

of 2025 has been prepared by the the original Swedish report prevails.

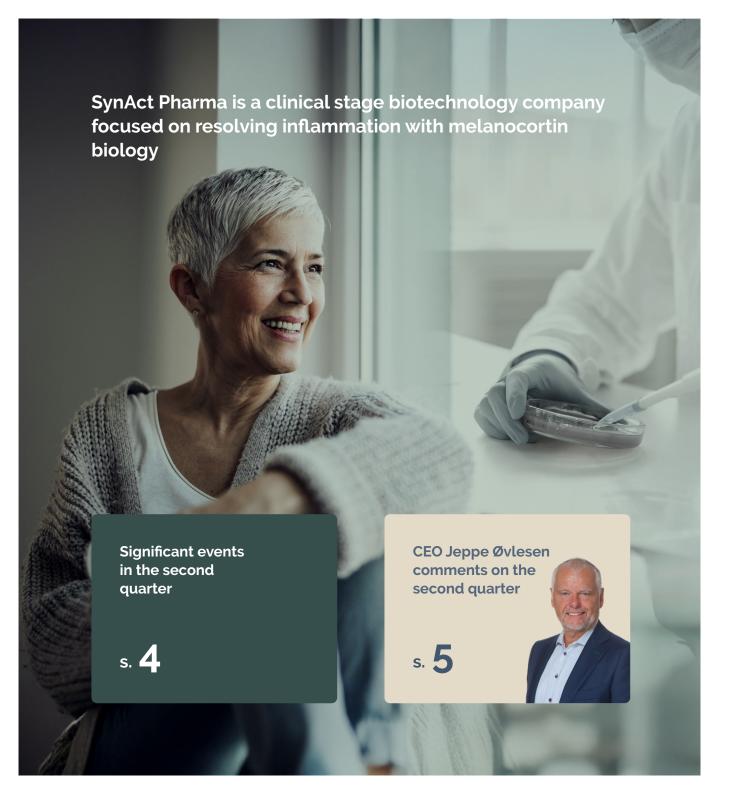
**INTERIM REPORT** 

January - June 2025

Research and development in inflammatory diseases

This English version of SynAct Pharma's Interim Report for the second quarter of 2025 has been prepared by the Company as a service to its non-Swedish stakeholders. In case of differences, the original Swedish report prevails.

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### SynAct Pharma AB

Visiting address: Scheelevägen 2 223 63 Lund, Sweden

Postal: Scheelevägen 2 223 63 Lund, Sweden



+46 10 300 10 23



investor.relations@synactpharma.com

## Interim report for the second quarter and first six months 2025



## Quarter 2 (April - June)

- The Group's net sales amounted to SEK o (o) thousand.
- Operating expenses amounted to SEK 30,345 (19,167) thousand, an increase of 58%.
- The Group's loss after tax amounted to SEK 27,522 (18,628) thousand.
- The Group's earnings per share before and after dilution amounted to -0.56 (-0.47) SEK.
- Cash flow from operating activities amounted to SEK -18,788 (-36,153) thousand.
- Cash flow from financing activities amounted to SEK 35,969 (47,483) thousand.
- Cash flow for the period amounted to SEK 17,181 (11,331) thousand.
- Cash and cash equivalents at the end of the period amounted to SEK 68,890 (62,799) thousand.



## Six months (January - June)

- The Group's net sales amounted to SEK 0 (0) thousand.
- Operating expenses amounted to SEK 58,443 (44,873) thousand, an increase of 30%.
- The Group's loss after tax amounted to SEK 52,207 (43,534) thousand.
- The Group's earnings per share before and after dilution amounted to -1.07 (-1.16) SEK.
- Cash flow from operating activities amounted to SEK -47.614 (-47,342) thousand.
- Cash flow from financing activities amounted to SEK 55,672 (47,329) thousand.
- Cash flow for the period amounted to SEK 8,058 (-12) thousand.

## The Group's financial performance per quarter

(SEK thousand)	2025 Q2	2025 Q1	2024 Q4	2024 Q3	2024 Q2	2024 Q1	2023 Q4	2023 Q3
Net sales	-	-	-	-	-	-	-	-
Operating income	-30,345	-28,098	-20,797	-24,309	-19,167	-25 706	-91 062	-31 692
Profit before tax	-30,057	-30,326	-20,318	-24,687	-19,771	-26 049	-90 542	-31 988
Profit for the period	-27,522	-24,684	-18,379	-20,489	-18,628	-24 906	-90 543	-31 878
Total assets	243,595	219,171	270,520	217,131	241,053	213 354	228 019	275 925
Equity / asset ratio (%)¹	81%	83%	79%	78%	78%	71%	77%	76%
Earnings per share (SEK)	-0.56	-0.51	-0.44	-0.50	-0.47	-0,70	-2,58	-1,00
Research & development cost / operating expenses (%) <sup>1</sup>	78%	76%	70%	80%	38%	31%	12%	68%

1) Alternative performance measures - APM, ref. p. 25 for definitions

## Significant events during the second quarter of 2025 and after the end of the reporting period



## The CEO, Jeppe Øvlesen comments on the second quarter 2025

### Clear strategy and strong financials.

SynAct continued to strengthen its position during the second quarter, refining its development strategy for the lead compound resomelagon (AP1189) and bolstering its financial position to ensure the company has the tools needed to succeed.

The Phase 2b ADVANCE study in patients with newly diagnosed severe rheumatoid arthritis (RA) stays on track as it continues to enroll the 240 patients before the end of 2025. This study will confirm the treatment potential of resomelagon to identify optimal doses for Phase 3 development in patients with newly diagnosed RA.

Based on the potential of the compound SynAct announced during the quarter the company would focus on two parallel development tracks. The first being early intervention in autoimmune and inflammatory diseases with primary focus on RA and the second on host-directed treatment in viral infections as described at the company's CMD in June.

For autoimmune and inflammatory diseases, the lead project aim to position resomelagon as a novel patient friendly treatment option to newly diagnosed RA patients with high disease activity. The ADVANCE study is running according to plan with enrollment aimed to be completed in 2025 followed by reporting of key data in Q1 2026.

In addition, the ADVANCE study the company has decided to initiate an explorative phase 2 study in patients with Polymyalgia Rheumatica (PMR). This study will be initiated in H2 2025 at sites in Denmark. The aim of the study is to explore the potential of resomelagon to successfully discontinue the use of glucocorticoids in PMR.

The second track, host-directed treatment in viral infections, focuses on the compound's ability to treat viral-induced hyperinflammatory responses through resomelagon's unique ability to promote resolution. This track is supported by the positive outcome of the RESOVIR-1 study that looked at patients with severe COVID-19 and recent preclinical studies

showing significant disease modulating effects in virus infections such as Dengue, Chikungunya and influenza.

We announced in April the start of the RESOVIR-2 study for patients with Dengue to evaluate the potential of the drug to reduce disease activity measured by a composite clinical end point. The clinical phase of the study awaits the next epidemic as site(s) in Brazil that is expected to happen in Q1 2026.

In addition to the strategic and parallel development as described, the company has continued to try to recruit patients for the ongoing clinical study in Idiopathic membranous nephropathy, a rare disease associated with development of proteinuria and nephrotic syndrome. To significantly increase recruitment rate, major resources better spent on the primary projects should be allocated.

For the TXP peptide program ongoing study are running according to plan with the aim to prepare the lead compound TXP-11 for first in man studies in 2026

#### Strong Financial Position

We are extremely grateful to those shareholders who value our strategy and helped us further strengthen our financial situation to reach our goals. We raised SEK 37 million from several existing shareholders during the quarter, while also gaining a credit line of SEK 30 million. We also raised SEK 35.4 million with Heights Capital Management converting warrants on two separate occasions during Q3. This new financing puts us in a strong position and allows the team to expand the development plan, which will ultimately makes us a more valuable company to potential partners. These financing activities will extend the runway into 2027 based on the current development plan.

To highlight our dedication and belief in SynAct all of the members of the board of directors and management team agreed to a lock-up for their shares until the end of 2025. The new money raised and the lock-up agreements show SynAct's stakeholders are committed and trust our ability to execute on the company strategy.

It is also worth mentioning the two-year US patent extension covering a method of treating RA with resomelagon in combination with methotrexate (MTX). This gives SynAct additional exclusivity, adding value to the asset.

The team worked hard during the second quarter, and our ambition is to be as open as possible with our shareholders to keep them up to date with our progress. The success we have had is largely thanks to the continued support we are given.

I want to thank you all for your support.

"

"SynAct continued to strengthen its position during the second quarter, refining its development strategy for the lead compound resomelagon (AP1189) and bolstering its financial position to ensure the company has the tools needed to succeed."

Jeppe Øvlesen, Chief Executive Officer



## **SynAct Pharma in Brief**

## **About SynAct Pharma AB**

SynAct Pharma AB is a clinical stage biotechnology company focused on the resolution of inflammation through the selective activation of the melanocortin system. The company has a broad portfolio of oral and injectable selective melanocortin agonists aimed at inducing anti-inflammatory and inflammation resolution activity in autoimmune and inflammatory diseases to help patients achieve immune balance and overcome their inflammation.

### **Business model**

SynAct's business strategy is to drive projects into clinical development in order to secure proof-of-concept, i.e. support for clinical relevance. The company's ambition is to conduct Phase 2 clinical studies, and then to sign commercial agreements with one or more major pharmaceutical companies.

### Group relationship and shareholding

SynAct Pharma AB (with corporate registration number 559058-4826) is the parent company of a group that includes the wholly owned subsidiaries SynAct Pharma ApS and TXP Pharma AG. The "Company" or "SynAct" means the Group i.e., SynAct Pharma AB and its wholly owned subsidiaries. In addition to the above, SynAct has no additional shareholdings.

## **Review by the Company's Auditor**

This interim report has not been reviewed by the Company's Auditor.

## Forward looking statements

This financial report contains statements that are forward-looking. Such forward looking statements necessarily involve known and unknown risks and uncertainties, which may cause actual performance and financial results in future periods to differ materially from any projections of future performance or result expressed or implied by such forward-looking statements.



## Vision

SynAct's vision is to lead the development of inflammation resolution therapeutics, a new approach to treating inflammatory diseases that does not suppress the immune system and that enables patients to achieve immune balance and live beyond their inflammation.



## **Mission**

SynAct seeks to develop AP1189 and its peptide melanocortin agonists through proof-of-concept Phase 2 clinical studies. SynAct will seek to establish partnerships and collaborations with like-minded parties for Phase 3 studies and beyond.



## Research and development

### Inflammatory disease

Inflammation is the immune system's way of responding to infections or injuries. Normally an inflammatory response is self-limiting. The immune system will "deactivate" itself and the inflammation will be resolved after the invading pathogen has been removed or the injury has begun to heal.

However, in many cases, the inflammation can be excessive or chronic and it can overwhelm the immune system's ability to resolve the inflammation. This can lead to pain, destruction of tissue, and loss of function.

Autoimmune or chronic inflammatory diseases, like rheumatoid arthritis (RA) are associated with an inappropriate inflammatory response that is not resolved through endogen mechanisms and therefore becomes chronic.

Other examples of diseases with uncontrolled inflammatory responses are virus infections such as respiratory virus including Covid-19 and a number of mosquito borne diseases such as Dengue fever associated with an exacerbated inflammatory response that brings the patient into a hyperinflammatory state with high risk for organ dysfunction where patients need hospitalization.

Currently, these inflammatory diseases are treated with various drugs including drugs that target the inflammatory response with the risk of suppressing the immune system to a degree that unwanted side effects develop.

#### Inflammation resolution

Recent research has shown that resolution of inflammation is not a passive process, but it can be promoted by activating certain biological pathways, and thereby inflammatory response may be treated without immune suppression.

Activation of the melanocortin receptors (MCR) is believed to lead to inflammation resolution, specifically the receptor subtypes MC1R and MC3R, are believed to be key receptors involved in direct effects on the immune system.

MC1R and MC3R are located on many cell types and are spread throughout most of the body, including immune cells and associated structural and supportive cells. MC4R is primary found in the central nervous system and plays a pivotal role in central regulation of metabolism including food intake. MC5R is found in exocrine glands, expressed by some subtypes of immune-active cells in the eye among others. MC2R is primary expressed in the adrenal glands where stimulation is directly associated with the release of cortisol, a steroid.

Activation of the MCRs is causing the immune cells to produce fewer pro-inflammatory molecules, resulting in relief of symptoms. At the same time, the stimulation also resets the homeostasis of the immune system, which is out of balance. Anti-inflammatory drugs that cause pro-resolution effects, such as switching cells to perform inflammation "cleanup" or to regulatory functions, add to the treatment options for inflammatory diseases and provide an alternative to immunosuppressive anti-inflammatory drugs.

# Rheumatoid arthritis (RA) is an autoimmune disease

RA is an autoimmune disorder, a disease where the immune system mistakenly attacks your body's own tissues. The disease affects the lining of the joints, causing painful swelling that can result in cartilage and bone erosion and joint deformity, but it is often associated with symptoms also involving other parts of the body including skin, eyes, lungs, heart, and blood vessels.

While new types of medications have improved treatment options, significant unmet needs still exist.

For most patients, RA still progresses, and damage accumulates. Patients cycle through therapies and classes of therapies and must deal with periods of acute disease activity called flares, which can occur several times per year and drive the need to adjust the dose of current drugs or to change to a new therapy to maintain control of the disease.

# Current treatment guidelines for rheumatoid arthritis (RA)

Today, inflammatory joint diseases like RA are treated with many different drugs. From classical nonsteroid anti-inflammatory drugs (NSAID) to Disease Modifying Anti Rheumatic Drugs (DMARDs) and expensive biologics (bDMARDs) given as injections. Even if the drugs are effective, they may also carry a risk, as they suppress the immune system and can lead to adverse events for the patient.

RA patients are today treated according to international treatment guidelines. These treatment guidelines build on specific criteria to obtain the best treatment for the specific patient. Treatment decisions are based on disease activity, safety issues and other patient factors, such as comorbidities (other disorders that the patient might have) and progression of structural damage in the joints. The guidelines also emphasize the importance of patients requiring access to multiple drugs with different modes of action to address the heterogeneity of RA; and that patients may require multiple successive therapies throughout life.

According to the treatment guidelines, treatment with DMARDs should be started as soon as the diagnosis of RA is made (so called first line treatment). Treatment with DMARDs inhibits the inflammatory process so that the joint pain, swelling, and stiffness are relieved or disappear.

Early and effective treatment is emphasized as being very important in the treatment Guidelines, as this will have an impact on the long-term outcome of the disease and therefore also a profound impact on patient's everyday life.

The treatment guidelines also emphasize that Methotrexate should be part of the first treatment for the RA-patient. However, the challenge is, many patients treated with Methotrexate do not reach sufficient dose due to adverse events and therefore do not reach what is called sustained remission or low disease activity.

Therefore, there is a clear unmet medical need for these early diagnosed RA patients. There is a need for a new medicine, which can be combined with Methotrexate, so that a larger proportion of early diagnosed RA patients can have a positive impact on their disease. However, this new medicine should have a positive adverse event profile.

According to the treatment guidelines the early RA patient may also be treated short-term with glucocorticoids (GC), that is steroids. GCs can be given orally or as joint injections either alone or together with Methotrexate. The reason why GCs is considered is to obtain a clinical meaningful disease reduction within 3 to 6 months. However, GCs has significant adverse events and therefore should be tapered and discontinued as rapidly as clinically feasible according to treatment guidelines. Also, the use of GCs even though intended to be temporary often results in more chronic use, which is unwanted due to the side effects profile.

Overall, up to 50 % of the early diagnosed RA patients do not respond adequately to recommended first line treatment.

If the treatment target is not achieved (the patients is not sufficiently treated) with the first line treatments the rheumatologist should consider biological disease-modifying antirheumatic drugs (bDMARD) according to the Treatment Guidelines.

The bDMARD are potent medicine decreasing the inflammation. However, the bDMARD also implies the risk of suppression of the immune system, which could lead to unwanted infections. Typically, the patient is treated with a TNF-blocker as an add on to the first line treatment.

According to the treatment guidelines, JAK-inhibitors may also be considered, but pertinent risk factors¹ must be considered. The risk factors include both cardiovascular risks and the risk for malignancies, and these should be considered, before the patient can receive JAK-inhibitors. As many RA patients are elderly and therefore might have cardiovascular disorders and increased risk of malignancy, the JAK-inhibitors are often considered third-line treatment.

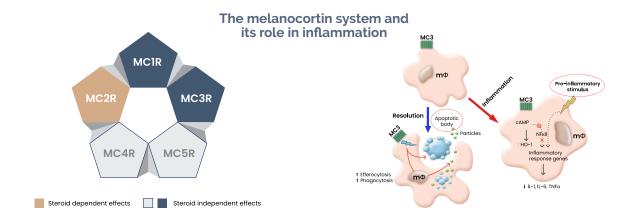
# Our aspiration within RA – to adress the huge unmet medical need

In accordance with the treatment guidelines, there is an unmet medical need within RA, despite the current drugs on the market.

A novel medicine, which fit into the treatment guidelines, could potentially improve treatment due to the following:

- Could be given early in RA treatment (newly diagnosed RA patients)
- Ability to be combined with Methotrexate
- Increase disease control (remission or low disease activity) – increase efficacy
- Have a favorable adverse event profile
- Avoid suppression of the immune system and potential infections (decreased use of GC, bDMARDs and JAK-inhibitors)
- A convenient once a day tablet
- Cost effective treatment
- Saving costs for society for RA treatment

The aspiration of SynAct Pharma is to develop a new medicine which addresses the above unmet medical needs. This new medicine will be an advantage for the patient and the relatives around the patient, for rheumatologists and for society.



<sup>1.</sup> The following risk factors for cardiovascular events and malignancies must be considered when intending to prescribe a JAK-inhibitor. Age over 65 years, history of current or past smoking, other cardiovascular risk factors (such as diabetes, obesity, hypertension), other risk factors for malignancy (current or previous history of malignancy other than successfully treated non-melanoma skin cancer), risk factors for thromboembolic events (history of myocardial infarction or heart failure, cancer, inherited blood clotting disorders or a history of blood clots, as well as patients taking combined hormonal contraceptives or hormone replacement therapy, undergoing major surgery or immobile).

## Resomelagon

Lead drug candidate

# SynAct Pharma's drug candidate, resomelagon (AP1189), is a once-daily oral selective melanocortin agonist.

Resomelagon selectively stimulates the MC1R and MC3R on target cells in the immune system that are directly involved in inflammation and its resolution. It is a clear advantage that the compound does not stimulate MC2R, and hence the anti-inflammatory and immune resolution effects (restoring the balance of the immune system) are not mediated by increase in the cortisol level, as seen with adrenocorticotropic hormone (ACTH) based therapies. Induction of cortisol levels will induce side effects as also seen following GC treatment. Further as resomelagon is a biased agonist, it does not stimulate melanocortin pathways that are responsible for off target activity such as skin hyperpigmentation, which is therefore avoided. Resomelagon has so far demonstrated an advantageous safety and tolerability profile.

The development of resomelagon is focused on two development paths

- 1. Inflammatory and autoimmune diseases where the lead compound resomelagon (AP1189) cur-rently is in phase 2b clinical development in rheumatoid arthritis (RA) and in phase 2a in idio-pathic membranous nephropathy (iMN).
- 2. Host-directed therapy in viral infections where resomelogon has the potential to interact with a viral-induced hyper-inflammatory responses as demonstrated in Covid-19 when administration of the compound facilitated faster respiratory recovery. Recently a phase 2 proof of concept study has been initiated in Dengue fever.

Resomelagon is primarily being developed for treatment of rheumatoid arthritis (RA). Our phase 2 studies focus on helping newly diagnosed rheumatoid arthritis patients, who have a high disease activity including signs of systemic inflammation and where treatment with disease modulating antirheumatic drugs (DMARD) not yet has been initiated.

As outlined above, the RA patients are today treated based on international treatment guidelines. The newly diagnosed RA patients are initially treated with the conventional DMARD Methotrexate. However, often these patients need co-treatment with other medicines like GCs and in many cases biologic DMARDs, typically a TNF-blocker, to get RA under control. However, both GCs and biologic DMARDs are associated with unwanted side effects, as JAK-inhibitors – which are recommended second line RA treatment. Furthermore, biologic medicine is expensive (even if biosimilars have been marked) as is JAK-inhibitors. Overall, current RA treatment is quite costly for society.

The clinical development for resomelagon has been designed to address the huge unmet medical need within RA-treatment with focus on newly diagnosed patients with high disease activity including signs of systemic inflammation, i.e. patients is high risk for early development of poor prognosis factor as they are less likely to response to current treatment option and are I risk for early development of loss of joint functionally. Previous phase 2 studies have been conducted in RA to gain knowledge about resomelagon in these patients.

Resomelagon is expected to become an important novel medicine based on the following: Fit into existing treatment guidelines Can be given early in RA treatment (newly diagnosed RA patients) Can be combined with Methotrexate Expected to increase disease control (remission or low disease activity) increase efficacy Have a very favorable adverse event profile Avoid suppression of the immune system and potential infections (decreased use of GC, bDMARDS and JAK-inhibitors) Is a convenient once a day tablet May save costs for society Resomelagon is expected to provide a unique first line patient-friendly treatment for newly diagnosed RA patients together with MTX to increase early disease control (efficacy) and at the same time reduce the need for GCs and potentially delay and reduce the need for second line treatment options including the TNFblockers. Several phase 2 studies have been conducted in RA to gain knowledge about resomelagon in RA patients and characterize the safety profile in this population.

### **BEGIN**

# Phase 2a in early severe RA together with methotrexate

The BEGIN study in early severe RA was completed in 2021. The study was a randomized, double-blind, placebo controlled multicenter study in previous treatment naïve RA patients where either 50 mg or 100 mg of resomelagon or placebo were given in addition to MTX treatment.

Resomelagon given once daily for four weeks was safe and well tolerated. Based on the primary read out, changes in clinical disease activity index (CDAI), the data showed a clear dose response for 50 and 100 mg resomelagon relative to placebo, with 100 mg of resomelagon demonstrating a statistically significant 65% higher mean reduction in CDAI during the treatment period compared to placebo-treated control group (mean reduction in CDAI: resomelagon 100 mg (n=33): 15.5 points compared with placebo (n=30): 9.3 points, p =0.0394). The 100 mg resomelagon group also demonstrated a significantly higher fraction of patients achieving ACR20 than placebo treated patients (ACR20: resomelagon (n=33) 100 mg: 60.6%; Placebo (n=30): 33.3%, p=0.0437) within the 4 weeks treatment period.

### **EXPAND**

# Phase 2b in MTX-naïve RA patients with severe disease activity

In continuation of the BEGIN study, the EXPAND study was designed to investigate the safety and disease activity (measured by the ACR20 response rate and other RA disease measures) following 12-weeks of treatment with a once daily 100 mg resomelagon tablet plus MTX compared to placebo plus MTX.

Resomelagon was safe and well tolerated. Similar incidence rates of treatment-emergent adverse events (TEAEs) were

seen across treatment groups (44.4% and 42.2%). TEAEs were seen in 11.1% and 6.3% in the resomelagon vs placebo groups, respectively and included upper respiratory tract infections (6.3% vs 6.3%), abdominal pain upper (6.3% vs 3.1%), nausea (6.3% vs 3.1%), and headache (0% vs 9.4%), resomelagon vs placebo respectively. Two serious TEAEs were reported; one in the resomelagon group and one in the placebo group but both were unrelated to study drug. Six subjects reported TEAEs leading to discontinuation; five in the resomelagon group (3 of these subjects with drug related gastrointestinal disorders); and one in the placebo group (unrelated to study drug).

No statistically significant difference was obtained between resomelagon and placebo in the ACR20 response rate at week 12 (54.7% and 55.7% in the resomelagon and placebo groups, respectively) - meaning that the primary endpoint of the study was not met.

However, of the patient population in the EXPAND study, 39% did not show signs of systemic inflammation, as high-sensitive C-reactive protein (hsCRP) were in the normal range (i.e. hsCRP<3 mg/L). Further, a fraction of the patients was not considered newly diagnosed with some being without adequate treatment for years before entering into the study. Therefore, these patients should probably not have been included in the study.

When focusing of the segment of patients, that were considered newly diagnosed (defined as having been diagnosed with RA within 6 months of inclusion into the study) and who showed signs of systemic inflammation (hsCRP>3 mg/L at introduction to the study), ACR20 actually reached 82% in the resomelagon group (n=28) vs 52% in the placebo group (n=27), p<0.05 using Fisher's exact test.

The treatment effect in this very relevant patient segment, mimicking the patients in the BEGIN study, i.e. to be considered the target population for resomelagon in RA was

further supported by significantly larger reduction in disease activity measures: CDAI: resomelagon (n=28): 24.6 points vs placebo (n=27): 14.7 points, p<0.01; DAS28-CRP: resomelagon (n=28): 1.9 points vs placebo (n=27): 1.2 points, p<0.01. Also, the improvement in health assessment questionnaire HAQ), a measure of the patient's ability to handle daily living was significantly larger in the resomelagon group: change in HAQ: resomelagon (n=28): 0.69 points vs placebo (n=27): 0.31 points, p<0.05.

Together these above post-hoc analyses strongly support further development of resomelagon in newly diagnosed RA patients with high disease activity including signs of systemic inflammation treated together with MTX.

### **RESOLVE**

# Phase 2b in RA patients with an inadequate response to methotrexate

Only the first part of the study was conducted, providing results with respect to the efficacy and safety of multiple doses of resomelagon combined with MTX over 4 weeks. Also, in this study resomelagon was safe and well tolerated. Similar incidence rates of TEAEs were observed across treatment groups (range: 21.4% to 34.4% across treatment groups). Treatment related TEAEs were reported in 10%, 10.7%, 12.5%, and 5.7% in the resomelagon 60 mg, 80 mg, and 100 mg vs placebo groups, respectively. Gastrointestinal disorders were the most common treatment-related SOC category (3.3%, 7.1%, 9.4%, and 5.7% in the resomelagon 60 mg, 80 mg, and 100 mg vs placebo groups, respectively). No statistically significant difference was observed between resomelagon and placebo in the primary efficacy endpoint (ACR20 response rate at week 4) and most secondary variable analyses.

#### **ADVANCE**

### Phase 2b 12-week study in early DMARD naïve RA-participants with high disease activity and active inflammation in combination with MTX

Based on the above knowledge of resomelagon in RA, the ADVANCE study is a phase 2B proof of concept study in the target population for resomelagon. That is newly diagnosed RA patients with high disease activity including signs of systemic inflammation

The ADVANCE study is a randomized, double blind, placebo controlled, dose response, phase 2b, multicentre trial to evaluate the efficacy and safety of once daily oral resomelagon (AP1189) administered at the doses of 40, 70, or 100 mg for 12 weeks in combination with MTX, in DMARD-naïve newly diagnosed RA patients with high disease activity and signs of systemic inflammation.

The aim is to recruit a total of 240 patients with a reduction in DAS28-CRP as the primary efficacy readout and will be conducted as an international study under the current US-IND (FDA) for development of resomelagon (AP1189) in RA.

The ADVANCE is ongoing in several European countries as well as in the USA. The recruitment is according to plan and currently the safety profile is in accordance with earlier studies.

It is planned to have all patients enrolled before year end 2025.

## Resomelagon in Polymyalgia Rheumatica (PMR)

Polymyalgia rheumatica (PMR), an inflammatory condition characterized by severe bilateral pain and morning stiffness of the shoulder, neck and pelvic girdle. PMR typically affects people that are middle aged to older and ranks at the second-most common rheumatic disease after RA in Northern Europe and North America. The current first line treatment in PMR is GCs given orally.

To reduce the risk for GC induced side effects the recommendation in the current treatment guideline is to tamper GCs over a few weeks. GC discontinuation is associated with high risk for relapses. Conse-quently, early intervention with resomelagon could be a treatment option to reduce the use of GC, re-duce the risk for relapses, and provide better disease control.

SynAct has therefore decided to enter into as clinical collaboration with leading Nordic rheumatologists with the aim to test the compound's potential to reduce the use of GC in PMR. Initially, an investigator initiated clinical trial is being set up at sites in Denmark to test resomelagon versus placebo given orally once daily to patients for 3 months after initial tampering of GCs.

### Resomelagon in Idiopathic Membranous Nephropathy - Nephrotic Syndrome (NS)

Nephrotic Syndrome (NS) is a condition associated with increased loss of protein into the urine resulting in tissue swelling and eventually development of edemas.

Untreated or insufficiently treated NS will in many cases be associated with hypercholesterolemia, increased risk for blood clots, increased risk for infections and can develop into chronic kidney disease that is associated with increased risk of development of cardiovascular disease and risk of development of end stage kidney disease and thereby need for renal replacement therapy (dialysis or transplant).

Resomelagon is currently tested in Idiopathic Membranous Nephropathy (iMN), one of more common causes of primary NS, in an exploratory, randomized, double-blind, multicenter, placebo controlled Phase 2a study with repeated once-daily 100 mg dosing to assess the safety, tolerability, pharmacokinetics, and efficacy of resomelagon.

The study population consists of patients with iMN, who are on an ACE inhibitor or angiotensin II receptor blocker treatment.

The main efficacy read-out is the effect on urinary protein excretion. The recruitment has been lower than expected due to a lack of eligible patients. Over the period recruitment has increased and based on that the company will continue recruitment during 2025 to establish clinical dataset to support decisions for further development of resomelagon in iMN.

# Resomelagon in host-directed therapy in viral infections

Host-directed therapies target the effects of the viral infection, in our case induced inflammatory diseases, independently of which virus type or virus strain, is causing the disease. Thus, applying resomelagon as host-directed therapy offers a treatment opportunity in a wide range of virus infections causing inflammatory diseases.

Viral induced hyperinflammation is associated with respiratory insufficiency, as seen in viral infections such as Influenza and Covid-19, where infected patients evolve hyperinflammation in the lungs, but also in other viral infections, including arboviral infections, where the inflammation relates to more systemic effects and more organs.

Arboviral infections are caused by a group of viruses spread to people by the bite of infected arthropods (insects) such as mosquitoes and ticks. Arboviral infections are no longer exclusive to the Global South but are going to become more common also in the Global North.

SynAct Pharma has set up a strategic collaboration with the William Harvey Research Institute (WHRI) at Queen Mary University of London, UK and Department of Biochemistry and Immunology at the Universidade Federal de Minas Gerais (UFMG) Belo Horizonte, Brazil, called RESOVIR (resolution in viral infection) collaboration, with world leading scientists and clinicians in resolution biology, including Professor, Mauro Perretti PhD (WHRI) and Professor Mauro Teixeira, MD, PhD (UFMG).

Resomelagon is tested in preclinical models as well as ex vivo settings using human monocytes incubated with highly clinically relevant viruses. Data from these studies will be used to evaluate the continued clinical development of resomelagon as a novel treatment approach to modulate viral-induced hyperinflammation for the benefit of the patients. Already, these studies have resulted in two clinical trials, RESOVIR-1, in Severe Covid-19 infection, and the ongoing RESOVIR-2 in dengue fever.

### Severe Covid-19 infection

Resomelagon was tested in the RESOVIR-1 study, a 60-patient placebo-controlled Phase 2A clinical trial of treatment of hospitalized Covid-19 infected patients who required supplemental oxygen. 100 mg resomelagon or placebo was administered orally once daily for 2 weeks.

All resomelagon treated patients (including the first 6 openlabel safety patients) achieved respiratory recovery on average 4.0 days (40%) quicker than placebo treated patients (5.9 days and 9.9 days on average respectively). Resomelagon patients were discharged on average 3.3 days earlier than placebo and by day 4, 41% of resomelagon patients had been discharged vs 0% for placebo.

#### Severe arboviral infections

The most prevalent arboviral disease is dengue fever. Other arboviral disorders include chikungunya virus, Zika virus, yellow fever, Japanese encephalitis, and West Nile virus.

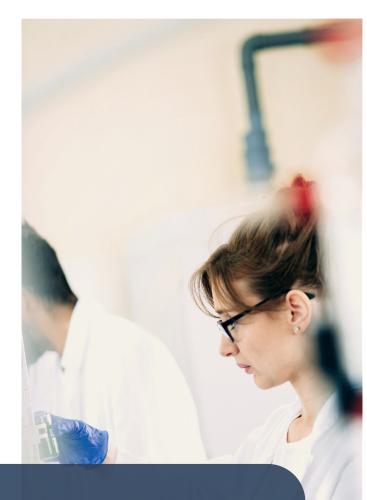
Serious complications of post-infection may occur and are due to a deregulated immune response (hyper inflammation), which can lead to internal bleeding and organ damage.

Infections with Dengue virus have already been reported in Italy, France, Spain and Greece. Severe infections bring serious morbidity in a proportion of patients and can be lethal on reinfection.

Preclinical evaluation of resomelagon ability to modulate the inflammatory response and restoring the balance (homeostasis) of the immune system to Dengue virus supports the possibility to apply resomelagon in a clinical setting.

RESOVIR-2 is a randomized placebo-controlled, phase 2 study testing once daily oral dosing of resomelagon (AP1189) vs placebo (1:1 randomization, n=120) as add on to standard treatment in patients with symptomatic Dengue. The potential treatment effect of resomelagon will be evaluated by time to disease resolution though a composite clinical end point. Secondary clinical end points include the ability to reduce the incidence of warning signs of and/or the development of severe dengue.

The study is initiated and led by Professor Mauro Teixeira, MD, PhD Universidade Federal de Minas Gerais (UFMG), Belo Horizonte at clinical sites in Brazil. Recruitment to and completion of the study depends on the severity of this year's Dengue epidemic at sites.



#### **PEPTIDE AGONISTS**

#### TXP-11

The lead peptide agonist is TXP-11. This peptide also shows high potency at MC1R and MC3R. However, TXP-11 is taken as an intravenous administration and expected to be used in complicated medical conditions where patients are hospitalized with the risk of developing organ/life threatening hyperinflammation. The development potential of TXP-11 is to prevent organ failure following major surgery, traumas, and infections. TXP-11 is currently in preclinical development.

# Pipeline overview

ASSET	INDICATION	PRECLINICAL	PHASE 1	PHASE 2A	PHASE 2B	PHASE 3	STATUS
	Rheumatoid arthritis (RA) - 1st line treatment together Methotrexate						ADVANCE Ph2b study ongoing
Resomelagon (AP1189)	Host-Directed Therapy in Viral Infections					<b>m</b> (	RESOVIR-2 - Ph2a study in Dengue Fever ongoing
	Idiopathic Membranous Nephropathy (iMN)						Ph2a study onging
	Polymyalgia Rheumatica (PMR)			₩.		•	Phase IIa study to be initiated
TXP-11	Prevent organ failure in surgery						Preclinical pharmacology to support Ph-1 CTA ongoing - aim to be Ph-1 ready in 2025
Next generation molecules	Autoimmune & inflammatory diseases		1	<i> </i>	-		Discovery phase
		Completed	Ong	oing			

## The SynAct Pharma Share

### **Share information**

SynAct Pharma's share has been listed on Nasdaq Stockholm since July 12, 2022. The stock is traded with the ticker or short name SYNACT. From the initial public offering in 2016 until July 11, 2022, the company's stock was traded on Spotlight.

The closing price of the SynAct share on the last trading day in June 2025 was SEK 19.16.

In January, the company announced the outcome of the rights issue and resolved on a directed issue to guarantors and announced that the number of shares and votes has increased by 2,521,451 to 49,008,918 as a result of the rights issue, including the payment in shares to the guarantors resolved by the Extraordinary General Meeting on 13 December 2024.

On June 4, 2025, the Board of Directors resolved, based on the authorization granted by the Annual General Meeting on May 27, 2025, on a directed share issue of SEK 37 million before issue costs. Through the directed share issue, the number of shares will increase by 2,313,125 shares, of which 865,625 shares were registered on June 30. The remaining shares in the new share issue were registered on July 8.

## Ownership (June 30, 2025)

Shareholder	Capital and votes(%)
NBCD A/S	10.63%
Avanza Pension	9.32%
Thomas Jonassen	5.21%
Thomas Ringberg	5.12%
Nordnet Pensionsförsäkring	4.46%
Oliver Aleksov	2.31%
Kenneth Bjerg-Nielsen	1.42%
OR invest	1.00%
Quantass ApS	0.74%
Patrik Strempl	0.72%
Total (top-10)	40.9%
Others (~15,700)	59.1%

Compiled and processed data from the share register of SynAct Pharma AB kept by Euroclear AB. Share of capital and votes is based on the number of shares outstanding at the time, 49.874.543.

### **Share-based incentive programs**

The company has one employee option program, Employee Option Program 2024, ESOP (for employees) and BSOP (for the Board of Directors).

For further information, please refer to Note 4 of the financial statements.

### Lock-up agreement

On July 4, SynAct announced a lock-up agreement for its Board of Directors and executive management regarding their respective holdings of shares. The lock-up agreement means that no sale of existing shares for a member of the board of directors or executive management except what is reasonable for the management of tax effects on said holdings.





## Comments on the development for the first quarter and first six months of 2025

### **Net sales**

Net sales for the first quarter amounted to SEK 0 (0) thousand. The company is not expected to generate any revenue until after the completion of Phase 2 program involving the drug candidate resomelagon (AP1189), at the earliest in 2026.

### Research and development (R&D) costs

Total costs for R&D in the second quarter amounted to SEK 23,710 (7,249) thousand. For the first six months R&D costs amounted to SEK 45,175 (15,270) thousand and includes the ongoing ADVANCE study.

#### **Administration costs**

Administrative expenses amounted to SEK 6,688 (11,782) thousand in the second quarter and SEK 13,320 (29,419) thousand for the first six months. Last year, the administrative costs were charged by severance pay for former CEO Torbjörn Bjerke.

### Financial items

Net financial items amounted to SEK 288 (-604) thousand in the second quarter and SEK -1,940 (-947) thousand for the first six months and is attributable to exchange rate adjustments.

## Tax for the period

Tax revenues in the second quarter amounted to SEK 2,534 (1,143) thousand. For the first six months the accrued tax credit amounted to SEK 8,176 (2,286) thousand. See Note 7 - Tax receivables.

## Loss for the period

The Group's loss for the second quarter amounted to SEK 27,522 (18,628) thousand and for the first six months the reported loss was SEK 52,207 (43,534) thousand.

### Cash flow, financial position and going concern

Total assets amounted to SEK 243,595 (241,053) thousand. The working capital was affected by an increase of SEK 5,770 thousand related to the Danish "tax credit scheme", see note 7, and an decrease in pre-paid expenses of SEK 11,142 thousand mainly related to the ongoing ADVANCE study. Equity increased as a result of the new share issues carried out in the first and second quarter of 2025.

Receivables from the Danish tax authorities that follow from the so-called "Tax Credit Scheme" (see Tax on profit for the period above and Note 7 - Tax receivables) amounted to SEK 16,434 (10,664) thousand.

Cash flow from operating activities amounted to SEK -18,788 (-36,153) thousand in the second quarter and SEK -47,614 (-47,342) thousand for the first six months.

Cash flow from financing activities amounted to SEK 35,969 (47,483) thousand in the second quarter and SEK 55,672 (47,329) thousand for the first six months and includes the outcome of the rights issue that was finalized in January and in June.

Cash flow for the period amounted to SEK 17.181 (11.331) thousand and SEK 8,058 (-12) thousand for the first six months.

The Group's cash and cash equivalents as of June 30, 2025, amounted to SEK 68,890 (62,799) thousand.

The Board of Directors continuously evaluates the Company's financial position and has determined that its current cash and cash equivalents, including the recent share issues, are sufficient to finance the operations for the next 12 months.

### **Employees**

The number of employees was 6 (5) of which four employees (3) were employed by the affiliate SynAct Pharma ApS.

### **Parent Company**

The parent company's sales are from services delivered to the Danish subsidiary and amounted to SEK 1,600 (1,979) thousand in the second quarter and SEK 3,244 (3,922) thousand year to date.

In the Parent Company, net financial items amounted to SEK -22,464 (-43,951) thousand in the quarter and SEK -46,936 (-44,151) thousand year to date. The group reports no proprietary intangible assets because the criteria according to IAS 38 are not met. To be able to continue the development activities in Denmark, the Swedish parent company provides ongoing capital contributions to the company that conducts the development activities. Under normal circumstances, the parent company would capitalize the contribution as shares in subsidiaries, but since no part of these funds is capitalized in the balance sheet, the contribution is a cost to the parent company and this cost is reported as a financial cost.

## **General meetings**

### Annual general Meeting

On May 27, 2025, the Annual General Meeting of SynAct Pharma AB Stockholm was held. The AGM resolved to elect Jeppe Ragnar Andersen as a new member of the Board of Directors. The AGM also resolved to give the Board of Directors a mandate to issue shares corresponding to a maximum of 20% dilution

Figures in parentheses refer to comparative figures from the same period last year. Numbers in this report are, with a few explicit exceptions, presented rounded to thousand SEK. Due to rounding, deviations (<1 TSEK) may occur in row totals.

## Consolidated income statement

SEK (thousand)	Note	2025	2024	2025	2024	2024
		Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Net sales		-	-	-	-	-
Gross profit		-	-	-	-	-
Research and development costs		-23,710	-7,249	-45,175	-15,270	-49,312
General and administration costs	4,5	-6,688	-11,782	-13,320	-29,419	-40,492
Other operating income/expenses		53	-136	52	-184	-175
Total operating expenses		-30,345	-19,167	-58,443	-44,873	-89,980
Operating income		-30,345	-19,167	-58,443	-44,873	-89,980
Net financial items		288	-604	-1,940	-947	-846
Profit after financial items		-30,057	-19,771	-60,382	-45,820	-90,825
Tax on profit/loss for the period	7	2,534	1,143	8,176	2,286	8,424
Profit for the period		-27,522	-18,628	-52,207	-43,534	-82,401
Earnings per share (SEK)		-0.56	-0.47	-1.07	-1.16	-2.08
Diluted earnings per share (SEK)		-0.56	-0.47	-1.07	-1.16	-2.08
Average number of shares outstanding ('000)	6	49,018	39,472	49,014	37,521	39,533

The result for the period is attributable in its entirety to the owners of the parent company

# **Consolidated statement of comprehensive Income**

SEK (thousand) Note	2025	2024	2025	2024	2024
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Profit for the period	-27,522	-18,628	-52,207	-43,534	-82,401
Items reclassifiable to profit or loss					
Translation differences from foreign operation	6,082	-286	-3,012	-1,893	2,473
Comprehensive income after tax for the period	-21,441	-18,915	-55,218	-45,427	-79,928
Comprehensive income for the period	-21,441	-18,915	-55,218	-45,427	-79,928

The total comprehensive income for the period is attributable in its entirety to the owners of the parent company

# Consolidated statement of financial position

SEK (thousand)	Note	06/30/2025	06/30/2024	12/31/2024
Assets				
ASSETS				
Subscribed but unpaid capital		-	-	19,845
Non-current assets				
			0	
Intangible assets		151,429	149,726	154,593
Right-of-use assets		1,566	1,463	1,937
Financial assets	8	140	142	144
Total non-current assets		153,136	151,331	156,674
Current assets				
Tax credit	7	16,434	10,664	8,469
Other current receivables		2,503	2,485	5,958
Prepaid expenses		2,632	13,774	18,366
Cash and cash equivalents	8	68,890	62,799	61,209
Total current assets		90,459	89,723	94,001
Total assets		243,595	241,053	270,520

SEK (thousand)	Note	06/30/2025	06/30/2024	12/31/2024
Equity and liabilities				
Share capital		6,234	5,162	5,811
Ongoing share issue		181	-	315
Other paid-in capital	4	799,977	702,091	762,803
Reserves		15,230	13,875	18,241
Retained earnings/losses including net profit		-625,209	-534,134	-573,002
Total equity		196,413	186,993	214,169
Non-current liabilities				
Deferred tax liability		17,929	17,728	18,304
Leasing liability		937	982	1,286
Contingent earnout		8,362	7,602	7,973
Other provision	4	492	6,624	331
Total non-current liabilities		27,720	32,936	27,894
Current liabilities				
Accounts payable	8	5,415	5,691	17,347
Leasing liability		605	454	595
Other current liabilities		376	4,141	424
Accrued expenses	8	13,065	10,838	10,092
Total current liabilities		19,462	21,124	28,458
Total equity and liabilities		243,595	241,053	270,520

# Consolidated statement of changes in equity

Share capital

423

6,234

-134

181

37,174

799,977

Ongoing new

Other paid-in

Reserves Retained earnings, including

01/01/2024 - 12/31/2024

Total transaction with owners

Closing equity

SEK (thousand)	энаге саркас	share issue	capital	Reserves	profit for the period	Total
Opening equity	4,446	-	646,572	15,768	-490,600	176,186
Profit for the period	-		-	-	-82,401	-82,401
Other comprehensive income	-		-	2,473	-	2,473
Comprehensive income for the period	-	-	-	2,473	-82,401	-79,928
Transactions with owners						
Directed share issues	1,365		92,777		-	94,141
Issue expenses			-6,140		-	-6,140
Employee option program			10,065		-	10,065
Ongoing share issue		315	19,530		-	19,845
Total transaction with owners	1,365	315	116,231	-	-	117,911
Closing equity	5,811	315	762,803	18,241	-573,002	214,169
01/01/2025 - 06/30/2025 SEK (thousand)	Share capital	Ongoing new share issue	Other paid-in capital	Reserves	Retained earnings, including profit for the period	Total
Opening equity	5,811	315	762,803	18,241	-573,002	214,169
Profit for the period	-		-	-	-52,207	-52,207
Other comprehensive income	-		-	-3,012	-	-3,012
Comprehensive income for the period	-	-	-	-3,012	-52,207	-55,218
Transactions with owners						
Rights issue (reg 14/01/2025)	315	-315	-		-	-
Directed share issue	108		36,721			36,829
Issue expenses			-900			-900
Ongoing share issue		181				181
Employee option program	-		1,353	-	-	1,353

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15,230

37,463

196,413

-625,209

# Condensed consolidated statement of cash flows

SEK (thousand)	te 2025	2024	2025	2024	2024
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Cash flow from operations					
Operating income	-30,345	-19,167	-58,443	-44,873	-89,980
Adjustment for non-cash items	370	3,578	2,199	13.477	10,828
Interest received	-134	362	-	367	778
Interest paid	215	-387	-1,367	-490	-978
Corporate income tax received/paid	-	-	-	-	8,430
Cash flow from operations before change in working capital	-29,895	-15,615	-57,610	-31,520	-70,922
Change in working capital	11,107	-20,537	9,996	-15,822	-18,275
Cash flow from operating activities	-18,788	-36,153	-47,614	-47,342	-89,197
Cash flow from financing activities	35,969	47.483	55,672	47.329	87,405
Cash flow for the period	17,181	11,331	8,058	-12	-1,792
Cash and cash equivalents at beginning of period	51,161	51,553	61,209	62,395	62,395
Decrease/increase in cash and cash equivalents	17,181	11,331	8,058	-12	-1,792
Exchange rate difference in cash and cash equivalents	548	-85	-377	417	607
Cash and cash equivalents at end of period	68,890	62,799	68,890	62,799	61,209

# Parent company's condensed income statement

# Parent company's statement of comprehensive income

SEK (thousand)	Note	2025	2024	2025	2024	2024
		Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Net sales		1,600	1,979	3,244	3,922	6,969
Gross profit		1,600	1,979	3,244	3,922	6,969
General and administration costs	4,5	-3,837	-5,491	-7,860	-21,618	-29,316
Other operating expenses		55	4	-18	-42	-11
Total operating expenses		-3,781	-5,487	-7,878	-21,661	-29,328
Operating income		-2,181	-3,508	-4,634	-17,739	-22,359
Net financial items		-22,464	-43,951	-46,936	-44,151	-68,264
Profit after financial items		-24,645	-47,459	-51,570	-61,891	-90,623
Tax on profit for the period		-	-	-	-	-
Profit for the period		-24,645	-47,459	-51,570	-61,891	-90,623

SEK (thousand)	Note	2025	2024	2025	2024	2024
		Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Profit for the period		-24,645	-47.459	-51,570	-61,891	-90,623
Other comprehensive income		-	-	-	-	-
Total comprehensive income		-24,645	-47,459	-51,570	-61,891	-90,623

# Parent company's condensed balance sheet

SEK (thousand)	Note	06/30/2025	06/30/2024	12/31/2024
Assets				
Subscribed but unpaid capital		-	-	19,845
Non-current assets				
Financial assets		181,207	181,207	181,207
Total non-current assets		181,207	181,207	181,207
Current assets				
Receivables in group companies		12,686	7,535	9,065
Other receivables		207	388	553
Prepaid expenses		1,939	396	335
Cash and cash equivalents		44,104	44,728	46,752
Total current assets		58,936	53,048	56,705
Total assets		240,143	234,255	257,757

SEK (thousand)	Note	06/30/2025	06/30/2024	12/31/2024
Equity and liabilities				
Restricted equity				
Share capital		6,234	5,162	5,811
Ongoing new share issue		181	-	315
Non-restricted equity				
Other paid-in capital	4	776,762	678,876	739,588
Retained earnings/losses		-504.354	-413,731	-413.731
Profit for the period		-51,570	-61,891	-90,623
Total equity		227,253	208,416	241,360
Non-current liabilities				
Contingent earnout		8,362	7,602	7.973
Other provisions	4	492	6,624	331
Total non-current liabilities		8,854	14,226	8,304
Current liabilities				
Accounts payable		410	673	684
Other liabilities		364	4,132	288
Accrued expenses		3,262	6,808	7,121
Total current liabilities		4,036	11,613	8,093
Total equity and liabilities		240,143	234,255	257,757

## **Notes and disclosures**

### Note 1 - General information

This interim report covers the Swedish parent company SynAct Pharma AB (publ) ("SynAct" or the "Parent Company"), corporate identity number 559058-4826 and its subsidiaries (collectively, the "Group"). The Group's main business is to conduct the development of pharmaceuticals. The parent company is listed on Nasdaq Stockholm, with ticker SYNACT. The Parent Company is a limited liability company registered with its registered office in Lund, Sweden. The address of the head office is Scheelevägen 2, 223 63 Lund, Sweden. This interim report was approved for publishing on August 20, 2025.

### Note 2 - Accounting principles

The interim report has been prepared in accordance with IAS 34 Interim Reporting. The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) with interpretations from the IFRS Interpretation Committee, approved by and implemented in the European Union.

The accounting principles applied in this interim report are aligned with the ones used for the Annual Report 2024, note 2 pages 36 to 39. No new or changed standards implemented on or after January 1, 2025 have had any significant impact on the company's financial reporting.

## Note 3 - Significant risks and uncertainties

The risks and uncertainties to which SynAct's operations are exposed are, in summary, related to, among other things, drug development, competition, technology development, patents, regulatory requirements, capital requirements, currencies and interest rates.

The Group's overall risk management focuses on identifying, analyzing and evaluating risks that could affect the business and the Company's overall goals with the intention of minimizing potential adverse effects. The most significant risks and uncertainties are described below. See the Annual Report for 2024, pages 21-26 for further information on the Group's general risk management.

As the company does not have approved products on the market that can generate positive cash flow, the business requires additional capital. The Company's operations require new capital injections in the medium term, which is why this refinancing risk cannot be considered negligible.

The macroeconomic situation with concerning inflation and interest rates did not have a significant impact on SynAct's operations in the period. Our suppliers and partners have been able to produce and deliver according to the plans we work with and without any significant cost increases. However, it cannot be ruled out that increased inflation and rising interest rates may lead to price increases for goods and services that could have a negative impact on the Company's future financial results and position.

The Group's operation is exposed to currency risks with its financing in SEK and main operations in DKK and EUR. SynAct took mitigating steps to reduce the risk through placement of liquidity in FUR and DKK accounts.

SynAct Pharma conducts clinical trials at clinics in Eastern Europe in the vicinity of the conflict in Ukraine, including in neighboring Moldova. The risks of this have been considered and action plans in the scenario where the conflict spreads and further affects the neighboring countries have been developed. To-date, SynAct and its collaborating partners have not encountered any difficulties that have not been overcome with only minor cost increases but without delays in the execution of the studies. Minor delays and/or minor impact on the Company's operating costs cannot be completely ruled out.

## Notes and disclosures (continued)

### Note 4 - Share-based payments

The purpose of the employee option programs is to secure a long-term commitment for the employees in the Company through a compensation system which is linked to the Company's future value growth. Through the implementation of a share-based incentive program, the future value growth in the Company is encouraged, which implies common interests and goals for the shareholders of the Company and employees. Such share-based incentive programs are also expected to increase the Company's possibilities to retain competent persons.

### **Employee Option Program 2024**

At the Annual General Meeting on May 31, 2024, it was resolved to introduce an employee option program, ESOP (for employees) and BSOP (for the Board of Directors).

These employee option programs shall comprise a maximum of 3,097,228 employee stock options, 2,271,301 for ESOP and 825,927 for BSOP. The allotted employee options vest with 1/3 from the date that is 12, 24 and 36 months after the date of allotment. Previous option holders, who have waived the rights to the earlier options programs, will vest 25% directly as a compensation for the waiver. The option holders shall be able to exercise granted and vested employee options during the period starting on the day that falls 3 years after the date of allotment and ending on 30 June 2029. Each employee option entitles the holder to acquire one new share in the company. Exercise price amounting to SEK 12,25, corresponding to 175 percent of the volume-weighted average share price of the company's share on Nasdaq Stockholm during 10 trading days immediately prior to the day on which a participant is granted options. The employee options shall be granted free of charge, shall not constitute securities and shall not be transferable or pledged. The allotment of 3,097,228 of the options included in the program took place on June 1, 2024.

As of June 30, 2025, SynAct had 49,874,543 shares outstanding. If the outstanding options (2,271,301) for the ESOP 2024 are vested and exercised in full, it would result in a dilution of 4.6%. If the outstanding options (825,927) for the BSOP 2024 are vested and exercised in full, it would result in a dilution of 1.7%.

The costs for the programs are estimated at SEK 6,216 thousand and refer to both the estimated cost of the value of the employees' services during the entire vesting period, valued at the market value at the time of allocation, and the estimated earned social security contributions related to Swedish participants. In the second quarter of 2025, the costs for the employee option programs amounted to SEK 681 thousand (1 035) and the costs for six months amounted to SEK 1,513 thousand (1,035).

Change in outstanding incentive programs (number of options)	2025	2024	2025	2024	Totalt
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	
Alloted instruments					
ESOP 2023 I	-	-	-		195,000
ESOP 2023 II	-	-	-		404,000
ESOP 2024	-	2,271,301	-	2,271,301	2,271,301
BSOP 2024	-	825,927	-	825,927	825,927
Recalled/voided instruments					
ESOP 2023 I	-	-105,000	-	-105,000	-195,000
ESOP 2023 II	-	-270,667	-	-404,000	-404,000

Maximum number of shares to which allocated options can entitle	06/30/2025
ESOP 2024	2,271,301
BSOP 2024	825,927
Total Employee Option	3,097,228

## Note 5 - Transactions and agreements with related parties

In addition to salaries and other remuneration (including invoiced) to the Company's management, board remuneration, according to the resolution of the Annual General Meeting, to the board, and intra-group transactions no transactions have taken place with related parties in the reporting period.

The Company has entered into an agreement with Boesen Biotech ApS regarding the transfer of intellectual property rights. The agreement did not involve any financial transactions in reported periods. See Note 9, Contingent liabilities for more information.

## Notes and disclosures (continued)

### Note 6 - Number of registered shares

Thousand	2025	2024	2025	2024	2024
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Number of shares at the beginning of the period	49,009	35,571	46,487	35,571	35,571
Number of shares at the end of the period	49,875	41,296	49,875	41,296	46,487
Average number of shares outstanding in the period	49,018	39,472	49,014	37,521	39,533

All shares are freely traded and the Company does not hold any shares.

### Note 7 - Tax receivables

According to Danish tax law (the tax credit scheme), the subsidiary SynAct Pharma ApS is entitled to receive a current tax income for some of the expenses that are directly attributable to the company's research and development (R&D). Settled expenses for R&D that result in tax revenue received reduce the company's tax loss carryforwards with the corresponding amount. SynAct Pharma ApS can settle a maximum of tax deficits attributable to research and development up to DKK 25 million per year. This corresponds to DKK 5.5 million as possible tax revenue, as the tax rate in Denmark is 22%.

The claim on the Danish tax authorities that follows from this scheme amounted to SEK 16,434 (10,664) thousand. The balance related to fiscal year 2024 with an amount of SEK 8,469 thousand is expected to be received in November 2025.

Note 8 - Financial assets and liabilities

SEK (thousand)	06/30/2025	06/30/2024	12/31/2024
Financial assets			
Non-current financial assets	140	142	144
Cash and cash equivalents	68,890	62,799	61,209
Total financial assets	69,030	62,941	61,353
Financial liabilities			
Accounts payable	5,415	5,691	17,347
Accrued expenses	13,065	10,838	10,092
Total financial liabilities	18,480	16,529	27,439

SynAct Pharma har inga finansiella instrument som värderas och redovisas till verkligt värde. För samtliga finansiella tillgångar och skulder anses det redovisade värdet enligt ovan vara en rimlig approximation av verkligt värde. Någon ändring i klassificeringen av finansiella tillgångarna har ej skett för redovisade perioder.

## Note 9 - Contingent liabilities

In March 2021, the subsidiary SynAct Pharma ApS acquired the rights to a number of innovative chemical molecules from Boesen Biotech ApS, a company controlled by COO Thomas Boesen. The transfer took place free of charge, but according to the agreement, Boesen Biotech ApS is entitled to receive milestone payments and royalties in the future related to any progress in the Company's development and commercialization of products based on these rights. Upon successful achievement of defined milestones, Boesen Biotech ApS may receive up to a maximum of DKK 4.5 million in payment. In the event of any future commercialization of a product where these IP rights are used, Boesen Biotech ApS is entitled to royalties amounting to 3% of net sales for 10 years from launch and with a maximum amount of DKK 500 million.

As the remunerations that may be paid to Boesen Biotech is not considered to be secure or probable commitment for SynAct, they are not reported as a liability (accrual or provision). Based on current plans, a first milestone payment may be charged to the income statement and balance sheet at the earliest in 2025 and have a cash flow effect no earlier than 2026.

## Alternative performance measures - APM

The use of Alternative Performance Measures in financial reports is regulated by the European Securities and Markets Authority (ESMA) in guidelines issued in 2015. According to these guidelines, an alternative key ratio refers to a financial measure of historical or future earnings development, financial position, financial result or cash flows. It is not such a financial measure that is defined or specified in the applicable rules for financial reporting.

SynAct Pharma uses alternative key figures to increase the understanding of the information provided in financial reports, both for external analysis, comparison and internal evaluation. The company has chosen equity / assets ratio and research and development costs / operating expenses as alternative key figures in its reporting. Definitions and tables for deriving these are shown below.

### Equity / asset ratio

The equity ratio is a financial ratio indicating the relative proportion of equity used to finance a company's assets. The two components are taken from the SynAct Pharma's balance sheet or statement of financial position (so-called book value). Equity divided by total assets.

#	SEK (thousand)	06/30/2025	06/30/2024	12/31/2024
	Assets			
	Subscribed but unpaid capital	-	-	19,845
	Total non-current assets	153,136	151,331	156,674
	Total current assets	90,459	89,723	94,001
[1]	Total assets	243,595	241,053	270,520
	Equity and liabilities			
[2]	Total equity	196,413	186,993	214,169
	Total non-current liabilities	27,720	32,936	27,894
	Total current liabilities	19,462	21,124	28,458
	Total liabilities	47,182	54,060	56,351
	Total equity and liabilities	243,595	241,053	270,520
[2]/[1]	Equity / asset ratio (%)	81%	78%	79%

### Research and development costs / operating expenses

Total cost of Research and Development as a percentage of total operating expenses. Indicates the share of total investment allocated to R&D. Subsequently, the residual (1 - R&D/Operating Expenses), indicates share of total invested into General & Administration activities.

#	SEK (thousand)	2025	2025	2024	2025	2024
		Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
[1]	Research and development costs	-23,710	-7,249	-45,175	-15,270	-49,312
	General and administration costs	-6,688	-11,782	-13,320	-29,419	-40,492
	Other operating income / expense	53	-136	52	-184	-175
[2]	Total operating expenses	-30,345	-19,167	-58,443	-44,873	-89,980
[1]/[2]	Research and development costs / operating expenses (%)	78%	38%	77%	34%	55%

## **Declaration of the Board of Directors**

The CEO assures that this interim report provides a true and fair view of the development and the Group's and the Parent Company's operations, position and results, and describes significant risks and uncertainties that the Parent Company and the companies included in the Group face.

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) adopted by the EU and the interim report has been prepared in accordance with IAS 34 - Interim Financial Reporting. The interim report has been reviewed by the company's auditors.

Lund, August 20, 2025	
Anders Kronborg Chairman of the Board	Jeppe Ragnar Andersen Board Member
Sten Scheibye Board Member	<b>Sten Sörensen</b> Board Member
	_
Jeppe Øvlesen	

## **Dictionary**

#### **ACE** inhibitor

A group of drugs that lower blood pressure by inhibiting the angiotensin-converting enzyme (ACE).

#### **ADVANCE**

Ongoing clinical Phase 2b study in newly diagnosed treatment naive rheumatoid arthritis patients characterized by high disease activity including signs of systemic inflammation who are eligible for Methotrexate (MTX) treatment. In the study 3 doses of resomelagon (AP1189) vs placebo (n=240) given once daily for 12 weeks are tested in combination with standardized MTX treatment. The aim is to identify clinically active doses of resomelagon to be taken into Phase 3 clinical development. The primary efficacy readout, set in accordance with US-FDA recommendation for phase 2 dose range studies is changes in the clinical score DAS28-CRP relative to placebo treatment. The study is conducted at more than 30 sites in Europe and US with the aim to have last patient dosed in Q4 2025.

### **Agonist**

An agonist is a chemical that activates a receptor to produce a biological response. Receptors are cellular proteins whose activation causes the cell to modify what it is currently doing. In contrast, an antagonist blocks the action of the agonist, while an inverse agonist causes an action opposite to that of the agonist.

## **Angiotensin**

Angiotensin is a peptide hormone important for the regulation of blood pressure.

### **Arboviral Infections**

Infections due virus infection following mosquito bites. Examples of arbo-virus are Dengue virus, Chikungunya virus, Zica virus and West Nile virus. Arboviral infections are more common in tropical and subtropical climates but has spread in recent years also to Europe and the US where the mosquitos have become endemic. A major reason to the spreading of the virus is most likely global warming.

### **Autoimmune disease**

An autoimmune disease is a condition arising from an abnormal immune response to a functioning body part.

#### **BAP**

Branched Amino Acid Probes (BAP) is a proprietary technology improving the properties of peptides, developed by TXP Pharma for the modification of therapeutic peptides.

### **BEGIN**

The BEGIN study was a multi-center, two-part, double-blind, placebo-controlled study, in which two doses of resomelagon (50 mg and 100 mg orally administered once daily) were evaluated against placebo as adjunctive therapy to methotrexate in newly diagnosed patients with acute, active RA. The study's primary endpoint is a reduction in disease activity from high (defined as clinical disease activity> 22) to moderate or low activity during the four-week treatment period. Key data from the study were presented on November 30, 2021.

#### **CAMP**

cAMP, or cyclic adenosine monophosphate, is an adeninebased (nitrogen-based), cyclic nucleotide (molecular building block) that participates in the formation of DNA and RNA, by acting as a secondary messenger for several signaling substances and hormones and their receptors, inside the cells.

### **Clinical study**

Clinical studies are conducted to test the efficacy and safety of new drugs, diagnostic tests, products, or treatments. Before human studies begin tests have already been done in several different ways in laboratory experiments and in animal studies. Clinical studies or trials are carried out both with healthy volunteers and individuals with the disease being studied.

#### **CMC**

CMC is an acronym for Chemistry, Manufacturing and Controls which are critical activities in the development of new drug products. In addition to the processes themselves, CMC also refers to practices and specifications that must be followed and met to ensure product safety and batch-to-batch consistency.

### **Contract Research Organization (CRO)**

Within the life science industry, a contract research organization (CRO) is a company that provides support to the pharmaceutical, biotechnology and medical technology industry in the form of research services outsourced on contract. A CRO can provide such services as biopharmaceutical development, development of biological assays, commercialization, clinical development, management of clinical studies, safety monitoring, outcome research and so-called real world evidence studies.

### **DMARD**

Disease-modifying anti-rheumatic drugs (DMARD) are a category of otherwise unrelated drugs defined by their use in rheumatoid arthritis and other rheumatic diseases. The term often finds its meaning in contrast to non-steroidal anti-inflammatory drugs and steroids (NSAIDs). The term overlaps with antirheumatics, but the two terms are not synonymous.

### **EXPAND**

The EXPAND (SynAct-CS007) study was a multi-center, randomized, double-blind, placebo-controlled, 12-week study in MTX naive patients with highly active RA (Clinical Disease Activity Score (CDAI) > 22). In EXPAND, 120 RA patients with high disease activity (CDAI > 22) was randomized to treatment with resomelagon 100 mg once daily or placebo for 12 weeks in combination with MTX treatment. The overall conclusion from the study was that resomelagon was well tolerated, but no treatment effects compared to placebo treatment was observed. However, in the fraction of patients (approx. 50 of the recruited pts) who were newly diagnosed and with signs of systemic inflammation, ie patients presenting with poor prognosis parameters, the response rate to treatment was significantly increased in the resomelagon treated when compared to placebo treatment. This finding, together with comparable finding in the BEGIN study, the first study of resomelagon in RA, support the further development of resomelagon in the ADVANCE study.

#### **FDA**

The United States Food and Drug Administration (FDA or USFDA) is the US food and drug authority responsible for food (for humans and animals), dietary supplements, drugs (for humans and animals), cosmetics, medical devices (for humans and animals), radioactive equipment and blood products.

## Hypercholesterolemia

Hypercholesterolemia, also called high cholesterol, is the presence of high levels of cholesterol in the blood.

## Hyperinflammation

Exacerbated inflammatory response in the body and or in organs/tissues. Hyperinflammatory responses are seen secondary to infections or in response to major surgery, severe bleeding or traumas. When present hyperinflammation can develop into tissue and/or organ dysfunction and in the most

severe cases in systemic inflammatory response syndrome (SIRS) with multi-organ failure. No current treatment are available to control hyperinflammatory responses in controlled fashion.

#### **iMN**

Idiopathic membranous nephropathy is an autoimmune disease in which the membranes of the glomerulus are attacked by generated autoantibodies, resulting in progressive deterioration of kidney function.

### IND (Investigational New Drug) Application

An application to the FDA that must be submitted and approved before a drug can be tested on humans, so-called permit application for drug testing.

### Melanocortin

Melanocortin is a body-specific hormone that acts by activating specific melanocortin receptors on the cell surface of certain white blood cells.

## Melanocortin receptors

When these receptors are activated, processes start in the body that lead to reduced release of pro-inflammatory mediators (slowed down inflammation) and stimulation of healing processes (dead cells and cell debris are cleaned away and the tissue heals).

### Methotrexate (MTX)

Methotrexate is a folic acid antagonist that belongs to the group of cytostatics. Today it is used in rheumatoid arthritis, psoriasis and Crohn's disease as a disease-modifying drug but can also be used as a cancer treatment.

## Nephrotic syndrome (NS)

Nephrotic syndrome is a syndrome (a collection of symptoms) resulting from a change in the kidneys.

### Organ dysfunction/Organ failure

Organ dysfunction is a condition where an organ does not perform its expected function. Organ failure is organ dysfunction to such a degree that normal homeostasis cannot be maintained without external clinical intervention.

### **Peptide**

A peptide is a molecule that consists of a chain of amino acids (also called monopeptides) joined together by peptide bonds to form a short chain. Peptides differ from proteins only in that they are smaller. Peptides occur naturally in the body but can also be produced synthetically.

### pERK pathway

The pERK pathway (also known as the MAPK/ERK or RasRaf-MEK-ERK pathway) is a chain of proteins in the cell that communicates a signal from a receptor on the surface of the cell to the DNA in the nucleus of the cell

### **Pharmacokinetics**

Pharmacokinetics (PK) is the study of drug metabolism in the body, i.e. how the levels of a drug in the body change through absorption, distribution (distribution), metabolism and excretion.

#### RA

Rheumatoid arthritis is an autoimmune disease characterized by chronic inflammation (arthritis) and pain (arthralgia) in the body's joints. Inflammation has a strong ability to break down cartilage, adjacent bones, tendons and arteries.

### **RESOLVE**

The RESOLVE study (SynAct-CS006) was setup under a USIND to evaluate the potential of resomelagon in so-called DMARD-IR patients, i.e. RA patients who had inadequate response to first line treatment defined as MTX including co-administration of glucocorticoids. The study was set up in two-parts, as randomized, double-blind, multi-center, placebo-controlled studies. Part A was a 4-week dose range study testing 3 doses of resomelagon vs placebo. The primary aim for part A was to identify feasible doses for part B of the study. Part B was planned as Phase 2b randomized, doubleblind, multi-center, placebo-controlled studies testing up to three doses of resomelagon vs placebo in DMARD-IR patients. As the outcome of Part A was inconclusive as regard to dose response and efficacy relative to placebo treatment it was decided not to initiate part B. The reason for the inconclusive results in part A could most likely be attribute to the short treatment period (4 weeks) and the fact the only a fraction, less than 105 of the patients had been treated with MTX for less than 12 months with a fraction not been optimally titrated with MTX. SynAct Pharma has decided to postpone further development in RA DMARD-IR patients to a later timepoint.

## Resomelagon (AP1189)

The mechanism of action of SynAct Pharma's lead drug candidate resomelagon is the promotion of inflammation resolution through the selective activation of melanocortin receptors 1 and 3. These receptors are found on all immune cells, including macrophages and neutrophils. Activation of these receptors leads to two direct anti-inflammatory effects: it influences these cells to produce fewer inflammation-driving molecules and also alters them to initiate clearance of the inflammation, also known as efferocytosis (J Immun 2015, 194:3381-3388). This process has been shown to be effective in models of inflammatory and auto-immune diseases and the clinical potential is being tested in clinical programs in patients with rheumatoid arthritis (RA), nephrotic syndrome (NS) and COVID-19. The safety and efficacy of resomelagon have not been reviewed by any regulatory authority globally.

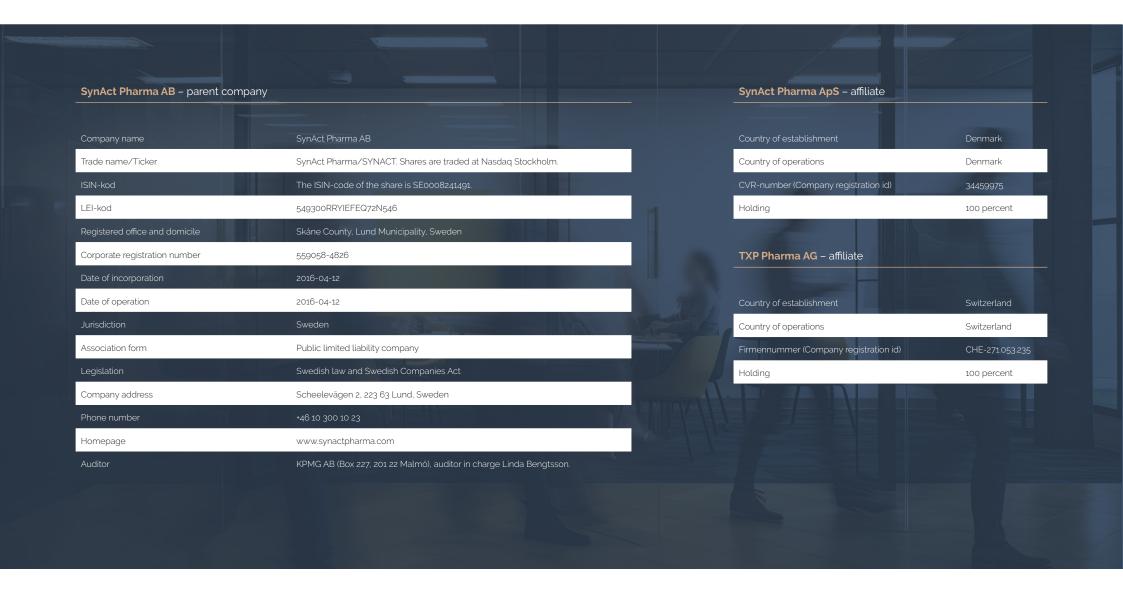
#### **RESOVIR**

RESOVIR (Resolution Therapy for Viral Inflammation Research) is a scientific and clinical collaboration between Professor Mauro Teixeira, MD, PhD, Universidade Federal de Minas, Belo Horizonte, Brazil, Professor Mauro Perretti, PhD William Heavy Research Institute, Barts and London School of Medicine, Queen Mary University, London, UK, and SynAct. The aim of the RESOVIR collaboration is to investigate the utility of resolution therapy to resolve the cytokine storm inflammation associated with significant viral infections.

### Respiratory insufficiency

Means that breathing does not work as it should, which leads to a lack of oxygen.

# Other company information



# SYNACT PHARMA

### SynAct Pharma AB

Visiting address: Scheelevägen 2, 223 63 Lund, Sweden Postal address: Scheelevägen 2, 223 63 Lund, Sweden Phone: +46 10 300 10 23

E-mail: investor.relations@synactpharma.com

www.synactpharma.com

Graphic design: Plucera Webbyrå (www.plucera.se)