# Factbook

# **Corporate Profile and Strategy**

Vienna, November 2009

Information for private and institutional investors



The Specialty Pharma Company

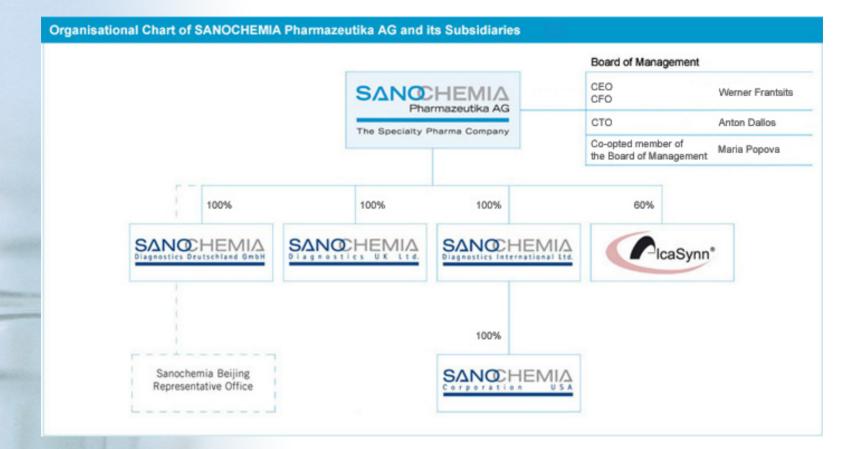
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# Content

The Specialty Pharma Company

# SANOCHEMIA

- Overview
- Strategic positioning
- Business model
- Target markets
- Product strategy

# A Company with Attractive Products

- Pharmaceuticals
- Imaging agents
- Diagnostics
- Facts & Figures
- Sound Reasons to Invest
  - Specialty pharmaceuticals segment
  - Development pipeline with innovative projects

# **Overview**

# Our Objective

High, sustainable profitability

# Our Strategy

Significant value-added in complementary business areas

# Our Focus

Niche markets with a high degree of unmet medical need

# Our Strengths

- Clinical development
- API synthesis
- Pharmaceutical production
- Contract manufacturing\*

\* Following the expansion of its Neufeld site, SANOCHEMIA acts as a full service provider in the specialty pharmaceuticals industry by offering top quality development services and pharmaceutical production expertise in the areas of sterile, liquid and semi-solid products



# **Strategic Positioning**

In contrast to Classical Pharma and Biotech

	R&D	Preclinic	Clinic / Registration	Production	Sales & Marketing
Pharmaceuticals					
Biotech					
Specialty Pharmaceuticals					
SANOCHEMIA					

# **Business Model**

- **Development and production of innovative specialty pharmaceuticals** 
  - CNS / Neurodegeneration
  - Pain
  - Oncology
- API synthesis for premium quality pharmaceutical products
  - APIs for Sanochemia products
  - Contract synthesis

# • Manufacture and global distribution of imaging agents\* and diagnostics

- Radiological imaging agents
- Diagnostics

# **Product Strategy**

# Development

of own patent-protected products and processes

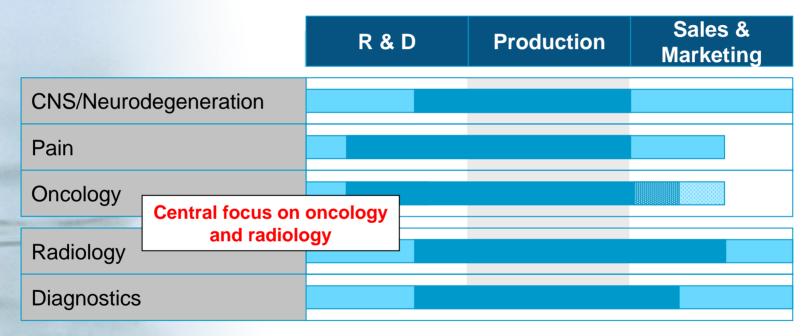
- Life Cycle Management
   of established drugs
- In-licensing
   of innovative product candidates
- Investments / Cooperations

with major pharmaceutical players (API and pharmaceutical production)

 Contract Manufacturing of APIs and pharmaceutical products

# **Product Strategy**

# A development-oriented manufacturer of specialty pharmaceuticals



Focus on projects which primarily aim to generate value added through the utilisation of our own production facilities



# **Pharmaceuticals**

- Central Nervous System / Neurodegeneration
  - Galantamine

# • Pain

- Topical galantamine
- Tolperisone
- Opiates (AS006 and derivatives)

# Cardiovascular\*

Torsemide

# Oncology

PVP hypericin (development as a therapeutic)

\* Due to a loss of patent protection, the so-called Form 2 of torsemide produced by SANOCHEMIA will no longer attain earlier sales volumes. For this reason, torsemide will no longer feature so prominently in our communication, being replaced instead by news of up-and-coming growth drivers such as Viveo<sup>®</sup> (tolperisone) and MR-Lux<sup>®</sup> (Gd-DPTA).

# **CNS / Neurodegeneration**

# **The Market**

### Indication areas

- Neurodegenerative diseases such as Alzheimer's Disease (AD), Parkinson's, etc.
- Alzheimer's Disease is the fastest growing CNS segment
- Growth at a rate (10-12%) twice that of the overall pharmaceutical market

# Market potential

- Rising sharply, 26 million Alzheimer's patients worldwide
- Market saturation (patients treated): < 20%
- Demographic factors: 5-10% of the over 65s

# SANOCHEMIA's market segment

- Global market for antidementives in 2005: USD 4.1bn.
- Acetylcholinesterase inhibitor (AChE-I) for mild to moderate AD
- 1 NMDA inhibitors (Namenda/Ebixa/Axura) for moderate to severe AD



# **CNS / Neurodegeneration**

# The Market for Alzheimer's Drugs

# **Acetylcholinesterase inhibitors (AChE-I)**

Drug	Marketed / manufactured by	API	US market share
Aricept™	Pfizer / Eisai	donepezil	approx. 50%
Exelon™	Novartis	rivastigmine	approx. 10%
Razadyne™/ Reminyl™	J&J, Janssen, Shire	galantamine	approx. 10%

# **NMDA receptor antagonists (NMDA-I)**

Drug	Marketed / manufactured by	API	US market share
Namenda™/ Axura™/ Ebixa™	Forest, Lundbeck, Merz	memantine	approx. 30%

# **CNS/Neurodegeneration**

# **The Product – GALANTAMINE**

# **Product advantages**

- Purity and availability of consistent API quality vis-à-vis biological galantamine
- Proven efficiency of API class established
- Additional function of galantamine as a nicotinic receptor modulator

# Competitive edge

- API synthesis process patented until 2014
- Patenting of improved manufacturing process could mean patent protection until 2027 (Austrian patent awarded in September 2008)
- Many years development and production experience in this API class

### Status quo/prospects

- Synthetic galantamine as an API (used in Razadyne<sup>®</sup> &/ Reminyl<sup>®</sup>)
- Use patent in USA expired (2008), valid until 2012 in Europe

# Pain Management

# **The Market**

### Indication areas

- Acute: trauma and post-operative pain (US + EU approx. EUR 5bn.)
- Chronic: tumour pain, osteoporosis and back pain
- Neuropathic: fibromyalgia, stroke, DPN (diabetic peripheral neuropathy), CRP (complex regional pain)

# Market potential

- Global pain management market 2005: approx. EUR 25bn.
- Growth: 8-10 % p.a.
- Opioid share of the market: EUR 5.4 6.8 bn. (substance library of AlcaSynn)

# SANOCHEMIA/AlcaSynn market segment

- Concentration on attractive sub-segments such as neuropathic pain associated with diabetic neuropathy and spasticity associated with neurological disorders such as Multiple Sclerosis and stroke.
- A further therapeutic area is that of pain treated with opiates



# **Neuropathic Pain**

# The Market

Indication areas

• Neuropathic pain associated with diabetes (DPN = diabetic peripheral neuropathy)

### Market potential

- Diabetics in USA: approx. 5m; in Europe: approx. 4m; numbers rising sharply
- 20 24% of diabetics (Types I and II) suffer from DPN

### SANOCHEMIA's market segment

- Neuropathic pain: USD 6bn.
- Sub-segment DPN therapy: USD 2bn. (mainly systemic therapies at present)
- Topical therapies: urgent medical need
- Patient potential: approx. 15 million



# **Neuropathic Pain**

# Seventages Topical (non-systemic) administration by the trials at present Favourable side effect profile Competitive edge Existing API registration of the trial of the trial

### Status quo / p

Phase IIa stud

Project on out-licensing platform , galantamine successfully concluded (Feb. 2007)

- 2008: optimised mulation in clinical development with the aim of further increasing the bio-availability of galantamine at the site of action (in deeper skin and tissue layers)
- Peak sales: EUR 300m. (forecast 3 5 years after launch)



# **Muscle Relaxants - Spasticity**

# The Market

### Indication areas

 First registration in "spasticity associated with neurological disorders such as stroke and Multiple Sclerosis"

# Market potential

- Market for muscle relaxants in USA: > USD 1bn.
- Market for muscle relaxants in EU: > EUR 260m.
- Neurological segment in Germany: > EUR 40m.

# SANOCHEMIA's market segment

- In approved markets (e.g. Germany): > 30% market share as target
- Additional growth through launch of tolperisone in other EU markets and US



# **Spasticity**

# **The Product – TOLPERISONE**

### Product advantage

 Centrally acting muscle relaxant: improved administration form for IR formulation, non-sedating or with minimal sedative effect

# Competitive edge

- Established drug substance (Eastern Europe), known risk profile
- EU patent protection of the API production process until at least 2022
- Patent application for new development process for high-purity tolperisone in USA and Europe

# Status quo/prospects

- Marketing authorisation in Germany (April 2007): Viveo<sup>®</sup> brand name of Orion Corp.
- Additional registrations sought via national filings and MRP (2 DCP clusters submitted in 2008)
- No US clinical trial ongoing at present
- Out-licensed to Orion (D, CH, Scandinavia and Baltic States) in 2007, other territories planned

IcaSynn

# **Morphinans – AS006 and Derivatives**

# AlcaSynn Pharmaceuticals GmbH, Innsbruck (SANOCHEMIA holds: 60%)

- Substance developer with a focus on opiates (morphinans)
- Technology platform in the field of morphinan chemistry and neuroreceptors
- Proprietary substance library

### Potential

- Substance patents with long expiry periods
- Lead product AS006: strong analgesic substance (European patent granted in November 2006)
- Broad portfolio of innovative substance candidates for the treatment of various diseases – external screening to define lead candidates in 2008
- Industrial and university-based R&D cooperations planned in the indication areas:
  - Inflammatory pain, Alzheimer's, Parkinson's and pruritus (itching)



# Imaging – Contrast Media\*

- Ionic contrast media
- Non-ionic contrast media
- Barium sulphate
- MRT contrast media

\* To highlight internal structures and organs with the aid of contrast media or, for example, CT and MRT imaging agents.

# A Full Range of Radiological Products

Application	X-ray	СТ	MRT	Entire body	Head, spine	Gastro- intestinal	Kidney, heart,	Kidney, urinary	Pancreas
Preparation					12-12-12-1 1-1-1-1-1-1-1-1-1-1-1-1-1-1-1		vessels		
Barilux® (barium sulphate)									
Colognost <sup>®</sup> (radio opaque marker)						ast master			
Gastrolux <sup>®</sup> (ionic contrast medium)		•							
MR-Lux <sup>®</sup> (paramagnetic contrast medium)						ALCONTRACT MARYNE			
Secrelux® (pancreas function diagnostic)									
Scanlux <sup>®</sup> /Unilux <sup>®</sup> (non-ionic contrast medium)	•			•		na marine in		and a second	
Urolux Retro® (ionic contrast medium)		12			Santa Inter		n na ministra Na ministra		



# Imaging – Contrast Media

# For Imaging Diagnostics (x-ray, CT and MRT)

# The market

- The undisputed market leader: Bayer Schering Pharma.
- SANOCHEMIA's market share under 5% in all segments
- The majority of registrations in Europe are via the MRP and DCP

# Market potential

- Europe 2005: USD 1.2bn. (of which 75% in Germany and Spain)
- US 2005: USD 2.2bn.

# SANOCHEMIA's market segments

- Ionic and non-ionic contrast media and barium sulphate
- Following the launch of MR-Lux<sup>®</sup> in Germany, SANOCHEMIA now offers a full basic range of imaging diagnostics for all major investigative procedures
- SANOCHEMIA an Austrian company with in-house production of contrast media for the entire EU market



# Imaging – Contrast Media

# The Product – SCANLUX®/UNILUX® \*

### **Product advantages**

- Best documented substance (more than 250 million applications worldwide)
- Status as a contrast media specialist offering excellent value for money

# Competitive edge

 Own manufacture and marketing through effective sales channels (either via own subsidiaries or selected distributors)

### Status quo / prospects

- Scanlux<sup>®</sup> is the top-seller and the product spearheading SANOCHEMIA's international expansion
- Sales volume growth through geographic expansion
  - Already registered in 37 territories, on-going roll outs
  - 2009/2010: marketing authorisation and launch expected in the USA
- Market share target: 10%

<sup>\*</sup> Scanlux<sup>®</sup> is the registered international trademark, Unilux<sup>®</sup> is a trademark registered only in Germany.

# Imaging – Contrast Media

# The Market – MR-Lux®

### **Indication areas**

• MR-Lux<sup>®</sup> is a paramagnetic contrast medium for use in magnetic resonance tomography (MRT) of the entire body as well as for cranial and spinal application.

### Market potential

- MRT is the most attractive market segment in the areas of imaging diagnostics and is characterised by double-digit growth (in terms of the number of investigations)
- The market volume in Germany is currently between EUR 80 90m.



# Imaging – Contrast Media

# The Product – MR-Lux®

### **Product advantages**

- Proven substance (over 80 million administrations worldwide)
- On a par with original product manufacturers due to high quality standards

# Competitive edge

- MR-Lux<sup>®</sup> rounds off basic imaging product portfolio and increases competitiveness
- Marketed by existing subsidiaries and global distribution partners
- In-house production for SANOCHEMIA Diagnostics and other parties (for use in EU)

### Status quo/prospects

- Approved in D and CH, dossier submissions planned in 13 other EU markets
- Launch in Germany in March 2008; Launch in Switzerland in March 2009
- 10% market share forecast
- API supplier for the entire European market (and customer-specific manufacture)



# **Diagnostics**

- Pancreas function test
  - Secrelux<sup>®</sup>

# Diagnostics for imaging processes

PVP hypericin

# Medicinal products

- HIV assay Fluorognost<sup>™\*</sup>
- Colognost<sup>®</sup>\*\*

\* IFA Anti-HIV Fluorognost is used in conjunction with additives to test blood serum under UV light.

\*\* Colognost<sup>®</sup> is a radiological marker used in patients with disorders of the digestive tract and negative GI values.

# **Diagnostics**

# The Market – Secrelux®

### Indication areas

- Diagnosis of exocrinal pancreatic function and Zollinger-Ellison Syndrome
- ERCP diagnosis

Diagnosis of exocrinal pancreatic function:

Also known as the secretin (pancreozymin) test. This investigation involves a probe in the duodenum to establish the quantity of pancreatic juice and other laboratory parameters following stimulation with secretin and/or pancreozymin.

### Diagnosis of Zollinger-Ellison Syndrome:

This is a rare condition afflicting only four people in a population of one million. The cause of this syndrome is a tumour of the pancreatic islet cells producing the enzyme gastrin which stimulates the secretion of acids in the stomach and, as a result, leads to stomach ulcers. The normal concentration of gastrin in the blood is increased and rises further when stimulated by secretin.

## Market potential

• Germany: estimated to be around EUR 10m

# **Diagnostics**

# **The Product – Secrelux®** (pancreatic function diagnostic)

### Product advantage

 Secrelux<sup>®</sup> induces a marked increase in pancreatic juice secretion and bicarbonate production for a period of one to two hours.

### Competitive edge

 No other product available in Europe. Secrelux<sup>®</sup> makes possible early and clear diagnosis of pancreatic carcinomas as the precursor to targeted therapeutic intervention.

# Status quo / prospects

- Already marketed in Germany, other European and international registrations sought
- Europe-wide sales on a named-patient basis
- Regulatory submissions for further diagnostic procedures such as CP, MR and sonography are being evaluated (clinical trials planned in 2009)



# **Bladder Cancer Diagnostic**

# The Market

### Indication areas

- Photodynamic diagnosis of bladder carcinomas (first diagnosis)
- Early recognition of relapses after bladder cancer therapy

### Market potential

- Four million cystoscopes are performed in the EU and US each year
- The incidence of bladder cancer has nearly doubled since 1950

### SANOCHEMIA's market segment

- Global sales of bladder cancer diagnostics: USD 625m.
  - Forecast growth for: 11% p.a.
  - USA: over 400,000 sufferers in total and over 60,000 new cases diagnosed p.a.
- Europe: similar scenario



# **Bladder Cancer Diagnostic**

# **The Product – PVP Hypericin**

### Product advantages

- Greater sensitivity in terms of tumour detection (compared to white light)
- Low level of photo bleaching

### Competitive edge

- Patent protection of formulation and use of the API in the EU and US
- Distribution through existing sales network alongside contrast media portfolio
- SANOCHEMIA: integrated manufacturer for these products

### Status quo/prospects

- Randomised, multi-centre Phase II clinical trial comparing efficacy versus fluorescence cystoscopy (HFC) and white light cystoscopy (WLC)
- Possibility of therapeutic applications (PDT)
- Extensions to include other tumour-related indication areas possible

Financial Highlights		
in T€	2006/2007	
Sales revenues	29,531	
EBIT*	-1,225	
Cash flow from operating activities	-3,709	
Equity capital	54,109	
Investment*	3,891	
Average headcount during financial year	185	

\* One-off write-down of AlcaSynn investment



For further information regarding facts and figures, please refer to the 2007/2008 Annual Report or our quarterly reports.

Share details (ISIN AT 0000776307)			
Name	SANOCHEMIA Pharmazeutika AG		
ISIN	AT0000776307		
WKN	919963		
Symbol	SAC		
Index	Pharma		
Industrial sector	Pharmaceuticals		
Transparency level	Prime Standard		
Market segment	Regulated market		

Ke	y equit	y details	(ISIN AT0000776307)
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Reuters Instrument Code	SCPH.DE
Classification	non-par bearer shares
Approved capital in EUR	10,155,598
Approved capital in shares issued	10,155,598
Capital stock in EUR	10,155,598
Capital stock in shares issued	10,155,598
Free float	28.8 %

# ... in Specialty Pharmaceuticals

# Focus on specific sections of the value-added chain

- Clinical product development and production
- No discovery research or pharmaceutical sales
- Life Cycle Management of proven substances
  - Cost advantages
  - Lower risk of failure during clinical development

# • Attractive niche markets with high margins

Partnerships with big pharmaceutical players rather than competition

# ... in SANOCHEMIA

- Innovative and flexible specialty pharmaceuticals company in growing health market
- Urgent medical need for new tailored therapies
  - Above-average growth in these markets
- Clear focus on development and production
  "We can also produce what we develop"
- Lean R&D pipeline with high-potential projects
  - Short to mid-term prospects for growth and profits
- Products on the market with increasing profit potentials
   Viveo<sup>®</sup>, Scanlux<sup>®</sup>, Secrelux<sup>®</sup> and MR-Lux<sup>®</sup>





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