



Research and development in inflammatory diseases





This English version of SynAct Pharma's Interim Report for the second quarter and first six months of 2023 has been prepared by the Company as a service to its non-Swedish stakeholders. In case of differences, the original Swedish report prevails.

www.synactpharma.com

# CONTENT

Summary of annual results and interim report	3
Significant events in the quarter	4
CEO comments	5
SynAct Pharma in brief	6
Research and Development	6
SynAct Pharma share	9
Financial development	10
Income statement	11
Report on financial position	12
Report on changes in equity	13
Report on cash flow	14
The parent company's income statement	15
The parent company's balance sheet	16
Notes and disclosures	17
Alternative performance measures	22
The CEO declaration	23
Dictionary	24
Other company information	26

#### SynAct Pharma AB

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Significant events in the fourth quarter



CEO Torbjørn Bjerke comments on the fourth quarter



SynAct Pharma is a clinical stage biotechnology company focused on resolving inflammation with melanocortin biology

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# Interim report for the fourth quarter and annual results 2023



# Quarter 4 (October - December)

- The Group's net sales amounted to SEK 0 (0) thousand.
- Operating expenses amounted to SEK 91,062 (30,523) thousand, an increase of 198%.
- The Group's loss after tax amounted to SEK 90,543 (30,477) thousand.
- The Group's earnings per share before and after dilution amounted to SEK -2.58 (-1.06).
- Cash flow from operating activities amounted to SEK -20,395 (-22,306) thousand.
- Cash flow from financing activities amounted to SEK 54,561 (76,025) thousand.
- Cash flow for the period amounted to SEK 34,166 (53,747) thousand.
- Cash and cash equivalents at the end of the period amounted to SEK 62,395 (108,245) thousand.



# Twelve months (January - December)

- The Group's net sales amounted to SEK 0 (0) thousand.
- Operating expenses amounted to SEK 224,496 (105,705) thousand, an increase of 112%, driven primarily by the two clinical studies in RA and higher administrative costs caused by the acquisition of TXP and write down of goodwill.
- The Group's loss after tax amounted to SEK 215,810 (99,205) thousand.
- The Group's earnings per share before and after dilution amounted to SEK -6.64 (-3.60).
- Cash flow from operating activities amounted to SEK -100,177 (-117,555) thousand.
- Cash flow from financing activities amounted to SEK 53,984 (200,712) thousand.
- Cash flow for the period amounted to SEK -45,823 (83,184) thousand.

The Group's financial performance per quarter			187 P. 1						
(SEK thousand)	2023 Q4	2023 <mark>Q</mark> 3	2023 Q2	2023 Q1	2022 Q4	2022 Q3	2022 Q2	2022 Q1	
						A DECEMBER OF THE OWNER.	Sector 1		
Net sales	-	-	-	-	-	-	-	-	
Operating income	-91,062	-31,692	-43,495	-58,248	-30,523	-26,461	-26,417	-22,304	
Profit before tax	-90,542	-31,988	-43,601	-58,146	-30,554	-26,569	-27,625	-22,317	
Profit for the period	-90,543	-31,878	-43,511	-49,878	-30,477	-23,919	-24,754	-20,055	
Total assets	228,019	275,925	298,472	320,999	142,597	96,206	133,972	22,155	
Equity / asset ratio (%)¹	77%	76%	81%	84%	89%	83%	77%	3%	
Earnings per share (SEK)	-2.58	-1.00	-1.37	-1.59	-1.06	-0.84	-0.91	-0.77	
Research & development cost / operating expenses (%) $^{1}$	12%	68%	67%	75%	71%	78%	54%	60%	

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



# The CEO, Torbjørn Bjerke comments on the fourth quarter

### Dear Shareholders,

Leaving a disappointing year behind, we move forward with continued determination to deliver on the promise of resomelagon and resolution therapy. Despite all the therapies available to treat rheumatoid arthritis, many patients still have ongoing disease activity and require additional efficacy. A once daily oral and well tolerated therapy like resomelagon that works by a non-immunosuppressive mode of action – inflammation resolution – could positively impact the lives of many patients dealing with the challenges of rheumatoid arthritis and other inflammatory diseases.

While the EXPAND and RESOLVE outcomes did not meet our expectations, we now know how to identify patients more likely to respond to resomelagon and better understand how to design trials to give resomelagon every chance to demonstrate maximal patient benefit. In EXPAND, while there was no benefit seen at 3 months in the overall patient population, we saw a 71% ACR20 response rate with resomelagon treatment versus 54% for placebo in patients who had elevated levels of an inflammation marker called C-reactive protein (CRP). When further analyzed, we saw that the response further improved in patients who entered the study within 6 months after receiving their diagnosis of RA where we saw an 82% ACR20 rate versus 52% in placebo. Another important lesson from both EXPAND and RESOLVE is the need to treat for at least 3 months, a painful but important learning.

And while our belief in the potential of resomelagon remains undeterred, so does our belief in our develop to partner strategy. While momentum to partnering has obviously waned given the disappointing results, we need to stay focused on their feedback on their desire to see resomelagon activity in a commercially relevant population. With limited resources this is why we have decided to put our focus on conducting a trial in patients who are experiencing moderate to severe disease activity after up to 6 months of initial treatment with methotrexate, which is a commercially relevant and attractive patient segment with significant unmet needs.

In parallel we seek to diversify our clinical risk with resomelagon by doing a study in virus-induced respiratory insufficiency caused by influenza similar to the COVID induced study conducted under the RESOVIR collaboration. While we will remain focused on resomelagon we will look to prepare TXP-11 to enter the clinic in 2025 and look for collaborative ways to advance additional peptides.

The R&D expenses in Q4 were much less than in the previous quarter as the final dosing in clinical studies was completed in Q3. Other expenses included a goodwill write-off of SEK 74.5m related to the TXP acquisition from January 2023. The goodwill was largely related to the increase in SynAct's share price from signing to closing. You can say the remaining intangible asset of SEK 152.2m is more balanced as it better reflects the value at signing.

We have worked hard as a management team and board along with our expanded clinical key opinion leader advisors to fashion a capitally efficient plan to address partner data requests, diversify resomelagon risk and to advance the melanocortin peptides. We look forward to a more prosperous 2024 as we strive to deliver on the promise of resolution therapy. We are excited that Kirsten Harting who brings a broad wealth of clinical development experience has joined the team as our new CMO and will be instrumental in designing, executing, and managing our trials and development programs going forward.

Our belief in resomelagon and resolution therapy remains steadfast, but we need to be capitally efficient and maximize our resources to drive resomelagon partnering and build shareholder value. We will need further financing to be to follow our strategy and achieve our objectives and goals. The current situation is of course challenging, but we are greatly encouraged by the opinions and support from our key opinion leader advisors. This taken together with our belief in resomelagon is already being leveraged to help investors see the same potential we do.

We sincerely appreciate the investment and continued support of our shareholder who we know are committed with us to unlock the potential of resolution therapy. We have excellent opportunities before us, and we remain focused on delivering patient, company and shareholder value. Lastly, I would like to thank our Board of Directors. The board of Synact Pharma comprises expert knowledge and valuable experience in drug development and capital markets, as well as the building and governance of biotech and pharma companies. With perspectives from the US to the Nordics and with a diverse composition, I believe we have a superior platform to drive the company in the right direction going forward.

"We have excellent opportunities before us, and we remain focused on delivering patient, company and shareholder value."

Torbjørn Bjerke | CEO

# 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 not been reviewed by the Company's Auditor, KPMG.

### **Forward looking statements**

This financial report contains statements that are forwardlooking. 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 forwardlooking 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 available treatments used to treat inflammation are immunosuppressive. They suppress the immune system by removing key signaling molecules or by depleting certain immune cells. Both strategies can lead to a heightened risk of serious infections and other significant side effects and safety issues. These therapies are anti-inflammatory, but they do not resolve the underlying uncontrolled inflammation.

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.

### Melanocortin biology

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 are spread throughout most organs.

MC1R and MC3R are believed to be the key receptors involved in direct effects on the immune system and 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 can help the immune system resolve excessive or chronic inflammation.

### Resomelagon (AP1189)

SynAct is developing selective melanocortin therapeutics to address inflammatory and autoimmune diseases. SynAct's lead drug candidate, resomelagon (AP1189), is an oral available biased MC1R and MC3R agonist mediating its pharmacological effects through pERK signaling pathway rather than the cAMP pathway which is activated by most melanocortin agonists. Activation of MC1R cAMP pathway is believed to be responsible for certain off-target activity such as skin hyperpigmentation which are avoided with resomelagon (AP1189).

The Company is evaluating resomelagon (AP1189) in three Phase 2 clinical programs: rheumatoid arthritis (RA), idiopathic membranous nephropathy (iMN), a form of nephrotic syndrome, and virus-induced respiratory insufficiency (VIRI) like that seen in COVID-19. We plan to close down the iMN study due to low recruitment, as this is a very rare disease.

## Rheumatoid arthritis (RA)

Rheumatoid arthritis (RA) is a chronic inflammatory disorder that typically affects more than just your joints. RA is an autoimmune disorder, a disease where the immune system mistakenly attacks your body's own tissues. RA affects the lining of the joints, causing painful swelling that can result in cartilage and bone erosion and joint deformity. RA is often associated with symptoms involving other parts of the body including the 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.

#### Clinical development of resomelagon (AP1189) in RA

In 2021, SynAct successfully completed Phase 2 clinical trial in early severe RA. The study, called BEGIN, was a randomized, double-blind, placebo controlled multicenter study in previous treatment naïve RA patients where either 50 mg or 100 mg of resomelagon (AP1189) or placebo was administered in addition to methotrexate (MTX). MTX is a disease modifying antirheumatic drug (DMARD) that is used as a first line therapy. MTX tends to work well in most patients, but it can take up to 8-12 weeks for the drug to take full effect, and up to 40% of patients will not achieve a full response to MTX therapy despite dose escalation to the highest tolerated dose level and will in many cases induce treatment limiting adverse events. Consequently, addition of additional drugs like biological therapies is often needed. Although effective in many patients, the risk for additive adverse events including immunosuppression represents a clinical challenge. These patients who experience an inadequate response to DMARDs are referred to as DMARD-IR (inadequate responder).

Resomelagon (AP1189) given once daily for four weeks was safe and well tolerated in the applied patient population. 100 mg of AP1189 demonstrated a statistically significant mean reduction in the clinical disease activity index (CDAI), the primary study endpoint, from baseline to four weeks that was more than 65% higher than the effect seen in the placebo-treated control group (mean reduction in CDAI: AP1189 100 mg (n=33): 15.5 points compared with placebo (n=30): 9.3%, p = 0.0394). The 100 mg AP1189 group also demonstrated a significantly higher fraction of patients achieving ACR20 than placebo treated patients (ACR20: AP1189 (n=33) 100 mg: 60,6%; Placebo (n=30): 33.3%, P=0.0437) within the 4 weeks.

In 2022, the Company initiated two new phase 2 clinical trials in RA, EXPAND: a Phase 2b trial in newly diagnosed RA patients experiencing severe disease activity and RESOLVE a Phase 2a/b trial in RA patients experiencing an incomplete or lack of response to methotrexate (the main treatment in 1st line RA treatment).

# EXPAND - A 12-week P2b study of daily AP1189 in MTX-naïve patients with severe disease activity

In continuation of BEGIN, the EXPAND study was designed to test the treatment effect of 12-weeks of resomelagon (AP1189), administered orally once-daily as a tablet, on disease activity as measured by the ACR20 response rate as well as other RA disease measures and to confirm the safety profile of the molecule. The study also involved several exploratory endpoints that are expected to underscore the unique mode of action of resomelagon (AP1189). Full recruitment of patients was accomplished in April, and the treatment phase of the study completed in July 2023.

Top line data, reported September 4, showed that resomelagon did not meet the primary endpoint of a statistically higher level of a 20 percent improvement, according to the ACR20 scoring system, versus placebo treatment after 12 weeks. Furthermore, the subjective measures, being used part of the stud assessment, was not in line with expectations and seemed to contribute to

ASSET	INDICATION	PRECLINICAL	PHASE 1	PHASE 2A	PHASE 2B	PHASE 3	STATUS & NEXT MILESTONE
	RA – 1 <sup>st</sup> line treatment					Bart 1	<ul> <li>Ph-2B study, result presented</li> <li>Final report to be completed</li> </ul>
Resomelagon (AP1189)	RA - DMARD-IR				-		Ph-2A study, result to be presented     New study planned
Resoniciation (AF1107)	Nephrotic syndrome (iMN)						Ph-2A study closed – low recruitment
	Virus-induced respiratory insufficiency						Complementary P-C study required     Ph-2B planned, start 2024-H2
TXP-11	Prevent organ failure in surgery		and the second	120			Additional P-C study required     Ph-1 planned 2025
Next generation molecules	Inflammatory diseases						

# **Research and Development (continued)**

a much higher placebo response than expected, together with difficulties in differentiating active groups and placebo groups. Continued assessment of the top line results and the complete setup of data from the study was conducted to better understand the results. The Company announced, September 12, additional study data, where a subpopulation of patients with active inflammation showed an effect of dosing with resomelagon versus placebo of the primary end point, ACR>20, and also for other secondary end points. This confirms the activity of resomelagon shown in previous studies. The Company announced, October 3, additional data from the study which further supports effect and activity of patients with an active inflammation.

### RESOLVE - A 12-week P2a/b study of daily AP1189 in patients with an incomplete response to first-line disease modifying antirheumatic drugs (DMARD-IR) who are experiencing moderate to severe disease activity

The Company believes that resomelagon (AP1189) could be very well suited for DMARD-IR patients given the emerging profile of an efficacious, safe, and well tolerated once daily oral therapy. The DMARD-IR patient population has high commercial attractiveness, and the Company considers further clinical development in DMARD-IR to be both relevant and necessary.

Development of resomelagon (AP1189) in DMARD-IR patients was done under an IND (Investigational New Drug) application with clinical sites in the both the US and in European countries. The clinical study called RESOLVE was designed as a two-part safety and dose finding study with four weeks dosing in part A like in the BEGIN study, followed by a part B resembling EXPAND with 12 weeks once daily dosing. In Part A of the study recruitment of patients was completed in July 2023. The outcome of the study is still pending as the Company decided to perform a study audit due to findings that suggested irregularities in the study before any conclusions can be drawn.

# 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).

#### Clinical development of AP1189 in iMN

Resomelagon (AP1189) has been tested Idiopathic Membranous nephropathy (iMN), one of causes of NS, in an exploratory, randomized, double-blind, multicenter, placebo controlled P2a study with repeated once-daily 100 mg dosing to assess the safety, tolerability, pharmacokinetics, and efficacy of resomelagon (AP1189).

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 lack of eligible patients, the Company has announced that recruitment will be stopped and the study to be closed.

#### Virus Induced Respiratory Insufficiency (VIRI)

Virus infected patients can develop respiratory insufficiency and can develop pneumonia or acute respiratory distress syndrome (ARDS), where patients often require mechanical ventilation in order to breathe adequately. Infections can also cause the immune system to be overly active with a risk of damage to key organ systems like the lungs, kidneys and heart.

The goal of treating viral induced inflammation should be to resolve the excessive inflammation without suppressing the

immune system's ability to fight the viral infection and thereby arrest the excessive inflammation to prevent severe disease.

#### Clinical development of AP1189 in VIRI

Resomelagon (AP1189) was tested in a 60-patient placebo controlled Phase 2a clinical trial of treatment of hospitalized COVID-19 infected patients who required supplemental oxygen. The study was a part of the RESOVIR collaboration, 100 mg AP1189 or placebo was administered orally once daily for 2 weeks.

All AP1189 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 (AP1189) patients were discharged on average 3.3 days earlier than placebo and by day 4, 41% of AP1189 patients had been discharged vs 0% for placebo.

The unmet medical need in VIRI associated with common annual or seasonal viral infections such as viral pneumonia and or influenza could be addressed with resomelagon (AP1189). The company has initiated pre-clinical pharmacological studies in preparation of any potential next clinical study. No clinical development was made in 2023. The Company now plans to initiate a PoC-study (Proof of Concept) in virus induced patients suffering from respiratory insufficiency.

### **Peptide Agonists**

SynAct's 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 analogs 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. The compound is expected to advance into Phase 1 clinical development in 2025.

# The SynAct Pharma Share

### Share information

SynAct Pharma's share has been listed on Nasdag 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.

January 16, 2023, SynAct Pharma AB completed the acquisition of TXP Pharma AG. The transaction was structured as an issuein-kind and implied that the number of shares increased by 2,172,523 to 31,820,980 and the share capital increased by SEK 271,565 to SEK 3,977,623.

October 11, 2023, the Board of Directors resolved on a directed share issue of SEK 60.5 million before issue costs. Through the directed share issue, the number of shares increased by 3.750.000 to 35.570.980 shares.

The closing price of the SynAct share on the last trading day in December 2023 was SEK 8.83.

### Ownership (December 31, 2023)

Shareholder	Capital and votes(%)
Avanza Pension	7.1%
Thomas Jonassen	6.2%
Nordnet Pensionsförsäkring	4.9%
Heights Capital Management Inc.	4.2%
Goodwind Holding GmbH	3.3%
Thomas von Koch	3.1%
Torbjörn Bjerke	2.4%
Handelsbanken fonder	2.3%
Niklas Borgquist	0.9%
SEB fonder	0.9%
Total (top-10)	35.2%
Others (~16,000)	64.8%

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, 35,570,980.

### Share-based incentive programs

The company has two employee option programs, Employee Option Program 2023 I ("ESOP 2023 I") and Employee Option Program 2023 II ("ESOP 2023 II").

At the Extraordinary General Meeting on 12 January 2023, the Board of Directors' proposal for ESOP 2023 I for two senior executives and one other employee was adopted. This program has been charged to the Group's and the Parent Company's financial results during the quarter.

At the Annual General Meeting on May 25, 2023, it was resolved to introduce ESOP 2023 II for senior executives and one other employee. This program has been charged to the Group's and the Parent Company's financial results during the quarter. For further information, please refer to Note 6 to the financial statements.

### Lock-up agreement

There have been no lock-up agreements in force during the quarter.



### Analyst coverage

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

Gonzalo Artiach Castañón, ABG Sundal Collier AB

Patrik Ling, DNB Markets

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#### Financial calendar

Date:

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

Repor

03/20/2024	Extra General meeting
04/10/2024	Annual Report 2023
05/17/2024	Interim Report Q1 2024
05/23/2024	Annual General meeting 2024
08/20/2024	Interim Report Q2 2024
10/30/2024	Interim Report Q3 2024

# Comments on the financial development for the fourth quarter and the whole year of 2023

### Net sales

Net sales for the forth 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 2025.

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

Total costs for R&D in the fourth quarter amounted to SEK 10,761 (21,663) thousand. For the whole year, R&D costs amounted to SEK 105,055 (70,067) thousand. The main reason for the cost increase for the year are the two clinical phase 2 studies, EXPAND and RESOLVE, that were started during 2022 and have been fully active for most of the year. In addition, investments have been made in pre-clinical activities that support both the drug candidates resomelagon (AP1189) and TXP-11 and projects in the early research phase.

### Administration costs

Administrative expenses amounted to SEK 5,747 (8,987) thousand in the fourth quarter and SEK 44,826 (35,611) thousand for the whole year. The increase for the year is driven by costs related to the acquisition of TXP Pharma, employee option programs and severance pay.

#### Other operating income/expenses

The increase in the quarter is mainly driven by SEK 74,558 thousand impairment of goodwill related to the TXP acquisition. The impairment has been made based on an impairment test of the cash-generating unit that TXP constitutes. The impairment test has considered the updated strategic plan adopted by the Board of Directors and the value of TXP has been negatively impacted by delays in the development of the most advanced peptide agonist, TXP-11, as well as other projects in the TXP portfolio. In connection with this, it is also important to emphasize that the goodwill value that is impaired largely arose as an accounting consequence of the share price of the SynAct Pharma share rising by 40% from the time of signing of the acquisition agreement to the date of closing of the shares in TXP Pharma.

#### Financial items

Net financial items amounted to SEK 520 (-31) thousand in the fourth quarter and SEK 220 (-1,360) thousand for the whole year. The change is attributable to exchange rate adjustments.

#### Tax for the period

Tax revenues in the fourth quarter amounted to SEK -2 (77) thousand. For the whole year the accrued tax credit amounted to SEK 8,466 (7,860) thousand. See Note 10 - Tax receivables.

### Loss for the period

The Group's loss for the fourth quarter amounted to SEK 90,543 (30,477) thousand and for the whole year, the reported loss was SEK 215,810 (99,205) thousand.

### Cash flow, financial position and going concern

In connection with the acquisition of TXP Pharma AG, intangible assets corresponding to SEK 227,261 thousand arose, of which capitalized development costs amounted to SEK 152,159 thousand, an associated deferred tax liability of SEK 18,016 thousand and a goodwill amounting to SEK 75,602 thousand. The goodwill amount has been written down in the 2023 financial statements, see comments under Other operating income/ expenses. In addition, the conditional additional purchase price was reported as long-term debt with an assessed fair value of SEK 7,248 (0) thousand. See note 4 – Business combinations.

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 10 - Tax receivables) amounted to SEK 8,188 (8,231) thousand.

Cash flow from operating activities amounted to SEK -20,395 (-22,306) thousand in the quarter. Full year cash flow for operating activities amounted to SEK -100,177 (-117,555) thousand. The change is driven by increased clinical activities and by payments related to the acquisition of TXP Pharma AG.

Cash flow from financing activities amounted to SEK 54,561 (76,025) thousand in the fourth quarter. For the whole year the cash flow from financing activities were SEK 53,984 (200,712) thousand.

Cash flow for the period amounted to SEK 34,166 (53,747) thousand and SEK -45,823 (83,184) thousand for the whole year.

The Group's cash and cash equivalents as of December 31, 2023, amounted to SEK 62,395 (108,245) thousand.

The Board of Directors continuously evaluates the Company's financial position and has determined that its current cash and cash equivalents are sufficient to finance the operations for the next 12 months. To be able to start any of the new phase 2 studies in rheumatoid arthritis, which is a part of the company's new strategic plan, however, additional financing is needed.

### Employees

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

#### Parent Company

The parent company's sales are from services delivered to the Danish and Swiss subsidiary and amounted to SEK 2,309 (1,310) thousand in the fourth quarter and SEK 8,262 (5,144) thousand for the whole year.

In the Parent Company, net financial items amounted to SEK -73,297 (-1) thousand in the quarter. For the whole year, net financial items was SEK -122,689 (-110,299) 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.

The financial fixed assets increased during the period as a result of the acquisition of TXP Pharma AG to SEK 181,207 (SEK 24,419) thousand. The increase consists of the acquisition value, adjusted in the quarter for impairment of subsidiaries, as well as transaction costs as set out below. The parent company follows the accounting guideline in RFR 2, which for the treatment of acquisition costs, deviates from IFRS. During the period, the parent company has capitalized acquisition cost amounting to SEK 10,870 thousand as financial fixed assets.

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	2023	2022	2023	2022
		Okt-Dec	Okt-Dec	Jan-Dec	Jan-De
Net sales		-	-	-	
Gross profit		-	-	-	
Research and development costs	6	-10,761	-21,663	-105,055	-70,06
General and administration costs	6, 7	-5,747	-8,987	-44,826	-35,61
Other operating income/expenses	5	-74,553	127	-74,615	-2
Total operating expenses		-91,062	-30,523	-224,496	-105,70
Operating income		-91,062	-30,523	-224,496	-105,70
Net financial items		520	-31	220	-1,36
Profit after financial items		-90,542	-30,554	-224,276	-107,06
Tax on profit/loss for the period	10	-2	77	8,466	7,86
Profit for the period		-90,543	-30,477	-215,810	-99,20
Earnings per share (SEK)		-2.58	-1.06	-6.64	-3.6
Diluted earnings per share (SEK)		-2.58	-1.06	-6.64	-3.6
Average number of shares outstanding ('000)	9	35,082	28,621	32,524	27,58

# **Consolidated statement of comprehensive Income**

SEK (thousand)	Note	2023	2022	2023	2022
		Okt-Dec	Okt-Dec	Jan-Dec	Jan-Dec
Profit for the period		-90,543	-30,477	-215,810	-99,205
Items reclassifiable to profit or loss					
Translation differences from foreign operation		-844	646	13,003	3,164
Comprehensive income after tax for the period		-91,387	-29,831	-202,807	-96,041
Comprehensive income for the period		-91,387	-29,831	-202,807	-96,041

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

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

# **Consolidated statement of financial position**

SEK (thousand)	Note	12/31/2023	12/31/2022
Assets			
Non-current assets			
Intangible assets	4, 5	152,159	-
Right-of-use assets		660	2,095
Financial assets	13	139	270
Total non-current assets		152,959	2,365
Current assets			
Tax credit	10	8,188	8,231
Other current receivables		4,220	6,464
Prepaid expenses	12	258	17,293
Cash and cash equivalents	13	62,395	108,245
Total current assets		75,060	140,232
Total assets		228,019	142,597

SEK (thousand)	Note	12/31/2023	12/31/2022
Equity and liabilities			
Share capital	4, 8	4,446	3,706
Other paid-in capital	4, 6	646,572	394,839
Reserves		15,768	2,765
Retained earnings/losses including net profit		-490,600	-274,790
Total equity		176,186	126,520
Non-current liabilities			
Deferred tax liability	4	18,016	-
Leasing liability		58	1,064
Contingent earnout	4	7,248	-
Other provision	6, 7	1,573	-
Total non-current liabilities		26,894	1,064
Current liabilities			
Accounts payable	13	9,670	4,723
Leasing liability		579	1,000
Other current liabilities	11	4,876	4,381
Accrued expenses	12, 13	9,815	4,909
Total current liabilities		24,939	15,012
Total equity and liabilities		228,019	142,597

# **Consolidated statement of changes in equity**

<b>01/01/2022 - 12/31/2022</b> SEK (thousand)	Share capital	Other paid-in capital	Reserves	Retained earnings, including profit for the period	Total
Opening equity	3,251	193,602	-399	-175,585	20,869
Profit for the period	-	-	0	-99,205	-99,205
Other comprehensive income	-	-	3,164	-	3,164
Comprehensive income for the period	-	-	3,164	-99,205	-96,041
Transactions with owners					
New share issue	455	228,490	-	-	228,945
Issue expenses	-	-27,252	-	-	-27,252
Total transaction with owners	455	201,238	-	-	201,693
Closing equity	3,706	394,840	2,765	-274,790	126,520

<b>01/01/2023 - 12/31/2023</b> SEK (thousand)	Share capital	Other paid-in capital	Reserves	Retained earnings, including profit for the period	Total
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

# **Condensed consolidated statement of cash flows**

SEK (thousand) Note	2023	2022	2023	2022
	Okt-Dec	Okt-Dec	Jan-Dec	Jan-Dec
Cash flow from operations				
Operating income	-91,062	-30,523	-224,496	-105,705
Adjustment for non-cash items	75,563	-43	85,566	712
Interest received	34	1	34	47
Interest paid	-76	136	-123	-119
Corporate income tax received/paid	8,478	7,860	8,472	7,860
Cash flow from operations before change in working capital	-7,063	-22,569	-130,547	-97,206
Change in working capital	-13,333	263	30,370	-20,349
Cash flow from operating activities	-20,395	-22,306	-100,177	-117,555
Cash flow from investing activities	-0	27	370	27
Cash flow from financing activities	54,561	76,025	53,984	200,712
Cash flow for the period	34,166	53,747	-45,823	83,184
Cash and cash equivalents at beginning of period	28,876	54,898	108,245	23,997
Decrease/increase in cash and cash equivalents	34,166	53,747	-45,823	83,184
Exchange rate difference in cash and cash equivalents	-647	-400	-27	1,063
Cash and cash equivalents at end of period	62,395	108,245	62,395	108,245

# Parent company's condensed income statement

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Parent company's st	atement of comprehe	ensive income
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SEK (thousand)	Note	2023	2022	2023	2022
		Okt-Dec	Okt-Dec	Jan-Dec	Jan-Dec
Net sales		2,309	1,310	8,262	5,144
Gross profit		2,309	1,310	8,262	5,144
Research and development costs		2,551	-	-	-
General and administration costs	6, 7	-4,929	-3,054	-31,277	-25,726
Other operating expenses		43	99	-3	-90
Total operating expenses		-2,335	-2,955	-31,280	-25,815
Operating income		-26	-1,645	-23,018	-20,671
Net financial items		-73,297	-1	-126,510	-110,299
Profit after financial items		-73,324	-1,646	-149,529	-130,970
Tax on profit for the period		-	-	-	-
Profit for the period		-73,324	-1,646	-149,529	-130,970

SEK (thousand)	Note	2023	2022	2023	2022
		Okt-Dec	Okt-Dec	Jan-Dec	Jan-Dec
Profit for the period		-73,324	-1,646	-149,529	-130,970
Other comprehensive income		-	-	-	-
Total comprehensive income		-73,324	-1,646	-149,529	-130,970

# Parent company's condensed balance sheet

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SEK (thousand)	Note	12/31/2023	12/31/2022
Assets			
Non-current assets			
Financial assets		181,207	24,419
Total non-current assets		181,207	24,419
Current assets			
Receivables in group companies		4,696	-
Other receivables		518	2,231
Prepaid expenses		215	4,325
Cash and cash equivalents		44,133	88,250
Total current assets		49,561	94,806
Total assets		230,768	119,225

SEK (thousand)	Note	12/31/2023	12/31/2022
Equity and liabilities			
Restricted equity			
Share capital	4, 8	4,446	3,706
Non-restricted equity			
Other paid-in capital	4, 6	646,572	371,624
Retained earnings/losses		-287,418	-133,233
Profit for the period		-149,529	-130,970
Total equity		214,072	111,127
Non-current liabilities			
Contingent earnout	4	7,248	-
Other provisions	6, 7	1,573	-
Total non-current liabilities		8,821	-
Current liabilities			
Accounts payable		565	1,072
Other liabilities	11	4,506	4,044
Accrued expenses		2,804	2,981
Total current liabilities		7,876	8,098
Total equity and liabilities		230,768	119,225

# 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 February 23, 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 2022, note 2 pages 34 to 37. No new or changed standards implemented on or after January 1, 2023, 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 2022, pages 19-24 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. After analyzing and evaluating various financing alternatives, the Board of Directors decided on October 11, 2023 to carry out a directed share issue of SEK 60.5 million, which provided the company with approximately SEK 55 million after deduction of issue expenses. Although this risk is mitigated in the short term, 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 rising inflation and interest rates did not have a significant impact on SynAct's operations in the fourth 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 2023.

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.

The Covid-19 pandemic affected the ongoing clinical studies in 2020 and 2021 with delays in patient recruitment. Regarding the studies that started in 2022 and ended in 2023, the assessment is that the pandemic (as it appears right now) has not significantly affected the recruitment and implementation of the studies.

### **Note 4 - Business combination**

In the beginning of 2023, Synact Pharma AB acquired 100% of the issued share capital of TXP Pharma AG, a swiss biotech company. The acquisition was completed on the 16th of January 2023 TXP is consolidated into Synact's consolidated financial reporting from January 16 and of the Group's results in the reporting period, TXP accounts for SEK 4,573 thousand.

The purchase price consisted of a fixed purchase price corresponding to SEK 136 million and a potential additional purchase price (earnout) of SEK 55 million, where the fixed purchase price was paid through 2,172,523 newly issued shares in SynAct.

The acquisition of TXP strengthens SynAct's position as a leader in resolution therapy therapies through melanocortin biology. The acquisition of TXP gives SynAct two platforms that complement each other and create a versatility for developing therapies to address the full range of inflammatory and autoimmune diseases.

The purchase price of the acquisition is as follows:	Fair value (SEK thousands)
Cash and cash equivalents	0
Ordinary shares issued	189,879
Provision for earnout	7,077
Total purchase consideration	196,956

The initial purchase price was paid by SynAct issuing 2,172,523 consideration shares, equivalent to SEK 136 million at the time of signing of the deal and based on a share price of SEK 62.60. In accordance with IFRS 3, the acquirer must recognize the fair value of share-based payments on the acquisition date. The fair value was determined using a share price of SEK 87.40 to SEK 189,879 thousand, which led to recognition of goodwill on SEK 70,954 thousand. The acquisition was carried out on a debt- and cash-free basis.

The provision for earnout is based on a number of events, and can amount to a maximum of SEK 55 million; (i) positive results of a Phase 2a study (leading to the start of Phase 2b or Phase 3), (ii) divesting or out-licensing of one or more TXP projects, or (iii) the sale of TXP. The fair value of the earnout consideration was calculated, by discounting to present value and a probability estimate, at SEK 7,077 thousand.

#### Final purchase price allocation analysis

The table to the right shows the final purchase price allocation analysis of the acquisition of TXP Pharma AG.

Assets and Liabilities	Fair value (SEK thousand)
Intangible assets	142,805
Property, plant and equipment	0
Current receivables excl cash and bank	98
Cash and cash equivalents	236
Non-current liabilities	0
Deferred tax liability	-16,908
Current liabilities	-229
Total net assets acquired excluding goodwill	126,002
Goodwill	70,954
Total net assets acquired	196,956
Less	
Ordinary shares issued	-189,879
Provision for earnout	-7,077
Received cash and cash equivalents	236
Net cash outflow/effect on cash and cash equivalents on acquisition of business	236

The reported other intangible asset, SEK 142,805 thousand, consists of the company's lead candidate, TXP-11. The goodwill recognized in the acquisition, SEK 70,954 thousand, is attributable to intellectual property rights that cannot qualify as intangible assets, such as TXP's other pharmaceutical projects and patent portfolio. Reported goodwill is not expected to be deductible. The acquisition-related expenses related to valuation, tax and legal advisors, etc., amounts to SEK 10.9 million, which have been expensed in the Group, but are capitalized in the Parent Company.

### Note 5 - Intangible assets and goodwiil

Intangible assets and goodwill have been subject to customary impairment testing in accordance with IAS 36. Regarding the cash-generating unit TXP, an impairment test in 2023 has been carried out as follows.

The valuation is based on a probabilistic cash flow model where the most critical assumptions are deemed to be assumptions about the timing of potential commercialization, market size, market share and probability of reaching the market as well as the discount rate. Impairment testing of TXP is based on estimated risk-adjusted future cash flows and has been calculated with a discount rate of 15 percent. The discount rate has been determined by taking into account the risk-free interest rate and the risk associated with the specific asset.

The impairment test resulted in an impairment of goodwill of SEK 74,558 thousand. The impairment has been made based on an impairment test of the cash-generating unit that TXP constitutes. The impairment test has considered the updated strategic plan adopted by the Board of Directors and the value of TXP has been negatively impacted by delays in the development of the most advanced peptide agonist, TXP-11, as well as other projects in the TXP portfolio. In connection with this, it is also important to emphasize that the goodwill value that is impaired largely arose as an accounting consequence of the share price of the SynAct Pharma share rising by 40% from the time of signing of the acquisition agreement to the date of closing of the shares in TXP Pharma.

Impairment testing of intangible assets is a significant estimate and assessment as several assumptions about future conditions and estimates of parameters are made when calculating the recoverable amount of cash-generating units.

### **Note 6 - 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 2023 I**

At the Extraordinary General Meeting of SynAct Pharma AB on January 12, 2023, it was resolved to implement an employee option program ("ESOP 2023 I") for two senior executives and one other employee of the company.

The ESOP 2023 I shall comprise a maximum of 195,000 options. The allotted employee options will vest with 1/3 as of the date that falls 12, 24 and 36 months after the date of allotment. The holders can exercise allotted and vested options during 30 days from the day following after the announcement of the Company's quarterly reports, the first time after the announcement of the quarterly report for the fourth quarter of 2025 and the last time after the announcement of the quarterly report for the fourth quarter of 2026. Each option entitles the holders a right to acquire one new share in the Company against cash consideration. The exercise price amounts to SEK 138.93, equivalent to 175 per cent of the volume weighted average share price of the Company's share on Nasdaq Stockholm during 30 trading days immediately prior to the extraordinary general meeting on 12 January 2023. The employee options shall be allotted without consideration and shall not constitute securities and shall not be possible to transfer or pledge. Allotment of the options occurred on January 13, 2023.

### Employee Option Program 2023 II

At the Annual General Meeting on May 25, 2023, it was resolved to introduce a second employee option program ("ESOP 2023 II") for senior executives and one other employee.

This employee option program shall comprise a maximum of 469,000 employee stock options. The allotted employee options vest with 1/3 from the date that is 12, 24 and 36 months after the date of allotment. 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 2028. Each employee option entitles the holder to acquire one new share in the company. Exercise price amounting to SEK 110.43, corresponding to 150 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 404,000 of the options included in the program took place on June 1, 2023. The remaining 65,000 warrants can be granted after a Board decision until the 2024 Annual General Meeting of SynAct.

Change in outstanding incentive programs (number of options)	2023	2023	Total
Alloted instruments	Oct-Dec	Jan-Dec	
ESOP 2023 I	-	195,000	195,000
ESOP 2023 II	-	404,000	404,000
Recalled/voided instruments			
ESOP 2023 I	-	-90,000	-90,000
Instruments decided, not allocated			
ESOP 2023 II	-	65,000	65,000
Change			
ESOP 2023 I	-	105,000	105,000
ESOP 2023 II	-	469,000	469,000

Maximum number of shares to which allocated options can entitle	12/31/2023
ESOP 2023 I	105,000
ESOP 2023 II	469,000
Total Employee Option	574,000

As of December 31, 2023, SynAct had 35,570,980 shares outstanding. If the outstanding options (105,000) for the ESOP 2023 I are vested and exercised in full, it would result in a dilution of 0.3%. If the outstanding options (469,000) for the ESOP 2023 II are vested and exercised in full, it would result in a dilution of 1.3%.

The costs for the programs are estimated at SEK 19,310 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 fourth quarter of 2023, the costs for the employee option programs amounted to SEK 2,227 thousand (0) and the costs for the whole year amounted to SEK 7,884 thousand (0).

### Note 7 - 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)		2023	2022	2023	2022
Related party	Service	Okt-Dec	Okt-Dec	Jan-Dec	Jan-Dec
UST Leadership AB	Consultancy	-	525	525	525
(Torbjørn Bjerke, former chairman)					

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.

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 14, Contingent liabilities for more information.

On December 12, SynAct Pharma AB entered into a conditional share purchase agreement with the owners of TXP Pharma AG. Among the sellers are, directly and indirectly, Torbjørn Bjerke, then chairman of the board of directors of SynAct, Jeppe Øvlesen, then CEO of SynAct, Thomas Jonassen, board member and CSO of SynAct, Thomas Boesen, COO of SynAct and Jim Knight, CBO of SynAct. Therefore the transaction and the agreement has been defined as a related party transaction. Please refer to note 4 for more information of the transaction.

In April 2023, Torbjörn Bjerke was elected new CEO of Synact, starting in connection with the Annual General Meeting in May, and an agreement on severance pay to outgoing CEO Jeppe Øvlesen was entered into, this is reported as other provision in the amount of SEK 1,569 thousand.

### Note 8 - Share issues

The acquisition of TXP Pharma AG, which was completed in January, was carried out as a non-cash issue and increased the number of shares by 2,172,523 to 31,820,980 and increased the share capital by SEK 271,565 to SEK 3,977,623.

In October, the Company carried out a directed share issue of SEK 60.5 million before issue expenses and increased the number of shares by 3,750,000 to 35,570,980 and increased the share capital by SEK 468,750 to SEK 4,446,373.

### Note 9 - Number of registered shares

Thousand	2023	2022	2023	2022
	Okt-Dec	Okt-Dec	Jan-Dec	Jan-Dec
Number of shares at the beginning of the period	31 ,821	28,371	29,648	26,006
Number of shares at the end of the period	35,571	29,648	35,571	29,648
Average number of shares outstanding in the period	35,082	28,621	32,524	27,585

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

# Note 10 - 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 8,188 thousand (8,231). The balance related to fiscal year 2022 with an amount of SEK 8,231 thousand was received in November 2023.

## Note 11 - 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. During the process SynAct agreed to pay part of the disputed amount to the Swedish Tax Agency, approximately SEK 2 million, and accrued for the remaining amount of approximately SEK 1.6 million.

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.

The company has continued to reserve for the full amount of VAT and tax surcharges of SEK 3,689 (1,614) thousand as an other short-term liability in the financial reporting pending a final judgment. The change since the previous year is due to the fact that at the beginning of 2022, after the judgment in the Administrative Court, the Tax Agency refunded the part of the dispute that the Company had previously paid.

### Note 12 - Prepaid and accrued expenses

The company reports prepaid expenses of SEK 258 thousand (17,293). The decrease since the comparison period is mainly due to the initial payments to the CRO that handled the two clinical studies SynAct-CS006 (RESOLVE) and SynAct-CS007 (EXPAND).

The company reports accrued expenses of SEK 9,815 thousand (4,909). The increase is partly due to remaining activities in the two clinical studies SynAct-CS006 (RESOLVE) and SynAct-CS007 (EXPAND) and thus increased accrued costs.

### Note 13 - Financial assets and liabilities

SEK (thousand)	12/31/2023	12/31/2022
Financial assets		
Non-current financial assets	139	270
Other current receivables	-	1,560
Cash and cash equivalents	62,395	108,245
Total financial assets	62,534	110,075
Financial liabilities		
Accounts payable	9,670	4,723
Accrued expenses	9,815	4,909
Total financial liabilities	19,484	9,632

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 14 - 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 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.

### **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)	12/31/2023	12/31/2022
	Assets		
	Total non-current assets	152,959	2,365
	Total current assets	75,060	140,232
[1]	Total assets	228,019	142,597
	Equity and liabilities		
[2]	Total equity	175,873	126,520
	Total non-current liabilities	58	1,064
	Total current liabilities	24,939	15,012
	Total liabilities	24,997	16,077
	Total equity and liabilities	200,870	142,597
[2] / [1]	Equity / asset ratio (%)	77%	89%

#	SEK (thousand)	2023	2022	2023	2022
		Okt-Dec	Okt-Dec	Jan-Dec	Jan-Dec
[1]	Research and development costs	-10,761	-21,663	-105,055	-70,067
	General and administration costs	-5,747	-8,987	-44,826	-35,611
	Other operating income / expense	-74,553	127	-74,615	-28
[2]	Total operating expenses	-91,062	-30,523	-224,496	-105,705
[1] / [2]	Research and development costs / operating expenses (%)	12%	71%	47%	66%

# 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, February 23 2024

Torbjørn Bjerke Chief Executive Officer (CEO)

# 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.

## Angiotensin

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

# APM

Alternative performance measure. An alternative key figure 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.

## 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 AP1189 (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 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.

# СМС

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.

# ESMA

European Securities and Markets Authority.

## EXPAND

The EXPAND (SynAct-CS007) study is a multicenter, randomized, double-blind, placebo-controlled, 12-week study in newly diagnosed, treatment naïve patients with highly active RA (Clinical Disease Activity Score (CDAI) > 22) who are to start treatment with methotrexate (MTX). In EXPAND, 120 RA patients with high disease activity (CDAI > 22) will be randomized 1:1 for treatment with either the newly developed 100 mg AP1189 tablets or placebo tablets for a once daily dose for 12 weeks, concurrently with the prescribed dosing with MTX. The primary efficacy read-out in the EXPAND is proportion of patients achieving 20% improvement in ACR (ACR20) at week 12 relative to placebo.

# 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

# **Glossary (continued)**

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 (PK)**

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) is a two-part, randomized, double-blind, multi-center, placebo-controlled study of the safety, dose-range finding confirmation, and efficacy of 4 (Part A) and 12 weeks (Part B) of treatment with AP1189 in adult RA patients with an inadequate response to MTX alone. The objectives of the two-part study are to evaluate the efficacy and safety of multiple doses of AP1189 when combined with MTX in DMARD-IR patients.

### 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. The safety and efficacy of AP1189 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 AB – parent company

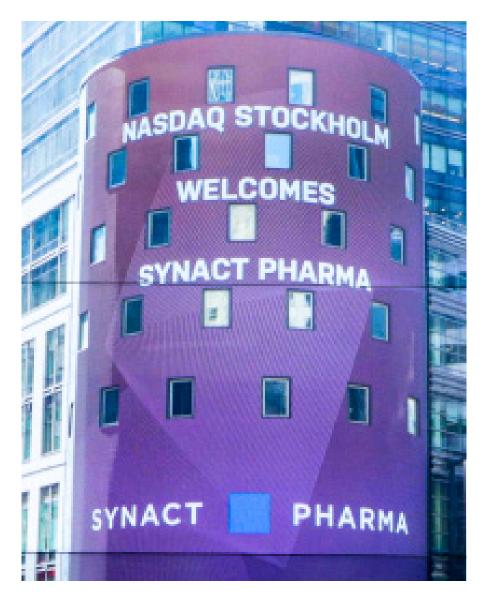
Company name	SynAct Pharma AB
Trade name/Ticker	SynAct Pharma/SYNACT. Shares are traded at Nasdaq Stockholm.
ISIN-kod	The ISIN-code of the share is SE0008241491.
LEI-kod	549300RRYIEFEQ72N546
Registered office and domicile	Skåne County, Lund Municipality, Sweden
Corporate registration number	559058-4826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

### SynAct Pharma ApS – affiliate

Country of establishment	Denmark
Country of operations	Denmark
CVR-number (Company registration id)	34459975
Holding	100 percent

### TXP Pharma AG - affiliate

Country of establishment	Switzerland
Country of operations	Switzerland
Firmennummer (Company registration id)	CHE-271.053.235
Holding	100 percent



# SYNACT PHARMA

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Grafisk form: Plucera Webbyrå (www.plucera.se)