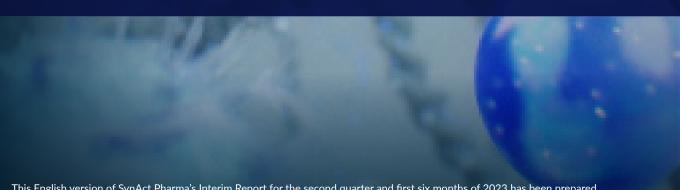




Q2

Research and **development** in inflammatory diseases



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

www.synactpharma.com

CONTENT

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

SynAct Pharma AB

Visiting address: Scheelevägen 2 223 63 Lund, Sweden

Postal: Scheelevägen 2 223 63 Lund, Sweden



investor.relations@synactpharma.com

Significant events in the second quarter



CEO Torbjørn Bjerke comments on the second quarter



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

www.synactpharma.com

Interim report for the second quarter 2023 and first six months



Quarter 2 (April - June)

- 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 43,495 (26,417) thousand, an increase of 65%, driven mainly by the two clinical studies in RA and higher administrative costs.
- The Group's loss after tax amounted to SEK 43,511 (24,754) 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 90 (2,871) thousand in the quarter.
- The Group's earnings per share before and after dilution amounted to SEK -1.37 (-0.91).
- Cash flow from operating activities amounted to SEK -34,657 (-36,922) thousand.
- Cash flow from financing activities amounted to SEK -179 (125,158) thousand.
- Cash flow for the period amounted to SEK -34,704 (88,236) thousand.
- Cash and cash equivalents at the end of the period amounted to SEK 44,421 (96,465) thousand.



Six months (January - June)

- The Group's net sales amounted to SEK 0 (0) thousand.
- Operating expenses amounted to SEK 101,743 (48,722) thousand, an increase of 109%, 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 93,389 (44,809) 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 8,358 (5,133) thousand for six months.
- The Group's earnings per share before and after dilution amounted to SEK -2.96 (-1.68).
- Cash flow from operating activities amounted to SEK -65,129 (-53,913) thousand.
- Cash flow from financing activities amounted to SEK -425 (124,916) thousand.
- Cash flow for the period amounted to SEK -65,186 (71,003) thousand.

The Group's financial performance per quarter								
(SEK thousand)	2023 Q2	2023 Q1	2022 Q4	2022 Q3	2022 Q2	2022 Q1	2021 Q4	2021 Q3
Net sales	-	-	-	-	-	-	-	-
Operating income	-43,495	-58,248	-30,523	-26,461	-26,417	-22,304	-26,153	-20,885
Profit before tax	-43,601	-58,146	-30,554	-26,569	-27,625	-22,317	-26,207	-20,676
Profit for the period	-43,511	-49,878	-30,477	-23,919	-24,754	-20,055	-26,210	-18,222
Total assets	298,472	320,999	142,597	96,206	133,972	22,155	38,369	59,836
Equity / asset ratio (%) ¹	81%	84%	89%	83%	77%	3%	54%	79%
Earnings per share (SEK)	-1.37	-1.59	-1.06	-0.84	-0.91	-0.77	-1.01	-0.70
Research & development cost / operating expenses (%) ¹	67%	75%	71%	78%	54%	60%	77%	78%

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

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

٢	- 0 — 0
	APR 3

ר0<u>-0</u>-0

APR 24

SynAct's board appoints current board chairman Torbjørn Bjerke as new CEO. He succeeds Jeppe Øvlesen, who has been CEO since 2015, in connection with the general meeting on May 25. The nomination committee proposes that the AGM elects current board member Uli Hacksell as new chairman and Thomas von Koch as new board member.

Recruitment to SynAct's phase 2b clinical trial, EXPAND, with resomelagon (AP1189) in patients with severe, newly diagnosed rheumatoid arthritis (RA) is completed ahead of schedule. 127 patients have been randomized to the study. The company expects to be able to report key results within five months.



SynAct announces that Björn Westberg has been appointed CFO and member of the group management in SynAct. Björn has extensive experience from the life-science sector, from smaller pharmaceutical companies to contract manufacturing and "Big Pharma". He will take office on 15 June 2023.

SynAct's annual general meeting was held in Malmö. The meeting confirmed the financial statements and accounts for 2022 and disposition of the company's results. The board and the CEO were granted discharge for the financial year 2022. Board members Thomas Jonassen, Terje Kalland, Uli Hacksell, Marina Bozilenko and Kerstin Hasselgren were re-elected, and Thomas von Koch was elected as a new board member. Uli Hacksell was elected as the new chairman of the board. KPMG was given renewed trust as auditor and remuneration to the board and auditor and the remuneration report for 2022 was determined. In addition, the meeting decided on changes to the articles of association, authorization for the issue of shares and an employee option program. Jeppe Øvlesen resigned and Torbjørn Bjerke took office as CEO.

SynAct announces that dosing has been completed in the company's Phase 2b EXPAND study, which evaluates the daily dose of resomelagon (AP1189) for patients with early rheumatoid arthritis (RA) with severe disease activity. SynAct expects to be able to publish top-line data from the study in September.

SynAct announces that it completed patient recruitment for part A of the P2a/b RESOLVE clinical study of resomelagon (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. A total of 125 patients were randomized into the study. With all patients recruited SynAct anticipates releasing top-line study data in October this year.

The CEO, Torbjørn Bjerke comments on the second quarter

Dear Shareholders,

We have certainly had a productive first half of 2023 and we have set the stage for what will be a monumental second half of the year for SynAct, for our shareholders and for the future of how we treat debilitating inflammatory and autoimmune diseases. We focused in the first half of this year on preparing the company for the upcoming data releases, active partnering discussions and building out our pipeline of resolution therapeutics. Now is the time for us to put that preparation into action to meet the tremendous opportunities in front of us.

On the company organization front, I assumed the role of CEO after our AGM in May. I became CEO to lead the company through the exciting future that lies ahead, and I am committed to build upon all the hard work, investment and dedication that has brought us to this exciting inflection point.

As I transitioned from Chairman to CEO, Uli Hacksell stepped up to become the new Chairman. Uli has an extensive track record of building dynamic pharma companies and I am excited to be able to transfer the Chairman's mantle to him. We were also pleased to announce that Thomas von Koch joined the board, significantly bolstering our board's strength and capabilities. We also appointed Björn Westberg as CFO. Björn has extensive experience in the life science sector, including both smaller pharmaceutical companies and "big pharma." His addition will be important for SynAct's future growth journey.

On the development front, we are very excited about the progress we have made with resomelagon (AP1189) rheumatoid arthritis (RA) program. In July we announced that we completed dosing in the EXPAND 12-week trial of resomelagon in combination with methotrexate (MTX) in newly diagnosed rheumatoid arthritis (RA) patients experiencing severe disease activity. We are excited to see the trial results in September. This is an important patient population who can have a poor disease prognosis given the early severity of their disease. We also announced recently that we have completed enrollment in the Phase 2a portion of the RESOLVE P2a/b trial of resomelagon as add-on therapy to MTX in RA patients who have had an insufficient or incomplete response to MTX (a population known as DMARD-IR patients). We expect the 4-week Phase 2a dose ranging data to be released in October which will set the stage for initiating the 12-week P2b portion of the RESOLVE study in the first half of 2024. Last year we redesigned the nephrotic syndrome study to benefit from the possibility to dose for 12 weeks with our new tablet formulation with aim to have recruitment completed in the second half of 2023. Despite strong commitment from our investigators it has shown difficult to identify eligible patients. We have therefore initiated work to identify how we with our current and additional sites can ensure that we get eligible patients identified and recruited. However, it is foreseen that it is unlikely that recruitment will be completed in 2023.

Operating expenses for the first six months amounted to MSEK 102 (49), an increase of 109%, driven primarily by the two clinical studies.

On the corporate front, we significantly increased our pipeline of resolution assets by acquiring TXP Pharma and its portfolio melanocortin agonists. While our focus remains on resomelagon, these new assets afford the ability to target a wide range of inflammatory and autoimmune disease and provide a much broader platform for long-term growth. We were also able to increase communication with our shareholders by holding a capital market day in May where we were able to take a deep dive on the promise of resolution therapy, progress made with resomelagon and the rationale for the TXP acquisition. We had a strong turnout, highlighting the depth of interest in SynAct and we are grateful to all of those who took the time to join.

With these advancements, we continue to be on the leading edge of delivering on the promise of resolution therapy. The last few decades have witnessed amazing advancements in treating autoimmune diseases like RA with an anti-inflammatory strategy. While these therapies have been game changers, there is still between 50-70% of the patients that do not experience a relief of their symptoms. In addition, the current treatments have also demonstrated the risks that can come with suppressing the immune system. With resomelagon, we seek to go beyond suppression by stimulating the body to resolve inflammation. We have designed aspects of the ongoing trials and initiated additional non-clinical investigations to better demonstrate resolution in action. We hope to have many of these readouts in the second half of the year alongside the clinical trial results. Over the first half of this year, as has been our approach in the past, we have delivered meaningful advancements in a capital efficient manner. Resomelagon is approaching the stage where development costs and complexity will increase significantly. We continue to talk with key companies in the inflammation space to identify like-minded partners who believe in resomelagon and resolution therapy. Importantly, we are looking for a partner who sees the broad potential for resolution therapy who will develop resomelagon beyond RA into other key inflammatory conditions. In addition to partnering activities, we are also actively working to attract new like-minded institutional investors to our shareholder base. We continue to generate a good deal of interest in SynAct from both potential partners and from new institutional investors in preparation for the fall data releases.

We are truly at an exciting inflection point for SynAct. I am excited to continue to work with the talented management team we have at SynAct, and we are all eagerly awaiting the upcoming clinical trial results that will build off the strong data demonstrated in the BEGIN study. I want to express our sincere appreciation to our shareholder base for supporting our shared vision of resomelagon and the promise of resolution therapy. Our combined resolve remains strong.

"I want to express our sincere appreciation to our shareholder base for supporting our shared vision of resomelagon and the promise of resolution therapy. Our combined resolve remains strong."

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

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. 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 not 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.

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 antiinflammatory 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).

Research and Development (continued)

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 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).



Research and Development (continued)

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 (AP1189). The aim is to report key results in September 2023. Full recruitment of patients was accomplished in April, and the treatment phase of the study completed in July 2023.

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

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

Development of resomelagon (AP1189) in DMARD-IR patients 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 placebocontrolled 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 issuein-kind and implied that the number of shares increased by 2,172,523 to 31,820,980 and the share capital increased by SEK 271,565 to SEK 3,977,623.

The closing price of the SynAct share on the last trading day in June 2023 was SEK 74.40.

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.

Ownership (June 30, 2023)

Shareholder	Capital and votes(%)
Bioinvest ApS	11.1%
Avanza Pension	6.0%
Nordnet Pensionsförsäkring	4.7%
Goodwind Holding GmbH	3.7%
Thomas von Koch	3.5%
Torbjörn Bjerke	2.6%
Handelsbanken fonder	1.4%
Henrik Stage	0.8%
Swedbank Försäkring	0.8%
Per Granath	0.8%
Total (top-10)	35.4%
Others (~14,000)	64.6%

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. 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

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 agreement did not affect the results or financal position of the Group.

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



Analyst coverage

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

Gonzalo Artiach Castañón ABG Sundal Collier AB

Sebastian van der Schoot Van Lanschot Kempen BV



Financial reporting calendar

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

Date:	
11/03/2023	
02/23/2024	
05/17/2024	

Report: Interim Report Q3 2023 Annual Results 2023 Interim Report Q1 2024

Comments on the financial development for the second quarter and first six 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 29,038 (14,275) thousand. For the first six months R&D costs amounted to SEK 72,634 (27,765) 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 six 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.

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

Administration costs

Administrative expenses amounted to SEK 14,481 (12,127) thousand in the second quarter and SEK 29,128 (20,885) thousand for the first six months. The increase for the first half of the year is driven by costs related to the acquisition of TXP Pharma and severance pay to the previous CEO.

Financial items

Net financial items amounted to SEK -106 (-1,208) thousand in the second quarter and SEK -4 (-1,221) thousand for the first six months. The change is attributable to exchange rate adjustments.

Tax for the period

Tax revenues in the second quarter amounted to SEK 90 (2,871) thousand. For the first six months the accrued tax credit

amounted to SEK 8,358 (5,133) thousand. See Note 9 - Tax receivables for more information.

Loss for the period

The Group's loss for the second quarter amounted to SEK 43,511 (24,754) thousand and for the first six months, the reported loss was SEK 93,389 (44,809) thousand.

Cash flow, financial position and going concern

In connection with the acquisition of TXP Pharma AG, intangible assets corresponding to SEK 229,452 (0) thousand, of which goodwill amounts to SEK 76,163 thousand, and an associated deferred tax liability of SEK 18,149 (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 7,423 (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 17,418 (13,129) thousand.

Cash flow from operating activities amounted to SEK -34,657 (-36,922) thousand in the quarter. Year-to-date cash flow for operating activities amounted to SEK -65,129 (-53,913) thousand. 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 -179 (125,158) thousand in the second quarter. For the first six months the cash flow from financing activities were SEK -425 (124,916) thousand.

Cash flow for the period amounted to SEK -34,704 (88,236) thousand and SEK -65,186 (71,003) thousand for the first six months. The Group's cash and cash equivalents as of June 30, 2023, amounted to SEK 44,421 (96,465) 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) 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 3,895 (1,262) thousand in the second quarter and SEK 3,895 (2,556) thousand for the first six months.

In the Parent Company, net financial items amounted to SEK -843 (-96,059) thousand in the quarter. Year-to-date, net financial items were SEK -54,213 (-110,296) 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

Consolidated statement of comprehensive Income

SEK (thousand)	Note	2023	2022	2023	2022	2022
		Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-De
Net sales		-	-	-	-	
Gross profit		-	-	-	-	
Research and development costs	5	-29,038	-14,275	-72,634	-27,765	-70,06
General and administration costs	5, 6	-14,481	-12,127	-29,128	-20,885	-35,61
Other operating income/expenses		23	-16	20	-72	-2
Total operating expenses		-43,495	-26,417	-101,743	-48,722	-105,70
Operating income		-43,495	-26,417	-101,743	-48,722	-105,70
Net financial items		-106	-1,208	-4	-1,221	-1,36
Profit after financial items		-43,601	-27,625	-101,746	-49,942	-107,06
Tax on profit/loss for the period	9	90	2,871	8,358	5,133	7,86
Profit for the period		-43,511	-24,754	-93,389	-44,809	-99,20
Earnings per share (SEK)		-1.37	-0.91	-2.96	-1.68	-3.6
Diluted earnings per share (SEK)		-1.37	-0.91	-2.96	-1.68	-3.6
Average number of shares outstanding ('000)	8	31,821	27,305	31,581	26,659	27,58

SEK (thousand) Not	e 2023	2022	2023	2022	2022
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Profit for the period	-43,511	-24,754	-93,389	-44,809	-99,205
Items reclassifiable to profit or loss					
Translation differences from foreign operation	14,871	1,231	16,506	1,175	3,164
Comprehensive income after tax for the period	-28,640	-23,523	-76,883	-43,634	-96,041
Comprehensive income for the period	-28,640	-23,523	-76,883	-43,634	-96,041

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

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

Consolidated statement of financial position

SEK (thousand)	Note		6/30/2022	12/31/2022
Assets				
Non-current assets				
Intangible assets	4	229,452	-	-
Right-of-use assets		993	2,209	2,095
Financial assets	12	148	286	270
Total non-current assets		230,594	2,495	2,365
Current assets				
Tax credit	9	17,418	13,129	8,231
Other current receivables		5,612	7,283	6,464
Prepaid expenses	11	428	14,599	17,293
Cash and cash equivalents	12	44,421	96,466	108,245
Total current assets		67,878	131,476	140,232
Total assets		298,472	133,972	142,597

SEK (thousand)	Note	6/30/2023	6/30/2022	12/31/2022
Equity and liabilities				
Share capital	4, 7	3,978	3,546	3,706
Other paid-in capital	4, 5	586,430	318,725	394,839
Reserves		19,271	776	2,765
Retained earnings/losses including net profit		-368,179	-220,394	-274,790
Total equity		241,500	102,654	126,520
Non-current liabilities				
Deffered tax liability	4	18,149	-	-
Leasing liability		346	1,322	1,064
Contingent earnout	4	7,423	-	-
Other provision	6	3,672	-	-
Total non-current liabilities		29,591	1,322	1,064
Current liabilities				
Accounts payable	12	6,011	15,353	4,723
Leasing liability		627	850	1,000
Other current liabilities	10	4,737	4,315	4,381
Accrued expenses	11, 12	16,007	9,478	4,909
Total current liabilities		27,381	29,996	15,012
Total equity and liabilities		298,472	133,972	142,597

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
Opening equity	3,251	193,602	-399	-175,585	20,869
Profit for the period	-	-	0	-99,205	-99,205
Other comprehensive income	-	-	3,164	-	3,164
Comprehensive income for the period	-	-	3,164	-99,205	-96,041
Transactions with owners					
New share issue	455	228,490	-	-	228,945
Issue expenses	-	-27,252	-	-	-27,252
Total transaction with owners	455	201,238	-	-	201,693
Closing equity	3,706	394,840	2,765	-274,790	126,520

01/01/2023 - 06/30/2023 SEK (thousand)	Share capital	Other paid-in capital	Reserves	Retained earnings, including profit for the period	Total
Opening equity	3,706	394,840	2,765	-274,790	126,520
Profit for the period	-	-	-	-93,389	-93,389
Other comprehensive income	-	-	16,506	-	16,506
Comprehensive income for the period	-	-	16,506	-93,389	-76,883
Transactions with owners					
Issue in kind	272	189,607	-	-	189,879
Employee option program	-	1,983	-	-	1,983
Total transaction with owners	272	191,590	-	-	191,862
Closing equity	3,977	586,430	19,271	-368,179	241,500

Condensed consolidated statement of cash flows

SEK (thousand) Note	2023	2022	2023	2022	2022
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Cash flow from operations					
Operating income	-43,495	-26,417	-101,743	-48,722	-105,705
Adjustment for non-cash items	5,810	259	6,628	530	712
Interest received	22	-0	27	46	47
Interest paid	-45	-102	-70	-147	-119
Corporate income tax received	-	-	-	-	7,860
Cash flow from operations before change in working capital	-37,709	-26,261	-95,158	-48,293	-97,206
Change in working capital	3,052	-10,662	30,028	-5,621	-20,349
Cash flow from operating activities	-34,657	-36,922	-65,129	-53,913	-117,555
Cash flow from investing activities	132	-	368	-	27
Cash flow from financing activities	-179	125,158	-425	124,916	200,712
Cash flow for the period	-34,704	88,236	-65,186	71,003	83,184
Cash and cash equivalents at beginning of period	78,214	6,806	108,245	23,997	23,997
Decrease/increase in cash and cash equivalents	-34,704	88,236	-65,186	71,003	83,184
Exchange rate difference in cash and cash equivalents	911	1,424	1,361	1,466	1,063
Cash and cash equivalents at end of period	44,421	96,465	44,421	96,465	108,245

Parent company's condensed income statement

_

SEK (thousand)	Note	2023	2022	2023	2022	2022
		Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Deo
Net sales		3,895	1,262	3,895	2,556	5,144
Gross profit		3,895	1,262	3,895	2,556	5,144
General and administration costs	5	-12,145	-10,637	-18,642	-18,135	-25,72
Other operating expenses		21	-112	13	-168	-90
Total operating expenses		-12,125	-10,749	-18,630	-18,303	-25,81
Operating income		-8,229	-9,487	-14,734	-15,747	-20,67
Net financial items		-843	-96,059	-54,213	-110,296	-110,29
Profit after financial items		-9,072	-105,546	-68,948	-126,044	-130,97
Tax on profit for the period		-	-	-	-	
Profit for the period		-9,072	-105,546	-68,948	-126,044	-130,97

SEK (thousand) No	ote	2023	2022	2023	2022	2022
		Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Profit for the period		-9,072	-105,546	-68,948	-126,044	-130,970
Other comprehensive income		-	-	-	-	-
Total comprehensive income		-9,072	-105,546	-68,948	-126,044	-130,970

Parent company's condensed balance sheet

SEK (thousand)	Note	6/30/2023	6/30/2022	12/31/2022
Assets				
Non-current assets				
Financial assets	4	232,244	24,419	24,419
Total non-current assets		232,244	24,419	24,419
Current assets				
Receivables in group companies		1,811	-	-
Other receivables		705	2,403	2,231
Prepaid expenses		454	239	4,325
Cash and cash equivalents		18,374	24,666	88,250
Total current assets		21,344	27,308	94,806
Total assets		253,588	51,727	119,225

SEK (thousand)	Note	6/30/2023	6/30/2022	12/31/2022
Equity and liabilities				
Restricted equity				
Share capital	4, 7	3,978	3,546	3,706
Non-restricted equity				
Other paid-in capital	4, 5	586,430	295,510	371,624
Retained earnings/losses		-287,418	-133,233	-133,233
Profit for the period		-68,948	-126,044	-130,970
Total equity		234,042	39,779	111,127
Non-current liabilities				
Contingent earnout	4	7,423	-	-
Other provisions	6	3,672	-	-
Total non-current liabilities		11,095	-	-
Current liabilities				
Accounts payable		904	5,196	1,072
Other liabilities	10	4,379	3,990	4,044
Accrued expenses		3,167	2,762	2,981
Total current liabilities		8,451	11,949	8,098
Total equity and liabilities		253,588	51,727	119,225

Notes and disclosures

Note 1 - General information

This interim report covers the Swedish parent company SynAct Pharma AB (publ) ("SynAct" or the "Parent Company"), corporate identity number 559058-4826 and its subsidiaries (collectively, the "Group"). The Group's main business is to conduct the development of pharmaceuticals. The parent company is listed on Nasdaq Stockholm, with ticker SYNACT. The Parent Company is a limited liability company registered with its registered office in Lund, Sweden. The address of the head office is Scheelevägen 2, 223 63 Lund, Sweden. This interim report was approved for publishing on August 4, 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.

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 2,741 thousand.

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

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

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

The initial purchase price was paid by SynAct issuing 2,172,523 consideration shares, equivalent to SEK 136 million at the time of signing of the deal and based on a share price of SEK 62.60. In accordance with IFRS 3, the acquirer must recognize the fair value of share-based payments on the acquisition date. The fair value was determined using a share price of SEK 87.40 to SEK 189,879 thousand. 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
Total net assets acquired excluding goodwill	126,002
Goodwill	70,954
Total net assets acquired	196,956
Less	
Ordinary shares issued	-189,879
Provision for earnout	-7,077
Received cash and cash equivalents	236
Net cash outflow/effect on cash and cash equivalents on acquisition of business	236

The reported other intangible asset, SEK 142,805 thousand, consists of the company's lead candidate, TXP-11. The goodwill recognized in the acquisition, SEK 70,954 thousand, is attributable to intellectual property rights that cannot qualify as intangible assets, such as TXP's other pharmaceutical projects and patent portfolio. Reported goodwill is not expected to be deductible.

The acquisition-related expenses related to valuation, tax and legal advisors, etc., amounts to SEK 10.9 million, which have been expensed in the Group, but are capitalized in the Parent Company.

Note 5 - Share-based payments

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

Employee Option Program 2023 I

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

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

Employee Option Program 2023 II

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

This employee option program shall comprise a maximum of 469,000 employee stock options. The allotted employee options vest with 1/3 from the date that is 12, 24 and 36 months after the date of allotment. The option holders shall be able to exercise granted and vested employee options during the period starting on the day that falls 3 years after the date of allotment and ending on 30 June 2028. Each employee option entitles the holder to acquire one new share in the company. Exercise price amounting to SEK 110.43, corresponding to 150 percent of the volume-weighted average share price of the company's share on Nasdaq Stockholm during 10 trading days immediately prior to the day on which a participant is granted options. The employee options shall be granted free of charge, shall not constitute securities and shall not be transferable or pledged. The allotment of 404,000 of the options included in the program took place on June 1, 2023. The remaining 65,000 warrants can be granted after a Board decision until the 2024 Annual General Meeting of SynAct.

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

Maximum number of shares to which allocated options can entitle	6/30/2023
ESOP 2023 I	105,000
ESOP 2023 II	469,000
Total Employee Option	574,000

As of June 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 0.6%. 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 second quarter of 2023, the costs for the employee option programs have amounted to SEK 1,561 thousand (0) and the costs for the half year have amounted to SEK 2,189 thousand (0).

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	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
UST Leadership AB	Consultancy	210	-	525	-	525
(Torbjørn Bjerke, former chairman)						

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

The Company has entered into an agreement with Boesen Biotech ApS regarding the transfer of intellectual property rights. The agreement did not involve any financial transactions in reported periods. See Note 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, Torbjörn Bjerke was elected new CEO of Synact, starting in connection with the Annual General Meeting in May, and an agreement on severance pay to outgoing CEO Jeppe Øvlesen was entered into, this is reported as other provision in the amount of SEK 3,672 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
	Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
Number of shares at the beginning of the period	31,821	26,006	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	27,305	31,581	26,659	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 17,418 thousand (13,129). 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 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. At the end of the reporting period, there were no prepaid expenses relating to the clinical studies.

The company reports accrued expenses of SEK 16,007 thousand (9,478). The change since the comparison period of approximately SEK 6 million is mainly due to increased activity in the clinical studies and thus increased accrued costs.

Note 12 - Financial assets and liabilities

SEK (thousand)	06/30/2023	06/30/2022	12/31/2022
Financial assets			
Non-current financial assets	148	286	270
Other current receivables	-	-	1,560
Cash and cash equivalents	44,421	96,466	108,245
Total financial assets	44,569	96,752	110,075
Financial liabilities			
Accounts payable	6,011	15,353	4,723
Accrued expenses	16,007	9,478	4,909
Total financial liabilities	22,018	24,831	9,632

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

Note 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.

Alternative performance measures - APM

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

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

Equity / asset ratio

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

Research and development costs / operating expenses

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

#	SEK (thousand)	6/30/2023	6/30/2022	12/31/2022
	Assets			
	Total non-current assets	230,594	2,495	2,365
	Total current assets	67,878	131,476	140,232
[1]	Total assets	298,472	133,972	142,597
	Equity and liabilities			
[2]	Total equity	241,500	102,654	126,520
	Total non-current liabilities	29,591	1,322	1,064
	Total current liabilities	27,381	29,996	15,012
	Total liabilities	56,972	31,318	16,077
	Total equity and liabilities	298,472	133,972	142,597
[2] / [1]	Equity / asset ratio (%)	81%	77%	89%

#	SEK (thousand)	2023	2022	2023	2022	2022
		Apr-Jun	Apr-Jun	Jan-Jun	Jan-Jun	Jan-Dec
[1]	Research and development costs	-29,038	-14,275	-72,634	-27,765	-70,067
	General and administration costs	-14,481	-12,127	-29,128	-20,885	-35,611
	Other operating income / expense	23	-16	20	-72	-28
[2]	Total operating expenses	-43,495	-26,417	-101,743	-48,722	-105,705
[1] / [2]	Research and development costs / operating expenses (%)	67%	54%	71%	57%	66%

Declaration of the Board of Directors and the CEO

The Board and 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, August 4, 2023

Uli Hacksell Chairman of the Board Marina Bozilenko Board Member Kerstin Hasselgren Board Member

Terje Kalland Board Member Thomas Jonassen Board Member Thomas von Koch Board Member

Torbjørn Bjerke 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.

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 it 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 cAMPdependent 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.

СМС

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 monopeptides) joined together by peptide bonds to form a short chain. Peptides differ from proteins only in that they are smaller. Peptides occur naturally in the body, but can also be produced synthetically.

pERK pathway

The pERK pathway (also known as the MAPK/ERK or 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	www.synactpharma.com
Auditor	KPMG AB (Box 227, 201 22 Malmö), auditor in charge Linda Bengtsson.

SynAct Pharma ApS – affiliate

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

TXP Pharma AG – affiliate

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



SYNACT PHARMA

SynAct Pharma AB

Visiting address: Scheelevägen 2, 223 63 Lund, Sverige Postal address: Scheelevägen 2, 223 63 Lund, Sverige Phone: +46 10 300 10 23 E-mail: investor.relations@synactpharma.com



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