

SynAct Pharma AB

Treating Inflammation through **Resolution Therapy**

Forward Looking Statements

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- Company Overview and background
- Recent developments
- Strategy 2024-2026
- Lead program Resomelagon (AP1189) Rheumatoid Arthritis (RA)
- Other programs in development
- Milestones 2024

Synact Pharma – Background

2013 Company Founded

- **2016** Listed at Spotlight Stock Market in Sweden
- 2019 Completes Phase I AP 1189
- 2020 Completes Phase II AP 1189 in RA
- 2021 Completes Phase IIa AP 1189 COVID

Completes Phase IIa – AP 1189 - RA

- 2022 Uplisted to Nasdaq, Stockholm
- **2023** Acquisition of TXP Pharma

Completes Resolve and Expand studies – Phase IIB





Jeppe Øvlesen – CEO of Synact Pharma

Share price development

Synact Pharma – Nasdaq Stockholm



Synact Pharma – Strategy going forward

Q1- 2024 New Board and management

Raised 50 MSEK. in a directed issue at 30% premium

Strengthen of the investor base

Strengthen the organization with recruitment of a CMO

Q2 – 2024 Reduced costs to management with 27%

Reduced costs to board with 46%

Phase IIB ready – study to start over summer

Bio International 2024 – San Diego US – June 2024

Capital market day planned for September 2024



Anders Kronborg – Chairman of Synact Pharma

SynAct Pharma – Experienced Management Team

Jeppe Øvli Øvlesen, MBA – CEO

- Over 20 years of experience as CEO of various TXP = pharma companies
 Eounding Board Member of more than 10
 action = pharma
- Founding Board Member of more than 10 biotech and MedTech companies
- Co-founder of TXP Pharma
- Former CFO and VP of Business Development at Action Pharma

Thomas Jonassen, MD – CSO, Co-founder

- CE)
- Associate Professor at Cardiovascular Pharmacology, University of Copenhagen
- Visiting Professor at WHRI, Barts and London School of Medicine
- Co-founder of TXP Pharma and ResoTher Pharma
- Co-founder and former CSO of Action Pharma

Björn Westberg, MSc – CFO

- Over 25 years of experience within various financial roles in the pharmaceutical industry
 AstraZeneca
- Former CFO of Recipharm, Bonesupport, Enea
- Various finance management roles in AstraZeneca
- Experience in investor relations, financing, acquisitions and other business deals



Thomas Boesen, PhD – COO



- Over 20 years of experience in the biotech and pharmaceutical industry
- Inventor on 35 granted patents
- Co-founder of MedChem and TXP Pharma
- Former VP of Discovery at Action Pharma



TXP pharma

James Knight, MBA – CBO



- Over 25 years of experience in the biotech industry, ranging from R&D to Commercial Strategy and Business Development
- Former VP of Portfolio Strategy at Questcor Pharmaceuticals

TXP = pharma © QUESTCOR elan Biogen

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chemometec

TXP pharma

Kirsten Harting, MD & Executive MBA - CMO

- Over 30 years of experience from the global pharmaceutical industry and biotech
- Senior Vice president & Chief Medical Officer
- Responsible for development and approval of several new innovative drugs
- Global launch of new medicine
- Integrating medical and commercial understanding



SynAct Pharma – Board of Directors

Anders Kronborg – Chairman

Mr. Kronborg has extensive financial and leadership experience spanning more than 30 years. Mr. Kronborg holds a Master of Economics and spent close to 10 years in the Ministry of Finance – ending as head of department. From 1996-2007, Mr. Kronborg held different positions as CEO or CFO in different danish media companies. In 2007, he joined the Swedish investment company Kinnevik AB. From 2012-2015 he was COO for the entire group. Mr. Kronborg then moved to the Pharma Industry – from 2015-2022 he served as CFO and interim CEO at LEO Pharma – a Danish company with a turnover of more than SEK 10 billion – spending his time growing the company through several M&A activities.

Independent in relation to the company and the company management: Yes

Independent in relation to the major shareholders: Yes

Sten Scheibye – Board Member

Mr. Scheibye has a long career in pharma and med-tech, where he has been active for over 30 years. He has held positions such as medical sales rep, medical registration officer dealing with FDA as well as EU authorities. Later he moved into other commercial roles and senior leadership positions. For 13 years Mr. Scheibye was CEO of the Danish, listed company Coloplast. During his tenure, Coloplast 6-doubled turnover and 8-doubled share performance. Later Mr. Scheibye has focused on board positions where he has held numerous in private as well as public entities. Mr. Scheibye has served as chairman of Novo Nordisk A/S where he had a seat on the board for 10 years until he became chairman of the Novo Nordisk Foundation. Mr. Scheibye has a PhD in organic chemistry from Aarhus University and a B.Com. from Copenhagen Business School.

Independent in relation to the company and the company management: Yes

Independent in relation to the major shareholders: Yes

Shareholder.: Yes

Shareholder.: Yes







SynAct Pharma – Board of Directors

Sten Sørensen – Board Member

Mr. Sørensen has extensive leadership experience in the pharmaceutical and biotech industries spanning over 30 years. Mr. Sørensen is currently CEO of the clinical stage biotech company Cereno Scientific, a company which he joined as a board member 2014 and assumed the CEO role in 2015 when the company was still an early project project stage. Cereno is listed at NFGM with a current MCAp of approx. SEK 1 billion. Before Cereno, Mr. Sørensen has held senior positions in major pharma including Head of International Marketing Operations for SEK 10 billion pharma portfolio at Monsanto (GD Searle, Chicago, US) and Global Marketing Director for the SEK 4 billion portfolio of Secondary Prevention Products, Cardiovasculars at AstraZeneca (Gbg, Sweden). Mr. Sørensen has during his career iat Monsanto and AstraZeneca initiated two groundbreaking preventive survival studies in heart failure. Mr. Sørensen is Chairman of SARomics Biostructure since 2013. Mr. Sørensen holds a bachelor's degree in chemistry from Lund University.

Independent in relation to the company and the company management: Yes

Shareholder .: Yes

Independent in relation to the major shareholders: Yes

Jeppe Øvlesen – Board member

Mr. Øvlesen is an experienced biotech executive and has been involved as founder/CEO/Chairman/board member in a string of successful companies including Action Pharma, CLC Bio, Cetrea, ChemoMetec, Perfusion Tech, Resother Pharma, Cercare Medical, PNN Medical, Cereno Scientific and TXP Pharma. Mr. Øvlesen was CEO of Synact Pharma from 2015-2023 taking the company public at Spotlight and later at Nasdaq (Stockholm). Mr. Øvlesen holds an MBA from University of Hartford, United States.

Independent in relation to the company and the company management: No

Shareholder.: Yes

Cereno Scientific





TXP TXP



ResoTher 🗖 Pharma



SYNACT PHARMA INFLAMMATION RESOLUTION

Independent in relation to the major shareholders: Yes

Strategy going forward

Continue development of resomelagon (AP1189) as a first in class compound to promote resolution of inflammation as a new patient friendly treatment approach in autoimmune/inflammatory diseases

Main focus will be on generating clinical PoC in clinical Phase 2B in newly diagnosed Rheumatoid Patients (RA) with high disease activity where the current treatment approaches are associated insufficient response in up to 50% of all patients and with widely and unwanted use of Glucocorticoids (GCs)

Continue development of the resomelagon as a novel first in class compound to modulate viral-induced hyperinflammation where the RESOVIR-1 study in COVID-19 and continued preclinical pharmacology in models of other highly relevant viral infections strongly support that the compound can protect against complication associated with viral-induced hyperinflammation

As a parallel track prepare the TXP-11 peptide program to enter phase 1 clinical development in 2025.

Continued Business development will be conducted with the aim to identify industry partner for continued development of the programs towards the market-

SynAct compounds promotes resolution of inflammation



Cartoon adapted from Perretti et al. Trends Pharmacol Sci 2015;36:737-55

SynAct compounds promote resolution of inflammation through stimulation of melanocortin receptors on key cells in the inflammatory system



- Resomelagon induces selective stimulation of melanocortin receptors 1 and 3 (MC1R and MC3R) present on immune active cells promotes direct immunomodulatory effects
- SynActs MCR agonists have no activity against MC2R, present in the adrenal glands, which causes the release of cortisol when stimulated and results in steroid side effects and tolerability issues



- Exbibits anti-inflammatory activity via MC1R and MC3R stimulation on targets cells – such as lowering the release of proinflammatory cytokines
- Promotes pro-resolution pathways following stimulation of MC1R and MC3R on targets cells – such as increasing efferocytosis in macrophages



Resomelagon (AP1189)

Clinical stage biased MCr (1,3) agonist for once daily dosing currently in Phase 2 clinical development

Current status on clinical development of lead compound Resomelagon (AP1189)

- Autoimmune diseases with focus on Rheumatoid Arthritis
 - Resomelagon has the potential to be a first in class glucocorticoid sparing compound for first line treatment in newly diagnosed RA patients with high disease activity.
 - SynAct intent to continue development of the compound in Phase 2b with filing of the next clinical trial application in Q2 2024.
- Modulation of hyperinflammation in Virus infections
 - The RESOVIR-1 study conducted in pt with severe COVID-19 infection support the potential of Resomelagon as a first in class immune-modulating compound to reduce the devastating effects of hyperinflammation in severe viral infections
 - Continued preclinical research support development in relevant clinical settings

RA affects about 1% of the global population, and while there are several classes of approved therapies remission can remain elusive



Rheumatoid Arthritis: Global Drug Forecast and Market Analysis to 2029, Reference Code: GDHC209PID

SYNACT

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Resomelagon (AP1189) should be introduced to RA patients as early as possible

- Therapy with cDMARDs , ie MTX should be started as soon as the diagnosis of RA is made
- Treatment should aim at reaching a target of sustained remission or low disease activity in every patient
- GCs should be considered when initiating MTX treatment but should be tapered and discontinued within 3 months (EULAR 2022).
- TNF-blockers are not recommended for first line treatment because of the additional risks of toxicity (ACR)



EULAR treatment roadmap for moderate and severe RA

Early intervention with resomelagon (AP1189) could be a novel treatment approach to increase the likelihood of early disease control

SYNACT PHARMA EULAR 2019: Ann Rheum Dis 2020;79:685–699; ACR 2021: Arthritis Care & Research 2021: 73, 7:924–939; EULAR 2022: Ann Rheum Dis 2023;82:3–18.

Resomelagon (AP1189) in Rheumatoid Arthritis

Phase 2 data supports continued development of resomelagon as a novel innovative treatment option in RA

Resomelagon (AP1189) demonstrated significant treatment effects in treatment naive RA patients - the 4 week BEGIN P2a clinical trial

Phase 2a double- blind placebo-controlled study in treatment naive RA patients with high disease activity (CDAI >22 at randomization) in combination with MTX with 4 weeks treatment



80% of had CRP higher than normal range and the majority of the patients were treated within weeks of RA diagnose- None of the subjects were treated with GCs – Treatment: once daily oral dosing

The EXPAND study - ACR Scores following 12 weeks treatment in combination with MTX in newly diagnosed treatment naive patients with high disease activity (CDAI>22)

Patients with baseline hsCRP > 3 and RA diagnosis within 6 months from BL







once daily oral dosing with tablet - no GC bridge treatment - Double blind placebo controlled multicenter study

SYNACT PHARMA

Post hoc analyses: *****: p<0.05 (ACR20) or 0.01 (DAS28 and CDAI) vs placebo

Resomelagon (AP1189) has the potential to be a novel oral treatment option in RA

- In newly diagnosed RA patients with high disease activity CDAI>22, hsCRP>3 mg/L the compound shows significant treatment effects in combination with MTX –
- In combination with MTX, resomelagon has the potential to reduce the use of GC = GCsparring effect
- In combination with MTX as first line treatment, the compound has the potential to delay/reduce the use of second line as the bDMARDs (TNF-blockers)
- Following dosing of more than 75 healthy volunteers and 200 pts (RA and Covid-19) the compound shows a very favorable safety profile- no dose limiting adverse events identified including no signs of immuno-suppression

The ADVANCE Study

A Double blind placebo-controlled Phase 2b dose-range study in newly diagnosed treatment naïve RA patients with high disease activity

ADVANCE STUDY P2b dose-range study in treatment naive RA patients.

Patient Population:

- Newly diagnosed treatment naïve RA pts, eligible for initiation of MTX treatment
- CRP at baseline >3 mg/L
- CDAI >22 at baseline min of 6 swollen and tender joints
- Glucocorticoids only allowed as rescue medicine

Resomelagon (AP1189) 3	3 dose levels in combination with MTX
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Placebo, combination with MTX

12 Weeks dosing

Key Study Parameters	
Dosing and Duration	 12 weeks of once-daily dosing of resomelagon tablet or placebo- conducted at sites in US and Europe
Study Size and Sites	 Designed to recruit 60 patients per group – 12 -15 months recruitment
Primary Endpoints	 Safety and Tolerability Treatment effect evaluated by the ability to reduce DAS28 and by evaluation of ACR20 response rate at 12 weeks as compared to placebo
Secondary Endpoints	CDAI score; ACR50/ACR70; HAQ-DI
SYNACT PHARMA	



Resomelagon (AP1189) in Virus-induced hyperinflammation

Phase 2 data supports continued development of resomelagon as a novel innovative treatment option to control hyperinflammation in severe viral infections

Macrophages as a potential target for resomelagon treatment in severe viral infections associated with hyper-inflammatory responses

SYNACT







Hyperinflammation is a major clinical challenge in Virus infections includind Dengue-virus- Influenza virus - RS-virus-Chikungunya- Bird Flu (not yet in man) – ect Expected to be an even larger burden as climate changes facilitate endemic presence of vira previously restricted to areas with (sub)tropical climate-

Figures from: Nature Reviews Immunology, May 2020; Cell Death & Differentiation, March 2020

RESOVIR study (n=60) – Resomelagon treatment facilitate early recovery in severe COVID-19 infection



Resomelagon-treated patients experienced significantly faster respiratory recovery ((P<0.0001) and had shorter hospital stay than patients given placebo (P<0.0001)



Data on file

Resomelagon- Laboratory experiments support the potential of the compound to modulate viral- induced hyperinflammation



Disease model of Corona MHV-A59 virus-infection

Human monocytes incubated with Dengue-virus



Resomelagon (AP1189) has the potential to be a novel oral treatment option to control hyperinflammation in severe viral infections

- Resomelagon reduced time recovery and reduced time of hospitalization In Covid-19 patients with need for supplementary oxygen treatment due ti respiratory insufficiency
- Resomelagon showed effective in reducing Covid-19 incuced pulmonary infection in experimental disease model
- Resomelagon shows treatment effects in Dengue-virus ex vivo model using human monocytes
- The RESOVIR- project will continue with the aim to generate further PoC in disease models with the aim to prepare for further clinical development in pt with virus-induced hyperinflammation- Dengue-virus- Influenza virus RS-virus- Chikungunya- Bird Flu- other

<u>Q3-2024</u>

First patient in – ADVANCE study

Capital market day in Stockholm

<u>Q4-2024</u>

Continue partnering discussion at Bio Europe and other events

Prepare TXP compounds for clinical development

First half - 2025

TXP Compounds ready to enter clinical development

RESOVIR-II clinical ready to be initiated

Second half - 2025

Complete recruitment in ADVANCE study followed by Top line data = Phase IIb completed

Clinical Phase 1 on TXP Compound

RESOVIR-II