

# INTERIM REPORT

January - September 2023

SYNACT  PHARMA

**Research** and  
**development** in  
inflammatory  
diseases

# Q3

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.

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Significant events in  
the third quarter

p. 4

CEO Torbjørn Bjerke  
comments on the  
third quarter

p. 5



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

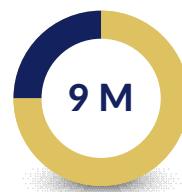
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## Interim report for the third quarter and first nine months 2023



### Quarter 3 (July - September)

- The Group's net sales amounted to SEK 0 (0) thousand.
- Operating expenses amounted to SEK 31,692 (26,461) thousand, an increase of 20%.
- The Group's loss after tax amounted to SEK 31,878 (23,919) thousand.
- The Group's earnings per share before and after dilution amounted to SEK -1.00 (-0.84).
- Cash flow from operating activities amounted to SEK -14,653 (-41,335) thousand.
- Cash flow from financing activities amounted to SEK -153 (-230) thousand.
- Cash flow for the period amounted to SEK -14,804 (-41,565) thousand.
- Cash and cash equivalents at the end of the period amounted to SEK 28,876 (54,898) thousand.



### Nine months (January - September)

- The Group's net sales amounted to SEK 0 (0) thousand.
- Operating expenses amounted to SEK 133,434 (75,182) thousand, an increase of 77%, driven primarily by the two clinical studies in RA and higher administrative costs caused by the acquisition of TXP Pharma AG.
- The Group's loss after tax amounted to SEK 125,267 (68,728) thousand.
- The Group's earnings per share before and after dilution amounted to SEK -3.96 (-2.52).
- Cash flow from operating activities amounted to SEK -79,782 (-95,248) thousand.
- Cash flow from financing activities amounted to SEK -577 (124,686) thousand.
- Cash flow for the period amounted to SEK -79,989 (29,438) thousand.

### The Group's financial performance per quarter

(SEK thousand)	2023 Q3	2023 Q2	2023 Q1	2022 Q4	2022 Q3	2022 Q2	2022 Q1	2021 Q4
Net sales	-	-	-	-	-	-	-	-
Operating income	-31,692	-43,495	-58,248	-30,523	-26,461	-26,417	-22,304	-26,153
Profit before tax	-31,988	-43,601	-58,146	-30,554	-26,569	-27,625	-22,317	-26,207
Profit for the period	-31,878	-43,511	-49,878	-30,477	-23,919	-24,754	-20,055	-26,210
Total assets	275,925	298,472	320,999	142,597	96,206	133,972	22,155	38,369
Equity / asset ratio (%) <sup>1</sup>	76%	81%	84%	89%	83%	77%	3%	54%
Earnings per share (SEK)	-1.00	-1.37	-1.59	-1.06	-0.84	-0.91	-0.77	-1.01
Research & development cost / operating expenses (%) <sup>1</sup>	68%	67%	75%	71%	78%	54%	60%	77%

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

## Significant events during the third quarter of 2023 and after the end of the reporting period

### Q3 - 2023

- JUL 14** SynAct announces that dosing has been completed in the company's Phase 2b EXPAND study, which evaluates the daily dose of resmelagon (AP1189) for patients with early rheumatoid arthritis (RA) with severe disease activity.
- JUL 20** SynAct announces that it completed patient recruitment for part A of the P2a/b RESOLVE clinical study of resmelagon (AP1189) in patients with an inadequate response to first-line disease modifying anti-rheumatic drugs (DMARD-IR) who are experiencing moderate to severe disease activity.
- AUG 17** SynAct today announces that dosing has been completed in the Phase 2a portion of the RESOLVE Phase 2a/b clinical study of once-daily oral resmelagon (AP1189) in patients with an inadequate response to first-line disease-modifying antirheumatic drugs (DMARD-IR). A total of 125 patients were randomized into the study with over 20% recruited in the US. With dosing completed SynAct anticipates releasing top-line study data in October of this year.

- SEP 4** SynAct announces top line data from the 12-week EXPAND P2b clinical trial in severely active newly diagnosed rheumatoid arthritis patients.
- SEP 12** SynAct announces additional data from the EXPAND P2b clinical trial and identifies population with responsiveness to resmelagon.

### Q4 - 2023

- OCT 3** SynAct announces additional data from the EXPAND P2b clinical trial further supporting efficacy and activity seen in patients with elevated CRP.
- OCT 11** SynAct carries out a directed issue of shares and warrants raising initial gross proceeds of SEK 60.5 million.
- OCT 12** SynAct publishes prospectus in connection with admission to trading of new shares on Nasdaq Stockholm.

## The CEO, Torbjørn Bjerke comments on the third quarter

Dear Shareholders,

**We faced some headwinds in the third quarter. Drug development is not an easy enterprise and headwinds are encountered with most programs. We are excited by the progress that we have made despite our own headwinds, and we are excited to take these lessons learned and use them to power our path forward in RA and other important inflammatory diseases.**

While we did not achieve the primary end point objective in the EXPAND study, we were very encouraged by the consistent response seen in the population with elevated C-reactive protein (CRP) at 12-weeks. In particular, the HAQ-DI, a patient-reported measure of the daily disability due to their RA, demonstrated that on average resomelagon patients with elevated CRP improved by almost 3x the level considered to be a clinically important improvement. This improvement was seen predominately in areas of the HAQ-DI that record disability associated with small joints like those in the hands. These findings were supported by data from the MRI sub-study that demonstrated a lower level of synovitis (joint inflammation) which correlated with decreases in tender and swollen joint counts in the hands and wrist.

CRP is a marker of systemic inflammation and is involved in inflammation resolution by binding to dead or dying cells at sites of inflammation to help identify them for removal through a process called efferocytosis. As resomelagon works in part by stimulating macrophages to increase efferocytosis, resomelagon may be working in conjunction with CRP to help resolve inflammation. This is a very relevant population of RA patients and is the population that was recruited in Phase 3 clinical trials with the JAK inhibitors and is a hard inclusion criterion for most RA clinical trials.

We will be announcing the topline results of the RESOLVE P2a trial in RA patients who have had an incomplete response to the traditional first-line disease modifying agent methotrexate

(DMARD-IR patients) within the next few weeks. This was a one-month trial designed to enable dose selection for the Phase 2b portion of the trial. This is the first trial of resomelagon under our US investigational new drug application (IND) that we opened with the FDA last year.

We believe that resomelagon works differently than the existing approved therapies, most of which are immunosuppressive in nature, by stimulating inflammation resolution to help the body restore immune balance. This mode of action could very well be complimentary to approved therapies and with a favorable safety profile, resomelagon could become a go-to combination therapy for patients requiring more efficacy. We will take some time to digest the EXPAND and RESOLVE data (once released) and have discussions with our advisors and clinicians to refine the RESOLVE P2b protocol and to discuss potential additional development initiatives in RA and potentially other attractive indications.

Operating expenses amounted to SEK 31.7m, an increase by SEK 5.2m versus Q3 last year, mainly due to higher costs related to the clinical studies. As we have finished the study recruitments and published key results, the study cost will be less the next few quarters before new studies are up and running.

Recently we successfully completed a directed issue of shares with Heights Capital Management (HCM is a highly regarded investment firm that invests in high growth, publicly listed entrepreneurial companies). The initial proceeds was SEK 60.5 million and with exercise of accompanying warrants we would receive an additional SEK 59.9 million in the future. This will enable SynAct the ability to fully assess and digest the EXPAND and RESOLVE data to effectively plan for next steps in the development of drugs for treatment of RA, investigations of other potential indications and initiate additional work with the TXP assets. This will also provide us time to continue our efforts at finding the right partner for resomelagon.

Once again, we are truly at an exciting inflection point for SynAct.

We have learned a lot about the promise of resomelagon and resolution therapy. While we encountered challenges with the overall results of EXPAND, we observed the consistent efficacy in patients with elevated CRP across all resomelagon trials, an important finding that will be factored into our next development steps. We remain optimistic about the prospects of resomelagon in RA and other inflammatory diseases where significant populations of patients are underserved by existing therapies. We will hold an R&D Day in the fourth quarter to provide an integrated overview of the entire resomelagon program and present our development plan. We will share more details about this event as they become available.

We sincerely appreciate the dedication of our shareholder community, and we remain determined as a management team to deliver on the promise of resomelagon and resolution therapy.

**"We remain optimistic about the prospects of resomelagon in RA and other inflammatory diseases where significant populations of patients are underserved by existing therapies."**

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 affiliates SynAct Pharma ApS and TXP Pharma AG. 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 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.

## Research and Development (continued)

### 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

SynAct has announced results from the phase 2a study of resomelagon (AP1189) in newly diagnosed and previously

untreated RA patients presenting with severe disease activity. 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 anti-rheumatic 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.

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

In continuation of BEGIN, the EXPAND study is 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 involves several exploratory endpoints that are expected to underscore the unique mode of action of resomelagon

### Pipeline overview

ASSET	INDICATION	PRECLINICAL	PHASE 1	PHASE 2A	PHASE 2B	PHASE 3	STATUS & NEXT MILESTONE
Resomelagon (AP1189)	Rheumatoid arthritis - First line treatment	Completed phase	Completed phase	Ongoing phase	Ongoing phase		<ul style="list-style-type: none"> <li>SynAct-CS007 (EXPAND):                             <ul style="list-style-type: none"> <li>Status: Ongoing</li> </ul> </li> <li>Topline data available – September 2023</li> </ul>
	Rheumatoid arthritis - DMARD-IR	Completed phase	Completed phase	Ongoing phase			<ul style="list-style-type: none"> <li>SynAct-CS006 (RESOLVE):                             <ul style="list-style-type: none"> <li>Status: Ongoing</li> </ul> </li> <li>Top line data (Part A) available - October 2023</li> </ul>
	Nephrotic syndrome (iMN)	Completed phase	Completed phase	Ongoing phase			<ul style="list-style-type: none"> <li>SynAct-CS003</li> <li>Status: Ongoing/Recruiting</li> </ul>
	Virus-induced respiratory insufficiency	Completed phase	Completed phase	Ongoing phase			<ul style="list-style-type: none"> <li>Pre-clinical viral disease models</li> </ul>
TXP-11	Prevention of organ failure in complicated surgery	Completed phase	Completed phase				<ul style="list-style-type: none"> <li>Ready for start of clinical development - 2024</li> </ul>
Next generation molecules	Inflammatory diseases	Completed phase	Completed phase				

## Research and Development (continued)

(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 study assessment, was not in line with expectations and seemed to contribute to 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 anti-rheumatic 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 is 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 is 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 study will be reported in October 2023.

### **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) is being 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. Recruitment is ongoing.

### **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.

### **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 2024.



# 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.

January 16, 2023, SynAct Pharma AB completed the acquisition of TXP Pharma AG. The transaction was structured as an issue-in-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. For further information, please refer to Note 14 to the financial statements.

The closing price of the SynAct share on the last trading day in September 2023 was SEK 17.90.

## Ownership (September 30, 2023)

Shareholder	Capital and votes(%)
Bioinvest ApS	11.1%
Avanza Pension	6.4%
Nordnet Pensionsförsäkring	4.6%
Goodwind Holding GmbH	3.7%
Thomas von Koch	3.5%
Torbjörn Bjerke	2.6%
Handelsbanken fonder	2.0%
SEB fonder	1.0%
Swedbank Försäkring	0.8%
Kinkon AB	0.5%
<b>Total (top-10)</b>	<b>36.1%</b>
Others (~17,000)	63.9%

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, 31,820,980.

## 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 5 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 three independent analysts:

**Gonzalo Artiach Castañón**, ABG Sundal Collier AB

**Sebastian van der Schoot**, Van Lanschot Kempen BV

**Patrik Ling**, DNB Markets



### Financial reporting calendar

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

#### Date:

02/23/2024

05/17/2024

05/23/2024

#### Report:

Annual Results 2023

Interim Report Q1 2024

Annual General meeting 2024

# Comments on the financial development for the third quarter and first nine months of 2023

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.

## Net sales

Net sales for the first quarter amounted to SEK 0 (0) thousand. The company is not expected to generate any revenue until after the completion of the ongoing Phase 2 program involving the drug candidate resomelagon (AP1189), at the earliest in 2024.

## Research and development (R&D) costs

Total costs for R&D in the second quarter amounted to SEK 21,660 (20,639) thousand. For the first nine months R&D costs amounted to SEK 94,295 (48,404) thousand. The main reason for the cost increase is the two clinical phase 2 studies, EXPAND and RESOLVE, that were started during 2022 and have been fully active in the first nine months. 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 9,951 (5,740) thousand in the third quarter and SEK 39,079 (26,624) thousand for the nine months. The increase for the first nine months of the year is driven by costs related to the acquisition of TXP Pharma, employee option programs and severance pay to the previous CEO.

## Financial items

Net financial items amounted to SEK -296 (-108) thousand in the third quarter and SEK -300 (-1,328) thousand for the first nine months. The change is attributable to exchange rate adjustments.

## Tax for the period

Tax revenues in the second quarter amounted to SEK 110 (2,650) thousand. For the first nine months the accrued tax credit amounted to SEK 8,468 (7,783) thousand. See Note 9 - Tax receivables for more information.

## Loss for the period

The Group's loss for the third quarter amounted to SEK 31,878 (23,919) thousand and for the first nine months, the reported loss was SEK 125,267 (68,728) thousand.

## Cash flow, financial position and going concern

In connection with the acquisition of TXP Pharma AG, intangible assets corresponding to SEK 226,418 (0) thousand, of which goodwill amounts to SEK 75,156 (0) thousand, and an associated deferred tax liability of SEK 17,909 (0) thousand have arisen and been reported. In addition, the conditional additional purchase price was reported as long-term debt with an assessed fair value of SEK 7,602 (0) thousand. See note 4 - Business combinations for more information on accounting for the TXP acquisition.

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 9 - Tax receivables for more information) amounted to SEK 16,954 (16,149) thousand.

Cash flow from operating activities amounted to SEK -14,653 (-41,335) thousand in the quarter. Year-to-date cash flow for operating activities amounted to SEK -79,782 (-95,249) 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 -153 (-230) thousand in the third quarter. For the first nine months the cash flow from financing activities were SEK -577 (124,686) thousand.

Cash flow for the period amounted to SEK -14,804 (-41,565) thousand and SEK -79,989 (29,438) thousand for the first nine months. The Group's cash and cash equivalents as of September 30, 2023, amounted to SEK 28,876 (54,898) thousand.

The Board of Directors continuously evaluates the Company's financial position and has determined that its current cash and cash equivalents, including the recent share issue, are sufficient

to finance ongoing clinical studies, other communicated activities and keep the Company up and running until the end of 2024.

## Employees

The number of employees was 5 (4) 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 subsidiary and amounted to SEK 2,058 (1,278) thousand in the third quarter and SEK 5,953 (3,834) thousand for the first nine months.

In the Parent Company, net financial items amounted to SEK -280 (-1) thousand in the quarter. Year-to-date, net financial items were SEK -53,213 (-110,298) 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 in the income statement.

The financial fixed assets increased to SEK 232,244 (24,419) thousand as a result of the acquisition of TXP Pharma AG. The increase consists partly of the acquisition value and partly of the transaction costs as described below. The parent company follows the accounting guideline in RFR 2, which for the treatment of acquisition costs, deviates from IFRS. During the quarter, the parent company has capitalized acquisition cost amounting to SEK 10,870 thousand as financial fixed assets.

## Consolidated income statement

SEK (thousand)	Note	2023		2022		2022
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Net sales		-	-	-	-	-
<b>Gross profit</b>		-	-	-	-	-
Research and development costs	5	-21,660	-20,639	-94,295	-48,404	-70,067
General and administration costs	5, 6	-9,951	-5,740	-39,079	-26,624	-35,611
Other operating income/expenses		-81	-83	-61	-155	-28
<b>Total operating expenses</b>		<b>-31,692</b>	<b>-26,461</b>	<b>-133,434</b>	<b>-75,182</b>	<b>-105,705</b>
<b>Operating income</b>		<b>-31,692</b>	<b>-26,461</b>	<b>-133,434</b>	<b>-75,182</b>	<b>-105,705</b>
Net financial items		-296	-108	-300	-1,328	-1,360
<b>Profit after financial items</b>		<b>-31,988</b>	<b>-26,569</b>	<b>-133,734</b>	<b>-76,511</b>	<b>-107,065</b>
Tax on profit/loss for the period	9	110	2,650	8,468	7,783	7,860
<b>Profit for the period</b>		<b>-31,878</b>	<b>-23,919</b>	<b>-125,267</b>	<b>-68,728</b>	<b>-99,205</b>
Earnings per share (SEK)		-1.00	-0.84	-3.96	-2.52	-3.60
Diluted earnings per share (SEK)		-1.00	-0.84	-3.96	-2.52	-3.60
Average number of shares outstanding ('000)	8	31,821	28,371	31,662	27,236	27,585

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	2023		2022		2022
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
<b>Profit for the period</b>		<b>-31,878</b>	<b>-23,919</b>	<b>-125,267</b>	<b>-68,728</b>	<b>-99,205</b>
<b>Items reclassifiable to profit or loss</b>						
Translation differences from foreign operation		-2,659	1,343	13,847	2,518	3,164
<b>Comprehensive income after tax for the period</b>		<b>-34,538</b>	<b>-22,576</b>	<b>-111,420</b>	<b>-66,210</b>	<b>-96,041</b>
<b>Comprehensive income for the period</b>		<b>-34,538</b>	<b>-22,576</b>	<b>-111,420</b>	<b>-66,210</b>	<b>-96,041</b>

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	9/30/2023	9/30/2022	12/31/2022
<b>Assets</b>				
<b>Non-current assets</b>				
Intangible assets	4	226,418	-	-
Right-of-use assets		825	2,309	2,095
Financial assets	12	144	293	270
<b>Total non-current assets</b>		<b>227,387</b>	<b>2,602</b>	<b>2,365</b>
<b>Current assets</b>				
Tax credit	9	16,954	16,149	8,231
Other current receivables		2,018	6,480	6,464
Prepaid expenses	11	690	16,076	17,293
Cash and cash equivalents	12	28,876	54,898	108,245
<b>Total current assets</b>		<b>48,537</b>	<b>93,604</b>	<b>140,232</b>
<b>Total assets</b>		<b>275,925</b>	<b>96,206</b>	<b>142,597</b>

SEK (thousand)	Note	9/30/2023	9/30/2022	12/31/2022
<b>Equity and liabilities</b>				
Share capital	4, 7	3,978	3,546	3,706
Other paid-in capital	4, 5	589,378	318,725	394,839
Reserves		16,612	2,119	2,765
Retained earnings/losses including net profit		-400,057	-244,313	-274,790
<b>Total equity</b>		<b>209,911</b>	<b>80,078</b>	<b>126,520</b>
<b>Non-current liabilities</b>				
Deferred tax liability	4	17,909	-	-
Leasing liability		180	1,302	1,064
Contingent earnout	4	7,602	-	-
Other provision	5, 6	3,324	-	-
<b>Total non-current liabilities</b>		<b>29,015</b>	<b>1,302</b>	<b>1,064</b>
<b>Current liabilities</b>				
Accounts payable	12	8,321	4,901	4,723
Leasing liability		626	963	1,000
Other current liabilities	10	5,117	4,346	4,381
Accrued expenses	11, 12	22,934	4,615	4,909
<b>Total current liabilities</b>		<b>36,998</b>	<b>14,826</b>	<b>15,012</b>
<b>Total equity and liabilities</b>		<b>275,925</b>	<b>96,206</b>	<b>142,597</b>

## Consolidated statement of changes in equity

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

01/01/2023 - 09/30/2023 SEK (thousand)	Share capital	Other paid-in capital	Reserves	Retained earnings, including profit for the period	Total
<b>Opening equity</b>	3,706	394,840	2,765	-274,790	126,520
Profit for the period	-	-	-	-125,267	-125,267
Other comprehensive income	-	-	13,847	-	13,847
<b>Comprehensive income for the period</b>	-	-	13,847	-125,267	-111,420
<b>Transactions with owners</b>					
Issue in kind	272	189,607	-	-	189,879
Employee option program	-	4,932	-	-	4,932
<b>Total transaction with owners</b>	272	194,539	-	-	194,811
<b>Closing equity</b>	3,977	589,379	16,612	-400,057	209,911

## Condensed consolidated statement of cash flows

SEK (thousand)	Note	2023	2022	2023	2022	2022
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
<b>Cash flow from operations</b>						
Operating income		-31,692	-26,461	-133,434	-75,182	-105,705
Adjustment for non-cash items		3,374	225	10,002	755	712
Interest received		-27	-	-	46	47
Interest paid		24	-108	-46	-255	-119
Corporate income tax received/paid		-6	-	-6	-	7,860
<b>Cash flow from operations before change in working capital</b>		<b>-28,327</b>	<b>-26,344</b>	<b>-123,484</b>	<b>-74,636</b>	<b>-97,206</b>
Change in working capital		13,674	-14,992	43,702	-20,612	-20,349
<b>Cash flow from operating activities</b>		<b>-14,653</b>	<b>-41,335</b>	<b>-79,782</b>	<b>-95,249</b>	<b>-117,555</b>
Cash flow from investing activities		2	-	370	-	27
Cash flow from financing activities		-153	-230	-577	124,686	200,712
<b>Cash flow for the period</b>		<b>-14,804</b>	<b>-41,565</b>	<b>-79,989</b>	<b>29,438</b>	<b>83,184</b>
Cash and cash equivalents at beginning of period		44,421	96,465	108,245	23,997	23,997
Decrease/increase in cash and cash equivalents		-14,804	-41,565	-79,989	29,438	83,184
Exchange rate difference in cash and cash equivalents		-741	-3	620	1,463	1,063
<b>Cash and cash equivalents at end of period</b>		<b>28,876</b>	<b>54,898</b>	<b>28,876</b>	<b>54,898</b>	<b>108,245</b>

## Parent company's condensed income statement

SEK (thousand)	Note	2023		2022		2022
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Net sales		2,058	1,278	5,953	3,834	5,144
<b>Gross profit</b>		<b>2,058</b>	<b>1,278</b>	<b>5,953</b>	<b>3,834</b>	<b>5,144</b>
Research and development costs	5	-1,270	-	-2,551	-	-25,726
General and administration costs	5, 6	-7,706	-4,537	-26,348	-22,672	-25,726
Other operating expenses		-58	-21	-46	-189	-90
<b>Total operating expenses</b>		<b>-9,035</b>	<b>-4,557</b>	<b>-28,945</b>	<b>-22,861</b>	<b>-25,815</b>
<b>Operating income</b>		<b>-5,707</b>	<b>-3,279</b>	<b>-20,441</b>	<b>-19,027</b>	<b>-20,671</b>
Net financial items		-280	-1	-53,213	-110,298	-110,299
<b>Profit after financial items</b>		<b>-7,257</b>	<b>-3,281</b>	<b>-76,205</b>	<b>-129,324</b>	<b>-130,970</b>
Tax on profit for the period						-
<b>Profit for the period</b>		<b>-7,257</b>	<b>-3,281</b>	<b>-76,205</b>	<b>-129,324</b>	<b>-130,970</b>

## Parent company's statement of comprehensive income

SEK (thousand)	Note	2023		2022		2022
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Profit for the period		-7,257	-3,281	-76,205	-129,324	-130,970
Other comprehensive income		-	-	-	-	-
<b>Total comprehensive income</b>		<b>-7,257</b>	<b>-3,281</b>	<b>-76,205</b>	<b>-129,324</b>	<b>-130,970</b>

## Parent company's condensed balance sheet

SEK (thousand)	Note	9/30/2023	9/30/2022	12/31/2022
<b>Assets</b>				
<i>Non-current assets</i>				
Financial assets	4	232,244	24,419	24,419
<b>Total non-current assets</b>		<b>232,244</b>	<b>24,419</b>	<b>24,419</b>
<i>Current assets</i>				
Receivables in group companies		3,812	-	-
Other receivables		484	877	2,231
Prepaid expenses		716	235	4,325
Cash and cash equivalents		12,198	17,738	88,250
<b>Total current assets</b>		<b>17,209</b>	<b>18,850</b>	<b>94,806</b>
<b>Total assets</b>		<b>249,454</b>	<b>43,269</b>	<b>119,225</b>

SEK (thousand)	Note	9/30/2023	9/30/2022	12/31/2022
<b>Equity and liabilities</b>				
<i>Restricted equity</i>				
Share capital	4, 7	3,978	3,546	3,706
<i>Non-restricted equity</i>				
Other paid-in capital	4, 5	589,378	318,725	371,624
Retained earnings/losses		-287,418	-156,448	-133,233
Profit for the period		-76,205	-129,324	-130,970
<b>Total equity</b>		<b>229,733</b>	<b>36,499</b>	<b>111,127</b>
<i>Non-current liabilities</i>				
Contingent earnout	4	7,602	-	-
Other provisions	5, 6	3,324	-	-
<b>Total non-current liabilities</b>		<b>10,926</b>	<b>-</b>	<b>-</b>
<i>Current liabilities</i>				
Accounts payable		1,108	147	1,072
Other liabilities	10	4,089	4,042	4,044
Accrued expenses		3,598	2,581	2,981
<b>Total current liabilities</b>		<b>8,794</b>	<b>6,770</b>	<b>8,098</b>
<b>Total equity and liabilities</b>		<b>249,454</b>	<b>43,269</b>	<b>119,225</b>



## 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 24, 2023.

### 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 presupposes additional capital. After analyzing and evaluating various financing alternatives, the Board of Directors decided on October 11 to carry out a directed issue of SEK 60.5 million before issue costs and the issuance of warrants which, if fully exercised, will provide the company with additional proceeds of SEK 59.9 million.

Even if this financing risk is mitigated in the short term, the Company's operations presuppose 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 third 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 clinical trials ongoing in 2020 and 2021 with delays in patient recruitment. With regard to current study program, the assessment is that the pandemic (as it is currently occurring) should not significantly affect the recruitment to and implementation of the studies.

## Notes and disclosures (continued)

### 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 3 875 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
<b>Total purchase consideration</b>	<b>196,956</b>

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. 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 below 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
<b>Total net assets acquired excluding goodwill</b>	<b>126,002</b>
Goodwill	70,954
<b>Total net assets acquired</b>	<b>196,956</b>
Less	
Ordinary shares issued	-189,879
Provision for earnout	-7,077
Received cash and cash equivalents	236
<b>Net cash outflow/effect on cash and cash equivalents on acquisition of business</b>	<b>236</b>

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.

The intangible assets will be subject to customary impairment testing in accordance with IAS 36. 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.

## Notes and disclosures (continued)

### Note 5 - 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
<b>Allotted instruments</b>	Jul-Sep	Jan-Sep	
ESOP 2023 I	-	195,000	195,000
ESOP 2023 II	-	404,000	404,000
<b>Recalled/voided instruments</b>			
ESOP 2023 I	-	-90,000	-90,000
<b>Instruments decided, not allocated</b>			
ESOP 2023 II	-	65,000	65,000
<b>Change</b>			
ESOP 2023 I	-	105,000	105,000
ESOP 2023 II	-	469,000	469,000

Maximum number of shares to which allocated options can entitle	9/30/2023
ESOP 2023 I	105,000
ESOP 2023 II	469,000
<b>Total Employee Option</b>	<b>574,000</b>

As of September 30, 2023, SynAct had 31,820,980 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 1.45%.

The costs for the programs are estimated at SEK 22,703 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 2023, the costs for the employee option programs amounted to SEK 3,468 thousand (0) and the costs for nine months have amounted to SEK 5,657 thousand (0).

## Notes and disclosures (continued)

### Note 6 - 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	2022
Related party	Service	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
UST Leadership AB (Torbjørn Bjerke, former chairman)	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.

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 13, 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, Torbjørn 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 2,560 thousand.

### Note 7 - 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.

### Note 8 - Number of registered shares

Thousand	2023	2022	2023	2022	2022
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Number of shares at the beginning of the period	31,821	28,371	29,648	26,006	26,006
Number of shares at the end of the period	31,821	28,371	31,821	28,371	29,648
Average number of shares outstanding in the period	31,821	28,371	31,662	27,236	27,585

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

### Note 9 - Tax receivables

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

The claim on the Danish tax authorities that follows from this scheme amounted to SEK 16,954 thousand (16,149). The balance related to fiscal year 2022 with an amount of SEK 8,231 thousand is expected to be received in November 2023.

### Note 10 - 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.

## Notes and disclosures (continued)

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 11 - Prepaid and accrued expenses

The company reports prepaid expenses of SEK 690 thousand (16,076). The decrease since the comparison period is mainly due to the initial payments to the CRO handling the two ongoing clinical studies SynAct-CS006 (RESOLVE) and SynAct-CS007 (EXPAND).

The company reports accrued expenses of SEK 22,934 thousand (4,615). The increase is partly due to increased activity in the two ongoing clinical studies SynAct-CS006 (RESOLVE) and SynAct-CS007 (EXPAND) and thus increased accrued costs.

### Note 12 - Financial assets and liabilities

SEK (thousand)	09/30/2023	09/30/2022	12/31/2022
<b>Financial assets</b>			
Non-current financial assets	144	293	270
Other current receivables	-	-	1,560
Cash and cash equivalents	28,876	54,898	108,245
<b>Total financial assets</b>	<b>29,020</b>	<b>55,191</b>	<b>110,075</b>
<b>Financial liabilities</b>			
Accounts payable	8,321	4,901	4,723
Accrued expenses	22,934	4,615	4,909
<b>Total financial liabilities</b>	<b>31,256</b>	<b>9,517</b>	<b>9,632</b>

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 13 - 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 at the end of 2023 and have a cash flow effect no earlier than 2025.

### Note 14 - Events occurring after the reporting period

The board of directors of SynAct has, based on the authorization granted by the annual general meeting held on 25 May 2023, resolved on a directed issue comprising a total of 3,750,000 new shares and 3,375,000 warrants. The shares in the directed share issue are issued at a subscription price of SEK 16.14 per share. The warrants are issued free of charge and each warrant entitles the holder to subscribe for one share and can be exercised up to four times until and including 13 October 2025 at a subscription price of SEK 17.75 per share. Through the directed share issue, the Company will receive initial proceeds of approximately SEK 60.5 million before transaction costs and will, upon full exercise of all warrants, receive additional proceeds of up to approximately SEK 59.9 million.

Through the directed share issue, the number of shares and votes in the Company will increase by 3,750,000 from 31,820,980 to 35,570,980 shares. The share capital will increase by SEK 468,750 from SEK 3,977,622.50 to SEK 4,446,372.50. The directed share issue entails a dilution of approximately 10.5% based on the number of shares and votes in the Company after the directed issue. If all warrants issued in connection with the directed issue are exercised for subscription of new shares in the Company, the number of shares and votes will further increase by 3,375,000 to 38,945,980 shares and the share capital will further increase by SEK 421,875 to SEK 4,868,247.50. This corresponds to an additional dilution effect from the warrants of a maximum of approximately 8.7%.

The Board of Directors of SynAct has, in connection with the directed issue of shares, prepared a simplified prospectus for the admission to trading of the new shares on Nasdaq Stockholm.

## Alternative performance measures - APM

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

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

### Equity / asset ratio

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

#	SEK (thousand)	9/30/2023	9/30/2022	12/31/2022
	<b>Assets</b>			
	Total non-current assets	227,387	2,602	2,365
	Total current assets	48,537	93,604	140,232
[1]	<b>Total assets</b>	<b>275,925</b>	<b>96,206</b>	<b>142,597</b>
	<b>Equity and liabilities</b>			
[2]	<b>Total equity</b>	<b>209,911</b>	<b>80,078</b>	<b>126,520</b>
	Total non-current liabilities	29,015	1,302	1,064
	Total current liabilities	36,998	14,826	15,012
	<b>Total liabilities</b>	<b>66,014</b>	<b>16,128</b>	<b>16,077</b>
	<b>Total equity and liabilities</b>	<b>275,925</b>	<b>96,206</b>	<b>142,597</b>
[2] / [1]	<b>Equity / asset ratio (%)</b>	<b>76%</b>	<b>83%</b>	<b>89%</b>

### 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)	2023	2022	2023	2022	2022
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
[1]	Research and development costs	-21,660	-20,639	-94,295	-48,404	-70,067
	General and administration costs	-9,951	-5,740	-39,079	-26,624	-35,611
	Other operating income / expense	-81	-83	-61	-155	-28
[2]	<b>Total operating expenses</b>	<b>-31,692</b>	<b>-26,461</b>	<b>-133,434</b>	<b>-75,182</b>	<b>-105,705</b>
[1] / [2]	<b>Research and development costs / operating expenses (%)</b>	<b>68%</b>	<b>78%</b>	<b>71%</b>	<b>64%</b>	<b>66%</b>

## The CEO declaration

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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 24 2023

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**Torbjørn Bjerke**  
Chief Executive Officer (CEO)

## The Auditor's Review Report

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### Introduction

We have reviewed the summarized interim financial information for SynAct Pharma AB (publ) on September 30, 2023 and for the nine-month period then ended. The board of directors and the CEO 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 the International Standard on Review Engagements ISRE 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review 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 the International Standards on Auditing, ISA, and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

### 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's part according to IAS 34 and the Annual Accounts Act and for the parent Company's part according to the Annual Accounts Act.

Malmö, October 24, 2023

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**Linda Bengtsson**  
KPMG AB  
Authorized Public Accountant

## Glossary

### ACE inhibitor

A group of drugs that lower blood pressure by inhibiting the enzyme 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 Measures. 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) was 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 its four-week treatment period.

### cAMP

Cyclic adenosine monophosphate (cAMP, cyclic AMP, or 3',5'-cyclic adenosine monophosphate) is a second messenger important in many biological processes. cAMP is a derivative of adenosine triphosphate (ATP) and used for intracellular signal transduction in many different organisms, conveying the cAMP-dependent pathway.

### Clinical study

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

### CMC

CMC is an acronym for chemistry, manufacturing and controls, which are crucial activities in the development of new pharmaceutical products. In addition to the processes themselves, CMC also refers to practices and specifications that must be followed and complied with to ensure product safety and consistency between batches.

### Contract Research Organization (CRO)

In the life sciences, a contract research organization (CRO) is a company that provides support to the pharmaceutical, biotechnology, and medical device industries in the form of research services outsourced on a contract basis. A CRO may provide such services as biopharmaceutical development, biologic assay development, commercialization, clinical development, clinical trials management, pharmacovigilance, outcomes research, and real world evidence.

### DMARD

Disease-modifying anti-rheumatic drugs (DMARDs) are a category of otherwise unrelated drugs that are 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. The term overlaps with antirheumatics, but the two terms are not synonyms.

### 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 Administration responsible for food (for humans and animals), dietary supplements, medicines (for humans and animals), cosmetics, medical equipment (for humans and animals), radioactive radiation 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.



## Glossary (continued)

### 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 inflammation) and stimulation of healing processes (dead cells and cell debris are cleaned away and the tissue heals).

### Melanocyte-stimulating hormone (MSH)

MSH is a group of peptide hormones with receptors on melanocytes. Three different molecules have been able to be verified: alpha-MSH, beta-MSH and gamma-MSH. The first variant, alpha-MSH, is the most active.

### Methotrexate (MTX)

Methotrexate is a folic acid antagonist that belongs to the group of chemotherapy drugs. 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 (sometimes abbreviated NS) is a syndrome (a collection of symptoms) due to 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 mono-peptides) 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 Ras-Raf-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 is the study of the metabolism of drugs in the body, i.e., how the levels of a drug in the body change through absorption, distribution, metabolism and excretion.

### 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.

### 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 leading drug candidate AP1189 is the promotion of inflammatory resolution by 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 affects these cells to produce fewer inflammation-driving molecules and is also able to change them to initiate cleaning 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 autoimmune diseases and the clinical potential is 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 global regulator.

### RESOVIR (Resolution Therapy for Viral Inflammation Research) collaboration

RESOVIR 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 the London School of Medicine, Queen Mary University, London, UK, and SynAct Pharma AB. 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	<a href="http://www.synactpharma.com">www.synactpharma.com</a>
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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