



**SONEAS**

# Corporate Introduction

January 2019

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# 1. Evolution overview

# Timelines and key milestones

1996

## Ubichem founded

Ubichem Research Ltd. (Budapest, Hungary) founded by Ubichem Plc of the UK, a trading company.

Research chemistry carried out in the Central Research Institute for Chemistry of the Hungarian Academy of Sciences.

2002

## Pilot plant commissioned

Pilot plant facility commissioned on an 8,000m<sup>2</sup> site in Budapest.

2012

## Adds large scale manufacturing capability

Acquired a manufacturing facility, on a ~65,000m<sup>2</sup> site also in Budapest (Ubichem Pharma Manufacturing).

2015

## Name change to Soneas

Name change to Soneas Chemicals and Soneas Research.

2018

## Becomes part of Uquifa

Soneas becomes a member of Uquifa, a manufacturer of Active Pharmaceutical Ingredients (APIs) and intermediates for the pharmaceutical Industry.

Soneas will focus on a strategy of investment and drive growth by enhancing technology tool box, manufacturing capability and customer mining.

The logo for Uquifa, featuring the word "Uquifa" in a stylized, multi-colored font. The letters are in shades of blue, green, yellow, and red.

# Our location

## Hungary: the landscape for chemistry

- The pharmaceutical industry has deep roots in Hungary
- Wealth of accumulated knowledge in chemistry
- Outstanding scientists include:
  - György Olah (carbocations/super-acids)
  - György Hevesy (radioactive tracers)
  - Albert Szent-Györgyi (vitamin C)
- Highly skilled scientists at reasonable cost



# Soneas group

## Soneas Research

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101 Employees:

- 32 R&D
- 35 Production
- 13 Analytical
- 21 Admin

## Soneas Chemicals

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97 Employees:

- 5 R&D
- 65 Production
- 12 Analytical
- 7 Admin



# Soneas facilities

## Soneas Research

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R&D laboratories:

- 7 research labs
- 3 analytical labs
- NMR lab

Pilot Plant (7847 m<sup>2</sup>):

- 1 kilo lab
- 1 analytical lab
- 1 IPC lab
- 2 process & scale-up labs
- 3 pilot plant production units

## Soneas Chemicals

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Large scale manufacturing site  
(63,000 m<sup>2</sup>):

- 2 production units
- Hydrogenation unit
- Distillation unit
- Drying and packaging unit

## Reactor capacity

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- 208,000 L



# Soneas services

## Soneas Research

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- Rapid scale up of lead candidates
- Route selection and safety evaluation
- Process development, optimisation, scale-up and validation
- Salt screening and crystallisation studies
- Stability studies (stress tests, accelerated and long term)
- Analytical method development and validation
- Impurity profiling
- Preparation of impurities and reference standards
- cGMP APIs for preclinical and clinical trials — lab to pilot plant scale

## Soneas Chemicals

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- Starting materials, intermediates and other fine chemical products in large/ commercial quantities (1–100s of tons)
- Products for pharmaceutical and non-pharmaceutical applications

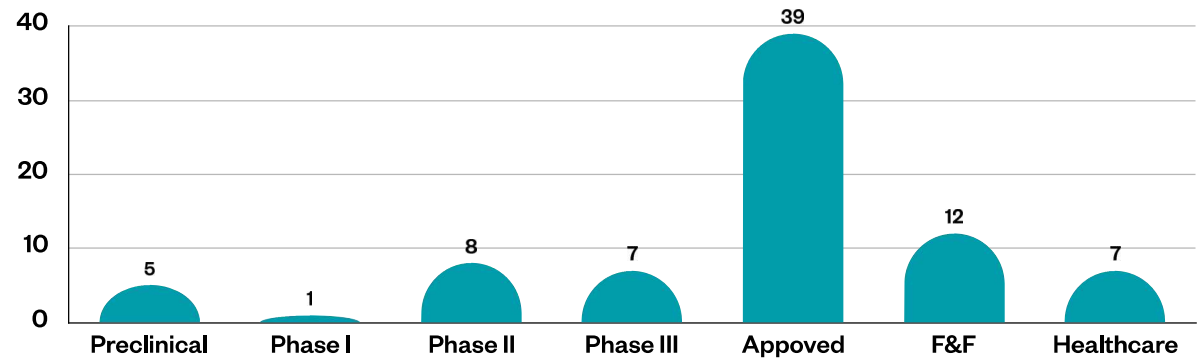




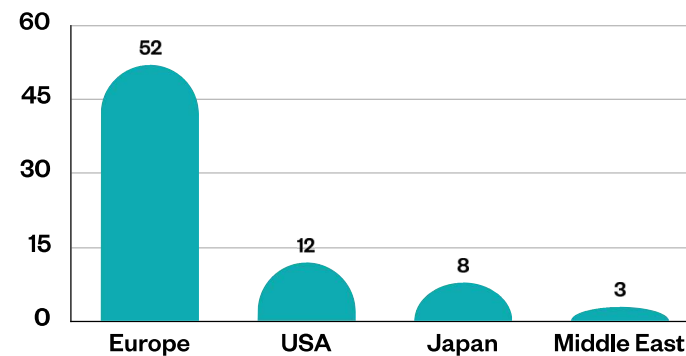
# API projects

- Key supplier of a big pharma company for the intermediates of a hormonal drug product family
- Intensive process development and scale up of pheromones, 6–10 compounds in the pipeline with good growth potential (Mt scale in 2019, 10 Mt scale in 2020)
- Supplier of key starting materials and late intermediates of 3–4 potential blockbusters (currently in Phase II and III)
- 3 new APIs for Phase I and Phase II in the last 1 year

API projects by phase



API projects by customer location



## **2. CDMO: Infrastructure and capability**

# CDMO focused

## Our mission

### To be the preferred partner and provider of services to the pharmaceutical industry

- Industry leading compliance culture and performance (HSE, Quality, EA)
- Full service offering to support projects through the entire product life cycle
- Tailored and flexible service and solutions for individual customer needs
- Technology and innovation embedded into the culture and company strategy
- Easy to do business with



# CDMO focused

## Value proposition

- Tailored solutions for our customers, delivering service, quality, speed and value
- Capabilities, facilities and people providing services and manufacturing at every scale across the whole drug development lifecycle
- Ability to go from Proof of Concept to Commercial Manufacture on one site
- Ability to manage complexity through our project management expertise
- Foundation of strong compliance (cGMP, safety, environmental)
- Ability to handle the most hazardous chemical processes safely
- Infusing proprietary technology to bring value to our customers



# CDMO focused

AQSCI: Delivering customer satisfaction

**Service**

**Innovation  
cost**

**Assurance  
of supply**

**Quality /  
regulatory**

# 3. Joining the Uquifa family

# Global presence: a strategic advantage

A global platform that combines quality with competitiveness



# Uquifa's facility overview



	<u>Lliçà de Vall Spain</u>	<u>St Celoni Spain</u>	<u>Cuernavaca Mexico</u>	<u>Budapest Hungary</u>
<b>Capacity</b>	140,000 L	170,000 L	180,000 L	208,000 L
<b>Number of reactors</b>	29 reactors	29 reactors	30 reactors	58 reactors
<b>Last US FDA Inspection</b>	September 2015	May 2017	July 2018	—
<b>8c-GMP Approval</b>	Yes	Yes	Yes	Yes
<b>Korean FDA</b>	June 2011	June 2011	June 2011	—
<b>Japanese Certification</b>	Yes	Yes	Yes	—
<b>Pilot plant in site</b>	Multipurpose	Multipurpose	Multipurpose	Multipurpose
<b>Residues treatment on-site</b>	Mercaptan incinerator, biological effluent treatment	Biological effluent treatment	Biological effluent treatment off-site	Catalytic incinerator, off-site waste treatment
<b>Technical expertise</b>	Sulphur chemistry, wiped film evaporation, hydrogenation, micronisation, sieving	Sulphur chemistry, roller compact unit, micronisation, sieving, lyophilisation	Nitration, hydrogenation, in-situ prep, chlorination	Optical resolutions, cryogenic and organometallic, high temperature, cyclopropanation, phosgenation (triphosgene), hydrogenations, halogenations, acid chloride preparations, carbene additions, diazotizations, Friedel-Crafts reactions, isomerizations, cyanations, carbonylation with CO





# Uquifa's chemistry capabilities

- Grignard reactions & Organometallic Chemistry
- Fisher esterification & trans-esterification
- Chiral Synthesis, Chiral resolution and Asymmetric Synthesis
- Borane derivatives & coupling reactions
- Heck reactions
- Ozonolysis
- Halogenations, Nitrations and Sulphur Chemistry
- Hydrogenations (up to 5 bar) & reductions with reductive agents and different kind of hydrides
- Triphosgene reactions (industrial precursor for phosgene)
- Cyclopentadiene chemistry
- Palladium catalysed carbonylation
- Protection & de-protection Chemistry
- Solid phase reactions
- Crystallisation
- PSD expertise
- Polymorphism Studies
- Pellets manufacturing capability in Spain



# Acquisition rationale

2018 budget sales of €15m has significant scope to expand in the next 3–4 years

Soneas customer base now has option to leverage Uquifa's large scale GMP manufacturing platform. Together, Uquifa and Soneas provide the option of an integrated value offering for the CDMO market.

## Access

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Access to Phase 1–2 development capabilities.

Bolts on well to Uquifa's large scale GMP base.



## Diversify

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Diversified customer base.

Exposure to faster cycle projects in order book.



## Leverage

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Opportunity to leverage EU presence  
Ramp up the low capacity utilization of Tetenyi site.



# 4. Soneas Research

# Soneas Research

## Research labs

- Excellent chemists (PhD and MSc) supported by experienced technicians
- Well-equipped analytical support

## Process development labs

- Walk-in and standard fume hoods
- Jacketed glassware to 20L; pressure vessels to 2L
- 24 theoretical plate SS distillation column
- Huber and Julabo mobile thermostats
- Büchi Rotavaps 2x 10L, 3x 20L



# Analytical development capabilities

## Comprehensive, modern analytical equipment including:

- Fully qualified cGMP analytical laboratory
- NMR (Bruker 500MHz Ultrashield)
- UHPLC (Thermo-Dionex UltiMate 3000)
- GC (headspace)
- FTIR, MS, GC-MS, HPLC (incl. Corona detectors), LC-MS, DSC
- XRPD (powder and single crystal)



# Technology toolbox case study

## Metathesis catalysts

- Olefine metathesis: versatile yet rarely used reaction
- Know-how is originated from XiMo (US-Swiss company) founded by Nobel Laurate, Professor Schrock and other professors in this field
- New generation of catalysts contains Molibdenum or Tungsten instead of Ruthenium which makes the catalyst less expensive
- Catalyst load can be decreased down to 30 ppm by optimizing reaction conditions
- Cost efficiency makes the catalyst a good option for multi-ton-scale products



# Kilo Labs

## Our capabilities

- 63L SCHOTT gl reactors
- 100L QVF gl reactor
- 50L QVF crystallisation reactor
- 250L QVF reactor with DN150 Sulzer graphite distillation column (20 theoretical plate numbers)
- Glass reactors to 100L
- 20L SS mobile hydrogenation reactor (10 bar)
- 20L and 50L SS mobile process filter/dryer
- 20L rotary evaporators
- 400mm SS Centrifuge; HEPA environment (class 100,000)
- Mobile filters to 60L
- Vacuum tray driers
- Scrubber



# Pilot plant: capabilities

## 2 production units

- 250L, 630L and 1600L gl reactors
- 1000L crystallisation reactor
- 1,000 mm SS centrifuge (Class 100,000 HEPA environment)
- Vacuum tray drier (Class 100,000 HEPA environment) (capacity up to 50kg)
- 20L SS mobile drum blender
- 0.6m<sup>2</sup> QVF glass thin film evaporator
- 1000L and 35L Hastelloy C reactor with glass and gl overheads (operable down to -80°C)
- 100L SS hydrogenation reactor (10 bar)
- 600mm PFA coated centrifuge
- 20L Glass-top Distillation reactor
- 20L gl reactor with DN100 distillation column
- Huber thermostat (-80 to 200°C) — cryogenic and high temperature capability





# Recent investment in the pilot plant unit

## 3rd unit

- 1600L DeDietrich gl reactor
- 1000L DeDietrich gl reactor
- 1000L DeDietrich gl reactor  
(Class 100,000 HEPA environment)
- 0.4 m<sup>2</sup> Rosenmund SS Process filter/dryer
- 0.4 m<sup>2</sup> Rosenmund SS Process filter/dryer  
(Class 100,000 HEPA environment)



# 5. Soneas Chemicals

# Soneas Chemicals

## Overview

- Starting materials, intermediates and other fine chemical products in large/commercial quantities (1–100s of tons)
- Products for pharmaceutical and non-pharmaceutical applications

## Capabilities

### Production unit 1

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- Glass lined reactors from 2,000L to 6,300L
- 1,000L copper lined reactor (operable up to 300°C)
- Dryers up to 200 kg
- Stainless steel centrifuges up to 1,200mm

### Distillation unit

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- Distillation columns with Sulzer oriented packing (up to Ø 500 mm)
- Thin film evaporator

### Production unit 2

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- Glass lined reactors from 250L to 12,500L
- Stainless steel reactors from 4,000L to 8,800L
- Process filter dryers from 100kg to 1,000kg
- Dryers up to 500 kg
- Stainless steel centrifuges up to 1,200mm

### Hydrogenation unit

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- Stainless steel hydrogenators from 500L to 1,200L (up to 10 bar)

# Soneas Chemicals

Recent investment

## Drying and packaging unit

- Stainless steel vacuum tray dryer (up to 200 kg)
- Stainless steel paddle dryer (1000 L)
- Stainless steel container blender (up to 800 L)
- Stainless steel hammer mill



# Chemistries

- Optical resolutions
- Cryogenic and organometallic reactions • High temperature reactions
- Cyclopropanation
- Phosgenation (triphosgene)
- Hydrogenations
- Halogenations
- Acid chloride preparations
- Carbene additions
- Diazotizations
- Friedel-Crafts reactions
- Isomerizations
- Cyanations
- Carbonylation with CO
- Cyclopentadiene chemistry
- Palladium catalysed carbonylation



# QA system

## Soneas Research

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- Works under cGMP and ISO 9001 : 2015 qualifications
- Regularly inspected by National Institute for Pharmacy and Nutrition as well as by SGS
- Successfully passed Kosher and Halal audits

## Soneas Chemicals

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- Operates under ISO 9001 : 2015 qualification
- Regularly inspected by SGS
- Successfully passed Kosher audit



# 6. A summary

# Summary of our value offering

- Quality services, systems, and products
- Good value to cost ratio
- Pragmatic approach to problem solving and scale-up
- Quality and tradition of Hungarian chemistry, especially in pharmaceutical area
- Professional communication and project management
- Proactivity and customer focus
- Speed and flexibility





# Visit us in Budapest





## Headquarters and Pilot Plant

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## Large Scale Manufacturing

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