

# INTERIM REPORT

January - March 2023

SYNACT  PHARMA

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

# Q1

This English version of SynAct Pharma's Interim Report for the first quarter 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](http://www.synactpharma.com)

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## SynAct Pharma AB

Visiting address:  
Scheelevägen 2  
223 63 Lund, Sweden

Postal:  
Scheelevägen 2  
223 63 Lund, Sweden

+45 28 44 75 67

joo@synactpharma.com

Significant events in  
the first quarter

p. 4

CEO Jeppe Øvlesen  
comments on the  
first quarter

p. 5



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

[www.synactpharma.com](http://www.synactpharma.com)

## Interim report for the first quarter 2023



### Quarter 1 (January - March)

- The Group's net sales amounted to SEK 0 (0) thousand, which is in line with expectations given the development phase that SynAct's projects are in. The Company is not expected to generate any revenues until after the completion of the clinical phase 2 program for the drug candidate resomelagon (AP1189), at the earliest in 2024.
- Operating expenses amounted to SEK 58,248 (22,304) thousand, an increase of 161%, driven mainly by the two clinical studies in RA and higher administrative costs derived from the acquisition of TXP Pharma AG. TXP Pharma is consolidated into the Group's reports as of this first quarter 2023.
- The Group's loss after tax amounted to SEK 49,878 (20,055) thousand.

- Profit after tax is improved by the effect that arises because of the Danish tax credit scheme, which means an early tax refund related to part of the research and development costs incurred. The effect of this tax credit was SEK 8,268 (2,262) thousand in the quarter.
- The Group's earnings per share before and after dilution amounted to SEK -1.59 (-0.77).
- Cash flow from operating activities amounted to SEK -30,472 (-16,991) thousand.
- Cash flow from financing activities amounted to SEK -246 (-242) thousand.
- Cash flow for the period amounted to SEK -30,482 (-17,233) thousand.
- Cash and cash equivalents at the end of the period amounted to SEK 78,214 (6,806) thousand.

### The Group's financial performance per quarter

(SEK thousand)	2023 Q1	2022 Q4	2022 Q3	2022 Q2	2022 Q1	2021 Q4	2021 Q3	2021 Q2
Net sales	-	-	-	-	-	-	-	-
Operating income	-58,248	-30,523	-26,461	-26,417	-22,304	-26,153	-20,885	-15,603
Profit before tax	-58,146	-30,554	-26,569	-27,625	-22,317	-26,207	-20,676	-15,856
Profit for the period	-49,878	-30,477	-23,919	-24,754	-20,055	-26,210	-18,222	-13,137
Total assets	320,999	142,597	96,206	133,972	22,155	38,369	59,836	75,273
Equity / asset ratio (%) <sup>1</sup>	84%	89%	83%	77%	3%	54%	79%	87%
Earnings per share (SEK)	-1.59	-1.06	-0.84	-0.91	-0.77	-1.01	-0.70	-0.51
Research & development cost / operating expenses (%) <sup>1</sup>	75%	71%	78%	54%	60%	77%	78%	83%

1) Alternative performance measures - APM, ref. p. 23 for definitions



"SynAct Pharma AB" means the parent company SynAct Pharma AB with corporate registration number 559058-4826. The "Company" or "SynAct" means the Group i.e., SynAct Pharma AB and its wholly owned affiliates SynAct Pharma ApS and TXP Pharma AG.

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.

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



## The CEO, Jeppe Øvlesen comments on the first quarter

# Continued progress in strengthened pipeline and change of guards

**SynAct Pharma had an eventful first quarter as the company continued to progress its pipeline with the lead compound resomelagon (AP1189) and worked to incorporate the assets from the newly acquired TXP Pharma. 2023 promises to be an eventful year for the company, and we are happy to say SynAct's studies are progressing as planned.**

The company's acquisition of TXP Pharma and the SEK 80 million investment from Thomas von Koch and Christian Kinch at the end of 2022 were key drivers for us heading into the first quarter. Our leading position within therapies for resolution treatment through melanocortin biology got a significant lift by combining the pipeline and scientific capabilities of TXP and SynAct, providing us a full range of inflammatory and autoimmune diseases with two complementary platforms. The development program in rheumatoid arthritis (RA) remains our focus, but we now have a much broader platform for long-term growth.

Our efforts with rheumatoid arthritis and the lead compound resomelagon, the new generic name for AP1189, continued to progress as planned.

At the end of April, we enrolled the last patient in Moldova and in Bulgaria in the Phase 2b EXPAND study in RA using resomelagon

(AP1189). The EXPAND study follows the successful results from the BEGIN study that showed resomelagon (AP1189) to be safe, well tolerated and induce a statistically significant reduction in disease.

To support the position of resomelagon (AP1189) as a novel compound with a unique mode of action in resolution of inflammation, several exploratory endpoints are included in EXPAND, such as MRI-scanning of affected joints. The completion of recruitment well before what we originally planned brings us in a very good position to continue our partnering discussions and accelerate our further development plan for resomelagon (AP1189) where data from EXPAND will be pivotal.

We also continued to enroll patients with inadequate response to disease-modifying antirheumatic drugs (DMARD-IR) in part A of the clinical Phase 2a/b study RESOLVE. 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.

This is important for SynAct, and we look very much forward to the results planned to be reported in the second half of 2023. As mentioned before, incorporating US clinics in the development program is important for our discussions with potential business partners, while also opening the US market, the world's most important market where rheumatoid arthritis has an estimated market value of about USD 20 billion annually.

After the end of the quarter, SynAct announced Torbjørn Bjerke, currently chairman, was appointed the company's new chief executive officer, effective as from the annual general meeting on May 25. I can assure everyone that I plan to be a committed, long-term shareholder, and as an entrepreneur, it has been a fantastic journey for me to help build and lead SynAct over the past nine years. I am confident SynAct will be in great hands with Torbjørn as CEO as the company moves into its next phase of growth. Also, Uli Hacksell was proposed new Chairman of the Board and Thomas von Koch was proposed as a new board member, ensuring we have the right leadership to help guide SynAct.

In the first quarter, our operating expenses were SEK 58 million, an increase of 161% over the same period last year. R&D investments were SEK 44 million or 30 MSEK higher than Q1 2022, driven by our key clinical studies running at full steam. Due to the acquisition of TXP Pharma, we incurred higher Administration costs than predicted, or SEK 15 million in the quarter, up 67% from the same period last year.

2023 will be a critical year for SynAct as we get results from both the RESOLVE and EXPAND studies in the second half. As mentioned, we are progressing as planned and look forward to the data later this year.

This is an exciting time for SynAct, and the team is working hard to position the company for success. We have accomplished so much over the past decade. I have thoroughly enjoyed the challenge and am confident the company is on the right path and in good hands. I want to thank all investors and other stakeholders who have supported the company during this journey. I look forward to continuing to follow SynAct in the years to come.

**"I want to thank all investors and other stakeholders who have supported the company during this journey. I look forward to continuing to follow SynAct in the years to come."**

Jeppe Øvlesen  
CEO



# SynAct Pharma in Brief

## About SynAct Pharma AB

SynAct Pharma AB is a biotech company in clinical phase listed on Nasdaq Stockholm's main market. The company's leading drug candidate, resomelagon (AP1189), is a "First-in-Class" melanocortin receptor agonist focused on active inflammatory and autoimmune diseases. The company's research and patents are based on the endogenous hormone, melanocortin, which is activated in inflammatory conditions and contributes anti-inflammatory effects, which are important components of the healing process and for recovery to normal tissue function.

## 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 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. In addition to the above, SynAct has no additional shareholdings in other companies.

## The acquisition of TXP Pharma AG

On December 12, 2022, SynAct announced the proposed acquisition of the privately owned Swiss biotech company TXP Pharma AG. The transaction, which was conditional upon the approval of the shareholders of SynAct Pharma AB on January 12 was formally closed on January 16, 2023.

TXP Pharma AG was incorporated in 2013 and has its base in Baar in the Zug kanton in Switzerland. It has generated a platform of more than 70 unique analogs to the naturally occurring melanocyte stimulating hormone (MSH). MSH is a melanocortin peptide that is produced by the body to help regulate immune and other systems. The peptides are modified using a proprietary technology to enhance receptor selectivity and stability.

TXP Pharma's patent portfolio is 100% owned and controlled by the company with the lead program being TXP-11. TXP-11 is currently in late pre-clinical phase, expected to enter into clinical testing within a year. Its primary indication is prevention of post-operative organ dysfunction and failure, which is associated with in-hospital mortality and high healthcare system costs.

In addition, TXP Pharma's pre-clinical pipeline consists of several promising assets that have potential to be developed for a wide range of indications where melanocortin receptor stimulating agents have been shown to work and that represents high unmet medical need and great value opportunities.

The acquisition significantly expands SynAct's melanocortin technology portfolio with complimentary peptide agonists that can be tailored to a wide range of autoimmune and inflammatory conditions.

Among the sellers of TXP Pharma AG were, directly and indirectly, Torbjørn Bjerke, chairman of the board of directors of SynAct, Jeppe Øvlesen, CEO of SynAct, Thomas Jonassen, board member and CSO of SynAct, Thomas Boesen, COO of SynAct and Jim Knight, CBO of SynAct. It has therefore been handled as a related party transaction governed by a committee composed of the four non-conflicted members of the board of directors, chaired by Uli Hacksell. In its work, the committee has been supported by legal and financial advisors and has also obtained a third-party valuation of TXP's assets as well as a so-called fairness opinion issued by Ernst & Young AB.

Following due diligence and negotiation, the agreed purchase price for the acquisition was composed of an initial purchase price of SEK 136 million and a potential additional purchase price of SEK 55 million. The initial purchase price was to be paid through the issuance of in the aggregate 2,172,523 new issued consideration shares in SynAct. In determining the number of shares issued, a settlement price of SEK 62.60 per share (corresponding to the volume-weighted average price of the Company's shares on Nasdaq Stockholm during 30 trading days

up to and including the trading day prior to the date of signing of the share purchase agreement) was used.

The additional purchase price is a one-time amount of SEK 55 million which will be payable, in cash or in new shares in SynAct at the discretion of SynAct, if or when the first of a set of conditions are met; (i) SynAct's board of directors, following the completion of the first Phase 2 study with one of TXP's compounds, resolves to continue the development of said compound for a subsequent Phase 2b or a Phase 3 study or if an application to commence such studies is filed; (ii) TXP divests or licenses one of TXP's compounds; or (iii) SynAct divests the shares in TXP.

TXP Pharma AG has been consolidated into the financial reporting of SynAct Pharma AB as of this first quarter 2023.

Please refer to note 4 to the financial statements for more information on the transaction.

## Review by the Company's Auditor

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

## Annual General Meeting

The Annual General Meeting will be held on May 25, 2023 at 1 p.m. at Setterwalls Advokatbyrå, Stortorget 23, 211 34 Malmö. Shareholders wishing to attend must be registered in the company's share register kept by Euroclear Sweden AB as of May 16, 2023, and have notified their participation to the company no later than May 19. The notice has been issued in Post- och Inrikes Tidningar and is available on the Company website.

## 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 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.

## 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			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 - H2 2023</li> </ul>
	Rheumatoid arthritis - DMARD-IR	Completed phase		Ongoing phase			<ul style="list-style-type: none"> <li>SynAct-CS006 (RESOLVE):                             <ul style="list-style-type: none"> <li>Status: Ongoing/Recruiting</li> </ul> </li> <li>Top line data (Part A) available - H2 2023</li> </ul>
	Nephrotic syndrome (iMN)	Completed phase		Ongoing phase			<ul style="list-style-type: none"> <li>SynAct-CS003                             <ul style="list-style-type: none"> <li>Status: Ongoing/Recruiting</li> </ul> </li> <li>Top line data available - H2 2023</li> </ul>
	Virus-induced respiratory insufficiency	Completed 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					<ul style="list-style-type: none"> <li>Ready for start of clinical development - 2024</li> </ul>
Next generation molecules	Inflammatory diseases	Completed phase					

## Research and Development (continued)

MC2R also exerts anti-inflammatory effects but these effects are indirect. MC2R is predominantly located in the adrenal glands and its stimulation causes the adrenals to release cortisol, the body's 'natural' steroid—a powerful anti-inflammatory and immunosuppressive molecule. Some melanocortin peptides like adrenocorticotrophic hormone (ACTH) are potent MC2R activators and can cause significant safety, side effect, and tolerability issues that are common with steroid therapies like prednisone. SynAct's selective melanocortin agonists do not activate MC2R and do not cause cortisol release.

### Resomelagon (AP1189)

SynAct is developing selective melanocortin therapeutics to address inflammatory and autoimmune diseases characterized by excessive or chronic inflammation. SynAct's lead drug candidate, resomelagon (AP1189), is an oral selective melanocortin agonist that was designed to stimulate MC1R and MC3R, but not MC2R, to help resolve excessive inflammation without steroid side effect and safety issues. Resomelagon (AP1189) is a biased agonist that stimulates MC1R and MC3R through the activation of the pERK signaling pathway rather than the cAMP pathway which is the classical approach. The 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.

### 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 a 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 typically used as a first line therapy. MTX tends to work well in most patients, but it can take up to 6-8 weeks for the drug to take full effect, and up to 40% of patients will not achieve a full response to MTX therapy and will require dose escalation or the addition of additional drugs like biological therapies which can induce a higher degree of immunosuppression.

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.

### Continued development

The company has initiated two additional Phase 2 clinical studies in RA with resomelagon (AP1189).

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

The EXPAND study is designed to test the treatment effect of 12-weeks of resomelagon (AP1189) 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 (AP1189). This study will utilize the newly developed solid tablet formulation of resomelagon (AP1189) and will dose for 12-weeks as opposed to the 4-weeks of dosing in the BEGIN trial. The Company conducts the study at clinics in Europe in a cost-efficient approach with the aim to report key results second half of 2023. The study started in September 2022 and recruitment of patients was completed in April 2023.

### 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

A large percentage of patients treated with DMARDs never achieve the full desired effect, have a diminishing treatment effect, or suffer from side effects that can prevent further treatment. These patients who experience an inadequate response to DMARDs are referred to as DMARD-IR (inadequate responder).

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.

## Research and Development (continued)

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. Recruitment of patients is ongoing and results from part A is expected in the second half of 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. The edemas can develop in the hands, feet, ankles, and face. Edemas can even develop in the lungs where it is associated with dyspnea (shortness of breath).

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).

Idiopathic Membranous nephropathy (iMN) is one of the frequent causes of NS. iMN can be primary or it can be secondary to other diseases, including systemic lupus (lupus nephritis), cancer or seen following treatment with certain drugs.

### Clinical development of AP1189 in iMN

Resomelagon (AP1189) is being tested 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 effect on urinary proteing excretion. Recruitment is ongoing.

### Virus Induced Respiratory Insufficiency (VIRI)

Virus infected patients can develop a variety of symptoms, but lung involvement is very common and in some viral infections like COVID-19 it can be the leading cause of death. Patients can develop respiratory insufficiency where they are unable to provide enough oxygen to the body and these patients require oxygen supplementation in order to maintain adequate levels. As respiratory insufficiency continues it can cause severe pneumonia and can also develop into acute respiratory distress syndrome (ARDS), a very serious condition where patients often require mechanical ventilation in order to breathe adequately.

Viral or secondary bacterial infections can also cause the immune system to be highly overly active and produce excessive quantities of pro-inflammatory molecules (a 'cytokine storm', also known as Systemic Inflammatory Distress Syndrome or SIDS) which can cause damage to key organ systems like the lungs, kidneys and heart.

Viral infections can cause significant respiratory issues. In order to prevent the inflammation-associated damage that viral infections can cause, it is important to resolve the excessive inflammation without suppressing the immune system's ability to fight the viral infection. The goal of therapy would be to arrest the excessive inflammation and prevent severe disease.

### Clinical development of AP1189 in VIRI

As part of the RESOVIR collaboration, 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 (experiencing respiratory insufficiency). AP1189 or placebo was administered orally once-daily for 2 weeks.

Patients treated with 100mg resomelagon (AP1189) orally once-daily for 2-weeks achieved respiratory recovery (no longer requiring oxygen therapy) on average 3.5 days (35%) quicker than placebo treated patients (6.4 days and 9.9 days on average respectively).

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.

### Next Steps for AP1189 in virus-induced respiratory insufficiency

Further clinical development in the COVID-19 infected patient population was deemed less viable.

There is still an unmet medical need in virus-induced respiratory insufficiency associated with common annual or seasonal viral infections such as viral pneumonia and or influenza. The company has initiated pre-clinical pharmacological studies in virus models with the aim of informing decisions on next steps for the program including the design of any potential next clinical study.

### Peptide Agonists

SynAct expanded its melanocortin agonist portfolio through the acquisition of TXP Pharma. TXP was a privately held, Swiss-incorporated biotech company researching and developing pharmaceutical drugs for autoimmune and inflammatory diseases by stimulation of melanocortin receptors. TXP has created a platform of more than 70 unique analogs of the naturally occurring melanocyte stimulation hormone (MSH) with a range of melanocortin receptor selectivity. The TXP analogs have both increased stability as well as enhanced receptor binding and stimulation over MSH.

### TXP-11

TXP-11 has completed regulatory toxicology studies required to initiate Phase 1 studies in humans. TXP-11 is a peptide which is administered intravenously and is being developed for the prevention of organ failure and damage in connection with major surgeries. TXP-11 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 which 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.

The closing price of the SynAct share on the last trading day in March 2023 was SEK 71.90.

## Share-based incentive programs

At the extraordinary general meeting on January 12, 2023, the board's proposal for a staff option program for two senior executives and one other employee was adopted. This program has impacted the financial results of the Group and Parent Company. Please refer to note 5 to the financial statements for further information.

## Ownership (March 31, 2023)

Shareholder	Capital and votes(%)
Bioinvest ApS	11.8%
Avanza Pension	6.0%
Nordnet Pensionsförsäkring	4.8%
Goodwind Holding GmbH	3.7%
Thomas von Koch	3.5%
Torbjörn Bjerke	2.6%
Quantum Leben AG	1.3%
Handelsbanken fonder	1.1%
Henrik Stage	0.8%
Swedbank Försäkring	0.8%
<b>Total (top-10)</b>	<b>36.4%</b>
<b>Others (~14,000)</b>	<b>63.6%</b>

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.

## Lock-up agreement

The board with Torbjörn Bjerke, Kerstin Hasselgren, Terje Kalland, Uli Hacksell, Marina Bozilenko and Thomas Jonassen and the management with Jeppe Øvlesen, Patrik Renblad, Thomas Boesen and Jim Knight have all entered into lock-in agreements, that with certain exceptions prohibited the sale of shares until the end of July 2022 and allowed sales of a maximum of 10% for three months until October 24, 2022.

In connection with the directed share issue in December 2022, new lock-in agreements were entered into for all members of the board and management. The new agreements are valid until March 15, 2023 with similar conditions as before.

The agreements above were entered between the respective directors & executives and the banks ABG Sundal Collier AB and Van Lanschot Kempen N.V.

In connection with the acquisition of TXP Pharma AG, the Company entered agreements with the sellers, that banned the sale of consideration shares for 90 days from the acquisition date January 16 through April 16, 2023.

The lock-up agreements did not affect the results or financial position of the Group.



## Analyst coverage

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

- Gonzalo Artiach Castañón från ABG Sundal Collier AB
- Sebastian van der Schoot från Van Lanschot Kempen BV



## Financial reporting calendar

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

### Date:

05/25/2023

08/04/2023

11/03/2023

### Report:

Annual General Meeting 2023

Interim Report Q2 2023

Interim Report Q3 2023

## Comments on the financial development for the first quarter of 2023

### 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 first quarter amounted to SEK 43,596 (13,490) thousand. The main reason for the cost increase is the two new clinical phase 2 studies, EXPAND and RESOLVE, that were started during 2022 and have been fully active in the first quarter. 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.

The reported costs for the two key clinical studies with resomelagon (AP1189) peaked in the quarter and are expected to be reduced in the second quarter.

### Administration costs

Administrative expenses amounted to SEK 14,647 (8,758) thousand in the first quarter. The increase is driven by costs related to the TXP Pharma acquisition.

### Financial items

Net financial items amounted to SEK 102 (-13) thousand in the first quarter. The change is attributable to exchange rate adjustments.

### Tax for the period

Tax revenues in the first quarter amounted to SEK 8,268 (2,262) thousand. See Note 9 - Tax receivables for more information.

### Loss for the period

The Group's loss for the first quarter amounted to SEK 49,878 (20,055) thousand.

### Cash flow, financial position and going concern

In connection with the acquisition of TXP Pharma AG, intangible

assets corresponding to SEK 215,228 (0) thousand, of which goodwill amounts to SEK 70,954 thousand, and an associated deferred tax liability of SEK 17,024 (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 7,248 (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 16,652 (9,877) thousand.

Cash flow from operating activities amounted to SEK -30,472 (-16,991) thousand in the quarter. The increase 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 -246 (-242) thousand in the first quarter.

Cash flow for the period amounted to SEK -30,482 (-17,233) thousand.

The Group's cash and cash equivalents as of March 31, 2023, amounted to SEK 78,214 (6,806) thousand.

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

### Employees

The number of employees was 5 (4). Three 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 0 (1,294) thousand in the first quarter.

In the Parent Company, net financial items amounted to SEK -53,371 (-14,238) thousand in the quarter. 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
		Jan-Mar	Jan-Mar	Jan-Dec
Net sales		-	-	-
<b>Gross profit</b>		-	-	-
Research and development costs	5	-43,596	-13,490	-70,067
General and administration costs	5, 6	-14,647	-8,758	-35,611
Other operating income/expenses		-4	-56	-28
<b>Total operating expenses</b>		<b>-58,248</b>	<b>-22,304</b>	<b>-105,705</b>
<b>Operating income</b>		<b>-58,248</b>	<b>-22,304</b>	<b>-105,705</b>
Net financial items		102	-13	-1,360
<b>Profit after financial items</b>		<b>-58,146</b>	<b>-22,317</b>	<b>-107,065</b>
Tax on profit/loss for the period	9	8,268	2,262	7,860
<b>Profit for the period</b>		<b>-49,878</b>	<b>-20,055</b>	<b>-99,205</b>
Earnings per share (SEK)		-1.59	-0.77	-3.60
Diluted earnings per share (SEK)		-1.59	-0.77	-3.60
Average number of shares outstanding ('000)	8	31,338	26,006	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
		Jan-Mar	Jan-Mar	Jan-Dec
<b>Profit for the period</b>		<b>-49,878</b>	<b>-20,055</b>	<b>-99,205</b>
<b>Items reclassifiable to profit or loss</b>				
Translation differences from foreign operation		1,635	-57	3,164
<b>Comprehensive income after tax for the period</b>		<b>-48,243</b>	<b>-20,111</b>	<b>-96,041</b>
<b>Comprehensive income for the period</b>		<b>-48,243</b>	<b>-20,111</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	3/31/2023	3/31/2022	12/31/2022
<b>Assets</b>				
<b>Non-current assets</b>				
Intangible assets	4	215,228	-	-
Right-of-use assets		1,861	2,944	2,095
Financial assets	12	273	277	270
<b>Total non-current assets</b>		<b>217,362</b>	<b>3,222</b>	<b>2,365</b>
<b>Current assets</b>				
Tax credit	9	16,652	9,877	8,231
Other current receivables		8,301	2,097	6,464
Prepaid expenses	11	470	153	17,293
Cash and cash equivalents	12	78,214	6,806	108,245
<b>Total current assets</b>		<b>103,637</b>	<b>18,933</b>	<b>140,232</b>
<b>Total assets</b>		<b>320,999</b>	<b>22,155</b>	<b>142,597</b>

SEK (thousand)	Note	3/31/2023	3/31/2022	12/31/2022
<b>Equity and liabilities</b>				
Share capital	4, 7	3,978	3,251	3,706
Other paid-in capital	4, 5	585,047	193,602	394,839
Reserves		4,400	-455	2,765
Retained earnings/losses including net profit		-324,668	-195,640	-274,790
<b>Total equity</b>		<b>268,756</b>	<b>758</b>	<b>126,520</b>
<b>Non-current liabilities</b>				
Deferred tax liability	4	17,024	-	-
Leasing liability		806	1,870	1,064
Contingent earnout	4	7,248	-	-
<b>Total non-current liabilities</b>		<b>25,079</b>	<b>1,870</b>	<b>1,064</b>
<b>Current liabilities</b>				
Accounts payable	12	10,087	3,672	4,723
Leasing liability		1,032	1,010	1,000
Other current liabilities	10	4,426	6,542	4,381
Accrued expenses	11, 12	11,619	8,303	4,909
<b>Total current liabilities</b>		<b>27,164</b>	<b>19,527</b>	<b>15,012</b>
<b>Total equity and liabilities</b>		<b>320,999</b>	<b>22,155</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 - 03/31/2023 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	-	-	-	-49,878	-49,878
Other comprehensive income	-	-	1,635	-	1,635
<b>Comprehensive income for the period</b>	-	-	1,635	-49,878	-48,243
<b>Transactions with owners</b>					
Issue in kind	272	189,607	-	-	189,879
Employee option program	-	600	-	-	600
<b>Total transaction with owners</b>	272	190,207	-	-	190,479
<b>Closing equity</b>	3,977	585,047	4,400	-324,668	268,756

## Condensed consolidated statement of cash flows

SEK (thousand)	Note	2023	2022	2022
		Jan-Mar	Jan-Mar	Jan-Dec
<b>Cash flow from operations</b>				
Operating income		-58,248	-22,304	-105,705
Adjustment for non-cash items		818	271	712
Interest received		5	46	47
Interest paid		-25	-45	-119
Corporate income tax received		-	-	7,860
<b>Cash flow from operations before change in working capital</b>		<b>-57,449</b>	<b>-22,032</b>	<b>-97,206</b>
Change in working capital		26,977	5,041	-20,349
<b>Cash flow from operating activities</b>		<b>-30,472</b>	<b>-16,991</b>	<b>-117,555</b>
Cash flow from investing activities		236	-	27
Cash flow from financing activities		-246	-242	200,712
<b>Cash flow for the period</b>		<b>-30,482</b>	<b>-17,233</b>	<b>83,184</b>
Cash and cash equivalents at beginning of period		108,245	23,997	23,997
Decrease/increase in cash and cash equivalents		-30,482	-17,233	83,184
Exchange rate difference in cash and cash equivalents		451	42	1,063
<b>Cash and cash equivalents at end of period</b>		<b>78,214</b>	<b>6,806</b>	<b>108,245</b>

## Parent company's condensed income statement

SEK (thousand)	Note	2023	2022	2022
		Jan-Mar	Jan-Mar	Jan-Dec
Net sales		-	1,294	5,144
<b>Gross profit</b>		-	<b>1,294</b>	<b>5,144</b>
General and administration costs	5	-6,497	-7,498	-25,726
Other operating expenses		-8	-55	-90
<b>Total operating expenses</b>		<b>-6,505</b>	<b>-7,554</b>	<b>-25,815</b>
<b>Operating income</b>		<b>-6,505</b>	<b>-6,260</b>	<b>-20,671</b>
Net financial items		-53,371	-14,238	-110,299
<b>Profit after financial items</b>		<b>-59,875</b>	<b>-20,498</b>	<b>-130,970</b>
Tax on profit for the period		-	-	-
<b>Profit for the period</b>		<b>-59,875</b>	<b>-20,498</b>	<b>-130,970</b>

## Parent company's statement of comprehensive income

SEK (thousand)	Note	2023	2022	2022
		Jan-Mar	Jan-Mar	Jan-Dec
Profit for the period		-59,875	-20,498	-130,970
Other comprehensive income		-	-	-
<b>Total comprehensive income</b>		<b>-59,875</b>	<b>-20,498</b>	<b>-130,970</b>

## Parent company's condensed balance sheet

SEK (thousand)	Note	3/31/2023	3/31/2022	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>				
Other receivables		802	919	2,231
Prepaid expenses		381	151	4,325
Cash and cash equivalents		22,658	2,436	88,250
<b>Total current assets</b>		<b>23,840</b>	<b>3,506</b>	<b>94,806</b>
<b>Total assets</b>		<b>256,084</b>	<b>27,925</b>	<b>119,225</b>

SEK (thousand)	Note	3/31/2023	3/31/2022	12/31/2022
<b>Equity and liabilities</b>				
<i>Restricted equity</i>				
Share capital	4, 7	3,978	3,251	3,706
<i>Non-restricted equity</i>				
Other paid-in capital	4, 5	585,047	170,387	371,624
Retained earnings/losses		-287,418	-133,233	-133,233
Profit for the period		-59,875	-20,498	-130,970
<b>Total equity</b>		<b>241,731</b>	<b>19,906</b>	<b>111,127</b>
<i>Non-current liabilities</i>				
Contingent earnout	4	7,248	-	-
<b>Total non-current liabilities</b>		<b>7,248</b>	<b>-</b>	<b>-</b>
<i>Current liabilities</i>				
Liabilities in group companies		400	-	-
Accounts payable		266	762	1,072
Other liabilities	10	4,038	3,801	4,044
Accrued expenses		2,401	3,456	2,981
<b>Total current liabilities</b>		<b>7,104</b>	<b>8,019</b>	<b>8,098</b>
<b>Total equity and liabilities</b>		<b>256,084</b>	<b>27,925</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 Schelevägen 2, 223 63 Lund, Sweden. This interim report was approved for publishing on May 5, 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 decided on March 28, 2022 to carry out a fully guaranteed rights issue of SEK 150 million, which added approximately SEK 125 million after deduction of issue expenses. In connection with the then proposed acquisition of TXP Pharma AG in December 2022, a directed issue of SEK 80 million, SEK 76.3 million net after issuing expenses, strengthened the Company's financial position.

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 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 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 845 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 will be 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 in the column 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
<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.

### Note 5 - Share-based payments

At the Extraordinary General Meeting of SynAct Pharma AB on January 12, 2023, it was resolved to implement an employee option program for two senior executives and one other employee of the company. The purpose of the proposed employee option program (the "Employee Option Program 2023") 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 program is also expected to increase the Company's possibilities to retain competent persons. The Employee Option Program 2023 shall comprise a maximum of 195,000 options. The allotted

## Notes and disclosures (continued)

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.

Change in outstanding incentive programs (number of options)	2023	Total
<b>Alloted instruments</b>	Jan-Mar	
Employee Option Program 2023	195,000	195,000
<b>Recalled/voided instruments</b>		
Employee Option Program 2023	-90,000	-90,000
<b>Change</b>		
Employee Option Program 2023	105,000	105,000
<b>Maximum number of shares to which allocated options can entitle</b>		<b>3/31/2023</b>
Employee Option Program 2023		105,000

As of March 31, 2023, SynAct had 31,820,980 outstanding shares. If the outstanding options (105,000) are fully vested and exercised, this would result in a dilution of 0.6%.

The costs of the program are estimated at SEK 4,105 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 the award, and the estimated earned social security contributions related to Swedish participants.

In the first quarter of 2023, the costs for the Employee Option Program 2023 amounted to SEK 627 (0) thousand.

### 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	2022
Related party	Service	Jan-Mar	Jan-Mar	Jan-Dec
UST Leadership AB (Torbjørn Bjerke, chairman)	Consultancy	315	-	525

The Board of Directors resolved on October 7, 2022, to approve an agreement engaging UST Leadership (Torbjørn Bjerke, chairman of the board of directors) as consultant to perform certain, defined tasks.

The Company has entered into an agreement with Boesen Biotech ApS regarding the transfer of intellectual property rights. The agreement did not involve any financial transactions in reported periods. See Note 11, Contingent liabilities for more information.

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, chairman of the board of directors of SynAct, Jeppe Øvlesen, 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.

### 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.

## Notes and disclosures (continued)

### Note 8 - Number of registered shares

Thousand	2023	2022	2022
	Jan-Mar	Jan-Mar	Jan-Dec
Number of shares at the beginning of the period	29,648	24,406	24,406
Number of shares at the end of the period	31,821	26,006	26,006
Average number of shares outstanding in the period	31,338	26,006	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 16,652 thousand (9,877). 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.

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 has made initial payments to the CRO handling the two ongoing clinical studies SynAct-CS006 (RESOLVE) and SynAct-CS007 (EXPAND). These payments are expensed during the course of the studies and for three months before and after.

The company reports accrued expenses of SEK 11,619 thousand (8,303). The change since the comparison period of approximately SEK 3 million is mainly due to increased activity in the clinical studies and thus increased accrued costs.

### Note 12 - Financial assets and liabilities

SEK (thousand)	03/31/2023	03/31/2022	12/31/2022
<b>Financial assets</b>			
Non-current financial assets	273	277	270
Other current receivables	-	-	1,560
Cash and cash equivalents	78,214	6,806	108,245
<b>Total financial assets</b>	<b>78,487</b>	<b>7,083</b>	<b>110,075</b>
<b>Financial liabilities</b>			
Accounts payable	10,087	3,672	4,723
Accrued expenses	11,619	8,303	4,909
<b>Total financial liabilities</b>	<b>21,706</b>	<b>11,975</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.

## Notes and disclosures (continued)

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### 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

On April 3, SynAct's Board of Directors appointed the current Chairman of the Board, Torbjørn Bjerke, as new CEO. He succeeds Jeppe Øvlesen, who has been CEO since 2015, in connection with the Annual General Meeting on 25 May.

## 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)	3/31/2023	3/31/2022	12/31/2022
	<b>Assets</b>			
	Total non-current assets	217,362	3,222	2,365
	Total current assets	103,637	18,933	140,232
[1]	<b>Total assets</b>	<b>320,999</b>	<b>22,155</b>	<b>142,597</b>
	<b>Equity and liabilities</b>			
[2]	<b>Total equity</b>	<b>268,756</b>	<b>758</b>	<b>126,520</b>
	Total non-current liabilities	806	1,870	1,064
	Total current liabilities	27,164	19,527	15,012
	<b>Total liabilities</b>	<b>27,970</b>	<b>21,397</b>	<b>16,077</b>
	<b>Total equity and liabilities</b>	<b>296,726</b>	<b>22,155</b>	<b>142,597</b>
[2] / [1]	<b>Equity / asset ratio (%)</b>	<b>84%</b>	<b>3%</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	2022
		Jan-Mar	Jan-Mar	Jan-Dec
[1]	Research and development costs	-43,596	-13,490	-70,067
	General and administration costs	-14,647	-8,758	-35,611
	Other operating income / expense	-4	-56	-28
[2]	<b>Total operating expenses</b>	<b>-58,248</b>	<b>-22,304</b>	<b>-105,705</b>
[1] / [2]	<b>Research and development costs / operating expenses (%)</b>	<b>75%</b>	<b>60%</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 not been reviewed by the company's auditors.

Lund, May 5, 2022

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**Jeppe Øvlesen**  
Chief Executive Officer (CEO)

## 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.

### ACTH

Adrenocorticotrophic hormone (ACTH; also adrenocorticotropin, corticotropin) is a polypeptide tropic hormone produced by and secreted by the anterior pituitary gland. It is also used as a medication and diagnostic agent.

### 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. Key data from the study were presented on November 30, 2021.

### 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.

### Cardiac surgery

Cardiac surgery, or cardiovascular surgery, is surgery on the heart or great vessels performed by cardiac surgeons. It is often used to treat complications of ischemic heart disease (for example, with coronary artery bypass grafting); to correct congenital heart disease; or to treat valvular heart disease from various causes, including endocarditis, rheumatic heart disease, and atherosclerosis. It also includes heart transplantation.

### CPB

Cardiopulmonary bypass (CPB) is a technique in which a machine temporarily takes over the function of the heart and lungs during surgery, maintaining the circulation of blood and oxygen to the body. The CPB pump itself is often referred to as a heart-lung machine or "the pump".

### 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.

### Edema

Edema, also spelled oedema, also known as fluid retention, dropsy, hydropsy and swelling, is the build-up of fluid in the body's tissue.

## Glossary (continued)

### 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.

### ICU

An intensive care unit (ICU) is a special department of a hospital or health care facility that provides intensive care medicine. Intensive care units cater to patients with severe or life-threatening illnesses and injuries, which require constant care, close supervision from life support equipment and medication to ensure normal bodily functions.

### iMN

Idiopathic membranous nephropathy is an autoimmune disease in which the membranes of the glomerulus are attacked by

generated autoantibodies, resulting in progressive deterioration of kidney function.

### IND (Investigational New Drug) Application

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

### Melanocortin

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

### Melanocortin receptors

When these receptors are activated, processes start in the body that lead to reduced release of pro-inflammatory mediators (slowed 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.

### Magnetic resonance imaging (MRI)

Magnetic resonance imaging (MRI) is a medical imaging technique used in radiology to form pictures of the anatomy and the physiological processes of the body. MRI scanners use strong magnetic fields, magnetic field gradients, and radio waves to generate images of the organs in the body. MRI does not involve X-rays or the use of ionizing radiation, which distinguishes it from CT and PET scans.

### 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.

### Proteinuria

Proteinuria is the presence of excess proteins in the urine. In healthy persons, urine contains very little protein; an excess is suggestive of illness. Severe proteinuria can cause nephrotic syndrome.

### 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.

## Glossary (continued)

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### **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.

### **Synovial joint**

A synovial joint joins bones with a fibrous capsule that is continuous with the periosteum of the joined bones. This joint unites long bones and permits free bone movement and greater mobility. The synovial cavity/joint is filled with synovial fluid. The joint capsule is made up of an outer layer of fibrous membrane, which keeps the bones together structurally, and an inner layer, the synovial membrane, which seals in the synovial fluid.

## 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	+45 28 44 75 67
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

**SynAct Pharma AB**

**Visiting address:** Scheelevägen 2, 223 63 Lund, Sverige

**Postal address:** Scheelevägen 2, 223 63 Lund, Sverige

**Phone:** +45 28 44 75 67

**E-mail:** [joo@synactpharma.com](mailto:joo@synactpharma.com)

[www.synactpharma.com](http://www.synactpharma.com)