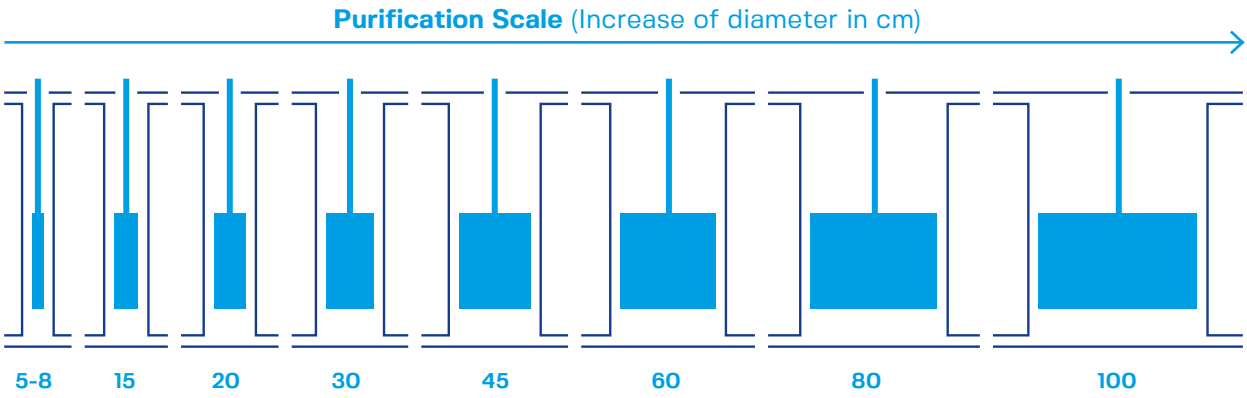
At CordenPharma we utilize automated SPPS synthesizers for non-GMP samples and clinical GMP manufacturing.

Liquid Phase Peptide Synthesis (LPPS)

- → Technology of choice for cost-effective large-scale manufacturing of short peptides or structures not easily prepared by SPPS
- → Hybrid fragment synthesis coupling shorter SPPS-generated sequences together in a solution
- → Cyclization manufacturing of commercial peptides containing a single or multiple disulfide bridges or cyclized lactam peptides

Purification

- → Reach or exceed the required purity at any scale leveraging preparative High-Pressure Liquid Chromatography (HPLC) technology
- → Automated reverse-phase HPLC with columns up to 100 cm in diameter, supported by different ion exchange chromatography columns



The spray drying process uses an advanced technology to isolate peptides in a very controlled way.

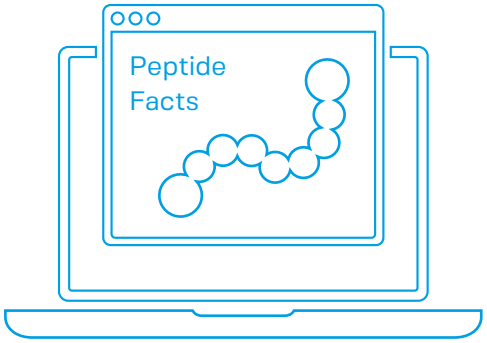
Isolation

- → Traditional final isolation using lyophilization or spray drying
- → Alternate isolation technique via precipitation process saves cost & improves API handling at the drug product site with easy scale-up & transfer
- → Ability to precipitate any peptide upon request (including long peptides with more than 35 AA)

Automated peptide synthesizers ranging from 12 L to 10,000 L for solid-phase peptide synthesis

Volume leader in custom peptide production

Produced the largest fully-synthetic peptide ever commercially manufactured: Enfuvirtide (FUZEON®) > up to 920 kg of synthesized fragments per batch



CordenPharma Colorado (USA) solvent handling infrastructure to support small molecule manufacturing.


1000 LBS MAX

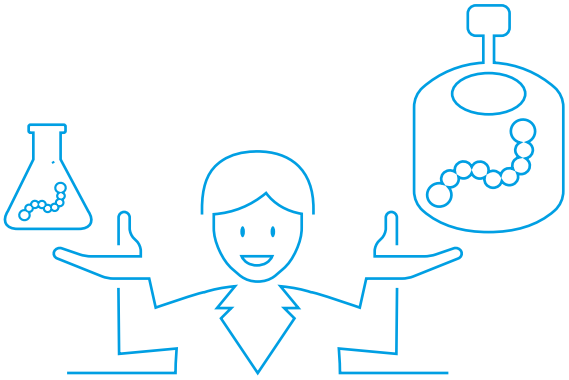

CONDENSATE
STRONGARM

Manufacturing of Peptides at CordenPharma Colorado (USA).

Complete & Flexible Support Services

Small-Scale
To be early to market, fast delivery speed, not cost, is the KEY!

Commercial-Scale
Robust processes with higher yields & purity for your secure supply chain is a MUST!



Phase-Appropriate Development & Manufacturing

As an industry leader in the peptide market, we understand the regulatory requirements you will encounter along the clinical & commercial stages of your development path.

Analytical Development & Validation Services

Method Development	Method Validation
→ Screen for Best Detection	→ System Suitability / Specificity
→ HPLC Columns at Various pHs	→ Linearity, Accuracy & Recovery
→ Temperatures & Ion-Pairs	→ Precision & Intermediate Precision
→ Buffer Systems for Impurity Separation	→ Limit of Detection (LOD)
→ Optimized Separation of Related Substances & Degradants	→ Limit of Quantification (LOQ)
→ Forced Degradation Studies	→ Stability of Solutions
	→ Robustness

«This was a really exciting project for me because I was able to see how my personal contribution as part of a larger team aided in the successful execution & transfer of the project.»

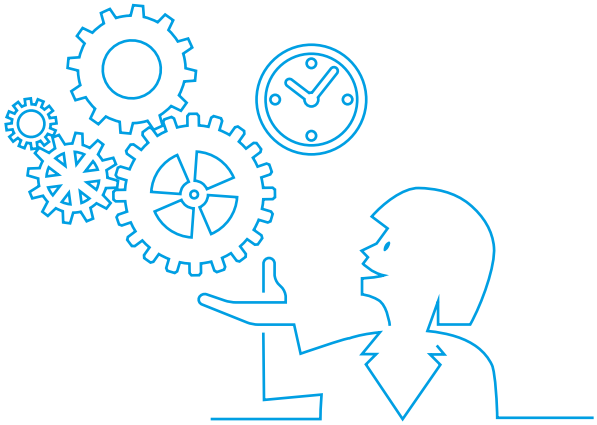
Philippe Gourlet, Head of Production, CordenPharma

Our team performed rapid & efficient development, scale-up and manufacturing of a Liquid Phase Peptide Synthesis (LPPS) process from low single digit to multiple 100s of kilogram scale in a short period.

The NRP project, which was a short peptide developed without chromatography purification, is not only a success story for our site but also a real demonstration of the strong, efficient collaboration within the CordenPharma integrated facility network.

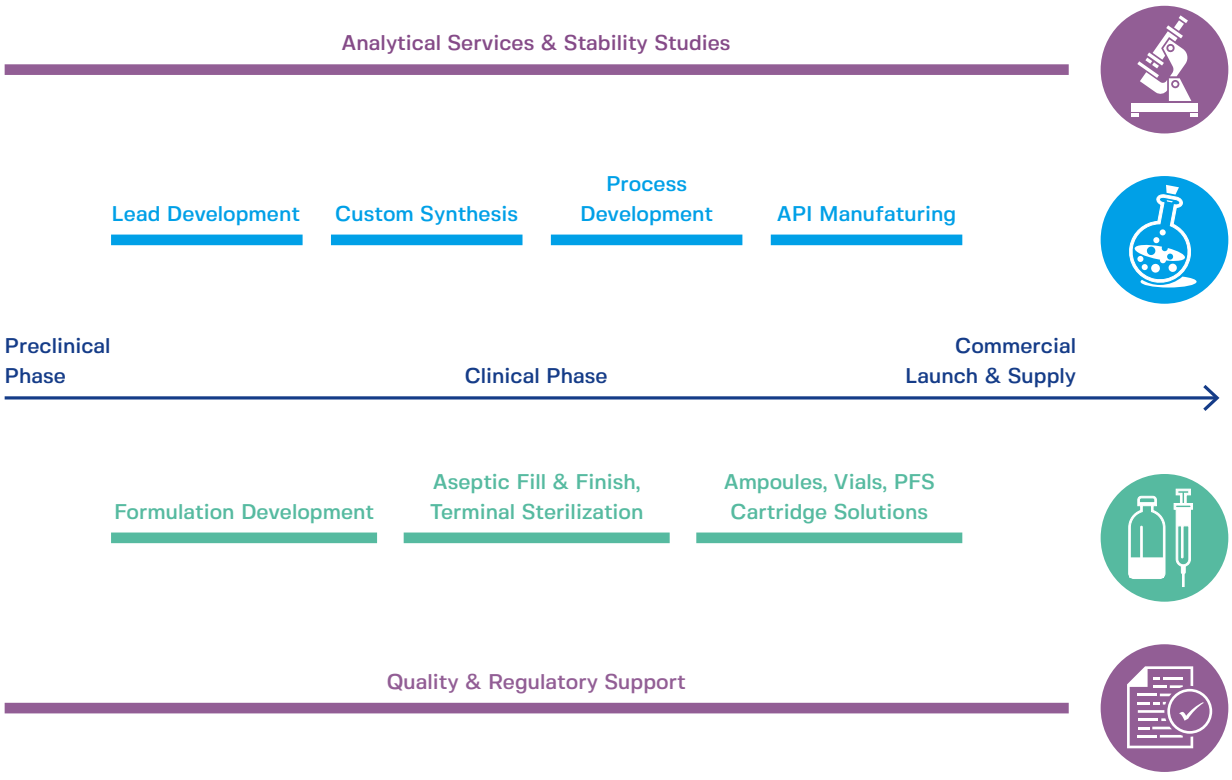
The strategy of the LPPS process used for the NRP project relied on our extensive expertise in developing & manufacturing short peptides, including the use of state-of-the-art spray-drying for isolation of the final API.

One Partner Process & Project Management



Streamlined Process Collaboration

Our approach to every project begins with fostering a constant exchange between the applicable API & Drug Product Process Development teams involved. Ongoing alignment with analytical, quality and compliance support guarantees you fast and consistent results, independently of where your project starts.



Aligned Project Management

CordenPharma's Global Project Management Team carefully assigns an appropriate amount of time & resources to each phase of development, while monitoring all tasks to ensure your project progresses forward in a controlled and timely way. Our project management organization safeguards the alignment of resources with local project managers throughout our network of facilities for your integrated supply projects involving multiple sites and technologies to deliver on our promise – one source, one partner.

Your One Partner Benefits:

- → Single point of contact throughout your project for both APIs & Drug Products
- → Global SOPs mean shorter tech transfer time for materials & documentation
- → Knowledge transfer guaranteed with consolidation of stability testing, analytical methods & physical property
- → One CDA / MSA with single data-entry point ensures ease of sharing data internally & externally and speed of execution
- → Improved data integrity guaranteed by controlled single-source data with integrated project planning

Sampling of a final API to support homogeneity testing plan at CordenPharma Switzerland.

Quality & Compliance First

Our commitment to seek the highest standards of Quality & Compliance First is the backbone of all our activities and projects. We make no compromises in this area. We have and continue to invest heavily in compliance programs, with the objective to meet and surpass applicable regulatory requirements & legislations. Our focus on quality & compliance will be ongoing, with budgeted investment in improvements such as compliance-enhancing IT solutions.

CordenPharma Continuous Improvement Program

You will benefit from the ongoing support of CordenPharma's Continuous Improvement Program, based on the consistent completion of corrective and preventive actions arising from self-initiated proactive third party group-wide gap assessments, agency inspections, as well as internal, annual corporate & customer audits. This approach enables us to not only meet, but surpass general requirements needed to see your project through to completion.

CordenPharma Global Compliance Team

The CordenPharma Global Compliance Team systematically interprets these continuous improvement program audit and assessment results on your behalf to generate corporate policies and global standards enabling employees at all levels to comply with current applicable guidelines and legislations in their daily activities.

Corporate compliance standards & policies are then implemented at all CordenPharma sites globally, with the objective of complete harmonization to foster transparency and straightforward communication, both internally and externally with our customers. The whole organization works together, from the Executive Leadership Team and Facility Managing Directors to the Marketing & Sales team and operators, to make sure all employees effectively comply with implemented policies, Standard Operating Procedures (SOPs), master work instructions, plans & forms to meet all the requirements for your pharmaceutical success.

Market	Agency	Colorado (US)	Caponago (IT)
	EMA, EU local	●	●
	FDA	●	●
	PMDA	●	●
	TGA	●	●
	Health Canada	●	●
	ANVISA	●	●

Our Manufacturing Sites

Manufacturing Sites	Products	Services
● CordenPharma Colorado, USA (Site 1)	Peptides	→ Largest Peptide Production & Purification Capacity Worldwide → Highly Active Peptide Manufacturing → R&D, non-GMP and GMP-Production
● CordenPharma Frankfurt, DE	Peptides	→ GMP Production for Early Clinical Phase → R&D & non-GMP Production
● CordenPharma Caponago, IT	Integrated Supply	→ Injectable Drug Product & LNP formulation


Corden
Pharma

CordenPharma
International

Aeschenvorstadt 71
4051 Basel
Switzerland

cordenpharma.com

Peptides

Lipids &
Carbohydrates

Highly Potent
& Oncology

Injectables

Small Molecules

Oligonucleotides