



Research and development in inflammatory diseases

Q3

This English version of SynAct Pharma's Interim Report for the third quarter of 2024 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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Interim report for the third quarter 2024 and first nine months



(SEK thousand)

Quarter 3 (July - September)

- The Group's net sales amounted to SEK 0 (0) thousand.
- Operating expenses amounted to SEK 24,309 (31,692) thousand, a decrease of 23%.
- The Group's loss after tax amounted to SEK 20,489 (31,878) thousand.
- The Group's earnings per share before and after dilution amounted to SEK -0.50 (-1.00).
- Cash flow from operating activities amounted to SEK -24,076 (-14,653) thousand.
- Cash flow from financing activities amounted to SEK -124 (-153) thousand.
- Cash flow for the period amounted to SEK -24,200 (-14,804) thousand.

2024 Q3 2024 Q2 2024 Q1 2023 Q4 2023 Q3 2023 Q2 2023 Q1

• Cash and cash equivalents at the end of the period amounted to SEK 38,487 (28,876) thousand.



Nine months (January - September)

- The Group's net sales amounted to SEK 0 (0) thousand.
- Operating expenses amounted to SEK 69,183 (133,434) thousand, a decrease of 48%.
- The Group's loss after tax amounted to SEK 64,023 (125,267) thousand.
- The Group's earnings per share before and after dilution amounted to SEK -1.65 (-3.96).
- Cash flow from operating activities amounted to SEK -71,418 (-79,782) thousand.
- Cash flow from financing activities amounted to SEK 47,206 (-577) thousand.
- Cash flow for the period amounted to SEK -24,213 (-79,989) thousand.

The Group's financial performance per quarter

· ·	•	•	•	•	•	•	•
Net sales	-	-	-	-	-	-	-
Operating income	-24,309	-19,167	-25,706	-91,062	-31,692	-43,495	-58,248
Profit before tax	-24,687	-19,771	-26,049	-90,542	-31,988	-43,601	-58,146
Profit for the period	-20,489	-18,628	-24,906	-90,543	-31,878	-43,511	-49,878
Total assets	217,131	241,053	213,354	228,019	275,925	298,472	320,999
Equity / asset ratio (%)¹	78%	78%	71%	77%	76%	81%	84%
Earnings per share (SEK)	-0,50	-0.47	-0.70	-2.58	-1.00	-1.37	-1.59
Research & development cost / operating expenses (%) ¹	80%	38%	31%	12%	68%	67%	75%

¹⁾ Alternative performance measures - APM, ref. p. 22 for definitions

Significant events during the third quarter of 2024 and after the end of the reporting period

Q3 - 2024

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SynAct initiates filing process for Phase 2b ADVANCE study with resomelagon.

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First scientific publication showing treatment potential of a pro-resolving compound in human virus infection.

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SynAct initiates the Phase 2b ADVANCE study with resomelagon (AP1189) in the US.

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The CEO, Jeppe Øvlesen comments on the third quarter 2024

The SynAct team continued to work focused during the third quarter as the company initiated the Phase 2b ADVANCE study in patients with newly diagnosed severe rheumatoid arthritis (RA) with the company's lead compound resomelagon (AP1189). There are more than 400,000 newly diagnosed patients each year in the Western World of which a large fraction would benefit from treatment with resomelagon as a new effective and safe treatment option.

Many patients will not reach the treatment goal of disease control in a timely manner with the current treatment options. Even though a large fraction of patients is cotreated with glucocorticoids and/or introduced to expensive biologics at an early stage in the treatment. Compounds who have unwanted side effects, meaning that their use should be reduced or postponed as much as possible. Together this setting has created an opportunity for resomelagon to be a novel patients friendly treatment option, lowering the need for glucocorticoids and postponing the use of biologics to later stages. There is a clear market need for resomelagon, and we have an ambitious plan to support these patients.

This year SynAct refocused itself by raising new funding at a premium, reducing its cost structure and laying out a new plan to push resomelagon forward. The company has a strong management team and board in place and is excited to see ADVANCE, which is a double-blind, placebo-controlled, Phase 2b clinical multi-center study conducted under the company's US-IND in RA. Active recruitment has already been initiated at sites in the US. Approval has been given in the first non-EU country in Europe and it is expected to have approval in EU in Q4. We plan to have recruitment across more than 20 sites in a total of seven countries before the end of this year. The study is on track with enrollment of all patients planned to be completed in Q4 2025 and key results expected as soon as possible thereafter.

During the third quarter we hosted a Capital Markets Day in Stockholm to share our latest views on the science and development, the market potential and listen to experts talk about the patient need for a better solution in RA. We heard from the management team and board about our strategy forward, the science behind resomelagon, as well as from the CSO at Sanos Group about the medical need for an early-line treatment. It was a great opportunity for us to connect with our shareholders and those interested in SynAct, so many thanks to all of those who participated.

SynAct is in a strong position now to execute on the ADVANCE study. I want to thank the team for all of their hard work, as well as those shareholders who believe in us and the potential for resomelagon to change the lives of RA patients.



Chief Executive Office and Board Member



"There are more than 400,000 newly diagnosed patients each year in the Western World of which a large fraction would benefit from treatment with resomelagon as a new effective and safe treatment option."

Jeppe Øvlesen
Chief Executive Officer and Board Member

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, where the latter is consolidated into the group from January 16, 2023. 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 report has been reviewed by the Company's Auditor, KPMG.

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.

Research and development

Inflammation resolution

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 some 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, tissue destruction, and loss of function.

When the immune system is overwhelmed, therapies like SynAct Pharma's lead compound, resomelagon (AP1189) may help resolve inflammation by providing both anti-inflammatory activity and by triggering the immune system's natural inflammatory resolution mechanisms.

Most currently available medicines to treat inflammation are immunosuppressive. They suppress the immune system by removing key signaling molecules or by depleting certain immune cells, which might increase the risk for serious infections and other significant side effects and safety issues. These medicines are anti-inflammatory, but they do not resolve the underlying uncontrolled inflammation.

Resomelagon from SynAct seeks to stimulate the body's natural resolution mechanisms and resolve excessive inflammation without suppressing the immune system's ability to respond to new infections or injuries.

This means that the safety profile of Resomelagon is more favorable than immunosuppressive medicine which are used today.

Melanocortin biology

Resomelagon activates receptors, which are part of the melanocortin system. The melanocortin system is an ancient modulatory system comprising a family of 5 melanocortin receptors and a set of naturally occurring melanocortin peptides that bind to and activate these receptors. The melanocortin receptors (MC1R - MC5R) are located on many cell types and organs.

MC1R and MC3R are believed to be the key receptors involved in direct effects on the immune system. These receptors are located on immune cells and associated structural and supportive cells. When activated, MC1R and MC3R provide both direct anti-inflammatory effects, such as causing immune cells to produce fewer pro-inflammatory molecules and stimulating pro-resolution effects such as switching cells to perform inflammation "cleanup" or regulatory functions.

Through these dual effects, targeted melanocortin therapies such as resomelagon can help the immune system resolve excessive or chronic inflammation – while at the same time having a favorable safety profile.

Resomelagon (AP1189) - leading compound

SynAct Pharma is developing selective melanocortin therapeutics to address inflammatory and autoimmune diseases. Resomelagon (AP1189), which is the leading drug candidate, is an oral available biased MC1R and MC3R agonist mediating its pharmacological effects through the pERK signaling pathway - in contrast to the cAMP pathway which is activated by most melanocortin agonists. Activation of MC1R cAMP pathway is known to be responsible for certain unwanted off-target activity such as skin hyperpigmentation, but this is avoided with resomelagon.

Resomelagon is primarily being developed for Rheumatoid Arthritis (RA). Our phase II 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.

Rheumatoid arthritis patients are today treated based on clinical guidelines. Therefore, these patients newly diagnosed rheumatoid arthritis patients are initially treated with, the conventional DMARD methotrexate (MTX). However, often these patients need co-treatment with other medicines like glucocorticoids (GCs) and in many cases biologic DMARDs, typically a TNF-blocker, are added to get the disease under control. Both GCs and biologic DMARDs are associated with unwanted side effects.

By combining MTX-treatment with resomelagon in these newly diagnosed RA-patients, the treatment is in line with the clinical guidelines. More patients than today will have the possibility to obtain control of their symptoms, compared to patients who only receive MTX. That would have a very positive impact both on these newly diagnosed patients and their relatives. As resomelagon seems to have a favorable safety profile, this will also ease the burden from the patients, as the likelihood of receiving glucocorticoids (GCs) and switching to biologic treatment decreases.

We therefore see resomelagon as an attractive new treatment option for these newly diagnosed RA-patients by increasing their efficacy of RA-treatment, reducing the need of GCs and delay or even reduce the need for biologic treatment.

Experimental studies show that resomelagon also has the potential to reduce loss of protein in the urine in conditions with severe proteinuria. The potential of the compound to reduce proteinuria in patients with idiopathic membranous nephropathy, an autoimmune disease associated with development of proteinuria/nephrotic syndrome is examined in a small Phase IIa proof of concept study. However, the recruitment rate is lower than expected.

Finally, the RESOVIR-1 study in COVID-19 patients showed that the resomelagon has the potential to modulate hyperinflammatory states in severe viral infections and thereby accelerate recovery and reduce the length of hospitalization. The possibility to use resomelagon in various viral disorders is currently being evaluated.

Rheumatoid arthritis (RA)

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

The current treatment guidelines for RA-treatment emphasize the importance of early intervention (medicine) with the aim to obtain disease control as fast as possible.

Early intervention (medicine) has an immediate impact on the pain and swelling of the joints. However, early intervention also has a more long-term effect, as it reduces the risk for irreversible loss of function in affected joints and tissues.

Current first line treatment for patients with moderate and severe disease activity is the conventional disease-modifying anti-rheumatic drug (cDMARD) methotrexate (MTX). MTX is given once weekly in a dose titration approach aiming to get the patients treated with the highest tolerable dose. As onset of action of MTX takes weeks it is conditionally recommended to co-treat with glucocorticoids (GCs) for faster control of symptoms.

The aim of the initial RA-treatment (first line treatment) is to obtain a significant reduction in disease activity within 3 months and symptom control within 6 months. Generally, only half of the patients achieve this treatment goal - and many only achieve it due to co-treatment with GCs.

The wide use of GCs is controversial, as the GCs are associated with several severe unwanted side effects and might be difficult to tamper with once introduced to the patient. Both the US and European treatment guidelines strongly recommend restricting the use of GCs as much as possible and never exceed dosing for more than 3 months. However, it has been reported that up to half of all RA patients are treated with GCs in more chronic dose regiment, which due to the side effect profiles of the compounds is highly unwanted.

An alternative to the use of GCs is to introduce second line RA-treatment at an earlier stage, in many cases already after 3 months of treatment with MTX. In more severe cases of RA, second line treatment is applied by adding a biologic-DMARD (bDMARD), in most cases as TNF-blocker to the MTX dose regiment. The bDMARDs are very effective associated with several severe adverse events including immunosuppression and thereby increased risk of infections among other. In fact, the side effect profile of the bDMARDs restricts them from being used as first line treatment as highlighted in the current US treatment guide. bDMARDs are also relatively expensive drugs.

Resomelagon has the potential of fulfilling the unmet medical need, that only about half of the newly diagnosed RA-patients obtain significant reduction in their disease activity within 3 months and symptom control within 6 months. By treating newly diagnosed RA-patients with high disease activity and active inflammation with MTX plus resomelagon as first line RA-treatment, it is anticipated that many more RA-patients will obtain symptom control, improving their symptoms and decreasing the damage to their joints. This will have a positive impact on the lives of the patients and their relatives, increasing also the likelihood of staying in the job market and having an active lifestyle.

The advantage of resomelagon is furthermore an advantageous safety profile. Compared to GCs, dDMARDs and JAK-inhibitors, resomelagon does not show any signs of immunosuppression.

As resomelagon is taken orally once daily, resomelagon provides a unique opportunity for a novel patient friendly first line RA-treatment together with MTX to facilitate disease control and at the same time reduce the need for GCs and potentially delay and reduce the need for second line treatment options including the TNF-blockers .

Clinical development of resomelagon in RA

Several phase II studies have been conducted in RA to gain knowledge about resomelagon in these patients.

BEGIN - Phase IIa in early severe RA together with MTX

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 IIb 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 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 around 40% did not show signs of systemic inflammation, as high-sensitive C-reactive protein (hsCRP) were in the normal range (ie 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, ie 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): 14.7 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 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 IIb in RA patients with an inadequate response to methotrexate

Only the first part of the study was conducted, providing results about 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.

New - ADVANCE - Phase IIb 12-week study in early DMARDnaïve RA-participants with high disease activity and active inflammation in combination with MTX

The ADVANCE study is setup as a phase 2b proof of concept study in the target population for resomelagon, ie newly diagnosed RA pts with high disease activity including signs of systemic

inflammation where there is unmet medical need for a safe an effective oral treatment with the potential in combination with the first line compound MTX to increase the likelihood of disease control with reduced use of glucocorticoid and when the potential to postpone the use of second treatments as the TNF-blockers.

The ADVANCE study is conducted as a randomized, double blind, placebo-controlled, dose response, phase IIb, 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 study is set up to recruit a total of 240 patients with 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 study has been initiated with active recruitment at sites in the US. Study initiation visits have been performed in Moldova where the application has been approved and the centralized EU application submitted in the EMA CTIS centralized application portal covering 5 EU countries including Denmark is currently under evaluation with the expectation to have application approved and sites initiated during Q4.

It is planned to have all patients enrolled and completed in H2 2025.

Idiopathic Membranous Nephropathy (iMN) - 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).

Clinical development of resomelagon in Idiopathic Membranous nephropathy

Resomelagon is currently tested in Idiopathic Membranous nephropathy (iMN), one of more common causes of primary NS, in an exploratory, randomized, double-blind, multicenter, placebocontrolled Phase Ila 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 in the study is the effect on urinary protein excretion. The recruitment has been lower than expected due to a lack of eligible patients. Currently two patients are in treatment in the study, one in Denmark and one in Sweden. The company currently assesses the opportunities to increase the recruitment rate, alternatively close the study preterm.

Virus Induced hyperinflammation including virus-induced Respiratory Insufficiency

Clinical development of resomelagon in virus infections
Resomelagon was tested in the RESOVIR-1 study, a 60-patient
placebo-controlled Phase IIa clinical trial of treatment of
hospitalized COVID-19 infected patients who required
supplemental oxygen. The study was a part of the RESOVIR
(resolution in viral infection) collaboration, 100 mg resomelagon or
placebo was administered orally once daily for 2 weeks.

All resomelagon treated patients (including the first 6 open-label 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.

The clinical study has been followed by testing the compound in a preclinical model of COVID-19 infection as well as in an ex vivo study with human monocytes incubated with the virus with both studies supporting profound effect of the compound on COVID-19 induced hyperinflammation.

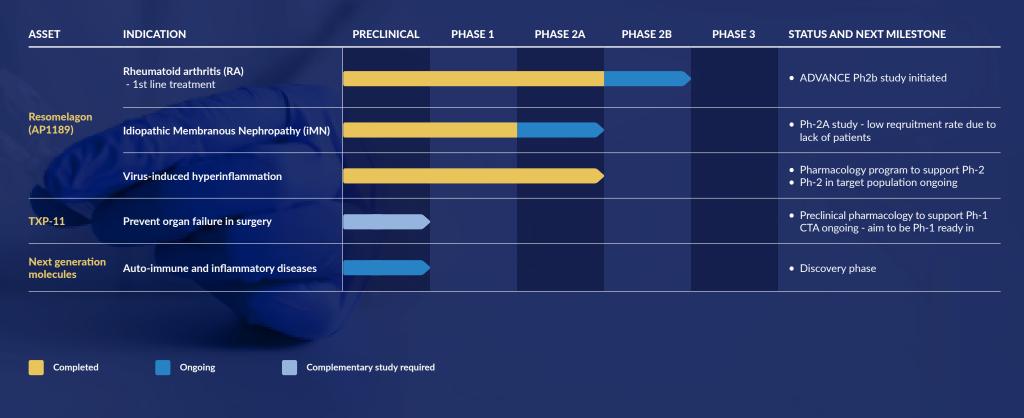
Currently the compound is tested in preclinical models as well as ex vivo settings using human monocytes incubated with highly clinically relevant viral. Data from these studies will be used to evaluate the continued clinical development of resomelagon as a novel treatment approach to modulate viral-induced hyperinflammation for the benefit of the patients.

Arboviral infections is 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. Serious complications post-infections are due to a deregulated response of our body classified as hyperinflammation. Infections with Dengue virus have already been reported in Italy, France, Spain and Greece. This infection brings serious morbidity in a proportion of patients and can be lethal on re-infection. Preclinical evaluation of resomelagon ability to modulate the inflammatory response to arbo-virus, including Dengue virus supports the possibility to apply resomelagon in a clinical setting. This is currently evaluated as a possibility through the RESOVIR strategic collaboration initiated under the pandemic as a collaboration sponsored by SynAct Pharma between the company, the William Harvey Research Institute at Queen Mary University of London, UK lead by Professor, Mauro Perretti PhD and Department of Biochemistry and Immunology at the Universidade Federal de Minas Gerais (UFMG) Belo Horizonte, Brazil lead by Professor Mauro Teixeira, MD, PhD.

Peptide Agonists - pipeline

SynAct Pharma' portfolio of peptide based melanocortin receptor agonists, consists of a variety of compounds, that differs in pharmacological profile and selectivity towards the melanocortin receptors. The analogues are optimized to have increased stability and enhanced receptor binding and stimulation over naturally occurring melanocyte stimulating hormone. The most advanced compound, TXP-11, is being developed for the prevention of organ failure and damage in connection with major surgeries and has completed regulatory toxicology studies required to initiate Phase 1 studies in humans. Ongoing pharmacology studies aimed to support a clinical trial application are ongoing with the expectation that the program could be PhI ready during 2025.

Pipeline Overview



The SynAct Pharma Share

Share information

SynAct Pharma's share has been listed on Nasdaq Stockholm in the Mid Cap segment 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 September 2024 was SEK 9.44.

April 24, 2024, the extraordinary general meeting resolved to approve the Board of director's resolution on March 26, 2024 on a directed share issue of SEK 49,2 million before issue costs. Through the directed share issue, the number of shares increased by 5,725,484 to 41,296,464 shares.

Ownership (September 30, 2024)

Shareholder	Capital and votes(%)
NBCD A/S	9.6%
Avanza Pension	6.8%
Thomas Jonassen	6.2%
Thomas Ringberg	5.5%
Nordnet Pensionsförsäkring	4.6%
Thomas von Koch	2.7%
Handelsbanken fonder	1.9%
Torbjörn Bjerke	1.9%
Kenneth Bjerg-Nielsen	1.6%
OR invest	1.0%
Total (top-10)	41.7%
Others (~15,000)	58.3%

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, 41,296,464.

Share-based incentive programs

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

With the introduction of the new employee option program, the Board of Directors has decided to terminate the Employee Option Program 2023 I ("ESOP 2023 I") and the Employee Option Program 2023 II ("ESOP 2023 II").

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

Lock-up agreement

There are no ongoing lock-up agreements at the end of the period.



Analyst coverage

SynAct Pharma and its share is covered by two independent analysts:

Alexander Krämer, ABG Sundal Collier AB

Patrik Ling, DNB Markets



Financial calendar

SynAct prepares and publishes a quarterly financial report. Upcoming reports and meetings are planned as follows:

 Date:
 Report:

 11/04/2024
 BIO Europe 2024

 11/14/2024
 ACR Convergence

 02/18/2025
 Annual reults 2024

Comments on the development for the third quarter and first nine months of 2024

Net sales

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

Research and development (R&D) costs

Total R&D costs in the third quarter amounted to SEK 19,481 thousand (21,660). For the first nine months, R&D costs amounted to SEK 34,751 thousand (94,295). For the third quarter, the new study ADVANCE is included, and the period last year included the two clinical phase II studies, EXPAND and RESOLVE.

General and administration (G&A) costs

G&A expenses amounted to SEK 4,781 (9,951) thousand in the third quarter and SEK 34,201 (39,079) thousand for the first nine months. All costs related to the share option programs are included as a part of G&A, see Note 4 - Share-based payments.

Financial items

Net financial items amounted to SEK -377 (-296) thousand in the third quarter and SEK -1,324 (-300) thousand for the first nine months and is attributable to exchange rate adjustments.

Tax for the period

Tax revenues in the third quarter amounted to SEK 4,198 (110) thousand. For the first nine months the accrued tax credit amounted to SEK 6,484 (8,468) thousand. See Note 7 - Tax receivables for more information.

Loss for the period

The Group's loss for the third quarter amounted to SEK 20,489 (31,878) thousand and for the first nine months the reported loss was SEK 64,023 (125,267) thousand.

Financial position, cash flow and going concern

Total assets amounted to SEK 217,131 (275,925) thousand, where the reduction in the TXP valuation from 2023 Q4 is partly offset by an increase in liquid assets. The working capital was also affected by a decrease of SEK 2,189 thousand related to the Danish "tax credit scheme", see note 7, and an increase in pre-paid expenses of SEK 6,850 thousand mainly related to the new ADVANCE study.

Equity decreased as a result of the accumulated loss partly offset by the new share issue in Q2.

Cash flow from operating activities amounted to SEK -24,076 (-14,653) thousand in the quarter. Year-to-date cash flow for operating activities amounted to SEK -71,418 (-79,782) thousand. Cash flow from financing activities amounted to SEK -124 (-153) thousand in the third quarter and SEK 47,206 (-577) thousand for the first nine months, primarily driven by the directed share issue that was completed in April.

Cash flow for the period amounted to SEK -24,200 (-14,804) thousand and SEK -24,213 (-79,989) thousand for the first nine months.

The Group's cash and cash equivalents as of September 30, 2024, amounted to SEK 38,487 (28,876) thousand.

The Company has determined that its current cash and cash equivalents are insufficient to meet its liquidity needs over the next 12 months. The board therefore follows the situation and evaluates various financial alternatives including the optimal timing and size of a capital raise. The board has a positive view of being able to carry out such a capital funding on terms beneficial to the company. However, insufficient financing may mean a risk that the group cannot continue its operations on the current scale.

Employees

The number of employees was 6 (5) of which four employees (2) 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 1,972 (2,058) thousand in the third quarter and SEK 5,893 (5,953) thousand for the first nine months.

In the Parent Company, net financial items amounted to SEK -815 (-1,551) thousand in the quarter. Year-to-date net financial items were SEK -44,966 (-55,764) thousand. 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

Extraordinary General Meeting

On March 20, 2024, an Extraordinary General Meeting was held in SynAct Pharma AB. The meeting was convened at the request of shareholders owning more than ten percent of the shares in the company.

The EGM resolved, in accordance with the proposal, presented by TJ Biotech Invest ApS, Goodwind Holding GmbH, Thomas Ringberg and some other shareholders in the company where no single shareholder holds more than 0.38 percent (together the "Major Shareholders"), that the company's Board of Directors shall consist of four ordinary Board members with no deputies. The EGM resolved, in accordance with the proposal from the Major Shareholders, to dismiss all current members of the Board of Directors and to elect Anders Kronborg, Sten Scheibye, Sten Sørensen and Jeppe Øvlesen as new members of the Board of Directors for the period until the end of the 2024 Annual General Meeting. The EGM further resolved, in accordance with the proposal from the Major Shareholders, to appoint Anders Kronborg as new Chairman of the Board.

On April 24, 2024, an Extraordinary General Meeting was held in SynAct Pharma AB in Stockholm. The EGM resolved to approve the three directed share issues announced by the Company through a press release on 27 March 2024.

Annual general Meeting

On May 31, 2024, the Annual General Meeting of SynAct Pharma AB Stockholm was held. The AGM resolved to introduce a new employee option program, ESOP (for employees) and BSOP (for the Board of Directors). For further information, please refer to Note 4 to the financial statements.

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	2024	2023	2024	2023	2023
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Net sales		-	-	-	-	-
Gross profit		-	-	-	-	-
Research and development costs		-19,481	-21,660	-34,751	-94,295	-105,055
General and administration costs	4, 5	-4,781	-9,951	-34,201	-39,079	-44,826
Other operating income/expenses		-47	-81	-231	-61	-74,615
Total operating expenses		-24,309	-31,692	-69,183	-133,434	-224,496
Operating income		-24,309	-31,692	-69,183	-133,434	-224,496
Net financial items		-377	-296	-1,324	-300	220
Profit after financial items		-24,687	-31,988	-70,507	-133,734	-224,276
Tax on profit/loss for the period	7	4,198	110	6,484	8,468	8,466
Profit for the period		-20,489	-31,878	-64,023	-125,267	-215,810
Earnings per share (SEK)		-0.50	-1.00	-1.65	-3.96	-6.64
Diluted earnings per share (SEK)		-0.50	-1.00	-1.65	-3.96	-6.64

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	2024	2023	2024	2023	2023
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Profit for the period		-20,489	-31,878	-64,023	-125,267	-215,810
Items reclassifiable to profit or loss						
Translation differences from foreign operation		1,948	-2,659	55	13,847	13,003
Comprehensive income after tax for the period		-18,540	-34,538	-63,968	-111,420	-202,807
Comprehensive income for the period		-18,540	-34,538	-63,968	-111,420	-202,807

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	9/30/2024	9/30/2023	12/31/2023
Assets				
Non-current assets				
Intangible assets		152,018	226,418	152,159
Right-of-use assets		1,438	825	660
Financial assets	10	142	144	139
Total non-current assets		153,598	227,387	152,959
Current assets				
Tax credit	7	14,765	16,954	8,188
Other current receivables		2,740	2,018	4,220
Prepaid expenses	9	7,540	690	258
Cash and cash equivalents	10	38,488	28,876	62,395
Total current assets		63,533	48,537	75,060
Total assets		217,131	275,925	228,019

SEK (thousand)	Note	9/30/2024	9/30/2023	12/31/2023
Equity and liabilities				
Share capital		5,162	3,978	4,446
Other paid-in capital	4	702,802	589,378	646,572
Reserves		15,823	16,612	15,768
Retained earnings/losses including net profit		-554,623	-400,057	-490,600
Total equity		169,164	209,911	176,186
Non-current liabilities				
Deferred tax liability		17,999	17,909	18,016
Leasing liability		929	180	58
Contingent earnout		7,785	7,602	7,248
Other provision	4,5	4,899	3,324	1,573
Total non-current liabilities		31,612	29,015	26,894
Current liabilities				
Accounts payable	10	6,450	8,321	9,670
Leasing liability		498	626	579
Other current liabilities	8	4,363	5,117	4,876
Accrued expenses	9,10	5,044	22,934	9,815
Total current liabilities		16,355	36,998	24,939
Total equity and liabilities		217,131	275,925	228,019

Consolidated statement of changes in equity

01/01/2023 - 12/31/2023 SEK (thousand)	Share capital	Other paid-in capital	Reserves	Retained earnings, including profit for the period	Total
	0.70/	004.040	0.7/5	074700	407.500
Opening equity	3,706	394,840	2,765	-274,790	126,520
Profit for the period	-	-	-	-215,810	-215,810
Other comprehensive income	-	-	13,003	-	13,003
Comprehensive income for the period	-	-	13,003	-215,810	-202,807
Transactions with owners					
Issue in kind	272	189,607	-	-	189,879
Directed share issue	469	58,991	-	-	59,459
Issue expenses		-4,746	-	-	-4,746
Employee option program	-	7,881	-	-	7,881
Total transaction with owners	740	251,732	-	-	252,473
Closing equity	4,446	646,572	15,768	-490,600	176,186

01/01/2024 - 9/30/2024 SEK (thousand)	Share capital	Other paid-in capital	Reserves	Retained earnings, including profit for the period	Total
Opening equity	4,446	646,572	15,768	-490,600	176,186
Profit for the period	-	-	-	-64,023	-64,023
Other comprehensive income	-	-	55	-	55
Comprehensive income for the period	-	-	55	-64,023	-63,968
Transactions with owners					
Directed share issue	716	48,523	-	-	49,239
Issue expenses		-1,614	-	-	-1,614
Employee option program	-	9,321	-	-	9,321
Total transaction with owners	716	56,231	-	-	56,946
Closing equity	5,162	702,802	15,823	-554,623	169,164

Condensed consolidated statement of cash flows

SEK (thousand) Note	2024	2023	2024	2023	2023
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Cash flow from operations					
Operating income	-24,309	-31,692	-69,183	-133,434	-224,496
Adjustment for non-cash items	669	3,374	14,146	10,002	85,566
Interest received	382	-27	748	-	34
Interest paid	-369	24	-859	-46	-123
Corporate income tax received/paid	-	-6	-	-6	8,472
Cash flow from operations before change in working capital	-23,628	-28,327	-55,148	-123,484	-130,547
Change in working capital	-449	13,674	-16,271	43,702	30,370
Cash flow from operating activities	-24,076	-14,653	-71,418	-79,782	-100,177
Cash flow from investing activities	-	2	-	370	370
Cash flow from financing activities	-124	-153	47,206	-577	53,984
Cash flow for the period	-24,200	-14,804	-24,213	-79,989	-45,823
Cash and cash equivalents at beginning of period	62,799	44,421	62,395	108,245	108,245
Decrease/increase in cash and cash equivalents	-24,200	-14,804	-24,213	-79,989	-45,823
Exchange rate difference in cash and cash equivalents	-111	-741	305	620	-27
Cash and cash equivalents at end of period	38,487	28,876	38,487	28,876	62,395

Parent company's condensed income statement

SEK (thousand) Note 2024 2023 2023 2024 2023 Jul-Sep Jul-Sep Jan-Sep Jan-Sep Jan-Dec 1,972 2,058 5,893 5,953 8,262 Net sales Gross profit 1,972 2,058 5,893 5,953 8,262 General and administration costs 4,5 -3,388 -7,706 -25,006 -26,348 -31,277 Other operating expenses -33 -58 -46 -3 -7,764 -25,081 -26,394 -31,280 Total operating expenses -3,420 Operating income -1,449 -5,707 -20,441 -23,018 -19,188 Net financial items -815 -1,551 -44,966 -55,764 -126,510 Profit after financial items -2,264 -7,257 -64,154 -76,205 -149,529 Tax on profit for the period -2,264 -7,257 -64,154 -76,205 -149,529 Profit for the period

Parent company's statement of comprehensive income

SEK (thousand)	lote	2024	2023	2024	2023	2023
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Profit for the period		-2,264	-7,257	-64,154	-76,205	-149,529
Other comprehensive income		-	-	-	-	-
Total comprehensive income		-2,264	-7,257	-64,154	-76,205	-149,529

Parent company's condensed balance sheet

SEK (thousand)	Note	9/30/2024	9/30/2023	12/31/2023
Assets				
Non-current assets				
Financial assets		181,207	232,244	181,207
Total non-current assets		181,207	232,244	181,207
Current assets				
Receivables in group companies		30,453	3,812	4,696
Other receivables		698	484	518
Prepaid expenses		1,951	716	215
Cash and cash equivalents		17,653	12,198	44,133
Total current assets		50,755	17,209	49,561
Total assets		231,962	249,454	230,768

SEK (thousand) Not	9/30/2024	9/30/2023	12/31/2023
Equity and liabilities			
Restricted equity			
Share capital	5,162	3,978	4,446
Non-restricted equity			
Other paid-in capital 4	702,802	589,378	646,572
Retained earnings/losses	-436,946	-287,418	-287,418
Profit for the period	-64,154	-76,205	-149,529
Total equity	206,864	229,733	214,072
Non-current liabilities			
Contingent earnout	7,785	7,602	7,248
Other provisions 4,5	4,899	3,324	1,573
Total non-current liabilities	12,684	10,926	8,821
Current liabilities			
Accounts payable	5,636	1,108	565
Other liabilities 8	4,353	4,089	4,506
Accrued expenses 9	2,425	3,598	2,804
Total current liabilities	12,414	8,794	7,876
Total equity and liabilities	231,962	249,454	230,768

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 October 30, 2024.

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 2023, note 2 pages 35 to 38. No new or changed standards implemented on or after January 1, 2024, 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 2023, pages 21-25 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 quarter. 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 EUR and DKK accounts. However, the depreciation of the Swedish currency against these major currencies has resulted in cost increases during the quarter.

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 program 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 a new employee option program, ESOP (for employees) and BSOP (for the Board of Directors).

This employee option program 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 September 30, 2024, SynAct had 41,296,464 shares outstanding. If the outstanding options (2,271,301) for ESOP 2024 are vested and exercised in full, it would result in a dilution of 5.5%. If the outstanding options (825,927) for BSOP 2024 are vested and exercised in full, it would result in a dilution of 2.0%.

The costs for the programs ESOP and BSOP 2024 are estimated at SEK 5,998 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 third quarter of 2024, the costs for the employee option program amounted to SEK 805 thousand and the costs for nine months have amounted to SEK 1,803 thousand.

Change in outstanding incentive programs (number of options)	2024	2023	2024	2023	Total
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	
Alloted instruments					
ESOP 2023 I	-	-	-	195,000	195,000
ESOP 2023 II	-	404,000	-	404,000	404,000
ESOP 2024	-	-	2,271,301	-	2,271,301
BSOP 2024	-	-	825,927	-	825,927
Recalled/voided instruments					
ESOP 2023 I	-	-	-105,000	-90,000	-195,000
ESOP 2023 II	-	-	-404,000	-	-404,000

Maximum number of shares to which allocated options can entitle	09/30/2024
ESOP 2024	2,271,301
BSOP 2024	825,927
Total Employee Option	3,097,228

With the introduction of the new employee option program, the Board of Directors has decided to terminate the Employee Option Program 2023 I ("ESOP 2023 I") and the Employee Option Program 2023 II ("ESOP 2023 II"). All participants in these programs have accepted the termination of the programs.

The total costs for ESOP 2023 I and ESOP 2023 II was SEK 0 thousand (3,468) in the third quarter and the costs for nine months amounted to SEK 7,682 thousand (5,657).

Notes and disclosures (continued)

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, the following transactions have taken place with related parties in the reporting periods:

SEK (thousand)		2024	2023	2024	2023	2023
Related party	Service	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
UST Leadership AB	Consultancy				525	525
(Torbjørn Bjerke, former CEO)	Consultancy	-	-	-	525	525

The Board of Directors resolved on October 7, 2022, to approve an agreement engaging UST Leadership (Torbjørn Bjerke, then chairman of the board of directors) as consultant to perform certain, defined tasks. The contract was discontinued upon Bjerke's appointment as CEO.

On May 25, 2023, Torbjörn Bjerke took over as CEO of Synact in connection with the Annual General Meeting and thus left the position as Chairman of the Board. Jeppe Øvlesen replaced Torbjörn Bjerke as CEO after an Extraordinary General Meeting on March 20, 2024, when a new Board of Directors took office.

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 11, Contingent liabilities for more information.

Note 6 - Number of registered shares

Thousand	2024	2023	2024	2023	2023
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Number of shares at the beginning of the period	41,296	31,821	35,571	29,648	29,648
Number of shares at the end of the period	41,296	31,821	41,296	31,821	35,571
Average number of shares outstanding in the period	41,296	31,821	38,789	31,662	32,524

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 14,765 thousand (16,954). The balance related to fiscal year 2023 with an amount of SEK 8,188 thousand is expected to be received in November 2024.

Notes and disclosures (continued)

Note 8 - VAT

SynAct Pharma has previously been denied a deduction for input VAT for the years 2018 and earlier. The Company disputed the Swedish Tax Agency's decision and appealed to the first instance, the Administrative Court. In December 2021, the Administrative Court ruled in the Company's favor in the case, whereby deductions were allowed. The Tax Agency appealed the Administrative Court's judgment to the Court of Appeal, which on 6 September 2022 rejected the appeal. On November 3, 2022, the Tax Agency appealed the Court of Appeal's judgment and applied for leave to appeal in the Supreme Administrative Court (HFD). On April 18, 2023, HFD granted the Tax Agency leave to review, meaning that the case will be tried by the court. On 28 May 2024, HFD announced that the court upholds the Tax Agency's appeal and sets aside the judgments of the Administrative Court and the Administrative Court of Appeal.

The company has previously reserved for the full amount of VAT and tax surcharges of SEK 3,689 (3,689) thousand as an other short-term liability in the financial reporting pending a final judgment.

Note 9 - Prepaid and accrued expenses

SynAct has made initial payments to the CRO handling the new clinical study, ADVANCE. The costs is recognized during the active treatment period and three months before and after. Hence the increase in prepaid expenses by more than SEK 6 million to SEK 7.540 (690) thousand.

The company reports accrued expenses of SEK 5,044 (22,934) thousand. The change since the comparison period is mainly due to decreased activity in the closed clinical studies. Accrued expenses include costs for personnel (holidays, bonus and pension) and board fees as well as other accrued costs.

Note 10 - Financial assets and liabilities

SEK (thousand)	09/30/2024	09/30/2023	12/31/2023
Financial assets			
Non-current financial assets	142	144	139
Cash and cash equivalents	38,488	28,876	62,395
Total financial assets	38,629	29,020	62,534
Financial liabilities			
Accounts payable	6,450	8,321	9,670
Accrued expenses	5,044	22,934	9,815
Total financial liabilities	11,494	31,256	19,484

SynAct Pharma does not hold any financial instruments that are valued at fair value. For all financial assets and liabilities, the reported value above is deemed to be an approximation of fair value. No change in classification of financial instruments has occurred over the reported periods.

Note 11 - 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 2024 and have a cash flow effect no earlier than 2025.

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 such a financial measure that is not 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) 09/30/2024 09/30/2023 12/31/2023 Assets Total non-current assets 153,598 227,387 152,959 63,533 48,537 Total current assets 75,060 [1] Total assets 217,131 275,925 228,019 **Equity and liabilities** [2] Total equity 169,164 209.911 176.186 Total non-current liabilities 31,612 29,015 26,894 Total current liabilities 16,355 36,998 24,939 Total liabilities 47,967 66,014 51,833 217,131 275,925 228,019 Total equity and liabilities [2] / [1] Equity / asset ratio (%) 78% 76% 77%

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)	2024	2023	2024	2023	2023
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
[1]	Research and development costs	-19,481	-21,660	-34,751	-94,295	-105,055
	General and administration costs	-4,781	-9,951	-34,201	-39,079	-44,826
	Other operating income / expense	-47	-81	-231	-61	-74,615
[2]	Total operating expenses	-24,309	-31,692	-69,183	-133,434	-224,496
[1] / [2]	Research and development costs / operating expenses (%)	80%	68%	50%	71%	47%

The CEO declaration

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, October 30 2024

Jeppe Øvlesen

Chief Executive Officer and Board Member

The Auditor's Review Report

Introduction

We have reviewed the condensed interim financial information (interim report) of SynAct Pharma AB (publ) as of 30 September 2024 and the nine-month period then ended. The Board of Directors and the Managing Director are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

Scope of Review

We conducted our review in accordance with International Standard on Review Engagements ISRE 2410 Review of Interim Financial Information Performed by the Independent Auditor of the Entity. A review of interim financial information consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with International Standards on Auditing and other generally accepted auditing practices and consequently does not enable us to obtain assurance that we would become aware of all significant matters that might be identified in an audit. Accordingly, we do not express an audit opinion.

Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the Group in accordance with IAS 34 and the Annual Accounts Act, and for the Parent Company in accordance with the Annual Accounts Act.

Material uncertainty regarding the going concern assumption

We would like to draw attention to the information disclosed in the interim report, under the section "Financial Position, Cash Flow, and Going Concern" on page 11, which indicates that the company has determined its current liquid assets are insufficient to meet its liquidity needs over the next 12 months. The Board of Directors has a positive view of being able to carry out a beneficial capital raising for the company, but insufficient financing may pose a risk to the Group's ability to continue its operations to the current extent. This situation indicates that there is a material uncertainty that may cast significant doubt on the company's ability to continue as a going concern. We have not modified our statement because of this.

Linda Bengtsson
KPMG AB

Malmö, October 30, 2024

Authorized Public Accountant

Glossary

ACE inhibitor

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

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.

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.

cAMP

cAMP, or cyclic adenosine monophosphate, is an adenine-based (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.

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.

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.

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.

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.

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.

RA

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

Resomelagon (AP1189)

The mechanism of action of SynAct Pharma's lead drug candidate AP1189 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.

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.

Other company information

Company name	SynAct Pharma AB	Country of establishment	Denmark
Trade name/Ticker	SynAct Pharma/SYNACT. Shares are traded at Nasdaq Stockholm.	Country of operations	Denmark
ISIN-kod	The ISIN-code of the share is SE0008241491.	CVR-number (Company registration id)	34459975
LEI-kod	549300RRYIEFEQ72N546	Holding	100 percent
Registered office and domicile	Skåne County, Lund Municipality, Sweden		
Corporate registration number	559058-4826	TXP Pharma AG – affiliate	
Date of incorporation	2016-04-12		
Date of operation	2016-04-12	Country of establishment	Switzerland
Jurisdiction	Sweden	Country of operations	Switzerland
Association form	Public limited liability company	Firmennummer (Company registration id)	CHE-271.053.235
Legislation	Swedish law and Swedish Companies Act	Holding	100 percent
Company address	Scheelevägen 2, 223 63 Lund, Sweden		
Phone number	+46 10 300 10 23		A IN
Homepage	www.synactpharma.com		
Auditor	KPMG AB (Box 227, 201 22 Malmö), auditor in charge Linda Bengtsson.		



SynAct Pharma AB

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