

# INTERIM REPORT

January - September 2022

SYNACT  PHARMA

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

# Q3

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

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Significant events in  
the third quarter

p. 4

CEO Jeppe Øvlesen  
comments on the  
third quarter

p. 5



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

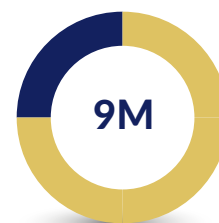
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## Interim report for the third quarter and the first nine months of 2022



### Quarter 3 (July - September)

- The Group's net sales amounted to SEK 0 (0) thousand, which is in line with expectations given the phase the company's research portfolio is in. The Company is not expected to generate any revenues until after the completion of the clinical phase 2 program for the drug candidate AP1189 planned for the end of 2023.
- Operating expenses amounted to SEK 26,461 (20,885) thousand, an increase of 27%, driven both by increased investments in R&D and higher administrative costs.
- The Group's loss after tax amounted to SEK 23,919 (18,222) 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 2,650 (2,454) thousand in the quarter.
- The Group's earnings per share before and after dilution amounted to SEK -0.84 (-0.70).
- Cash flow from operating activities amounted to SEK -41,335 (-18,250) thousand.
- Cash flow from financing activities amounted to SEK -230 (0) thousand.
- Cash flow for the period amounted to SEK -41,565 (-18,255) thousand.
- Cash and cash equivalents at the end of the period amounted to SEK 54,898 (44,402) thousand



### Nine months (January - September)

- The Group's net sales amounted to SEK 0 (0) thousand.
- Operating expenses amounted to SEK 75,182 (50,546) thousand, an increase of 49%, driven both by increased investments in R&D and higher administrative costs for the application for listing on Nasdaq Stockholm and expenses related to the rights issue that was decided in the first quarter of 2022.
- The Group's loss after tax amounted to SEK 68,728 (43,094) 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 7,783 (7,508) thousand in the first nine months.
- The Group's earnings per share before and after dilution amounted to SEK -2.52 (-1.67).
- Cash flow from operating activities amounted to SEK -95,249 (-44,740) thousand.
- Cash flow from financing activities amounted to SEK 124,686 (74,400) thousand.
- Cash flow for the period amounted to SEK 29,438 (29,652) thousand.

### The Group's financial performance per quarter

(SEK thousand)	2022 Q3	2022 Q2	2022 Q1	2021 Q4	2021 Q3	2021 Q2	2021 Q1
Net sales	-	-	-	-	-	-	-
Operating income	-26,461	-26 417	-22 304	-26 153	-20 885	-15 603	-14 058
Profit before tax	-26,569	-27 625	-22 317	-26 207	-20 676	-15 856	-14 070
Profit for the period	-23,919	-24 754	-20 055	-26 210	-18 222	-13 137	-11 735
Total assets	96,206	133 972	22 155	38 369	59 836	75 273	88 945
Equity / asset ratio (%) <sup>1</sup>	83%	77%	3%	54%	79%	87%	88%
Earnings per share (SEK)	-0.84	-0.91	-0.77	-1.01	-0.70	-0.51	-0.46
Research & development cost / operating expenses (%) <sup>1</sup>	78%	54%	60%	77%	78%	83%	79%

1) Alternative performance measures - APM, ref. p. 20 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 affiliate SynAct Pharma ApS. 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 third quarter of 2022 and after the end of the reporting period



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

# Building a strong business case around

## AP1189

**The hard work during the first half of the year continued during the third quarter. After a long period preparing, the company finally made the leap to the main list at Nasdaq Stockholm, while at the same time we pushed our pipeline forward. Shareholders have placed a great deal of trust in SynAct, and we remain determined to execute on our ambitious plan for AP1189.**

Making the move to Nasdaq Stockholm was a big moment for the company and truly is a stamp of quality for the organization we have built over the years. Being traded on the main list gives us greater access to even more international and institutional investors, critical for executing on our growth plan.

Following the Clinical Trial Application approval for the Phase 2b EXPAND study in rheumatoid arthritis (RA) using our candidate drug AP1189, we moved quickly to enroll our first patient. This first patient in Moldova is a nice milestone for the EXPAND study, and we will continue to enroll additional patients there and in Bulgaria.

AP1189 targets an unmet need for a novel treatment option in RA. Our compound aims to stimulate an immunological resolution, a unique treatment approach that we expect to have a significant impact on how the medical system tackles RA but also other autoimmune and inflammatory diseases.

The EXPAND study follows the successful results from the BEGIN study that showed AP1189 to be safe, well tolerated and induce a statistically significant reduction in disease. To bolster the position of 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.

Topline data is expected to be ready during the second half of 2023, assuming recruitment goes smoothly. EXPAND results will be pivotal in the ongoing interactions with potential partners and for the further development of AP1189.

The team pushed hard to file the investigational new drug (IND) application with the US Food and Drug Administration for the planned Phase 2a/b study called RESOLVE before the end of the third quarter. Following a very straightforward process with the agency, we obtained the IND without any comments to the proposed and previously communicated clinical study design. We are looking forward to initiating the study and collaborate with investigators and key opinion leaders in the US.

Advancing the development program in rheumatoid arthritis is our main focus, but we still believe AP1189 has a role as a safe and effective treatment of kidney diseases related to proteinuria and nephrotic syndrome (NS). Before the summer, we re-assessed and re-designed our clinical Phase 2a study in idiopathic membranous nephropathy (IMN) patients, (SynAct-CS003). Through the new design recruitment to the study should be accelerated, and we hope to obtain proof-of-concept in a third disease for AP1189 during 2023.

As mentioned, SynAct's efforts with AP1189 in RA is the main focus. We continue to have business development discussions, and our hard work hasn't gone unnoticed. Our goal is to build a rock-solid case around the mode of action for AP1189, going beyond producing clinical results. This is why we are including tertiary endpoints to further explore the effect of AP1189 on biomarkers and by evaluation of synovial inflammation using magnetic

resonance imaging (MRI). Our aim is to identify the full treatment potential of the compound.

In the third quarter, our operating expenses were SEK 26.5 million, an increase of 27% over the same period last year. R&D investments were SEK 20.6 million or 27% higher than Q3 2021. General and Administration costs fell as predicted to SEK 5.7 million in the quarter, from SEK 12.1 million in the previous quarter and up 23% from the same period last year.

It is exciting to see the company's pipeline continue to advance and the business case around AP1189 strengthening. SynAct has a strong pipeline and the programs are on schedule. We remain busy exploring business development opportunities. Thank you for showing interest in the company.

**"It is exciting to see the company's pipeline continue to advance and the business case around AP1189 strengthening."**

Jeppe Øvlesen  
CEO



## 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
AP1189	Rheumatoid arthritis First line treatment in select patients	[Progress bar spanning Preclinical, Phase 1, Phase 2A, and Phase 2B]					<ul style="list-style-type: none"> <li>• SynAct-CS007 (EXPAND):</li> <li>• Status: Ongoing/Recruiting</li> <li>• Topline data available - H2 2023</li> </ul>
	Rheumatoid arthritis DMARD-IR	[Progress bar spanning Preclinical, Phase 1, and Phase 2A]					<ul style="list-style-type: none"> <li>• SynAct-CS006 (RESOLVE):</li> <li>• Status: Planned</li> <li>• IND/CTA - Q4 2022</li> </ul>
	Nephrotic syndrome (iMN)	[Progress bar spanning Preclinical, Phase 1, and Phase 2A]					<ul style="list-style-type: none"> <li>• SynAct-CS003</li> <li>• Status: Ongoing/Recruiting</li> <li>• Implement redesign in ongoing Phase 2a - H2 2022</li> </ul>
	Virus-induced respiratory insufficiency	[Progress bar spanning Preclinical, Phase 1, and Phase 2A]					<ul style="list-style-type: none"> <li>• Data from pre-clinical viral disease models - H2 2022</li> </ul>
Next generation molecules	Inflammatory diseases	[Progress bar spanning Preclinical]					

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.

### **AP1189 - a selective, biased MC1R / MC3R agonist**

SynAct is developing selective melanocortin therapeutics to address inflammatory and autoimmune diseases characterized by excessive or chronic inflammation. SynAct's lead drug candidate, 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. 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 AP1189. Over stimulation of the cAMP pathway via MC1R has also been proposed as a potential risk factor for skin cancer.

The Company is evaluating 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.

In 2021, SynAct successfully completed P2a trials in early severe RA and in hospitalized patients with COVID-19-induced respiratory insufficiency. Also in 2021, SynAct successfully tested a new oral solid tablet formulation of AP1189 in healthy volunteers and filed additional patents that should provide exclusivity past 2040.

### **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 AP1189 in RA**

In November 2021, SynAct announced results from the phase 2a study of 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 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.

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**

Based upon the results of the BEGIN RA study, the company intends to initiate two additional Phase 2 clinical studies in RA with 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 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 AP1189. This study will utilize the newly developed solid tablet formulation of 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. Following approval of the Clinical Trial Application (CTA), recruitment to the study started in September 2022 and the first patients have been dosed.

### **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 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.

The intention is to develop AP1189 in DMARD-IR patients under an IND (Investigational New Drug) application. In June 2022, the Company obtained scientific and regulatory feedback from the FDA in a pre-IND process and filed the IND and CTAs in the relevant European countries during the third quarter. The agency approved the US IND on October 30, 2022, and European CTAs are still pending. 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.

#### **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**

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 AP1189. The study population consists of patients with iMN who are on an ACE inhibitor or angiotensin II receptor blocker treatment. In November 2021, SynAct announced its intention to amend the iMN P2a protocol. This amendment, which was submitted in July 2022 and approved in September, allows for the use of the new oral tablet as well as a 3-month dosing duration. The benefit of this redesign is that it increases the likelihood to show significant treatment effect on urinary protein excretion, the main efficacy read-out in the study, and increase patient compliance as a once-daily dosing with a tablet is much more convenient than daily intake of an oral suspension.

#### **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**

Working within the RESOVIR collaboration, SynAct designed and executed a 60 patient Phase 2a clinical trial in Brazil. Hospitalized COVID-19 infected patients were enrolled in the study who required supplemental oxygen (experiencing respiratory insufficiency). These patients were hospitalized, and all received steroids (dexamethasone) at an average dose of 6mg/day. After an initial open-label safety run-in of 6 patients, the blinded placebo-controlled portion of the trial dosed an additional 36 patients with 100mg of AP1189 and 18 patients with placebo, each given orally once-daily for 2 weeks.

The trial concluded in Q2 of 2021. Patients treated with 100mg 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) recovered respiratory recovery on average 4.0 days (40%) quicker than placebo treated patients (5.9 days and 9.9 days on average respectively). 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**

After the completed study, SynAct explored various opportunities for further development of AP1189 for use in patients suffering from COVID-19. The spread of the omicron and subsequent COVID-19 variants changed the way in which patients were affected, and further clinical development in this 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. The Company will make its decision on further development when the pre-clinical trials are completed during the fourth quarter of 2022.



# SynAct Pharma AB in brief

## About SynAct Pharma AB

SynAct Pharma AB is a biotech company in clinical phase listed on Nasdaq. The company's drug candidate 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 subsidiary SynAct Pharma ApS. In addition to the above, SynAct has no additional shareholdings in other companies.

## Ownership (September 30, 2022)

Shareholder	Capital and votes(%)
Bioinvest ApS	13.3%
Avanza Pension	6.5%
Nordnet Pensionsförsäkring	5.3%
Torbjörn Bjerke	2.9%
Henrik Stage	1.4%
Robert Sahlin	1.1%
Per Granath	0.8%
Patrik Strempl	0.8%
Peter Nordwall	0.7%
Peter Thurner	0.6%
<b>Total (top-10)</b>	<b>33.3%</b>
Others	66.7%

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, 28,370,503.

## 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.

The agreements above were entered between the respective directors & executives and the banks ABG Sundal Collier AB and Van Lanschot Kempen N.V in conjunction with the rights issue. The lock-up agreements did not affect the Group financially or in terms of accounting. Per the date of issuance of this interim report, there are no lock-up agreements in effect.

## Review by the Company's Auditor

This report has been reviewed by the Company's Auditor, KPMG.

## Forward looking statements

This financial report contains statements that are forward-looking and actual future results may differ materially from those stated. In addition to the factors discussed, factors that may affect the results are development in research programs.



## The Share

The share in SynAct Pharma AB was listed on Nasdaq Stockholm on July 12, 2022. The share is traded under the ticker "SYNACT" and is included in the Mid-Cap segment of the stock exchange.

In the second quarter of 2022, SynAct Pharma AB successfully completed a rights issue in which the number of shares increased by 2,364,208 to 28,370,503 shares and the share capital by SEK 295,526 to SEK 3,546,313.



## Financial reporting calendar

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

**Date:**  
02/17/2023  
05/05/2023  
08/04/2023  
11/03/2023

**Report:**  
Annual Results 2022  
Interim Report Q1 2023  
Interim Report Q2 2023  
Interim Report Q3 2023

# Comments on the financial development for the third quarter and the first nine months of 2022

## Net sales

Net sales for the third quarter and the first nine months of 2022 amounted to SEK 0 (0) thousand. The company is not expected to generate any revenue until at the earliest after the completion of the planned Phase 2 program involving the drug candidate AP1189, planned for the end of 2023.

The parent company's sales are from services delivered to the Danish subsidiary and amounted to SEK 1,278 (411) thousand in the third quarter, and SEK 3,834 (1,229) thousand for the first nine months of the year.

## Research and development (R&D) costs

Total costs for R&D in the third quarter amounted to SEK 20,639 (16,259) thousand. For the first nine months, R&D costs amounted to SEK 48,404 (40,284) thousand. The main reasons for the cost increase are increased activity in the clinical studies, investments in clinical manufacturing and control ("CMC") and pre-clinical activities that support both the drug candidate, AP1189 and projects in the early research phase.

As the recently initiated clinical Phase 2b study progresses and other planned clinical trial with AP1189 in RA starts, costs are expected to rise further.

SynAct's research and development is led and managed by the Company and its management, but in all essentials the activities are carried out by consultants and contract suppliers.

## General & administration costs

Administrative expenses amounted to SEK 5,740 (4,654) thousand in the third quarter and SEK 26,624 (10,308) thousand for the first nine months. The increase is driven by activities related to the preparations for and the actual listing of the company's share on Nasdaq Stockholm's Main Market. The level of administrative expenses was reduced in the third quarter compared with the previous quarters and is expected to be further reduced after the completion of the listing project.

## Financial items

Net financial items amounted to SEK -108 (209) thousand in the third quarter and SEK -1,328 (-56) thousand for the first nine months. The change is attributable to exchange rate adjustments and interest expenses from leasing liabilities.

In the Parent Company, net financial items amounted to SEK -1 (-50,002) thousand in the quarter. Year-to-date, net financial items were SEK -110,298 (-50,005) 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.

## Tax for the period

Tax revenues in the third quarter amounted to SEK 2,650 (2,454) thousand. For the first nine months the accrued tax credit amounted to SEK 7,783 (7,508) thousand. See Note 8 - Tax receivables for more information.

## Loss for the period

The Group's loss for the third quarter amounted to SEK 23,919 (18,222) thousand and for the first nine months, the reported loss was SEK 68,728 (43,094) thousand.

## Cash flow, financial position and going concern

Cash flow from operating activities amounted to SEK -41,335 (-18,250) thousand in the quarter. The increase is driven by increased activities and by initial start-up payments for the two new clinical trials. Year-to-date cash flow from operating activities amounted to SEK -95,249 (-44,740) thousand.

Cash flow from financing activities amounted to SEK -230 (0) thousand in the quarter, driven by the cash flow impact of leasing.

For the first nine months, cash flow from financing activities amounted to SEK 124,686 (74,400) thousand.

Cash flow for the period amounted to SEK -41,565 (-18,255) thousand and SEK 29,438 (29,652) thousand for the first nine months.

The Group's cash and cash equivalents as of September 30, 2022 amounted to SEK 54,898 (44,402) thousand.

The Board of Directors continuously assesses the Company's financial position and has determined that its current cash and cash equivalents is sufficient to fund ongoing activities for the coming 12 months, but does not meet the liquidity needed to initiate additional value generating activities. In light of this, the Board of Directors is reviewing various financing alternatives.

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 8 - Tax receivables for more information) amounted to SEK 16,149 (12,180) thousand.

The Group applies IFRS 16 Leasing on leased office premises, which generated a right of use in the balance sheet of SEK 2,309 (0) thousand and the corresponding short- and long-term leasing liabilities of SEK 963 (0) thousand and SEK 1,302 (0) thousand, respectively.

## Employees

The number of employees was 5 (3). Three employees (2) were employed by the affiliate SynAct Pharma ApS.

## Corporate Governance

The company chose not to publish a Corporate Governance Report for 2021, which is a requirement for companies listed on a regulated market but not on Spotlight Stock Market. With the only exception, SynAct follows the Swedish Code of Corporate Governance and will, after listing the Company's share on the regulated market (Nasdaq), publish the Corporate Governance Report for 2022.

## Consolidated income statement

SEK (thousand)	2022		2021		2021
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	
Net sales	-	-	-	-	-
<b>Gross profit</b>	-	-	-	-	-
Research and development costs	-20,639	-16,259	-48,404	-40,284	-60,490
General and administration costs	-5,740	-4,654	-26,624	-10,308	-16,225
Other operating income/expenses	-83	29	-155	46	16
<b>Total operating expenses</b>	<b>-26,461</b>	<b>-20,885</b>	<b>-75,182</b>	<b>-50,546</b>	<b>-76,699</b>
<b>Operating income</b>	<b>-26,461</b>	<b>-20,885</b>	<b>-75,182</b>	<b>-50,546</b>	<b>-76,699</b>
Net financial items	-108	209	-1,328	-56	-110
<b>Profit after financial items</b>	<b>-26,569</b>	<b>-20,676</b>	<b>-76,511</b>	<b>-50,602</b>	<b>-76,809</b>
Tax on profit/loss for the period	2,650	2,454	7,783	7,508	7,505
<b>Profit for the period</b>	<b>-23,919</b>	<b>-18,222</b>	<b>-68,728</b>	<b>-43,094</b>	<b>-69,304</b>
Earnings per share (SEK)	-0.84	-0.70	-2.52	-1.67	-2.68
Diluted earnings per share (SEK)	-0.84	-0.70	-2.52	-1.67	-2.68
Average number of shares outstanding ('000)	28,371	26,006	27,236	25,795	25,848

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

## Consolidated statement of comprehensive Income

SEK (thousand)	2022		2021		2021
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	
<b>Profit for the period</b>	<b>-23,919</b>	<b>-18,222</b>	<b>-68,728</b>	<b>-43,094</b>	<b>-69,304</b>
<b>Items reclassifiable to profit or loss</b>					
Translation differences from foreign operation	1,343	-82	2,518	44	-94
<b>Comprehensive income after tax for the period</b>	<b>-22,576</b>	<b>-18,304</b>	<b>-66,210</b>	<b>-43,050</b>	<b>-69,398</b>
<b>Comprehensive income for the period</b>	<b>-22,576</b>	<b>-18,304</b>	<b>-66,210</b>	<b>-43,050</b>	<b>-69,398</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)	09/30/2022	09/30/2021	12/31/2021
<b>Assets</b>			
<i>Non-current assets</i>			
Right-of-use assets	2,309	-	3,179
Financial assets	293	277	274
<b>Total non-current assets</b>	<b>2,602</b>	<b>277</b>	<b>3,454</b>
<i>Current assets</i>			
Tax credit	16,149	12,180	7,564
Other current receivables	6,480	2,656	3,107
Prepaid expenses	16,076	322	247
Cash and cash equivalents	54,898	44,402	23,997
<b>Total current assets</b>	<b>93,604</b>	<b>59,560</b>	<b>34,916</b>
<b>Total assets</b>	<b>96,206</b>	<b>59,836</b>	<b>38,369</b>

SEK (thousand)	09/30/2022	09/30/2021	12/31/2021
<b>Equity and liabilities</b>			
Share capital	3,546	3,251	3,251
Other paid-in capital	318,725	193,602	193,602
Reserves	2,119	-260	-399
Retained earnings/losses including net profit	-244,313	-149,376	-175,585
<b>Total equity</b>	<b>80,078</b>	<b>47,217</b>	<b>20,869</b>
<i>Non-current liabilities</i>			
Leasing liability	1,302	-	2,110
<b>Total non-current liabilities</b>	<b>1,302</b>	<b>-</b>	<b>2,110</b>
<i>Current liabilities</i>			
Accounts payable	4,901	7,445	4,254
Leasing liability	963	-	979
Other current liabilities	4,346	1,838	2,267
Accrued expenses	4,615	3,337	7,889
<b>Total current liabilities</b>	<b>14,826</b>	<b>12,619</b>	<b>15,390</b>
<b>Total equity and liabilities</b>	<b>96,206</b>	<b>59,836</b>	<b>38,369</b>

## Consolidated statement of changes in equity

01/01/2021 - 12/31/2021 SEK (thousand)	Share capital	Other paid-in capital	Reserves	Retained earnings, including profit for the period	Total
<b>Opening equity</b>	3,051	119,401	-304	-106,281	15,868
Profit for the period	-	-	-	-69,304	-69,304
Other comprehensive income	-	-	-94	-	-94
<b>Comprehensive income for the period</b>	-	-	-94	-69,304	-69,398
<b>Transactions with owners</b>					
New share issue	200	79,800	-	-	80,000
Issue expenses	-	-5,600	-	-	-5,600
<b>Total transaction with owners</b>	200	74,200	-	-	74,400
<b>Closing equity</b>	3,251	193,602	-399	-175,585	20,869

01/01/2022 - 09/30/2022 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	-	-	-	-68,728	-68,728
Other comprehensive income	-	-	2,518	-	2,518
<b>Comprehensive income for the period</b>	-	-	2,518	-68,728	-66,210
<b>Transactions with owners</b>					
New share issue	296	148,650	-	-	148,945
Issue expenses	-	-23,526	-	-	-23,526
<b>Total transaction with owners</b>	296	125,124	-	-	125,419
<b>Closing equity</b>	3,546	318,725	2,119	-244,313	80,078

## Condensed consolidated statement of cash flows

SEK (thousand)	2022		2021		2021
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
<b>Cash flow from operations</b>					
Operating income	-26,461	-20,885	-75,182	-50,546	-76,699
Adjustment for non-cash items	225	-	755	-	88
Interest received	-	-	46	-	-
Interest paid	-108	-29	-255	-56	-110
Corporate income tax received	-	-	-	-	4,625
<b>Cash flow from operations before change in working capital</b>	<b>-26,344</b>	<b>-20,913</b>	<b>-74,636</b>	<b>-50,602</b>	<b>-72,096</b>
Change in working capital	-14,992	2,664	-20,612	5,862	7,099
<b>Cash flow from operating activities</b>	<b>-41,335</b>	<b>-18,250</b>	<b>-95,249</b>	<b>-44,740</b>	<b>-64,997</b>
Cash flow from investing activities	-	-5	-	-8	-6
Cash flow from financing activities	-230	-	124,686	74,400	74,323
<b>Cash flow for the period</b>	<b>-41,565</b>	<b>-18,255</b>	<b>29,438</b>	<b>29,652</b>	<b>9,319</b>
Cash and cash equivalents at beginning of period	96,465	62,532	23,997	14,548	14,548
Decrease/increase in cash and cash equivalents	-41,565	-18,255	29,438	29,652	9,319
Exchange rate difference in cash and cash equivalents	-3	124	1,463	202	130
<b>Cash and cash equivalents at end of period</b>	<b>54,898</b>	<b>44,402</b>	<b>54,898</b>	<b>44,402</b>	<b>23,997</b>

## Parent company's condensed income statement

SEK (thousand)	2022		2021		2021
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Net sales	1,278	411	3,834	1,229	1,637
<b>Gross profit</b>	<b>1,278</b>	<b>411</b>	<b>3,834</b>	<b>1,229</b>	<b>1,637</b>
General and administration costs	-4,537	-3,042	-22,672	-8,315	-12,571
Other operating expenses	-21	-8	-189	-23	-27
<b>Total operating expenses</b>	<b>-4,557</b>	<b>-3,050</b>	<b>-22,861</b>	<b>-8,338</b>	<b>-12,598</b>
<b>Operating income</b>	<b>-3,279</b>	<b>-2,639</b>	<b>-19,027</b>	<b>-7,108</b>	<b>-10,962</b>
Net financial items	-1	-50,002	-110,298	-50,005	-50,005
<b>Profit after financial items</b>	<b>-3,281</b>	<b>-52,641</b>	<b>-129,324</b>	<b>-57,113</b>	<b>-60,966</b>
Tax on profit for the period	-	-	-	-	-
<b>Profit for the period</b>	<b>-3,281</b>	<b>-52,641</b>	<b>-129,324</b>	<b>-57,113</b>	<b>-60,966</b>

## Parent company's statement of comprehensive income

SEK (thousand)	2022		2021		2021
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Profit for the period	-3,281	-52,641	-129,324	-57,113	-60,966
Other comprehensive income	-	-	-	-	-
<b>Total comprehensive income</b>	<b>-3,281</b>	<b>-52,641</b>	<b>-129,324</b>	<b>-57,113</b>	<b>-60,966</b>

## Parent company's condensed balance sheet

SEK (thousand)	09/30/2022	09/30/2021	12/31/2021
<b>Assets</b>			
<i>Non-current assets</i>			
Financial assets	24,419	24,419	24,419
<b>Total non-current assets</b>	<b>24,419</b>	<b>24,419</b>	<b>24,419</b>
<i>Current assets</i>			
Other receivables	877	445	865
Prepaid expenses	235	151	202
Cash and cash equivalents	17,738	24,101	19,849
<b>Total current assets</b>	<b>18,850</b>	<b>24,697</b>	<b>20,915</b>
<b>Total assets</b>	<b>43,269</b>	<b>49,116</b>	<b>45,334</b>

SEK (thousand)	09/30/2022	09/30/2021	12/31/2021
<b>Equity and liabilities</b>			
<i>Restricted equity</i>			
Share capital	3,546	3,251	3,251
<i>Non-restricted equity</i>			
Other paid-in capital	318,725	170,387	170,387
Retained earnings/losses	-156,448	-72,267	-72,267
Profit for the period	-129,324	-57,113	-60,966
<b>Total equity</b>	<b>36,499</b>	<b>44,257</b>	<b>40,404</b>
<i>Current liabilities</i>			
Accounts payable	147	320	1,136
Other liabilities	4,042	1,869	2,163
Accrued expenses	2,581	2,670	1,630
<b>Total current liabilities</b>	<b>6,770</b>	<b>4,859</b>	<b>4,930</b>
<b>Total equity and liabilities</b>	<b>43,269</b>	<b>49,116</b>	<b>45,334</b>



## Notes and disclosures

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### 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 81 Lund, Sweden. This interim report was approved for publishing on November 4, 2022.

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### 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 2021, note 2 pages 32 to 36. No new or changed standards implemented on or after January 1, 2022, have had any significant impact on the company's financial reporting.

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### 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 2021, pages 18-21 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.

Even if this financing risk is mitigated in the short term, the Company's operations presuppose new capital injections in the medium term, which is why this refinancing risk cannot be considered negligible.

The macroeconomic situation with rising inflation and interest rates did not have a significant impact on SynAct's operations in the third quarter. Our suppliers and partners have been able to produce and deliver according to the plans we work with and without any significant cost increases. However, it cannot be ruled out that increased inflation and rising interest rates may lead to price increases for goods and services that could have a negative impact on the Company's future financial results and position.

The Group's operation is exposed to currency risks with its financing in SEK and main operations in DKK and EUR. SynAct has as taken mitigating steps to reduce the risk through placement of liquidity in EUR and DKK accounts.

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. 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 - Transactions and agreements with related parties

In addition to salaries and other remuneration (including invoiced) to the Company's management and board remuneration, according to the resolution of the Annual General Meeting, to the board, the following transactions have taken place with related parties in the reporting periods:

SEK (thousand)		2022	2021	2022	2021	2021
Related party	Service	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
UST Leadership AB (Torbjørn Bjerke, chairman)	Consultancy	-	-	-	174	654
JSH Biotech ApS (John Haurum, f. board member)	Consultancy	-	48	-	167	167

There have been no financial transaction with related parties in 2022. However, on October 7, 2022, the board of directors resolved to engage UST Leadership AB (Torbjørn Bjerke) as consultant to perform certain, defined tasks.

In addition to the transactions described above, 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 12, Contingent liabilities for more information.

#### Note 5 - Share issues

In February 2021, the Company carried out a directed new issue of SEK 80 million, net SEK 74.4 million after issue expenses. Through the issue, the number of shares and votes in the Company increased by 1,600,000 from 24,406,295 to 26,006,295, and the share capital increased by SEK 200,000 from SEK 3,050,787 to SEK 3,250,787.

On March 28, 2022, the Company's board of directors resolved on a fully guaranteed rights issue that provided the Company with SEK 125.1 million after issue expenses. Through the rights issue that was completed in the second quarter 2022, the number of shares increased by 2,364,208 to 28,370,503 shares. The share capital increased by SEK 295,526 to SEK 3,546,313.

#### Note 6 - Number of registered shares

Thousand	2022	2021	2022	2021	2021
	Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
Number of shares at the beginning of the period	28,371	26,006	26,006	24,406	24,406
Number of shares at the end of the period	28,371	26,006	28,371	26,006	26,006
Average number of shares outstanding in the period	28,371	26,006	27,236	25,795	25,848

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

#### Note 7 - Leasing

As of Q4 2021, the Group changed the assessment of lease agreements for office premises, which were previously assessed as short-term contracts and therefore were exempted from the main principle in IFRS 16 (Leasing agreements).

As of December 2021, the principle is fully applied to leased premises, which has generated a right of use in the balance sheet at the reporting date of SEK 2,309 (0) thousand and the corresponding short- and long-term lease liabilities amounting to SEK 963 (0) thousand and SEK 1,302 (0) thousand, respectively.

#### Note 8 - 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 5.5 MDKK 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 16,149 thousand (12,180). The company's balance under the "Tax Credit Scheme" for 2021 with an amount of SEK 8,075 thousand is expected to be received in November 2022.

## Note 9 - 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 2 MSEK, and accrued for the remaining amount of approximately 1.6 MSEK.

In December 2021, the Administrative Court in Malmö announced a ruling in the Company's favor in the case, whereby a deduction was granted. However, the Swedish Tax Agency has appealed the decision to the Court of Appeal, which is why the Company continues to report the liability, SEK 3,689 (1,614) thousand, under other liabilities in the consolidated and the parent company's balance sheets. The change from previous reporting is due to the fact that the Swedish Tax Agency, following the court ruling in December 2021, refunded the amounts previously paid-in by the Company early 2022.

## Note 10 - Prepaid and accrued expenses

SynAct has made initial payments to the CRO handling the two new clinical studies SynAct-CS006 (RESOLVE) and SynAct-CS007 (EXPAND). The costs will be recognized during the active treatment period and three months before and after. Hence the increase in prepaid expenses by almost SEK 16 million to SEK 16,076 (322) thousand.

The company reports accrued expenses of SEK 4,615 (3,337) thousand. The change since the comparison period is mainly due to increased provisions for costs related to personnel (social security, bonus, pension and holiday allowances).

## Note 11 - Financial assets and liabilities

SEK (thousand)	09/30/2022	09/30/2021	12/31/2021
<b>Financial assets</b>			
Non-current financial assets	293	277	274
Cash and cash equivalents	54,898	44,402	23,997
<b>Total financial assets</b>	<b>55,191</b>	<b>44,678</b>	<b>24,271</b>

SEK (thousand)	09/30/2022	09/30/2021	12/31/2021
<b>Financial liabilities</b>			
Accounts payable	4,901	7,445	4,254
Accrued expenses	4,615	3,337	7,889
<b>Total financial liabilities</b>	<b>9,517</b>	<b>10,781</b>	<b>12,143</b>

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

## Note 12 - 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 4.5 MDKK 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 2022 and have a cash flow effect no earlier than 2024.

## 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)	09/30/2022	09/30/2021	12/31/2021
<b>Assets</b>				
	Total non-current assets	2,602	277	3,454
	Total current assets	93,604	59,560	34,916
[1]	<b>Total assets</b>	<b>96,206</b>	<b>59,836</b>	<b>38,369</b>
<b>Equity and liabilities</b>				
[2]	<b>Total equity</b>	<b>80,078</b>	<b>47,217</b>	<b>20,869</b>
	Total non-current liabilities	1,302	-	2,110
	Total current liabilities	14,826	12,619	15,390
	<b>Total liabilities</b>	<b>16,128</b>	<b>12,619</b>	<b>17,500</b>
	<b>Total equity and liabilities</b>	<b>96,206</b>	<b>59,836</b>	<b>38,369</b>
[2] / [1]	<b>Equity / asset ratio (%)</b>	<b>83%</b>	<b>79%</b>	<b>54%</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)	2022	2021	2022	2021	2021
		Jul-Sep	Jul-Sep	Jan-Sep	Jan-Sep	Jan-Dec
[1]	Research and development costs	-20,639	-16,259	-48,404	-40,284	-60,490
	General and administration costs	-5,740	-4,654	-26,624	-10,308	-16,225
	Other operating income / expense	-83	29	-155	46	16
[2]	<b>Total operating expenses</b>	<b>-26,461</b>	<b>-20,885</b>	<b>-75,182</b>	<b>-50,546</b>	<b>-76,699</b>
[1] / [2]	<b>Research and development costs / operating expenses (%)</b>	<b>78%</b>	<b>78%</b>	<b>64%</b>	<b>80%</b>	<b>79%</b>

## The CEO declaration

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The CEO assures that this interim report provides a true and fair view of the development and the Group's and the Parent Company's operations, position and results, and describes significant risks and uncertainties that the Parent Company and the companies included in the Group face.

The consolidated financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) adopted by the EU and the interim report has been prepared in accordance with IAS 34 - Interim Financial Reporting. The interim report has been reviewed by the company's auditors.

Lund, November 4, 2022

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

## The Auditor's Review Report

### Introduction

We have reviewed the summarized interim financial information for SynAct Pharma AB (publ) on September 30, 2022 and for the nine-month period then ended. The board of directors and the CEO are responsible for the preparation and presentation of this interim report in accordance with IAS 34 and the Annual Accounts Act. Our responsibility is to express a conclusion on this interim report based on our review.

### Scope of Review

We conducted our review in accordance with the International Standard on Review Engagements ISRE 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". A review consists of making inquiries, primarily of persons responsible for financial and accounting matters, and applying analytical and other review procedures. A review is substantially less in scope than an audit conducted in accordance with the International Standards on Auditing, ISA, and other generally accepted auditing practices. The procedures performed in a review do not enable us to obtain a level of assurance that would make us aware of all significant matters that might be identified in an audit. Therefore, the conclusion expressed based on a review does not give the same level of assurance as a conclusion expressed based on an audit.

### Conclusion

Based on our review, nothing has come to our attention that causes us to believe that the interim report is not prepared, in all material respects, for the group's part according to IAS 34 and the Annual Accounts Act and for the parent Company's part according to the Annual Accounts Act.

Malmö, November 4, 2022

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**Linda Bengtsson**  
**KPMG AB**  
Authorized Public Accountant

# Dictionary

## 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.

## 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.

## 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.

## 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.

## 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.

## Dictionary continued

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### ESMA

European Securities and Markets Authority.

### 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.

### 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).

### 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.

### 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.

### 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, also known as diarthrosis, joins bones or cartilage with a fibrous joint capsule that is continuous with the periosteum of the joined bones, constitutes the outer boundary of a synovial cavity, and surrounds the bones' articulating surfaces. This joint unites long bones and permits free bone movement and greater mobility.[1] 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 81 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





SYNACT  PHARMA

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